CAN TOBACCO CURE SMOKING? A REVIEW OF TOBACCO HARM REDUCTION

HEARING

BEFORE THE

SUBCOMMITTEE ON
COMMERCE, TRADE, AND CONSUMER PROTECTION

OF THE

COMMITTEE ON ENERGY AND
COMMERCE
HOUSE OF REPRESENTATIVES

ONE HUNDRED EIGHTH CONGRESS

FIRST SESSION

JUNE 3, 2003

Serial No. 108–31

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CAN TOBACCO CURE SMOKING? A REVIEW OF TOBACCO HARM REDUCTION

TUESDAY, JUNE 3, 2003

HOUSE OF REPRESENTATIVES,
COMMITTEE ON ENERGY AND COMMERCE,
SUBCOMMITTEE ON COMMERCE, TRADE,
AND CONSUMER PROTECTION
Washington, DC.

The subcommittee met, pursuant to notice, at 10 a.m., in room 2123, Rayburn House Office Building, the Hon. Cliff Stearns (chairman) presiding.

Members present: Representatives Stearns, Whitfield, Cubin, Shimkus, Shadegg, Bass, Terry, Fletcher, Ferguson, Issa, Otter, Tauzin (ex officio), Schakowsky, Solis, Markey, Brown, Davis, Stupak, Green, McCarthy, and Strickland.

Also present: Representative Waxman.

Staff present: Kelly Zerzan, majority counsel; Ramsen Betfarhad, majority counsel; Jon Tripp, deputy communications director; Jill Latham, legislative clerk; and Jonathan J. Cordone, minority counsel.

Mr. STEARNS. Good morning. The subcommittee will come to order.

Without objection, the subcommittee will proceed pursuant to Committee Rule 4(e). So ordered.

The Chair recognizes himself for an opening statement.

I am pleased to welcome all of you to the Commerce, Trade, and Consumer Protection Subcommittee hearing on tobacco harm reduction.

No one disputes the harm to human health from cigarette smoking. Smokers are at a 16-fold increased risk of lung cancer, 12-fold increased risk of chronic obstructive pulmonary disease, and a two-fold increased risk of mild cardio-infarction. Oncologists estimate that smoking related illnesses were responsible for 100 million deaths in the 20th century. Those ilnesses killed some 400,000 Americans every year.

Over the last few decades this country has invested substantial public and private resources to encourage smokers to quit using tobacco. That investment has paid off. We have made great gains in reducing the use of cigarettes.

While in 1965, 42 percent of Americans smoked cigarettes, today only 26 percent of men and 22 percent of women are smokers. While this is the good news, as noted in the Institute of Medicine report, "Clearing the Smoke," the decline in the rates of smoking among adults has leveled off during the 1990's.

So where do we go from here? Today we are here to discuss tobacco harm reduction. Harm reduction strategies have been used for a number of years for a variety of different societal problems. For example, clean needle programs are used to prevent the spread of HIV. Methadone programs are employed to prevent the use of elicit drugs, and sex education is provided to stem the rising tide of teen pregnancy and disease.

The title of our hearing, "Can Tobacco Cure Smoking?" at first blush seems counterintuitive. However, there is an increasing amount of research suggesting that some tobacco products are less harmful than others. For those smokers who can't seem to quit smoking, switching to a less hazardous product could save lives.

Today we will hear from a diverse group of experts espousing a range of opinions on issues of tobacco harm reduction. We worked closely with the minority to insure a fair and balance panel of witnesses that can speak to the science of this issue.

One of our witnesses today, Dr. Brad Rodu, will assert that smokeless tobacco products are 98 percent safer than cigarettes, and that by switching committed smokers to smokeless products, we can save lives, reducing the potential societal harms that may result from the promotion of tobacco harm reduction claims.

Some believe that switching from one tobacco product to another does nothing to solve the tobacco problem. The Federal Trade Commission has general regulatory authority over misleading and deceptive advertising, as well as specific authority over the advertising and marketing of tobacco products.

As tobacco companies attempt to market their products as reduced risk, as one company has already tried to do, the Federal Trade Commission will be in the position of evaluating these claims.

So I look forward to hearing from Chairman Muris, how his Commission plans to deal with these, shall we say, vexing issues.

We also hear from the Surgeon General, who is the principal advisor to the Secretary of Health and Human Services on public health and scientific issues. Tobacco has long been a subject of Surgeon General reports. As we move into a new era of tobacco debates, we welcome Vice Admiral Carmona to the Commerce, Trade, and Consumer Protection Subcommittee.

Our goal should always be to reduce the use of tobacco. In that light, today's hearing provides an opportunity to examine the efficacy of the tobacco harm reduction approach which calls for minimizing and decreasing death among cigarette smokers without completely eliminating tobacco and nicotine use.

In closing, I want to thank the witnesses for appearing before the committee. I look forward to their testimony, and I seek, in addition, unanimous consent to enter into the record the written testimony of Mike Szymanczyk, Chairman and Chief Executive Office, Philip Morris USA.

Without objection, so ordered.

[The prepared statement of Michael Szymanczyk follows:]

PREPARED STATEMENT OF MIKE SZYMANCZYK, CHAIRMAN AND CHIEF EXECUTIVE OFFICER, PHILIP MORRIS USA

I. INTRODUCTION

On behalf of the more than 12,000 employees of Philip Morris USA, I am honored to submit these remarks regarding reduced exposure and reduced risk tobacco products, including their potential health impact and the challenges of sensibly regulating them. In particular, I'd like to emphasize our strong support for passage by the 108th Congress of meaningful and effective regulation of tobacco products by the Food and Drug Administration. We believe that legislation empowering the FDA to act should fully implement the thoughtful, comprehensive and rigorous regulatory principles articulated by the Institute of Medicine in its landmark report, *Clearing the Smoke,* which was commissioned by the FDA itself.

We applaud the subcommittee for its leadership in holding this hearing. We agree with its interest in seeking a bipartisan way to fashion a coherent national tobacco policy. We look forward to working with you and your colleagues in the full House towards the passage of legislation that is designed to benefit adult consumers by reducing the harm caused by tobacco consumption, and to establish clear rules that will be applied to, and enforced uniformly throughout the tobacco industry.

We hope to convey three critical points that we believe are relevant to the issues the subcommittee is considering:

- Philip Morris USA strongly supports legislation that would provide the FDA with comprehensive, meaningful and effective authority to regulate tobacco products. The FDA should have the power to fully implement all of the 11 regulatory principles—including those relating to potentially reduced exposure/reduced risk products—recommended by the IOM Report.
- For many years now, we have been hard at work trying to develop and consider ways to successfully market innovative tobacco products that have the potential to reduce smokers' exposure to harmful compounds in cigarette smoke. Our progress has been encouraging thus far, and we have high hopes for these products as we move forward.
- We would like very much to be able to bring these products to market in the regulated environment contemplated by the IOM Report, subject to FDA review of both the underlying science and the communications about this science that we would make to consumers. In the absence of FDA authority in this area, we are forced into making a difficult choice between making claims that haven't been validated by a government agency, on the one hand, and not providing smokers with information that may be important to them, on the other. Neither of these alternatives would be ideal, in our view, either from our own perspective or as a matter of public policy. Clearly, FDA regulation would be the best approach.

We hope that today will mark the beginning of a new and much better chapter in our nation's effort to feel confident that tobacco products, and the tobacco industry, are properly regulated, given both the dangers of the products and the acknowledgement that adults should continue to be able to make informed decisions about smoking for themselves.

We are mindful that it has been nearly eight years since Dr. Kessler made his initial rulemaking proposal, and two years since the IOM published its report. Yet today, there is still no FDA authority to regulate tobacco products. My company wants very much to be a part of resolving the impasse and is convinced that the remaining policy differences can be resolved through mutually respectful discussions that seek such a resolution. We believe that a coherent, national tobacco policy can be crafted that will effectively deal with tobacco issues, without unintended consequences for the millions of consumers, employees, tobacco growers and retailers who will be dramatically affected by the results of Congressional action.

II. OUR SUPPORT OF TOBACCO PRODUCTS REGULATION BY THE FDA, INCLUDING AUTHORITIES BASED ON IOM'S 11 REGULATORY PRINCIPLES

The Importance of FDA Regulation of Tobacco Products

FDA regulation of tobacco products is an important Federal initiative that is certainly needed. For more than three years now, we have urged passage of an effective and comprehensive FDA regulatory policy, and we remain determined to be a constructive force in the effort that lies ahead to shape this policy.

When we say that we strongly support "effective" regulation by the FDA, we mean it. We're not playing word games or referring to a weak or watered-down plan. "Effective", to Philip Morris USA, means a regulatory plan that is designed and funded in a way that can fully accomplish its stated objectives, including:

- Providing smokers with additional information about what's in their cigarettes, and about the dangers of smoking—both now and on an ongoing basis—as the science evolves and new information becomes available;
- Aiding in the development of products that meaningfully reduce the harm caused by smoking;
- And guiding the accurate communication of any implications of switching to reduced risk or reduced exposure products that may be developed, which includes being sure to communicate that there is no "safe" cigarette, and the best thing to do from a health standpoint is to quit smoking.

"Effective" to us does *not* mean regulations that are loophole-ridden or intentionally weak, punitively cumbersome, or likely to generate unintended negative consequences—it means real reforms that get the stated and agreed upon job done.

We believe that additional regulation makes sense for a number of reasons. Although these efforts are not often the focus of public attention, the fact is that we at Philip Morris USA devote enormous resources to developing products that have the potential of reducing the harm caused by smoking, running our factories, working with our suppliers, making our payroll and paying our taxes. We are asking for new regulation because today there are simply not sufficiently clear and consistent guidelines for the manufacture and performance of cigarettes. It is not clear, for example, how we and the rest of the tobacco industry should communicate to consumers about our products. What rules there are increasingly arise at the state level, which will inevitably lead to conflicting standards that could confuse consumers, disrupt interstate commerce and significantly complicate orderly and uniform manufacturing and distribution processes.

Meaningful, effective and uniform FDA regulation would better align our business practices with society's expectations, and would further our goal of being a responsible, effective and respected manufacturer and marketer of tobacco products for adults who smoke. We believe Americans support meaningful and effective new regulation of tobacco product manufacturing processes, performance standards and how we communicate with consumers, especially about potentially reduced exposure and reduced risk products. The public also supports efforts to continue to build the momentum that has developed toward reducing the incidence of youth smoking. However, we don't believe that there is strong support in the country for the new rules to go too far, and significantly intrude on adults' continued ability to smoke if they want to.

When Philip Morris USA first announced its support for FDA regulation of cigarettes, some were understandably surprised and skeptical, in part because our company—along with other major manufacturers, retailers and advertising groups—had opposed the agency's assertion of jurisdiction over tobacco products under the medical device statute in 1996. Our opposition to FDA's unilateral initiative was not disagreement with regulation *per se,* but rather disagreement with *that specific* kind of regulation. We continue to believe that regulation of tobacco products as medical products would be a mistake—despite the fact that nicotine is a drug, and we agree that cigarette smoking, and nicotine in cigarette smoke, are addictive "because tobacco regulation needs to focus on how we can reduce the harm to society of a dangerous, agriculturally-based product that is nonetheless legal for adults to use, and the medical device rules simply are not suited to that purpose.

That is why we believe it is most appropriate that both major legislative proposals that have attracted attention in the past year—H.R. 140, sponsored by Representatives Davis and McIntyre, and S. 2626 from the last Congress, sponsored by Senators Kennedy, DeWine and others—regulate tobacco products under a new chapter of the Food, Drug & Cosmetic Act designed especially for such products. We're convinced that this is the right approach, and are extremely encouraged by the enormous similarities between the two bills. We believe that there is far more common ground in our views than there are differences. And, although on some issues there are some important divergences of opinion among the various stakeholders on a few issues, they are truly differences in degree only.

Our Support of Regulation by the FDA of Potentially Reduced-Exposure and Reduced-Risk Products, Based on IOM's 11 Regulatory Principles

The IOM Report "recommends strengthened federal regulation of all modified tobacco products with risk reduction or exposure reduction claims, explicit or implicit", and proposes 11 regulatory principles to "build on the foundation of existing food and drug law, with appropriate adaptations to take into account the unique toxicity of tobacco products."

Philip Morris USA has, for more than three years, been advocating many of the elements encompassed by the 11 regulatory principles contained in the IOM Report; many of these elements are already contained in bills such as H.R. 140 from this

Congress and S. 2626 from the 107th Congress. As a step in moving forward to a thorough discussion of what we believe are the best components of an FDA regulatory process, we respectfully offer the following observations about IOM's 11 principles, the degree to which they are already reflected in bills like H.R. 140 and S. 2626, and ways in which we think that the legislation can be improved so as to better translate the IOM Report's principles into legislative language:

IOM Principle #1

The Principle. Manufacturers of tobacco products, whether conventional or modified, should be required to obtain quantitative analytical data on the ingredients of each of their products and to disclose such information to the regulatory agency.

• *Philip Morris USA's Position.* We support the principle of providing quantitative information about the ingredients used in the manufacture of our cigarettes, with appropriate safeguards to protect trade secrets. We think that the FDA should be able to provide smokers with confidence that the ingredients added to cigarettes do not increase the inherent health risks of smoking, including increasing addiction. And, as discussed below regarding Principle #8, we have no objection to disclosing the results of our own ingredients testing to the FDA, so it can assess every ingredient we use.

• *Translation into Legislative Language.* This principle is specifically covered by section 904 of the new FDA title in both H.R. 140 and S. 2626, which require all tobacco product manufacturers to provide to the agency, on an annual basis, "A listing of all tobacco ingredients, substances and compounds that are, on such date, added by the manufacturer to the tobacco, paper, filter, or other component of each tobacco product by brand and by quantity in each brand and subbrand", as well as "All documents (including underlying scientific information) relating to research activities, and research findings, conducted, supported, or possessed by the manufacturer . . ."

IOM Principle #2

The Principle. All tobacco products should be assessed for yields of nicotine and other tobacco toxicants according to a method that reflects actual circumstances of human consumption; when necessary to support claims, human exposure to various tobacco smoke constituents should be assessed using appropriate biomarkers. Accurate information regarding yield range and human exposure should be communicated to consumers in terms that are understandable and not misleading.

• *Philip Morris USA's Position.* We support this principle. We believe that the FDA should be authorized to require the disclosure of information about individual compounds in cigarette smoke, in addition to tar and nicotine, that it believes would be meaningful to consumers, as long as the information can be generated according to validated, standardized and commercially feasible test methods that reflect actual circumstances of human exposure, or reliably calculated on the basis of the test results obtained from such methods.

• *Translation into Legislative Language.* There are a number of provisions in H.R. 140 and S. 2626 that specifically embody this principle. Section 511(b) of H.R. 140 and section 917(b) of S. 2626, for example, both require the FDA—within 24 months—to create rules covering "the testing, reporting, and disclosure of tobacco product smoke constituents and ingredients that the Secretary determines should be disclosed to the public in order to protect the public health. Such constituents shall include tar, nicotine, carbon monoxide, and such other smoke constituents or ingredients as the Secretary may determine to be appropriate." In addition, the bills' provisions empowering the FDA to assess health claims are discussed in more detail in several of the Principles below.

IOM Principle #3

The Principle. Manufacturers of all potential reduced-exposure products should be required to conduct appropriate toxicological testing in preclinical laboratory and animal models as well as appropriate clinical testing in humans to support the health-related claims associated with each product and to disclose the results of such testing to the regulatory agency.

• *Philip Morris USA's Position.* We support this principle. In order to support marketing claims relating to reduced exposure or reduced risk, we believe that the best approach would be for a manufacturer to (i) design a cigarette that significantly reduces various harmful compounds in the inhaled smoke; (ii) provide scientific evidence that this change reduces biological activity in appropriate cellular and laboratory animal models; (iii) measure or model adult smoker exposure to the smoke from these cigarettes; (iv) share these results with the scientific and public health communities to seek to gain their agreement that the test results are scientifically valid and relevant to adult smokers, and also support a conclusion that the new cigarette

design may, in fact, reduce the risks of smoking; and (v) work with regulatory agencies to appropriately communicate these results and their significance to adult smokers.

• *Translation into Legislative Language.* This principle is largely embodied in the two major FDA bills, where section 912(a)(2) of H.R. 140 and section 913(a)(2) of S. 2626 both authorize the FDA to designate a tobacco product as "reduced risk" based on a manufacturer's application that, among other things, "demonstrates through testing on animals and short-term human testing that use of such product results in ingestion or inhalation of a substantially lower yield of toxic substances" than other tobacco products, and "if required by the Secretary, includes studies of the long-term health effects of the product." We believe that this language would more fully reflect the IOM Report's principle if, in addition to referring to "reduced risk" products, it specifically mentioned "reduced exposure" products. Clearly, as the IOM Report indicates and as its principles as a whole demonstrate, it is likely that the scientific data will support reduced-exposure claims before the FDA, or the scientific community in general, is prepared to conclude that a particular new cigarette will actually reduce the risk of contracting a tobacco-related disease.

IOM Principle #4

The Principle. Manufacturers should be permitted to market tobacco-related products with exposure-reduction or risk-reduction claims only after prior agency approval based on scientific evidence (a) that the product substantially reduces exposure to one or more tobacco toxicants and (b) if a risk reduction claim is made, that the product can reasonably be expected to reduce the risk of one or more specific diseases or other adverse health effects, as compared with whatever benchmark product the agency requires to be stated in the labeling. The "substantial reduction'" in exposure should be sufficiently large that measurable reduction in morbidity and/or mortality (in subsequent clinical or epidemiological studies) would be anticipated, as judged by independent scientific experts.

• *Philip Morris USA's Position.* As noted above, we support the principle that the FDA should regulate "reduced risk" claims. In addition, we support the principle that claims about reduced exposure to specific tobacco toxicants (i.e., harmful compounds in cigarette smoke) should be subject to FDA oversight. We agree with the IOM Report that government analysis of proposed exposure-reduction claims, and the data that should be required from manufacturers to support them, should be different than with respect to claims of actual risk reduction.

• *Translation into Legislative Language.* Section 912(a)(3) of H.R. 140 and section 913(a)(3) of S. 2626 both partially reflect this principle, as they provide the FDA with full authority to regulate risk-reduction (but not specifically exposure-reduction) claims, including requiring that the product carry "a label prescribed by the Secretary concerning the product's contribution to reducing harm to health" and comply "with requirements prescribed by the Secretary relating to marketing and advertising of the product." H.R. 140 also reflects the IOM Report's judgment that accurate, non-misleading claims should be permitted rather than suppressed. We would respectfully suggest that the language in both bills could be improved by adding clauses that would both specifically incorporate IOM's exposure-reduction concept, and adopt this Principle's specific language regarding the proper standard for what evidence would support either an exposure-reduction or risk-reduction claim.

We also note that S. 2626 could be interpreted to permit FDA to refuse to permit *any* truthful, non-misleading claim regarding "reduced risk" or "reduced exposure"—even if a valid scientific showing has been made—if the agency speculates that the claim could, for example, discourage quitting at some point in the future. This is a legitimate concern, but it is contrary to IOM Principle #4, and, we believe, should be addressed by clearly communicating the claim so that consumers are not misled, and accompanying the claim with a clear reminder that the best option from a health perspective is to quit. IOM also proposes dealing with this concern through post-market surveillance, which is discussed in Principle #6 below. Finally in this regard, both the Supreme Court and several Courts of Appeals have strongly indicated that the kind of suppression of truthful information advocated by some in the tobacco control community cannot withstand scrutiny under the First Amendment. A white paper discussing these cases in greater detail is attached to this Statement as Annex 1.

IOM Principle #5

The Principle. The labeling, advertising, and promotion of all tobacco-related products with exposure-reduction or risk-reduction claims must be carefully regulated under a "not false or misleading" standard with the burden of proof on the manufac-

turer, not the government. The agency should have the authority and resources to conduct its own surveys of consumer perceptions relating to these claims.

• *Philip Morris USA's Position.* We support this principle for the reasons stated regarding Principle # 4 above.

• *Translation into Legislative Language.* In addition to the analysis above regarding Principle #4, we note that H.R. 140—through its linkage of FDA regulation to a tobacco quota buyout and a user fee that would fund both the buyout and the new regulatory regime—is the only major legislative proposal currently under consideration that would ensure that, as the IOM Report's Principle #5 urges, the FDA will in fact have "the resources to conduct its own surveys of consumer perceptions relating to these claims." We would also respectfully suggest that both section 912(a)(3) of H.R. 140 and section 913(a)(3) of S. 2626 be amended so as to specifically incorporate IOM's "not false or misleading" standard for all claims regarding exposure or risk-reduction.

IOM Principle #6

The Principle. The regulatory agency should be empowered to require manufacturers of all products marketed with claims of reduced risk of tobacco-related disease to conduct post-marketing surveillance and epidemiological studies as necessary to determine the short-term behavioral and long-term health consequences of using their products and to permit continuing review of the accuracy of their claims.

• *Philip Morris USA's Position.* We support this principle as articulated and further believe it should be expanded to clearly include application to products with reduced exposure claims. As noted above, the effects of these products on the overall harm caused by tobacco is a legitimate and valid public health concern, and one which needs to be monitored and studied. And, as we believe that the FDA should be able to determine which marketing claims are appropriate, it is sensible that it should make use of the sort of surveillance and studies noted in this principle.

• *Translation into Legislative Language.* Both major FDA bills contain provisions that fully embody this principle. Section 912(e)(1) of H.R. 140 and section 912(a) of S. 2626 broadly empower the FDA to "require a tobacco product manufacturer to conduct postmarket surveillance for reduced risk [of] a tobacco product of the manufacturer if the Secretary determines that postmarket surveillance of the tobacco product is necessary to protect the public health or is necessary to provide information regarding the health risks and other safety issues involving the tobacco product." For clarity, as indicated above regarding other provisions, we would suggest also adding an explicit reference to exposure-reduction claims, to ensure that the FDA is authorized to require post-market surveillance of them, too.

IOM Principle #7

The Principle. In the absence of any claim of reduced exposure or reduced risk, manufacturers of tobacco products should be permitted to market new products or modify existing products without prior approval of the regulatory agency after informing the agency of the composition of the product and certifying that the product could not reasonably be expected to increase the risk of cancer, heart disease, pulmonary disease, adverse reproductive effects or other adverse health effects, compared to similar conventional tobacco products, as judged on the basis of the most current toxicological and epidemiological information.

• *Philip Morris USA's Position.* We support this principle. As IOM notes in its report, it is logical that the regulatory agency charged with evaluating the relative risks presented by different tobacco products—which we believe is most appropriately the FDA—should not be overwhelmed with what would be the enormous task of pre-approving every introduction of a new line extension using existing product designs, when such products do not make reduced risk or reduced exposure claims, and are certified by the manufacturer to present the same issues of public health as predicate tobacco products. Requiring pre-market approval of such products would not serve the public health interests identified by the IOM Report, and would pose substantial burdens on both the regulators and the manufacturers.

Moreover, we support the IOM Report's concept of placing the burden on manufacturers to certify that any new product (including any existing brand which is introduced with changed characteristics) would not present increased risk, and then, on the basis of such certification, to introduce the product (without reduced risk or exposure claims) into the marketplace. As the IOM Report suggests, the FDA would then have the authority, if upon investigation it disagrees with the manufacturer's certification and concludes that there is in fact an increased risk, to seek the product's removal from the market. We do not advocate—and we do not believe Principle #7 would require—that pre-market approval provisions "grandfather" today's tobacco products from further regulation. In whatever form they eventually take, per-

formance standards (see Principle #9 below) would apply to all tobacco products (whether on the market today or introduced in the future).

• *Translation into Legislative Language.* All of the existing legislative proposals relating to pre-market approval are very complex, but we believe that the provisions of section 910 of H.R. 140 come the closest to fully embodying this principle. First, section 910 reflects the IOM Report's suggestion that products carrying exposure-reduction or risk-reduction claims be treated separately from new products that do not. Second, it requires manufacturers to submit extensive information about any such new product to the FDA at least 90 days prior to commercial introduction, and empowers the agency to "suspend the distribution of the tobacco product that is the subject of that report if the Secretary determines that there is a reasonable likelihood that the tobacco product is not substantially equivalent to a tobacco product commercially marketed (other than for test marketing) in the United States . . ." Finally, the concept of "substantial equivalence" is defined in section 910(a)(2) of H.R. 140—consistent with IOM's "no increased risk" concept—as being a product that either "has the same characteristics as the predicate tobacco product" or, in the alternative, "has different characteristics and the information submitted contains information, including clinical data if deemed necessary by the Secretary, that demonstrates that it is not appropriate to regulate the product under this section because the product could not reasonably be expected to increase the health risks to consumers compared to a conventional tobacco product that is commercially marketed in the United States . . ."

IOM Principle #8

The Principle. All added ingredients in tobacco products, including those already on the market, should be reported to the agency and subject to a comprehensive toxicological review.

• *Philip Morris USA's Position.* We support this principle for the reasons stated regarding Principle #1 above and Principle #9 below.

• *Translation into Legislative Language.* From a legislative perspective in the major FDA bills, toxicological assessment of ingredients is part and parcel of the agency's performance standard authority, which is discussed below in the context of IOM Principle #9.

IOM Principle #9

The Principle. The regulatory agency should be empowered to set performance standards (e.g., maximum levels of contaminants; definitions of terms such as "low tar") for all tobacco products, whether conventional or modified, or for classes of products.

• *Philip Morris USA's Position.* We support this principle, and have been actively advocating a Congressional grant of authority to the FDA to reduce harm by imposing mandatory performance standards on tobacco products, even including those that would require design changes that consumers might not like. Our main concern with this concept is that, if not translated carefully into legislative language, it could permit—or even require—the agency to do what nobody should want: to impose performance standards requiring changes that are so radical that tobacco products are effectively banned, or consumers are driven away from the legitimate market and towards illicit, completely unregulated products. We think that consumers, tobacco growers and many other stakeholders support our view that these standards should not make tobacco products unpalatable for adult smokers; no one would benefit from performance standards so radical that they further increase the demand for counterfeit or other illicit products.

Specifically, we believe that the FDA should have the authority to ensure that ingredients used in the manufacture of tobacco products do not increase their inherent health risk or addictiveness; because the ingredients are under the manufacturers' control, this authority should, in our view, *include the power to prohibit the use of any ingredient shown to increase health risks even if the ban would impact the product's taste.* Apart from ingredients, we also support authority for the FDA to impose changes to the other design or inherent characteristics of a tobacco product—including the inherent properties of tobacco leaf itself—that it finds will protect public health, so long as the changes are technically feasible and would not negatively impact adult consumers' enjoyment of the product in a significant way. There is no public consensus supporting FDA actions that force radical changes on the design or inherent characteristics of today's tobacco products that adult smokers may not be prepared to accept. We believe that instead, FDA should use its enormous persuasive powers and regulatory tools to encourage consumers to quit, or—by utilizing the reduced risk/reduced exposure authorities contemplated by IOM's other prin-

ciples—to switch to products whose design and composition the agency favors from a public health perspective.

Ingredients. The major legislative proposals currently under consideration—including both H.R. 140 and S. 2626—contemplate the use of "performance standard" authority by the FDA to regulate ingredients used in the manufacture of tobacco products based on its belief of what would be appropriate to protect public health. We believe that this is a legitimate role for the agency to the extent it is used to ensure that ingredients do not increase the inherent risk of cigarette smoking, including by increasing its addictiveness. Tobacco products are inherently dangerous, but the government should have authority to make sure that nothing is used by manufacturers to make them even more so. Philip Morris USA stands ready to submit all of its ingredients to rigorous FDA review and testing, to share the results of testing it has previously conducted, and to work with the agency as it makes its own assessment of any added risks they may present.

An approach that focuses on increased risk from ingredients has been explicitly adopted by the IOM Report, which asserts that "...[FDA] should...have the authority to remove from the market ingredients...that do not meet [a] test of no increased risk..." To be clear, we think that FDA authority to test and, if necessary, prohibit the use of specific ingredients it finds to increase the inherent risks of smoking should apply to ingredients currently in use as well as to new ones. There should be no "grandfathering."

However, FDA authority over ingredients should not, in our view, extend beyond the concept of "increased risk". A broader scope—for example, based purely on what would be "appropriate to protect public health"—could permit the agency, for example, to prohibit specific ingredients solely because they improve the taste of a tobacco product, on the theory that, by trying to make the products taste bad, consumption will drop and public health will be benefited. Under such an approach, the FDA could even order that bad-tasting ingredients be added to cigarettes, so as to decrease their palatability. These powers would be, we respectfully submit, simply incompatible with the principle that tobacco products are legitimate and that adults should continue to be permitted to consume them if they wish. To quote from the preamble to the FDA's own proposed tobacco rule from 1996:

> Black market and smuggling would develop to supply smokers with these products...[which] would be even more dangerous than those currently marketed, in that they could contain even higher levels of tar, nicotine, and toxic additives.

If regulation of cigarettes is to be based purely on eliminating their known inherent dangers, we readily agree that it would be best if nobody smoked at all. But Americans want to see a new regulatory regime that incorporates other values as well—tolerance, adults' continued ability to make their own decisions about issues that affect their health, law enforcement considerations, and the degree to which government should intrude generally into the realm of personal issues.[1] If Congress is to reflect this consensus and balance these competing concerns, it will need to tailor FDA's authority so that it is focused on encouraging quitting and harm reduction for adults who continue to smoke, rather than trying to force Americans to adopt tobacco-free lifestyles.

Smoke Constituents and Other Performance Standards. For the same reasons, we believe that the FDA should have broad power to require the reduction or elimination of smoke constituents (the compounds produced by tobacco when burned), that will seek to reduce harm while ensuring that the agency will not order mandatory performance standards that are technically infeasible, or could only be met by design changes in tobacco products that adult smokers find unacceptable. For example, if there is no limitation whatsoever contained in the performance standard authority, the agency could force rapid, radical reductions in tar and nicotine yields, or require that manufacturers utilize filters that would eliminate the products' taste. Strategies such as these may well be legitimate in the effort to reduce harm, but we respectfully suggest that the strategies are best dealt with under the FDA's authority over reduced exposure and reduced risk tobacco products, discussed above.

• *Translation into Legislative Language.* H.R. 140 and S. 2626 both fully embody—with one important difference between them—IOM's suggestion that the FDA be provided with specific authority to impose performance standards, including those relating to added ingredients and smoke constituents. Section 907(a) of both bills empower the agency to

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[1] Indeed, the reason that the Supreme Court rejected FDA's initial "medical device" tobacco rule is that it determined that, under that approach, the agency would have *been required* to ban tobacco products, and that such a ban could not be squared with the overall national tobacco policy already put in place by Congress.

> adopt performance standards for a tobacco product if the Secretary finds that a performance standard is appropriate for the protection of the public health. This finding shall be determined with respect to the risks and benefits to the population as a whole, including users and non-users of the tobacco product, and taking into account—(A) the increased or decreased likelihood that existing users of tobacco products will stop using such products; and (B) the increased or decreased likelihood that those who do not use tobacco products will start using such products. A performance standard established under this section for a tobacco product shall include provisions to provide performance that is appropriate for the protection of the public health, including provisions, where appropriate—(i) for the reduction [or elimination][2] of nicotine yields of the product; (ii) for the reduction or elimination of other harmful constituents or harmful components of the product . . .

The authority this language confers over ingredients extends beyond the concept of "increased risk". By permitting the FDA to change any ingredient if it concludes that such action is "appropriate to protect public health" (so long as the removal does not render the tobacco product "unacceptable for adult consumption"), H.R. 140 would appear to permit FDA, for example, to prohibit or reduce specific ingredients solely because they improve the taste of a tobacco product, on the theory that, by trying to reduce the product's palatability, consumption will decline and public health will benefit. We're pleased that the notion of adult acceptability appears in H.R. 140, because it is compatible with the principle that tobacco products are legitimate and that adults should continue to be permitted to consume them if they wish. We respectfully suggest, however, that Congress consider revising this language, insofar as it relates to ingredients, to more fully reflect IOM's "no increased risk" concept.

For the same reasons, we appreciate the fact that H.R. 140's performance standard authority applies the concept of adult acceptability to FDA's power to require the reduction or elimination of smoke constituents, or to order other mandatory design changes in tobacco products. Sensibly, the bill appears to contemplate that the FDA will use its authority regarding reduced risk and reduced exposure products—including those with low initial consumer acceptability—to encourage the proliferation of new product designs that have the potential of reducing the harm caused by smoking. Using this authority, the agency will have enormous ability to use its credibility with the American people to persuade adult smokers to switch to any alternative product designs of its choosing. New products that achieve a critical mass of adult consumer acceptance would then be ready to move to the next regulatory phase. If FDA concludes, after monitoring the marketplace in the manner suggested by IOM, that such a product innovation has been proven to reduce harm in the long term, the agency could—and, in our view, should—incorporate the results of the technology into a performance standard so that it becomes the new baseline for the entire category of tobacco products.

The performance standard authority in S. 2626 does not contain any concept of adult acceptability, or any other limitation on the FDA's authority to radically redesign tobacco products "to protect the public health." There is clearly a difference of opinion between those who believe that there needs to be specific policy direction from Congress to the FDA regarding consumer acceptability, and others who view health impact as the sole issue that the agency should be permitted to consider when it sets performance standards for tobacco products. We would note in this regard that every regulated consumer product is governed by a statutory standard reflecting Congress' policy judgment as to the values governing the rulemaking process. Just as medical devices need to be "safe and effective", a motor vehicle standard may only be imposed if it is "reasonable, practicable, and appropriate for the particular type of motor vehicle . . .", and standards under the Consumer Products Safety Act require a finding regarding ". . . the probable effect of such rule upon the utility, cost, or availability of such products to meet such need."

Our view is that FDA's performance standard authority should recognize tobacco products as legitimate for adults to use if they wish; that the agency should operate within some reasonable boundaries making it clear that its mission is not to phase them out entirely. To us it seems entirely plausible that, under a pure "public health" standard, FDA could (or could be forced to) conclude that it is better for public health overall to ban tobacco products; that Prohibition would result in millions of people quitting, and that having millions more seeking black market products is an acceptable trade-off. Even if valid from a health perspective, this conclusion would not be good policy.

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[2] This bracketed language appears only in S. 2626.

The opposition by some to any notion of "consumer acceptability" for tobacco products has been justified by concerns that the term's vagueness will lead to "endless litigation", and that "a reduction of tobacco consumption by 1% or less could be the basis for an industry claim that a new performance standard has left the product unacceptable to adults."[3] There are responses to these concerns: many countries around the world have clearly demonstrated that it is possible to gradually impose performance standards on cigarettes that governments deem beneficial within the realm of what adults will accept; for example, the European Union has, over the past several years and taking a step-by-step approach, established increasingly lower ceilings on tar, nicotine and, more recently, carbon monoxide yields as measured by machine tests. Moreover, it is unclear why "consumer acceptability" should be any more susceptible to court challenge than equally-vague standards endorsed by the same advocates (and included in both S. 2626 and H.R. 140), such as "the increased or decreased likelihood that existing users of tobacco products will stop using such products", and, under the well-known Chevron doctrine, FDA would be afforded substantial deference by the courts in determining what the language means. In any case, there surely ought to be some language that can be worked out that would introduce some notion of reasonableness into the FDA's performance standard calculus, avoid unintended consequences, and serve the public health objective of tough, meaningful authority that will lead over time to real changes in tobacco products, and a significant reduction in the harm that they cause.

IOM Principle #10

The Principle. The regulatory agency should have enforcement powers commensurate with its mission, including power to issue subpoenas.

• *Philip Morris USA's Position.* We support this principle. We have spoken extensively about the need for meaningful and effective regulation of tobacco products; such regulation can be neither "meaningful" nor "effective" without adequate enforcement powers for the FDA.

• *Translation into Legislative Language.* H.R. 140, like S. 2626 before it, fully incorporates the existing enforcement authorities that the FDA is provided under the Food, Drug & Cosmetic Act, and applies those powers to enforcement of the new tobacco products chapter that the bill would create. We would respectfully suggest, in light of the recent influx of inexpensive foreign tobacco products—some of which are not in compliance with existing Federal and State laws applicable to all tobacco products, domestic or foreign—into our country, that these mechanisms be examined to ensure that the FDA will be both authorized and directed to ensure that all manufacturers and importers are required to fully comply with the full panoply of restrictions, requirements and standards that the agency decides to impose.

IOM Principle #11

The Principle. Exposure reduction claims for drugs that are supported by appropriate scientific and clinical evidence should be allowed by the FDA.

• *Philip Morris USA's Position.* We support this principle. Our belief in the ability of adults to make their own decisions about smoking—and not smoking—encompasses cessation of tobacco use, including the use of pharmaceutical therapies for those smokers who want to quit, are having difficulty, and believe that the treatments might help.

• *Translation into Legislative Language.* IOM correctly notes that, under current U.S. law, the FDA already has authority in this area for drugs and medical devices; this issue need not be addressed legislatively as Congress considers a new chapter of the law relating to tobacco products. We believe strongly that cigarettes should be regulated as cigarettes, and not as medical products. This means that, as both H.R. 140 and S. 2626 provide, cigarettes should be regulated by FDA, but under a separate chapter of its governing statute. We're convinced that any legislation that attempts to shoehorn tobacco products into the existing medical categories is, as the Supreme Court has already found, simply taking the wrong approach.

III. OUR EFFORTS TO DEVELOP TOBACCO PRODUCTS THAT COULD EVENTUALLY REDUCE THE HARM CAUSED BY SMOKING

Having described the regulatory regime that we believe should be built to apply to all tobacco products—both conventional and novel—we now turn to the status of Philip Morris USA's efforts to develop products that we hope will be subject to these new regulations. One of our highest priorities today continues to be the development of cigarettes that have the potential to reduce the harm caused by smoking. The

[3] Written statement of Matthew L. Myers, President, Campaign for Tobacco-Free Kids, to Senate HELP Committee (September 19, 2002).

IOM Report exhaustively examines many of the issues involved in attempting to achieve this goal by reducing smokers' exposure to harmful compounds in cigarette smoke.

Simply put, the public health community has identified a number of compounds—out of the thousands present in cigarette smoke—that are potentially harmful to smokers, without definitively settling on any specific one (or combination of them) as the recognized cause of lung cancer or other smoking-related disease. Accordingly, our basic strategy is to reduce smokers' exposure to as many of these compounds as we can, by means of products that will provide continued enjoyment to our consumers. If we're successful in finding ways of both reducing potentially harmful compounds and reducing smokers' actual exposure to them under real-world conditions, we believe that—although it will take some time—the FDA will be in position to help us evaluate whether our product development efforts are actually reducing the risk of tobacco-related diseases among current smokers. Then, determinations can ultimately be made about whether any reduced-risk tobacco product results in overall harm reduction across the population, because its risk-reduction potential is not offset by other factors, such as changes in smoking behavior, discouraging current smokers from quitting or encouraging nonsmokers to start.

Our goal—which we believe provides both societal and shareholder value—is to design the best products that we can, and then, ideally under the regulatory oversight of the FDA, to convince as many adult smokers (who don't quit) as possible to use them. It seems clear to us that we will not be able to make progress in this area unless two critical conditions are met: first, that manufacturers such as ourselves are successful at developing and making available tobacco products that reduce smokers' exposure to harmful compounds compared to conventional cigarettes, and second, that current smokers are given a reason—through the communication of truthful, non-misleading information that avoids unintended consequences—to switch to these products, even though they may be less enjoyable than the cigarettes that most adults smoke today. For people who continue to smoke, we believe that this is the best way to assure that the overall harm caused by smoking will be meaningfully reduced.

We have extensive research programs, both external and internal, that are focused on advancing our knowledge about tobacco smoke, including the compounds of smoke and smokers' actual exposure to them, to support our efforts to develop new product designs. We are continuing to devote substantial research and development efforts to develop and launch cigarettes that significantly reduce smokers' exposure to compounds that have been identified by public health authorities as harmful or potentially harmful. We are making progress in this area, and hope to introduce new products with appropriate consumer communications as quickly as possible.

For example, one current result of our efforts is the introduction of an electrically heated cigarette smoking system (EHC), called Accord, in a limited test market without communications to consumers regarding reductions in potentially harmful compounds. The specially-designed lighter heats the EHC to a lower temperature than that at which a lit cigarette burns; the lower the temperature of the tobacco, the lower the quantities of certain harmful compounds. In comparing the EHC to a standard lit-end industry reference cigarette, we first made evaluations of smoke chemistry, Ames activity (a measure of damage to DNA), cytotoxicity (a measure of cell damage and tissue irritation), and inhalation exposure in laboratory rats. Philip Morris USA scientists have shared many of these results with their colleagues in the scientific community; examples of their presentations are available on online at http://www.ehcss-science.com.

More recently, we have conducted tests—including both clinical studies to assess the levels of potentially harmful compounds that smokers are actually exposed to, and machine tests that we believe more closely approximate actual smokers' behavior than the existing FTC method—comparing the results of smoking the EHC to those of smoking various commercially available conventional cigarettes. While we are still in the process of evaluating these tests, we hope that they will show that smokers of the EHC were exposed to substantially lower amounts of certain harmful compounds present in tobacco smoke than smokers of the conventional brand styles that were tested.

In addition, we are working very hard on the development of a conventional lit-end cigarette which includes a state-of-the-art filter, that uses activated carbon that we hope will be shown to reduce certain harmful compounds in smoke. It works like a carbon water filter, which reduces some of the unwanted things in the water that people drink. This prototype cigarette design also includes flavor components to add flavor to replace tobacco flavors trapped by the carbon.

Neither the EHC nor the cigarette with the new filter has been proven to reduce the risk of smoking-related disease, and smokers of these products would still be inhaling many compounds that are potentially harmful. But we believe that these product technologies show promise for the future, and that the FDA should be empowered as quickly as possible so that the agency can begin to work with us to evaluate their potential for reducing the risk of contracting smoking-related disease, and the overall harm to the population caused by smoking.

As we consider the details of the various legislative proposals that are active today, we respectfully urge Congress to keep in mind that innovation in developing new products are crucial to their ultimate success. In order to have any real impact, reduced exposure products must be acceptable to adult smokers. We see little overall benefit to consumers or society if harm reduction is not pursued in the context of cigarettes that adult consumers will continue to enjoy smoking. As the 1998 Canadian Experts' Committee on this subject concluded, "[i]f smokers would not buy these products, product modification initiatives would fail."

IV. THE WISDOM OF THE IOM PRINCIPLES, AND THE NEED FOR ACTION.

We now turn to a general overview of the policy issues relating to potentially reduced exposure and reduced risk tobacco products. This portion of our statement discusses our strong belief that FDA regulation—in line with the IOM Report's recommendations—is an essential component to an effective overall harm reduction strategy, the debate over whether this strategy is a good one, and the consequences of simply preserving the status quo.

The Need for FDA Regulation of Innovative Tobacco Products

We strongly agree with the IOM Report that governments should help determine what is, and what is not, a "reduced exposure" or "reduced risk" tobacco product. Clearly, the best approach is for regulatory authorities to make such determinations, based on the best available scientific information. As the IOM Report indicates, a product should be designated and marketed as "reduced exposure" or "reduced risk" upon an adequate showing of potential exposure or risk reduction to current smokers. Whether a product offers potentially reduced exposure or risk to an individual smoker is a purely scientific (as opposed to a policy) question that FDA should determine based on the data; the policies of encouraging quitting, discouraging nonsmokers from starting and assessing overall harm reduction across populations is a separate question, and can and should be dealt with through post-market surveillance, educational programs and appropriate labeling.

Moreover, we believe that the purpose of regulation in this area—and the specific details of the FDA's legislative mandate—should be to encourage innovation, not to stifle competition and the development of potentially beneficial new technologies. We hope that everyone can agree that the FDA should not inadvertently be directed or permitted to actually inhibit the development of these products, and in the process to deny millions of today's smokers a genuine opportunity to potentially reduce their chance of contracting smoking-related diseases.

Once, as a matter of science, the FDA concludes that a new product has the potential to offer reduced exposure or reduced risk, the best approach would be for the agency to play an important role in overseeing any claims—explicit or implied—made about it by its manufacturer regarding exposure or risk-reduction.

Crafting appropriate claims regarding these tobacco products is an undertaking requiring great care and attention; we are mindful of the critical need for manufacturers to work with the FDA so that marketing messages clearly communicate that all smoking can be harmful, and that the best option from a health perspective is to quit. Once again, as with determinations regarding the scientific issues of potential exposure and risk-reduction, we believe that the best approach is for the FDA to decide what communications to consumers are appropriate on this subject.

On the one hand, regulation should ensure that consumers are not mistakenly led to believe that a particular product may be an acceptable alternative to quitting from a health perspective. On the other hand, regulation should not be utilized as a tool to suppress legitimate, accurate and objective information about product developments that individuals may find to be beneficial or important. The key here is for all communications to consumers to be truthful and not misleading in the context of the fact that there is no safe cigarette.

The Debate Over Harm Reduction as a Strategy

The IOM Report was commissioned by the FDA to (in the Report's words) "address the science base for harm reduction from tobacco. The committee concluded early in its deliberations that the science base for harm reduction will evolve over time."

We're keenly aware that some members of the public health community are opposed to the very concept of developing and offering "reduced exposure" or "reduced risk" tobacco products, because they are concerned that their availability might discourage smokers from quitting or encourage them to start smoking. These advocates appear to believe that the only acceptable message for the government to communicate, irrespective of potential alternatives, is a directive to not consume tobacco products at all. Philip Morris USA respectfully disagrees with this way of thinking, and strongly believes that it would be wrong, if products that could ultimately reduce the harm caused by smoking are developed, to deny adult smokers access to information about their potential benefits. We're convinced that information about potentially reduced-exposure or reduced-risk products—that is truthful and not misleading—should be disclosed to consumers, so that they can consider the information and then decide for themselves which path to take.

The IOM Report has some important things to say about the debate over whether "reduced exposure" and "reduced risk" tobacco products should be pursued:

> Some public health officials oppose the adoption of harm reduction strategies because of concerns that promoting this approach will not, over the long term, prove to be beneficial to public health or to the individual tobacco users who might otherwise have quit. Whatever the merits of this position, marketplace forces already at work have put this issue on the policy agenda, and new products are being developed and offered as harm-reducing alternatives to conventional tobacco products . . . Manufacturers should be permitted to market tobacco-related products with exposure reduction or risk reduction claims only after [FDA] approval based on scientific evidence (a) that the product substantially reduces exposure to one or more tobacco toxicants and (b) if a risk reduction claim is made, that the product can reasonably be expected to reduce the risk of one or more specific diseases or other adverse health effects, compared with whatever benchmark product [FDA] requires to be stated in the labeling . . . [The] regulatory process should not discourage or impede scientifically grounded claims of reduced exposure, so long as steps are taken to ensure that consumers are not misled . . .

The IOM Report recommends, among other things, that manufacturers be given "the necessary incentive to develop and market products that reduce exposure to tobacco toxicants"; that consumers be "fully and accurately informed" about the health consequences of these products; that claims about their potential for reducing harm be regulated; and that research be conducted to ascertain the products' "potential for harm reduction for individuals and populations."

In the absence of the regulatory oversight recommended by the IOM Report, Philip Morris USA is, as discussed in section III of this statement, making a genuine effort to develop potentially reduced exposure products in accordance with the Report's recommendations, recognizing that there is currently no regulatory agency to validate Philip Morris USA's research and development efforts, or any independent scientific experts available to fully assess these efforts without funding from either the government or ourselves.

The Status Quo is Unacceptable

The questions regarding the IOM Report's recommendations and harm reduction as a strategy are important ones, worthy of thorough discussion, and we urge Congress to find the common ground and to pass legislation which will finally resolve them.

Without Congressional action, Philip Morris USA will continue to face a genuine dilemma. We're aware that it would not be ideal to begin to communicate to consumers about our new products' potential benefits in the absence of FDA regulation; this is an important reason that we have been seeking it for such a long period of time. However, without new legislation and the regulatory oversight that would follow, we are faced with the choice of making good faith communications about our new products based solely on our rigorous internal and external scientific processes and our scientists' engagement with external stakeholders, or not communicating information that may prove to be important to over 40 million consumers across the country. We note in this regard that time is not standing still—many of Philip Morris USA's competitors are already communicating directly with consumers about their new product designs; as the IOM itself said in its report, "marketplace forces already at work have put this issue on the public policy agenda, and new products are being developed and offered as harm-reducing alternatives to conventional tobacco products."

Without new legislation that implements the IOM Report's principles, we would undoubtedly face criticism no matter which path we choose to take—but it is truly the millions of adult smokers in this country who have the most at stake here; we

strongly believe that we would all be doing them a real disservice if we fail to come together to support the passage of legislation that will implement the IOM Report's recommendations, and place the FDA in the center of the critical decisions about tobacco products that, with or without regulation, are going to need to be made in the months and years ahead.

V. CONCLUSION

We believe that Congress has the opportunity to forge a new national tobacco policy that will create substantial new authority for the FDA to adopt regulations for tobacco products in accordance with the principles articulated in the IOM Report, while continuing to permit adults who wish to use them to do so legally. The issues you are considering today could make a substantial contribution to progress towards that goal. We hope this statement provides you with helpful input, and makes it clear that our company truly is supportive of a comprehensive and effective new regulatory regime that includes every area addressed by the IOM Report, and in practice will actually result in what we think everyone should be able to agree upon as a primary objective: reduced harm from tobacco consumption for both current and future generations.

We also hope that you agree with our conclusion that the status quo simply is not serving the needs of American smokers, and that, as the IOM Report has noted, novel tobacco products are being—and will continue to be—marketed under whatever regulatory regime is in place. The issue before us is not whether such products will come into being; but rather what the degree of the governmental oversight of them will be. These issues are complex and controversial, but we pledge to work with anyone and everyone who wishes to join in this challenge, and commend this subcommittee for the progress this hearing represents as a critical next step.

ANNEX 1

THE DEBATE OVER REDUCED-EXPOSURE AND REDUCED-RISK TOBACCO PRODUCTS: FULL DISCLOSURE VS. GOVERNMENT SUPPRESSION OF TRUTHFUL AND NON-MISLEADING INFORMATION

Competing proposals to give FDA regulatory authority over tobacco products take different approaches to regulating potentially "reduced-exposure" and "reduced-risk" tobacco products. These products have the potential to reduce the health risks associated with conventional tobacco products by, for example, lowering the smoker's exposure to toxic substances in the smoke. This paper takes the view that the approach most consistent with sound public policy and First Amendment protections is that which provides consumers with more information, rather than less or none at all. The public health safeguard in this approach is that FDA would decide both whether a product does indeed present reduced exposure or reduced risks, and what marketing claims may be made about the product. But once this determination is made, neither FDA nor any other government body could gag truthful and non-misleading information about the product.

EXECUTIVE SUMMARY

The debate over how to regulate these products has resulted in a debate over consumer communications. On one side are those who share the view that the government should simply evaluate claims based on their scientific merits and deal with any public health concerns by providing for *full disclosure to consumers* and through other public health measures. On the other side are those who fear that the very existence of these products, despite the fact that FDA would review, approve and regulate any accompanying claims, would have a net adverse public health impact by encouraging more people to start smoking in the first place and/or by discouraging from quitting people who adopt the misguided view that smoking is now "safe." Therefore, this contingent supports giving the *government authority to suppress* reduced-exposure and reduced-risk claims about tobacco products.

The government suppression tact flies in the face of the First Amendment and sound public policy. The Supreme Court has made clear that suppression of information is not a useful or suitably tailored restriction on commercial speech.

The notion that benefits would result from suppressing truthful and non-misleading information tobacco products is premised on the speculation that adults might use this information in a manner that is disfavored by the government. A benefit deriving from this kind of paternalistic assumption, however, is not one that the Constitution recognizes as legitimate. Further, even if suppressed by the government, information concerning novel tobacco products is likely to reach consumers

through any number of alternative sources. And FDA or another government agency will not have scientifically vetted this information.

Moreover, suppressing information on reduced-exposure and reduced-risk tobacco products would not necessarily advance the government's interest in protecting public health. In order to provide this speculative benefit to certain individuals, the government would have to impose clear harms on others—specifically, on those people who will use tobacco products regardless and who, because of the suppression of information, would be denied the ability to select products with demonstrated potential benefits. Thus, a significant part of the population may be denied crucial information in order to "protect" a speculative segment of the population.

In addition, the government has available to it more narrowly tailored means of advancing its public health interests. For example, it could:

- ensure that consumers are given all necessary information to ensure that they are not misled regarding the health risks that remain with reduced-exposure and reduced-risk tobacco products, or that quitting or not starting is still the most risk-free approach; and
- stress other public health programs to encourage smoking cessation and prevention.

In short, to quote the Supreme Court, "*the preferred remedy is more disclosure, rather than less*," *Bates* v. *State Bar of Arizona,* 433 U.S. 350, 375 (1977) (emphasis added), and "[i]f the First Amendment means anything, it means that *regulating speech must be a last—not first—resort.*" *Thompson* v. *Western States Medical Center*, 122 S.Ct. 1497, 1507 (2002) (emphasis added). Indeed, "if the [g]overnment [can] achieve its interests in a manner that does not restrict speech, or that restricts less speech, the [g]overnment *must* do so." *Id.* at 1506 (emphasis added). Accordingly, legislation should task FDA with reviewing claims based on their scientific merits. FDA also should have ample authority to ensure that consumers are provided with full disclosure regarding such products. Other public health tools should supplement these efforts by continuing to encourage smoking cessation and prevention. This approach is consistent with the approach outlined by the Institute of Medicine: "The regulatory process should not discourage or impede scientifically grounded claims of reduced exposure, as long as steps are taken to ensure that consumers are not misled . . ." Institute of Medicine, "Clearing the Smoke: Assessing the Science Base for Tobacco Harm Reduction" (2001), at 7-13.

I. BACKGROUND

In 2001, the Committee to Assess the Science Base for Tobacco Harm Reduction (the "Committee") of the Institute of Medicine ("IOM") issued a report on reduced-exposure and reduce-risk tobacco products commissioned by the Food and Drug Administration ("FDA").

The Committee made clear that it recommends a regulatory approach based on *sound science* and *full consumer disclosure.* Prior to detailing its principles for the regulation of reduced-exposure and reduced-risk tobacco products (which the Committee referred to as "potential reduced-exposure products," or "PREPs"), the Committee stated:

> "The committee did come to conclude that regulation of PREPs is necessary and feasible . . . *[R]egulation is needed to ensure that the product labeling and advertising do not mislead consumers and accurately describe the products' risks, including the uncertainties that can only be resolved after long-term use.* Consumers should not use these new products on the basis of explicit or implicit claims that these products carry less risk than traditional tobacco products unless such claims are true. Absent careful regulation of industry claims about these products, informed choices by consumers will not be possible, the potential benefit of harm reduction strategy is likely to go unrealized, and the long and unsettling saga of light cigarettes may well be repeated."

IOM Report, at 7-2 (emphasis added).

Notwithstanding IOM's recommendations, however, certain legislative proposals to grant FDA authority to regulate tobacco products appear to authorize FDA to suppress information about PREPs even if FDA has verified that these products actually have the potential to present potential benefits for consumers. For example, some proposals would permit manufacturers to make reduced-exposure or reduced-risk health claims only if FDA determines that the product actually reduces the risk of harm to individuals as a matter of science *and* is otherwise "appropriate" for the "public health."[4]

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[4] *See e.g.*, H.R. 936, 108th Cong. § 572(a)(1), (2) (stating that FDA must determine that "based on the best available scientific evidence the product significantly reduces the *overall health risk*

This type of two-prong standard—with a "scientific merits prong"' and an "appropriateness" prong—appears to respond to those segments of the public health community that have called for FDA discretion to suppress reduced-risk claims, notwithstanding their veracity, based on their potential effect on consumer behavior. See, *e.g.*, National Cancer Society et al., *Why the FDA Should Regulate Tobacco Products* (June 27, 2002) (stating that FDA should have the authority "to prohibit or restrict . . . claims that discourage people from quitting or encourage them to start using tobacco"); Campaign for Tobacco Free Kids, *Critical Elements of FDA Authority Over Tobacco* (Feb. 18, 2000) ("FDA should have the authority to prohibit . . . health claims that have an adverse effect on the overall risk to the American public . . .").[5]

Thus, under this two-prong standard, even if valid scientific evidence demonstrates to FDA's satisfaction that a product presents potential benefits, the agency could prohibit truthful and non-misleading information about the product's reduced-exposure or reduced-risk potential from being communicated to consumers in the marketplace.

II. THE FIRST AMENDMENT PRECLUDES THIS KIND OF SUPPRESSION OF INFORMATION

This approach to the regulation of PREPs would violate the First Amendment and sound public policy. First, the suppression of information would not materially and directly advance the government's legitimate interests in encouraging tobacco cessation and prevention. Instead, the suppression of information would harm a clearly identifiable group of individuals. Second, the government has far more tailored means at its disposal to address any impact of PREPs on the rates of smoking cessation and initiation. Such alternatives include the mandatory use of public health disclaimers to ensure that PREPs are not perceived as safe, and the pursuit of other public health programs to encourage tobacco cessation and prevention.

The Supreme Court repeatedly has held that once a product is legally sold in the United States, the government may not deny adults truthful and non-misleading information about the product. Rather, the government must adopt more tailored restrictions to achieve its legitimate purposes. As the Supreme Court stated in its seminal commercial speech case:

> "There is, of course, an alternative to [a] highly paternalistic approach [to regulating commercial speech]. That alternative is to assume that this information is not in itself harmful, that people will perceive their own best interests if only they are well enough informed, and that the best means to that end is to open the channels of communication rather than to close them . . . It is precisely this kind of choice, between the dangers of suppressing information, and the dangers of its misuse if it is freely available, that the First Amendment makes for us."

Virginia Bd. of Pharmacy v. *Virginia Citizens Consumer Council,* Inc., 425 U.S. 748, 770 (1976).

"[B]ans against truthful, nonmisleading commercial speech . . . usually rest solely on the offensive assumption that the public will respond "irrationally" to the truth. The First Amendment directs us to be especially skeptical of regulations that seek to keep people in the dark for what the government perceives to be their own good." *Thompson* v. *Western States Medical Center,* 122 S.Ct. 1497, 1508 (2002), citing 44 *Liquormart* v. *Rhode Island,* 517 U.S. 484, 503 (1996) (plurality opinion).

In *Lorillard Tobacco Co.* v. *Reilly,* 533 U.S. 525 (2001), the Supreme Court struck down certain restrictions on the advertising of tobacco products because those restrictions were not sufficiently tailored to fit the government's objective of protecting children. This holding reaffirmed that the Court will carefully scrutinize commercial speech restrictions, including in the case of tobacco products, to determine if less restrictive means are available to achieve the government's purpose. The *Reilly* Court also made clear that commercial speech restrictions continue to be subject to the following four-part inquiry developed by the Supreme Court in the *Central Hudson* case:

> "For commercial speech to come within [the First Amendment], it at least must concern a lawful activity and not be misleading. Next, we ask whether the asserted government interest is substantial. If both inquiries yield positive answers, we must determine whether the regulation directly advances the govern-

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to the public when compared to other tobacco products," and that in approving reduced-risk claims, FDA must "ensure [the claim's] accuracy and, in the case of advertising, . . . *prevent such statement from increasing, or preventing the contraction of, the size of the overall market for tobacco products*" (emphasis added).

[5] For example, H.R. 936 provides that FDA must prevent reduced-risk advertising claims from "increasing, or preventing the contraction of, the size of the overall market for tobacco products." H.R. 936 § 575(a)(2).

ment interest asserted, and whether it is not more extensive than is necessary to serve that interest."

447 U.S. 557, 566 (1980). "We have said that the last two steps of the *Central Hudson* analysis basically involve a consideration of the 'fit' between the legislature's ends and the means chosen to accomplish those ends." *Rubin* v. *Coors Brewing Co.,* 514 U.S. 476, 486 (1995).

Simply put, the suppression of information about PREPs does not fit the government's interest in encouraging tobacco cessation and prevention.

A. The Suppression of Reduced-Risk Information Would Elevate Presumed Paternalistic Benefits for Some Over Real Harms for Others

The premise behind providing FDA with authority to suppress truthful and non-misleading information appears to be that the costs associated with the possible changes in the rates of cessation and initiation might outweigh the benefits resulting from communications about PREPs. To tilt the balance in this fashion, however, one would have to value the presumed benefits that may be provided to some individuals over the real costs that would be imposed on others. Such conjecture, however, cannot justify the suppression of truthful and non-misleading commercial speech under the First Amendment. "Such speculation certainly does not suffice when the [government] takes aim at accurate commercial information for paternalistic ends." *44 Liquormart,* 517 U.S. at 507.

Moreover, as detailed below, an abstract discussion about costs and benefits fails to illuminate the serious consequences of suppressing truthful information about PREPs.

1. *The Paternalistic and Speculative Benefits Provided by the Suppression of Information Are Insufficient to Pass Constitutional Muster*

The suppression of information presumably would be intended to benefit that segment of the population that would quit or never initiate smoking if information about PREPs is not available, but who would choose to switch to or begin using them if they were made aware of these products. Viewed from a "paternalistic" perspective, this segment of the population would be benefited by the suppression of information. Attempting to justify the suppression of information on this basis, however, is at odds with the Constitution, because paternalism is not a legitimate governmental interest, and because the realization of this paternalistic benefit would be impermissibly speculative.

The government "does not have the broad discretion to suppress truthful, nonmisleading information for paternalistic purposes . . . " *44 Liquormart,* 517 U.S. at 510. Indeed, the Supreme Court has "rejected the notion that the [g]overnment has an interest in preventing the dissemination of truthful commercial information in order to prevent members of the public from making bad decisions with the information." *Western States,* 122 S.Ct. at 1507. "[T]he argument [for suppression] assumes that the public is not sophisticated enough to realize the limitations of advertising, and that the public is better kept in ignorance than trusted with correct but incomplete information. We suspect the argument rests on an underestimation of the public . . . [W]e view as dubious any justification that is based on the benefits of public ignorance." *Bates* v. *State Bar of Arizona,* 433 U.S. 350, 374-375 (1977). "To endeavor to support a restriction upon speech by alleging that the recipient needs to be shielded from that speech for his or her own protection . . . is practically an engraved invitation to have the restriction struck." *Wash. Legal Found.* v. *Friedman,* 13 F. Supp. 2d 51, 70 (D.D.C. 1998) (judgment vacated on other grounds). "[T]he government may not restrict speech because it fears, however justifiably, that the speech will persuade those who hear it to do something of which the government disapproves." David A. Strauss, *Persuasion, Autonomy, and Freedom of Expression,* 91 Colum. L. Rev. 334, 334 (1991).

Moreover, this justification for suppression of information would fail the third prong of the *Central Hudson* test because it would require the court "to engage in the sort of "speculation or conjecture" that is an unacceptable means of demonstrating that a restriction on commercial speech directly advances the [government's] asserted interest." *44 Liquormart,* 517 U.S. at 507. For example, in *Rubin* v. *Coors Brewing Co.,* 514 U.S. 476 (1995), the Court concluded that the government's prohibition on displaying alcohol content on beer labels failed the third prong of *Central Hudson* because it would not sufficiently advance the government's interests in preventing "strength wars" in the marketing of alcoholic beverages. The Court reasoned that the government's burden "is not satisfied by mere speculation or conjecture; rather, a governmental body seeking to sustain a restriction on commercial speech must demonstrate the harms it recites are real and that its restric-

tion will in fact alleviate them to a material degree." *Id.* at 487, quoting *Edenfield* v. *Fane,* 507 U.S. 761, 770-771 (1993).[6]

It is far from clear that suppressing information would "in fact alleviate" the perceived harms that might arise from the introduction of PREPs. Any information suppressed by the government likely would find its way to consumers through other channels, though almost certainly in a less accurate form that has not been subject to scientific verification. As the IOM Report notes, "marketplace forces already at work have put this issue on the public policy agenda," and consumers will seek out PREPs "with or without scientific guidance." IOM Report at 7-1, 7-2. Moreover, as discussed below, any advance in the public health that purportedly results from the suppression of information would be undermined by the adverse effects of such suppression on individuals who would have used PREPs had the suppressed information been available to them.

2. *Real Harms Would Be Imposed by the Suppression of Information*

Though the benefits to be derived from the suppression of information about PREPS are speculative, it is clear that a separate group of individuals would be harmed by the suppression of such information. This group consists both of smokers who would have switched to PREPs instead of continuing to use conventional tobacco products, and nonsmokers who would have begun using PREPs instead of conventional tobacco products if they had been provided with information about PREPs. Regardless of one's philosophical bent, everyone should agree that this group, which ends up taking on more risks solely because of the suppression of information, is substantially harmed by that suppression.

It is neither sound public policy nor constitutionally permissible for the government knowingly to harm a certain group of individuals by suppressing information for the presumed benefit of others. The Supreme Court held in the *Western States* decision that such a suppression of commercial speech cannot be reconciled with the First Amendment. *Western States,* 122 S.Ct. at 1508-09. In this decision, the Court invalidated provisions of the Food and Drug Modernization Act ("FDAMA") that prohibited advertising of "compounded drugs,"[7] which the government argued were necessary to ensure that drug compounding was not used to circumvent the new drug approval requirements of the Federal Food, Drug, and Cosmetic Act ("FDCA"). Id. at 1504-06.

The Supreme Court found that the prohibition on advertising of compounded drugs was impermissible, *inter alia,* because of "the amount of beneficial speech" that it prohibited without furthering the asserted governmental objective. *Id.* at 1508.[8] Specifically, the Court pointed out that the prohibition would prevent pharmacists with "no interest in mass-producing medications" in circumvention of FDCA from telling doctors about alternative drugs available through compounding that would be useful in treating patients with special medical needs. *Id.* at 1508-09. The fact that such "useful speech" would be suppressed even though doing so would not "directly further" the government's asserted objective was "enough to convince" the Court that the challenged provisions were unconstitutional. *Id.* at 1509.

Following *Western States,* the suppression of information about PREPs would be unconstitutional because it would result in real harm for certain groups of people without furthering a substantial governmental interest. The suppression of truthful, non-misleading claims clearly would redound to the detriment of certain individuals—*i.e.,* those who, had they been exposed to the claims, would have switched to PREPs from conventional tobacco products. Moreover, the only motivation for suppressing truthful and non-misleading reduced-risk information would be the govern-

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[6] When viewed from a more "utilitarian" perspective, these individuals are not benefited at all by the suppression of information. From this perspective, adults are better off if they are left free to make their own decisions based on full information. As University of Chicago Law School Professor Cass Sunstein puts it, "people should be allowed to select their preferred mixes of risk, employment, salary, medical care, and so forth." Cass R. Sunstein, *Informing America: Risk, Disclosure, and the First Amendment,* 20 Fla. St. U. L. Rev. 653, 659 (1993); *see also* Martin H. Redish, *Tobacco Advertising and the First Amendment,* 81 Iowa L. Rev. 589, 592 (1996) ("The asserted justifications for such regulation of the truthful promotion of a lawful product derive exclusively from a premise of governmental paternalism that is fundamentally inconsistent with both the purposes served by free speech and the democratic system of which free speech is a central element.")

[7] Drug compounding, a "traditional component of the practice of pharmacy," is a process by which a pharmacist or doctor combines or alters drug ingredients to create a medication typically not commercially available and which is tailored to the needs of a particular individual, *e.g.,* an individual that is allergic to an ingredient in a mass-produced product. *Id.* at 1500.

[8] In response to the *Western States* decision, FDA issued a Federal Register notice seeking comments to "ensure that its regulations, guidances, policies, and practices continue to comply with the governing First Amendment case law." 67 Fed. Reg. 34,942 (May 16, 2002).

ment's desire to prevent people from using the information to make choices that the government disfavors. Yet, as discussed above, the Constitution does not recognize such a motivation as a legitimate basis for restricting commercial speech. Under these circumstances, not only would the government impermissibly be saying that it knows what is best for certain of its citizens, but in doing so, it would affirmatively harm other citizens.

The government's decision to suppress reduced-risk information also has severe consequences for the individual and, indeed, for our system of government as a whole:

> [T]he fundamental premise of the First Amendment—indeed, of the very democratic system of which the First Amendment is such an important part—is that citizens must be trusted to make their own lawful choices on the basis of a free and open competition of ideas, opinions, and information. If government is permitted paternalistically to shield its citizens from such open debate as a means of controlling their behavioral choices, it will have simultaneously affronted individual dignity and stunted the individual's personal and intellectual growth, a developmental process that lies at the heart of the free speech right. It will simultaneously have contributed to an intellectual atrophy of the citizen that ultimately will undermine her effective participation in the democratic system.

Redish, *Tobacco Advertising and the First Amendment, supra,* at 636.

B. More Targeted Approaches Are Available to Address Public Health Concerns About PREPs

Far more targeted approaches are available for the government to address concerns about the impact that PREPs might have on the rates of smoking cessation and initiation. FDA should ensure that information about the product's reduced-exposure or reduced-risk potential is presented to consumers in a truthful and nonmisleading manner. Indeed, authority to prevent false and misleading product information is a standard FDA regulatory tool that currently applies to all product labeling and promotional materials regulated under FDCA, and that would be extended to tobacco products by proposals granting FDA authority to regulate such products. In addition, other public health tools to encourage tobacco cessation and prevention are available and currently in use.

1. *FDA Should Consider Appropriate Use of Disclaimers to Address Public Health Concerns*

The Supreme Court held in *Western States* that "if the [g]overnment can achieve its interests in a manner that does not restrict speech, or that restricts less speech, the [g]overnment *must* do so." *Western States,* 122 S.Ct. at 1506-07 (emphasis added) (holding that the government failed to demonstrate that preserving the integrity of the FDCA drug approval process could not be achieved through means that imposed a lesser burden on speech than the FDAMA prohibition on advertising compounded drugs). Consequently, the advertising prohibition challenged in that case failed to satisfy the fourth prong of the *Central Hudson* test requiring that the restrictions not be more extensive than is necessary to serve the governmental interest. *Id. See also Pearson* v. *Shalala,* 164 F.3d 650, 655 (D.C. Cir. 1999) (there cannot be "an absolute prohibition on . . . potentially misleading information . . . if the information also may be presented in a way that is not deceptive"); *Wash. Legal Found.* v. *Friedman,* 13 F. Supp. 2d at 73 (FDA restrictions on particular forms of manufacturer promotion of off-label uses for FDA-approved drugs were considerably more extensive than necessary, and "[t]he most obvious alternative is full, complete, and unambiguous disclosure by the manufacturer").

In *Western States,* the Supreme Court identified the use of so-called "disclaimers" as an alternative way to ensure that consumers are not misled by advertisements. *Western States,* 122 S.Ct. at 1508 (a governmental interest in preventing misleading advertising could be achieved by "the far less restrictive alternative" of requiring compounded drugs to bear warnings stating that the drugs are not FDA-approved and that their risks are unknown). The D.C. Circuit made the same conclusion in Pearson, stating that "we are skeptical that the government could demonstrate with empirical evidence that disclaimers . . . would bewilder consumers and fail to correct for deceptiveness . . . ". *Pearson,* 164 F.3d at 659-660; *see also In re R.M.J.,* 455 U.S. 191, 203 (1982) ("[T]he remedy in the first instance is not necessarily a prohibition but preferably a requirement of disclaimers or explanation."). Furthermore, this principle is "consistent with a well-established body of law that points to First Amendment limits on federal agencies' restrictions on commercial speech where less restrictive alternatives are available." Steven B. Steinborn & Kyra A. Todd, *The End of Paternalism: A New Approach to Food Labeling,* 54 Food & Drug L.J. 401, 402 (1999). "*Pearson* stands as [a] reminder that regulatory agencies in general, and

FDA in particular, must adopt a regulatory approach that recognizes the consumer's right to receive pertinent information." *Id.* at 413-414.

Indeed, the Federal Trade Commission has long supported the position that disclaimers must be considered as an alternative when determining whether health claims about a product are misleading. *See Nat'l Comm'n on Egg Nutrition* v. *FTC,* 570 F.2d 157, 164 (7th Cir. 1977); Margaret Gilhooley, *Constitutionalizing Food and Drug Law,* 74 Tul. L. Rev. 815, 827 (2000); *see also FTC Enforcement Policy Statement on Food Advertising,* 59 Fed. Reg. 28,388, 28,393 (1994) (noting that the "significant scientific agreement" standard in the Nutrition Labeling and Education Act of 1990 (NLEA) is the appropriate standard to determine if health claims are misleading only in situations where the claims are *unqualified*).

Providing consumers with additional information, such as through the use of disclaimers, is thus a more tailored means to address the potential impact of PREPs on smoking cessation and initiation. "Any 'interest' in restricting the flow of accurate information because of the perceived danger of that knowledge is anathema to the First Amendment; *more speech and a better informed citizenry are among the central goals of the Free Speech Clause*." *Rubin,* 514 U.S. at 497 (Stevens, J., concurring) (emphasis added). FDA could require, for example, that every tobacco product designated as a PREP include labeling that reminds consumers that no tobacco product is safe and that the best option is to quit or not to start in the first place.[9]

2. *Other Public Health Tools are Available to Address Concerns Related to Smoking Cessation and Prevention*

An FDA-imposed restriction on the communication of information about PREPs is not the only policy tool available to address concerns related to tobacco use. As the Institute of Medicine noted, the regulatory system should not be viewed in isolation, but rather "as an essential component of a package of public policy initiatives (including research, education and surveillance) that this committee believes is necessary to realize whatever benefit tobacco or pharmaceutical product innovation can offer in reducing the nation's burden of tobacco-related illness and death." IOM Report at 7-21, 22. "Harm reduction [should be] implemented as a component of a comprehensive national tobacco control program that emphasizes abstinence-oriented prevention and treatment." *Id.* at 7-21.

In this regard, Congress appropriated more than $100 million to the Centers for Disease Control for its tobacco control efforts in FY—2003. Further, many states have increased their spending on tobacco control efforts in the wake of the state attorneys general tobacco settlements (the "MSA"). These state and federal tobacco control programs are in addition to the $1.5 billion that was earmarked in the MSA to fund tobacco control efforts through a national public health foundation, the American Legacy Foundation, which is overseen by the state attorneys general.

Indeed, the government would have the burden of demonstrating that programs such as these could not adequately address the public health concerns raised by PREPs, which would obviate the need to suppress truthful, non-misleading information. "If the First Amendment means anything, it means that regulating speech must be a last—not first—resort." *Western States,* 122 S.Ct. at 1507.[10]

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[9] Of course, FDA could prohibit any reduced-risk or health claims for tobacco products that have not been approved by FDA. *See, e.g., Whitaker* v. *Thompson,* 239 F.Supp. 2d 43, 54 (D.D.C. Jan. 3, 2003) (holding that claims concerning the therapeutic effects of a dietary supplement on an existing disease condition that were not approved as permissible reduced-risk claims for the product were unlawful health claims).

[10] The Supreme Court ruled in *Western States* that the government must consider non-speech related alternatives before resorting to restrictions on commercial speech. In the decision, the Court identified several non-speech alternatives to FDAMA's compounded drug advertising prohibition that might be effective in achieving the government's interest of ensuring the integrity of FDCA's drug approval process. Id. at 1506. These were (1) banning the use of commercial scale manufacturing or testing equipment for compounding drug products; (2) prohibiting pharmacists from compounding more drugs in anticipation of receiving prescriptions than in response to prescriptions already received; (3) prohibiting pharmacists from offering compounded drugs at wholesale to other state licensed persons or commercial entities for resale; (4) limiting the amount of compounded drugs that a pharmacist may sell out of State or sell or make in a given period of time; or (5) relying on the non-speech related provisions of FDAMA, which include requiring that compounding only be conducted in response to a prescription or a history of receiving a prescription, and limiting the percentage of a pharmacy's total sales that out-of-state sales of compounded drugs may represent. *Id.* at 1506. The government's failure to explain why these alternatives would not be adequate led the Court to conclude that FDAMA's advertising prohibition was more extensive than necessary. *Id.* at 1506-07.

III. CONCLUSION

Based on these precedents and the IOM Report's recommendations, proposals to grant FDA authority over tobacco products should ensure that adult consumers are provided with truthful and non-misleading information about PREPs. "[P]erhaps the first and most basic problem is that Americans lack the necessary information . . . [P]erhaps the first goal ought to be to ensure genuinely informed choices, rather than to dictate outcomes from Washington." Sunstein, *supra,* at 654.

An outright ban on such information concerning PREPs would be inappropriate and unconstitutional. Instead, FDA should be empowered to assess and approve PREPs based on the scientific merits of the claims and then ensure that consumers are not misled about the risks associated with those products. Additional public health programs should continue to encourage smoking cessation and prevention.

Mr. STEARNS. At this point I would invite other members to do the same if they wish to enter documents into the record, and with that, I welcome my ranking member for an opening statement.

Ms. SCHAKOWSKY. Thank you, Mr. Chairman. It is good to see you again.

Well, you have got to hand it to the tobacco lobby. If there were such a thing as a chutzpa award, which roughly translates into brazen gall, the effort today, in my humble opinion, would be worthy of a prize.

Under the guise of concern for public health, the tobacco industry has us here to discuss its efforts to gain advanced government approval or a marketing campaign that would promote tobacco products and their bottom line.

"Smokeless tobacco"—I put that in quotes—is a dressed up name for dip, chew or spit tobacco, U.S. Tobacco, UST, wants to market its spit tobacco as a safer alternative to smoking cigarettes. Smokeless tobacco is a threat to our Nation's public health and especially to the health of our children. Any type of claim that spit tobacco as a safer alternative to smoking requires a substantive body of evidence and an independent regulatory body capable of examining the claims.

Such evidence and regulation does not exist. UST cannot back up their campaign slogans, and that is why they have asked the FTC, not the FDA, the FTC being a nonscientific regulatory agency, to review the claims they want to make.

Tobacco causes cancer and other diseases, whether you smoke it, chew it, suck it, put it up your nose. It can and after sustained use probably will kill you.

UST's argument that smokeless tobacco use is a healthier alternative to smoking is analogous to suggesting that one is better off jumping off the fifth floor of the building rather than the 20th because, of course, both are likely to cost you your life. They want to convince smokers who may be trying to quit or have quit, nonsmokers, children and others that their product is okay to use.

If we allow them to make these false claims, then the Congress will share the blame for more lives lost to tobacco related diseases.

The government has no business endorsing media campaigns for products like spit tobacco that lead to disease and premature death. First we should do no harm. If we send a message to the American public that it is okay to chew tobacco, we will be doing harm. If we, instead, want to truly discuss ways to reduce harm and promote health, we should spend time and money on legitimate ways to end the use of tobacco in any form, period.

Today, along with Congressman Waxman, I will be releasing a report entitled "The Lessons of 'Light' and Low Tar Cigarettes." Without effective regulation, reduced risk tobacco products, so-called reduced risk tobacco products, threaten the public health.

Mr. Chairman, I ask unanimous consent to insert this report into the record.

Mr. STEARNS. Without objection, so ordered.

Ms. SCHAKOWSKY. Thank you.

[The report appears at the end of the hearing.]

Ms. SCHAKOWSKY. I think it is an important document to include in the official record because it underscores parallels documented by the Government Reforms Committee Democratic staff between the efforts of the tobacco industry to mislead the public into believing that so-called light and low tar cigarette products are a healthy alternative to regular cigarettes and the efforts currently underway by UST to convince the Congress the FTC, and the public of the virtues of its spit tobacco products.

This report includes previously undisclosed internal industry documents and demonstrates that the products that are marketed as light and low tar are, in fact, not. We know that the tobacco industry duped the FTC's tests by designing cigarettes that only appeared healthier when tested by machines, but did not provide lower amounts of tar and nicotine to smokers.

We know that the industry has for some time been well aware of the dangers these products pose. An internal company E-mail included in this report, a senior research scientists at British-American Tobacco stated, "Our main problem appears to be the notion that the technology exists to make cigarettes which are appreciably less lethal. The technology does not exist. It will not exist."

The report also demonstrates that tobacco industry officials continue to deceive the public with information from industry, the National Cancer Institute, and the Department of Justice. The report provides clear examples of current "reduced risk" product marketing, including the marketing of spit tobacco specifically designed to counter health fears, deceive consumers, deter quitting, and exploit the absence of effective regulation.

The FTC allowed for the marketing of light and low tar products in the past, and the public was harmed. Now major lawsuits have ensued. In my home State of Illinois, a court recently ruled against Philip Morris and found that its creation of these brands was "immoral, unethical, oppressive, and unscrupulous."

And UST is here today trying to present a case that their spit tobacco products are not as harmful as smoking and, therefore, the company should be allowed to make such statements on their packaging. UST's representatives want us to believe that they are offering a product that will improve overall health in the United States.

Quite the opposite is true. We know from industry documents that UST has purposely targeted tobacco consumers in an effort to promote "dual consumption," not cessation of smoking.

We should not even be entertaining UST's claims absent a comprehensive review and serious regulation by the FDA. The FDA should have authority over all tobacco products, including spit tobacco, and authority to oversee the content, manufacture, sale, and marketing of the product. Absent this regulation, allowing mar-

keting strategies that include comparative health claims will lure more kids into smokeless tobacco use and addiction, discourage current users from quitting, and may increase the overall amount of tobacco products being used in the United States.

Mr. Chairman, I thank you for your indulgence in letting me go over. I think this is a very, very serious issue, and I appreciate the opportunity to discuss this important issue today with our witnesses.

Mr. STEARNS. I thank the gentlelady, and I will now recognize the Chairman of the full committee, who probably will not agree with you when you mention Tabasco sauce. The chairman, distinguished chairman of the committee, Mr. Tauzin.

Chairman TAUZIN. Thank you, Mr. Chairman.

I would not recommend you smoke Tabasco sauce though. It is not necessarily a good idea.

Let me thank you, Mr. Chairman, for convening this hearing, and I want to thank the Chairman of the Federal Trade Commission and the Surgeon General for coming to join us, and I hope it will be a very instructive session, particularly as we move to the second panel as well and get some insights as to this extraordinary issue.

We have held hearings, as you know, in this committee on tobacco in the past, but this particular issue of tobacco harm reduction is not one I think that has been the subject of a great deal of congressional debate, frankly, a good understanding yet. It was back in 1964 that the Surgeon General released a report finding that cigarette smoking is a health hazard of sufficient importance to the United States to warrant appropriate remedial action.

And we now know that smoking kills over 400,000 people annually in the United States alone, and that is more deaths each year than from AIDS, from alcohol, cocaine, heroin, homicide, suicide, motor vehicle crashes, and fires combined. You cannot ignore those kinds of statistics.

And during the past 4 decades we have made unprecedented gains in preventing and controlling tobacco use. However, despite the massive education campaigns and years of litigation, and substantial price hikes designed to curb smoking, it has picked up. And when asked, most smokers say they want to quit. I think over 80 percent will say that in most surveys. Unfortunately very few of them are able to break the habit.

There is no debate that the best option for any person using tobacco products is to stop, to stop using tobacco products, and particularly we need to continue to do all we can to discourage the use of these products by children.

But we also know that nicotine is a remarkably addictive drug. Some have likened the addictive qualities of nicotine to the intense grip of cocaine or heroin. Unfortunately there are people who, try as they may, are unable or unwilling to kick the smoking addiction.

Some in the medical community argue that we are giving these hardened smokers only one uninviting option: quit or die. Increasingly there are calls for options other than the quit or die approach, such as tobacco harm reduction. There are studies now that have found that some tobacco products, such as smokeless tobacco, are

less hazardous than cigarettes, not unhazardous or safe, but less hazardous.

These studies have resulted in a call for campaigns that would encourage smokers to switch from cigarettes to smokeless tobacco, which arguably could save many of the 400,000 people who will die every year, and that is an intriguing concept, and if science bears out these conclusions, we are faced with a myriad of questions that I hope we begin to think about and perhaps begin to answer today or at least set up a process whereby we might have the type of forums and discussions with officials and citizens of our country to find the answers to these questions.

They include: should we communicate this reduced risk information to the consumer? Is a person who is faced with a quit or die option one of my children? Is that person to entitled to know that there is another option that can reduce the risk of death and perhaps even be a bridge to stopping smoking?

If so, how should we communicate this information. Obviously the concern is if you communicate it improperly, you might encourage people to continue using tobacco, and that is not the goal obviously. So how do you do it properly?

Will promotion of certain tobacco products as reduced risk dilute the anti-tobacco, anti-smoking message that we are sending children, in particular? And that is a deep concern.

Finally, does a consumer have a right to know about safer tobacco products, about reduced risk products? We know in other countries, such as Sweden, they made that decision, that consumers were entitled to know, and there have been some remarkable results as a result of simply communicating that information to people who were faced with the quit or die option.

So these are questions I hope we will answer today. The hearing is especially timely because the Federal Trade Commission is currently faced with a petition from the United States Tobacco Company that requests an advisory opinion on whether, based on current science, it may advertise its smokeless product as a safer alternative to smoking. I hope the Federal Trade Commission examines the issue carefully.

I urge Chairman Muris to invest the commission's time and energy in a tobacco harm reduction workshop to more thoroughly evaluate these claims. I think it is time for that, just to have a very open and informative workshop so that we can understand whether we need to make some new policy decisions in this country.

Few medical questions have stirred more public interest or created more scientific debate than the tobacco health controversy. The relationship between tobacco and health does not lead to easy answers.

Nevertheless, there are 400,000 deaths in the United States attributed to smoking. It is increasingly apparent that we must continue to search for new and novel solutions.

I want to thank you again, Mr. Chairman, for holding the hearing and look forward to hearing from our two distinguished witnesses today.

Mr. STEARNS. And I thank the Chairman.

The gentleman from Massachusetts is recognized.

Mr. MARKEY. Thank you, Mr. Chairman, very much and thank you for holding this hearing.

To say that smokeless tobacco is a safer alternative to smoking cigarettes is very misleading. Smokeless tobacco products have known carcinogens and that are linked to oral cancer and they are addictive. This method of harm reduction may simply be trading one vice for another.

A few years ago I introduced the Cigars Are No Safe Alternative Act that would impose restrictions on the sale of cigars because cigar use is not a safe alternative to smoking cigarettes either. People need to be informed of all of the risks of tobacco products.

Just as with cigars and cigarettes, children especially must not be influenced by misleading advertising that glorifies the use or these tobacco products. Three thousand young people begin smoking in the United States every day. One thousand of these 3,000 will die from some lung related disease. Twenty percent of all Americans who die each year, die from some lung related smoking related disease. Obviously our goal should be to just stop it dead in its tracks.

I believe that people should make informed decisions for themselves as to which is a better alternative and safer for them. However, people cannot make informed decisions about smokeless tobacco products because we do not even know all of the additives that these products contain and what harm they may cause.

In fact, when the State of Massachusetts asked that these ingredients be disclosed, the tobacco industry sued them and won. So we do not even know all of the ingredients in these products.

There are safe, FDA approved nicotine based products that are safe, and when Massachusetts used them in an advertising campaign it helped to reduce smoking from 20 percent to 14 percent in the male population. But I do not believe that any governmental agency, the food and drug agency, the Department of Health and Human Services, or the Federal Trade Commission, should promote the use of tobacco products, especially when we know they are addictive, cancer causing, and gateways to further tobacco use.

The U.S. Smokeless Tobacco Company continued to advertise in youth magazines despite signing a master settlement agreement in 1998 which prohibited indirect or direct advertising that targets youth. In Massachusetts, the Attorney General was sued by the tobacco industry after trying to implement regulations that would prevent advertising of smokeless tobacco products near schools or playgrounds.

It is immoral to enhance a company's sales by targeting children to use an addictive substance that is detrimental to their health and is also illegal.

I think that we have a very important subject that we are debating here today, but there is no greater cause of illness in the United States than tobacco. It is central to the responsibilities of this committee that we do nothing that enhances the likelihood that young people will embrace this as a life style habit.

I thank you, Mr. Chairman.

[The prepared statement of Hon. Edward J. Markey follows:]

PREPARED STATEMENT OF HON. EDWARD MARKEY, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF MASSACHUSETTS

Mr. Chairman thank you for holding a hearing on such an important issue. To say that smokeless tobacco is a "safer" alternative to smoking cigarettes is misleading. Smokeless tobacco products have known carcinogens, are linked to oral cancer, and are addictive. This method of "harm reduction" may simply be trading one vice for another.

A few years ago I introduced the CANSA Act (Cigar Are No Safe Alternative Act) that would impose restrictions on the sale of cigars, because cigar use is not a safe alternative to smoking cigarettes either. People need to be informed of *all* the health risks for *all* tobacco products. Just as with cigars and cigarettes, children especially must not be influenced by misleading advertising that glorifies the use of these tobacco products.

I believe that people should make informed decisions for themselves as to which is a better alternative and safer for them. However, people can not make informed decisions about smokeless tobacco products because we do not even know all the additives that these products contain and what harm they may cause. In fact when the Commonwealth of Massachusetts asked that these ingredients be disclosed, the tobacco industries sued them and won, so we still do not know of all the ingredients in these products.

There are safe FDA approved nicotine based products on the market which are made for the purpose of terminating a smoking habit. When Massachusetts promoted the use of these nicotine-based products to stop smoking the number of males who smoked daily was reduced from 20% to 14%. The nicotine-based products are also more likely to be used by women, who make up a very small portion of the users of smokeless tobacco products. These nicotine-based products are a safe and effective way to end smoking. Let's work to enhance and promote this safe alternative instead of cancer-causing smokeless tobacco products.

Smoking and tobacco use is a tremendous public health problem. Studies have shown that smokeless tobacco use is a gateway to smoking. We must end smoking, not shift the use of tobacco products.

I do not believe that any governmental agency, the Food and Drug Agency, The Department of Health and Human Services, or the Federal Trade Commission should promote the use of a tobacco products, especially when we know they are addictive, cancer causing, and gateways to further tobacco use.

The U.S. Smokeless Tobacco Company (USSTC) continued to advertise in youth magazine despite signing a Master's Settlement Agreement in 1998 which prohibited indirect or direct advertising that targets youth. In Massachusetts the Attorney General was sued by the tobacco industries after trying to implement regulations that would prevent advertising of smokeless tobacco products near schools or playgrounds. It is immoral to enhance a companies' sales by targeting children to use an addictive product that is detrimental to their health and it is illegal.

Promoting alternatives to smoking is a truly important endeavor and worthy cause but only when these products are safe, and will not enhance the use of tobacco products.

I am glad that we are having this hearing today and happy to hear the testimony from our witnesses. I hope that we continue to work together to stop smoking by the most effective but safest means.

Thank you.

Mr. STEARNS. I thank the gentleman.

And the gentleman, Mr. Whitfield.

Mr. WHITFIELD. Mr. Chairman, I guess we still have the policy of 8 minutes if you forego your——

Mr. STEARNS. We do if you want to forego your opening statement.

Mr. WHITFIELD. I forego my opening statement.

Mr. STEARNS. Okay. The gentleman forgoes his opening statement.

Ms. McCarthy.

MS. MCCARTHY. Thank you, Mr. Chairman.

I am going to be very brief and put my remarks in the record.

I do want to thank you for this hearing, and I am glad to see the panel that we have before us.

I am personally shocked by the tobacco industry and their gross misunderstanding of what an addiction is, and I certainly hope today that we can shed some light on that gross misunderstanding. I really believe their commitment should be to just fund program that dissuade our children from this addiction that their product causes and that they should be leading the effort to find and produce funds to help with programs that will actually get individuals to quit.

You cannot address an addiction successfully by saying, "Just have a little bit." It will not work.

And so I look forward to the panel's testimony, and hopefully that will help us help the industry understand that their gross misunderstanding of what an addiction is is not acceptable to this Congress.

Thank you, Mr. Chairman.

Mr. STEARNS. I thank the gentlelady.

The gentleman from New Hampshire, Mr. Bass.

Mr. BASS. Thank you very much, Mr. Chairman, and I appreciate this interesting and quite controversial hearing.

First of all, I do not smoke cigarettes and I do not chew tobacco. In fact, as a State senator, I introduced a bill to tax smokeless tobacco.

However, from my perspective there are policymakers in government and in Congress who, if they had their choice, would chisel off the tobacco leaves on the podium in the Congress because somehow it would pollute and kill Members of Congress who happened to walk nearby. And the issue that we are going to have a hearing on today is not whether tobacco is safe for somebody to pick up and take up, but whether or not somebody who is smoking cigarettes, who may die of lung cancer, who other remedial means such as stopping smoking completely or using some of these other products which are advertised all over the place, whether those individuals ought to be able or ought to at least know that if you have a cigarette or a pack or two of cigarettes a day or you have a can of smokeless tobacco, which is going to be better for you?

Now, they both may not be good for you, but I do not think you can escape the conclusion that if you have a choice between these two products that smokeless tobacco is probably going to be a better alternative that will prolong your life.

And as I understand it, the Federal Trade Commission has a procedure underway to address this issue as to whether or not this industry can advertise in this manner, not bringing children in, not talking about lung cancer. Nobody ever suggested that chewing tobacco caused lung cancer or anything like that, but whether or not individuals who are addicted to cigarettes and have no other option might be able to see advertising that indicates that chewing tobacco might be a better alternative.

I think it is a fair issue, and I am looking forward to hearing testimony from both our Surgeon General and the FTC, as well as the succeeding panels.

And I will yield back, Mr. Chairman.

Mr. STEARNS. The gentleman yields back the balance of his time.

The gentleman from Texas, Mr. Green.

Mr. GREEN. Thank you, Mr. Chairman, and I would like to thank you and our ranking member for holding this hearing on tobacco harm reduction and the Federal Trade Commission's role in determining the appropriate advertising of smokeless tobacco.

There is no question that smoking and tobacco use is hazardous to our health. That is hopefully one issue that all of us in the room can agree on. I represent an area where smokeless tobacco is used by a lot of our young men as a right of passage. Now, this may not be the case in New York or San Francisco, but when we discuss how to help Americans quit smoking and what warnings our tobacco products should display, the debate is bound to heat up.

One thing is certain in my mind. Our efforts to discourage Americans from smoking cigarettes should not include advocating the use of smokeless tobacco products. Tobacco kills, whether it is inhaled or whether it is chewed, and that is a message that I think most folks would want our FTC and our government to send.

Since the mid-1980's we have known that smokeless tobacco causes oral cancer, and to decrease one's risk of lung cancer by increasing his or her risk of oral cancer is not in the interest of public health.

In resolving this marketing issue, the FTC is charged with ensuring that we do not send mixed messages to the consumer. Currently three rotating warning labels appear on smokeless tobacco packages, and they read:

One, the warning "this product may cause mouth cancer."

Another warning, "this product may cause gum disease and tooth loss."

A warning, "this product is not a safe alternative to cigarettes."

These warnings all send the same message. Smokeless tobacco is hazardous to your health. For the FTC to consider a label effectively promoting smokeless tobacco as a lower risk alternative to cigarette smoking, however, sends a very different message. It says that if you are going to use tobacco products but you also worry about your health, smokeless tobacco is the way to go.

Not only is this message mixed. It also is based on questionable science. A policy shift of this magnitude should not be based on the study of the Swedish smokeless tobacco which contains fewer cancer causing agents, is regulated by the government and cannot be advertised. There simply are no parallels to be drawn.

While the FTC has limited jurisdiction over tobacco, its mission is clear. It ensures that companies do not market their products in misleading or deceptive ways. To advertise smokeless tobacco as healthier for you than cigarettes is, in my mind, both misleading and deceptive because it holds the consumer's hand as it leaps to the rationalization that smokeless tobacco use is somehow okay. I do not believe that we should be in the business of promoting that mindset.

Mr. Chairman, a former Speaker of the House, Jim Wright, a few years ago had reconstructive surgery at M.D. Anderson in Texas because of jaw cancer. I happened to see Speaker Wright after that and talked to him while he was in the hospital.

I do not know the reason, like a lot of times things develop, but having been to M.D. Anderson and some of our great cancer facili-

ties, I also know that cancer is not something we want to see, whether it is in a former Speaker of the House or in our children.

And I yield back the balance of my time.

Mr. STEARNS. The gentleman yields back the balance of his time.

The gentleman from Arizona, the Vice Chairman of the committee, Mr. Shadegg.

Mr. SHADEGG. Thank you, Mr. Chairman.

And other than to express my appreciation for your holding this hearing to enlighten us all on this subject and to welcome Dr. Carmona, who is a resident of my State of Arizona and who came to his current position from the faculty of the University of Arizona, my alma mater, I will waive my opening statement and take my 8 minutes of questioning.

Mr. STEARNS. The gentleman waives his opening statement.

The gentleman from Florida, Mr. Davis.

Mr. DAVIS. Thank you, Mr. Chairman.

I will reserve my time for questions.

Mr. STEARNS. The gentleman reserves the balance of his time.

Mr. Terry, welcome. An opening statement?

Mr. TERRY. No opening statement.

Mr. STEARNS. No opening statement.

Mr. Fletcher.

Mr. FLETCHER. I reserve.

Mr. STEARNS. Reserve the balance.

The gentlelady, Mrs. Cubin.

Mrs. CUBIN. I will submit my statement for the record.

Mr. STEARNS. By unanimous consent, so ordered.

[The prepared statement of Hon. Barbara Cubin follows:]

PREPARED STATEMENT OF HON. BARBARA CUBIN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF WYOMING

Thank you, Mr. Chairman, for holding this hearing today and sparking continued Congressional debate over what is right in educating consumers, reducing public health risks and proper regulation in communicating the truth about tobacco.

I would also like to thank the distinguished panelists for joining us. Your diverse insight and expertise will certainly guide the continued examination of the tobacco harm reduction debate.

The issue of tobacco related death and disease is one that deserves a fair, honest and scientifically-based debate. It is probable that each one of us here has a story to tell of a friend or loved one negatively affected by the dangers of smoking.

Progress undoubtedly has been made in the research on the impacts of tobacco use. We have come a long way in educating consumers—both young and old—about the risks involved and ways to quit.

There are also a growing number of options available to those addicted to nicotine with a desire to end their smoking habit by way of gradual or immediate means. These breakthroughs have opened new doors in overcoming addiction and new ground lies ahead that is worth continued exploration.

Regardless of what product there is to sell or potential profit that exists, we must hold in the highest regard the human lives at stake here. Knowledge is power and should not be withheld in the constraints of perhaps an outdated paradigm in the battle to reduce smoking related fatalities and disease.

According to the Centers for Disease Control, hundreds of Wyomingites die from diseases caused by smoking every year. If there is information available that would save the lives of hundreds of my constituents who smoke, then we have a responsibility to disseminate this life saving knowledge. To refrain from doing so would be deceitful.

Today I hope the debate will be balanced, passionate and committed to the scientific data available to us. The people of my home state deserve to know all of the facts about tobacco use, further empowering their decisions as consumers and potentially saving their lives. I look forward to determining how best this should be done.

I thank the Chairman again and yield back the remainder of my time.

Mr. STEARNS. Mr. Ferguson, an opening statement?

Mr. FERGUSON. I will make an opening statement, Mr. Chairman.

Mr. STEARNS. Okay.

Mr. FERGUSON. Thank you very much.

I would like to begin by thanking you for holding this hearing on a subject that is really terribly important to the public health of our Nation. It is an undisputed fact that smoking is a killer, and according to the American Lung Association, smoking related diseases claim an estimated 430,700 American lives each year, and it is directly responsible for 87 percent of lung cancer cases and causes most cases of emphysema and chronic bronchitis.

I have had several family members, including grandparents, who have died of lung disease, emphysema, lung cancer, and other ailments related to their smoking. This list of ailments that smoking causes or hastens is well founded and it is alarming, and it has proven that smoking contributes to cancer of the lungs, the oral cavity, the esophagus, the larynx, and is a contributing cause of cancer in the pancreas, bladder, kidney, and cervix.

Finally, smoking costs the United States approximately $97 billion each year in health care costs and lost productivity. We need to do all that we can to help current smokers to quit and to insure that our children do not fall victim to this deadly habit.

Increased education and various other public health initiatives have brought a gradual decline in smoking rates over the past 20 years. Studies have shown that 70 percent of smokers say that they are interested in quitting. Thirty-four percent of smokers actually attempt to quit.

However, only less than 10 percent of those people and only 2.5 percent of total smokers actually end up quitting. I think it is safe to say that if someone close to us has given up smoking or has tried, we all know how tough it actually is to break the habit. There are many products on the market that are specifically designed to help smokers break the habit. It is vital that the people of our country are fully informed of the risks involved not only by smoking, but of the various treatments and alternatives that help to wean someone off the habit.

Many of the alternatives have undergone rigorous testing by the FDA, but we must be mindful of those alternatives that may actually lead to smoking or that actually may be harmful in their own right.

Again, I want to thank you, Mr. Chairman, thank the members of this committee, and I want to thank our panelists who are here today.

I yield back.

Mr. STEARNS. The gentleman yields back. I thank the gentleman.

As is customary, we allow our colleagues who are not a member of the subcommittee, who are a member of the full committee for an opening statement, and that is Mr. Waxman from California. I welcome him.

Mr. WAXMAN. Thank you very much, Mr. Chairman, for allowing me to participate in this hearing.

Let me state at the outset I am not opposed in principle to harm reduction strategies that are targeted toward addicted smokers, but as we explore these possibilities, we need to remember that unsubstantiated health claims for tobacco products can have disastrous consequences, keeping smokers from quitting and encouraging teenagers to start.

These are not abstract concerns. We have had a failed experiment with light and low tar cigarettes, and the advent of new reduced risk products poses similar risks. The report we are releasing today with Representative Schakowsky finds disturbing parallels between the public health disaster of light and low tar cigarettes and what companies like U.S. Smokeless Tobacco, UST, are trying to do now.

Today the subcommittee is considering their request to market its dangerous and addictive product as safer than cigarettes. In November 1994, I chaired the last congressional hearing to focus on smokeless tobacco. We heard indisputable evidence that UST manipulated nicotine levels in its products to hook young users and then graduate them to stronger products. And we heard UST deny that smokeless tobacco is addictive.

Nearly 9 years later UST still argues that smokeless tobacco is not a proven cause of disease and denies smokeless tobacco is addictive. UST claims its goal is to help smokers quit, but one of the company's strategic objectives is to promote dual consumption of cigarettes and smokeless tobacco, the very opposite of cessation.

In a recent response, UST wrote to a "Dear Colleague" I sent out, they denied some of the points that I made. They said it was baseless to suggest the company added cherry flavoring to some of its products to appeal to children, but according to a 1980 memo, UST's Senior Vice President said that younger and lighter users prefer flavor and older users prefer tobacco taste.

They wrote that they never employed a strategy to graduate young users to a more addictive product. This same document, however, shows that the company's objective was to provide new users with an easy graduation process.

UST said it was misleading or inaccurate to suggest the company ever marketed to children, but a memo from a regional sales manager to the national sales manager indicates that UST had marketed smokeless tobacco to children as young as 13 or 14 years of age.

Mr. Chairman, because these documents speak to the clear need for an effective and comprehensive regulation prior to any health claims for smokeless tobacco, I would like to ask unanimous consent to include in the record a letter I have written to Chairman Tauzin that describes and attaches these documents.

Mr. STEARNS. By unanimous consent, so ordered.

[The material appears at the end of the hearing.]

Mr. WAXMAN. And I look forward to the testimony.

Mr. STEARNS. And I thank the gentleman.

No one else seeks recognition.

[Additional statements submitted for the record follow:]

PREPARED STATEMENT OF HON. ED TOWNS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW YORK

Mr. Chairman, and fellow Members, today's hearing raises an important issue do—"harm reduction" products have a role in addressing the health issues associated with smoking.

This issue of public health policy is of great importance. More than 50 million adult Americans smoke. The question we seek to address in this hearing is how may we, as policymakers, improve the health of those 50 million individuals. It should go without saying that public health policy of this nature cannot be made in a vacuum; we must take into account the ability, and indeed the rights, of individuals to make their own choices regarding their health.

The Constitution recognizes that individuals should be allowed to hear and evaluate product information for themselves. In no other area of life is this right more important than in the area of personal behavior and health. These choices may affect not only the health and well being of the individual, but also the health and well being of family members. As such, those decisions should be well informed, based on accurate, uncensored, truthful and nonmisleading information.

That is what is at the heart of this hearing today-the right of individuals to know the facts about products that impact their behavior and health. Today's witnesses have suggested in their written testimony that the facts are in dispute about the ability of tobacco "harm reduction" products to improve the health of those smokers who have not been able to quit smoking. Even if the research is unsettled on this issue, it does not mean that discussions should not begin on this matter. Mr. Chairman, I am hopeful that today's hearing will be the beginning of a dialogue on the question of "harm reduction" products and their relationship to health improvements for smokers.

PREPARED STATEMENT OF HON. SHERROD BROWN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF OHIO

A man is driving home on a busy boulevard, going 50 miles an hour through a residential neighborhood, swerving from lane to lane and blowing through stop signs. He likes to speed and has no intention of slowing down, but when a warning light on his dashboard flashes on, he decides to buckle his seat belt. So, is his behavior "less harmful" than before he buckled up? Less harmful to himself? Less harmful to the other motorists and pedestrians on the road?

Can you imagine a public service announcement saying "Reckless driving is dangerous, but if you do choose to drive recklessly, remember to wear your seat belt?"

Fundamentally, the same grim choice was implicit in the Federal Trade Commission's consideration of a petition by U.S. Smokeless Tobacco (UST) for an advisory opinion concerning the marketing of smokeless tobacco products as "less harmful" than cigarettes.

The simple fact is that both cigarettes and smokeless tobacco products are dangerous and often deadly. To focus exclusively on whether one is more or less harmful than the other is to obscure the truth that both are potentially lethal.

Because such a claim would obscure the truth, it would appear to be a textbook case of deceptive marketing. I was pleased to learn UST has withdrawn its petition.

I hope, should UST or another manufacturer decide to revive it, FTC will reject it as fundamentally inconsistent with the legal prohibition on deceptive marketing.

But the UST petition raised more than technical questions about commercial practices. It also reinvigorated debate over America's Quixotic and counterintuitive approach to the regulation of nicotine delivery systems.

In the United States, the federal Food and Drug Administration (FDA) must approve products designed and marketed to help Americans kick the habit of nicotine addiction. FDA must—and should—verify that such products are safe and effective, because their use is recognized to have important public health consequences. But products designed and marketed to feed that same nicotine addiction are not regulated by FDA, ignoring the simple fact that their use has equal or greater consequences for public health.

20,000 Ohioans die every year from tobacco-related illnesses, according to the Ohio Tobacco Use Prevention and Control Foundation. 17% of Ohio's Medicaid dollars are spent on treatment for tobacco-related disease, effectively imposing an annual tax of over $500 on every Ohio household. With these grave costs in mind, surely we should be working to end tobacco addiction, not perpetuate it.And approving misleading health-related marketing claims for smokeless tobacco would do just that: perpetuate America's addiction to tobacco.

Our experience with the marketing of filtered and "low-tar" cigarettes amply illustrates the perils of marketing some tobacco products as "safer" alternatives to others.

Clever marketing got consumers to try these products, but because they changed the way people smoked, they may well have been as harmful or more harmful than traditional cigarettes. Health claims for smokeless products may be even more dangerous, in that it is likely some consumers—including kids—will see smokeless products as supplements to, not substitutes for, smoking.

Claims that smokeless tobacco products are less harmful than cigarettes raise very expansive questions with profound public health consequences. These questions are much too sweeping a decision to answer based only on the narrow scope of the FTC Act's unfair and deceptive marketing standard. In addition, a meaningful evaluation of any health claim requires technical and medical expertise well beyond the FTC, which is chiefly a consumer protection agency.Fortunately, we have a federal agency that has just that technical expertise: the FDA. The Institute of Medicine has maintained for years that all tobacco products should be regulated by the federal government, to facilitate responsible research and meaningful evaluation of health-related claims. If sound science and the protection of public health are our objectives, we should take the IOM's advice and give the job to an agency equipped to meet the challenge.

Today's hearing raises important issues with broad implications for public health and responsible business practices. I welcome a lively discussion of these issues, and I look forward to the testimony of our witnesses.

Thank you, Mr. Chairman.

Mr. STEARNS. Then we will welcome our two distinguished panelists, the Honorable Timothy Muris, Chairman of the Federal Trade Commission; Vice Admiral Richard H. Carmona, U.S. Surgeon General and Acting Assistant Secretary for Health, U.S. Department of Health and Human Services.

Welcome, and, Chairman Muris, we will start with you.

STATEMENTS OF HON. TIMOTHY MURIS, CHAIRMAN, FEDERAL TRADE COMMISSION; AND VICE ADMIRAL RICHARD H. CARMONA, U.S. SURGEON GENERAL, PUBLIC HEALTH SERVICE, DEPARTMENT OF HEALTH AND HUMAN SERVICES

Mr. MURIS. Thank you very much, Mr. Chairman.

And I would just ask that the commission's full statement be placed in the record.

Mr. STEARNS. By unanimous consent, so ordered.

Mr. MURIS. I am Tim Muris, the Chairman of the Federal Trade Commission. I am certainly pleased to appear here today to discuss the FTC's role in the potential advertising of reduced risk tobacco products.

The FTC's mission is to prevent unfair competition and unfair or deceptive acts or practices in the marketplace. The Commission does this by insuring that advertising and marketing claims are truthful and not misleading.

Our jurisdiction over advertising and marketing claims includes jurisdiction over claims for cigarettes, smokeless tobacco, and other tobacco products. Indeed, the FTC's law enforcement activities involving tobacco advertising and promotion date back to the 1930's.

Congress has given the Commission administrative responsibilities for the health warnings required on cigarette packaging and advertising under the Cigarette Act. We also have both administrative and enforcement responsibilities for the health warning required on smokeless tobacco packaging and advertising under the Smokeless Tobacco Act.

The Commission does not pre-screen advertising or marketing claims for tobacco or any other product. Instead, the agency addresses deception through post market law enforcement. Health claims in advertising are particularly important to us, and I welcome your interest in the role we play in the marketing of potential reduced risk tobacco products.

This is a very important question. Despite the efforts of the government and the public health community, millions of Americans smoke today and are addicted to nicotine. Many of these smokers will ultimately die of smoking related illnesses if they do not change their behavior.

In an ideal world, we would wish that all of these people would choose to quit smoking and would be able to do so once they tried. The real world is quite different, however. If truthful and substantiated, marketing claims that a product will significantly reduce the health risk associated with smoking while satisfying the addicted smoker's craving for nicotine could provide a substantial health benefit to those consumers who cannot or will not quite.

Conversely, if those claims were untruthful, unsubstantiated, or misrepresent the extent of the benefit, they would harm consumers.

For these reasons, we would review advertising for potential reduced risk tobacco products on a case-by-case basis to try to insure that the information consumers receive about those products is accurate and substantiated. This review would be conducted using the same legal framework that we use for all consumer products under Section 5 of the FTC Act.

First, we ask what messages consumers take away from the advertising in question.

The next issue is whether the claims are truthful, including whether they are substantiated.

The Commission typically requires that health claims be supported by reliable scientific evidence. In determining whether harm reduction claims are substantiated, the Commission would turn to experts, both inside and outside the government's science-based agencies, for assistance in evaluating scientific evidence.

Let me close by mentioning that in my view, the discussion of potential harm reduction tobacco products should also encompass the question of whether so-called nicotine replacement products, which currently are marketed only for smoking cessation purposes, have a larger role to play in the harm reduction arena.

These products, which contain only nicotine and no tobacco, should certainly be further evaluated for use by consumers addicted to nicotine.

In conclusion, thank you for the opportunity to discuss the Commission's role in this important and evolving public health issue. I would be happy to answer any of your questions.

[The prepared statement of Hon. Timothy Muris follows:]

PREPARED STATEMENT OF HON. TIMOTHY J. MURIS, CHAIRMAN, FEDERAL TRADE COMMISSION

Mr. Chairman and members of the Committee, I am Timothy J. Muris, Chairman of the Federal Trade Commission ("Commission" or "FTC". The Commission is pleased to have this opportunity to provide information concerning the potential ad-

vertising of reduced risk tobacco products.[1] This statement discusses the Commission's mission, our activities in the tobacco area, and then addresses the process the Commission would use in examining the advertising of these products.

FTC JURISDICTION OVER TOBACCO ADVERTISING AND MARKETING

The FTC's mission is to prevent unfair competition and unfair or deceptive acts or practices in the marketplace. The Commission regulates national advertising, including the advertising and promotion of cigarettes, smokeless tobacco, and other tobacco products, pursuant to Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45, which prohibits "unfair or deceptive acts and practices in or affecting commerce." The Commission's activities promote informed consumer choice.

The FTC's law enforcement activities involving tobacco advertising and promotion date back to the 1930s.[2] In 1962, the FTC's request for technical guidance from the U.S. Public Health Service was among the factors that led the then-Surgeon General of the United States to establish an advisory panel to undertake a comprehensive analysis of the data on smoking and health. The work of the advisory panel, in turn, led to the historic 1964 Report of the Surgeon General finding that cigarette smoking presented significant health risks. In that same year, the Commission issued a regulation requiring tobacco companies to include health warnings in cigarette advertising and on packages.[3] The FTC's regulation was superseded in 1965, before it went into effect, by the Federal Cigarette Labeling and Advertising Act ("Cigarette Act"),[4] which required such warnings on cigarette packages.

In 1972, the Commission once again addressed the issue of health warnings in cigarette advertising. Pursuant to its Section 5 authority, the FTC issued consent orders mandating for the first time that the major cigarette manufacturers place health warnings in cigarette advertisements.[5]

Today, the Commission administers the Cigarette Act, and administers and enforces the Comprehensive Smokeless Tobacco Health Education Act ("Smokeless Tobacco Act").[6] The Cigarette Act instructs the Commission to take certain steps to implement the mandated Surgeon General's health warnings.[7] The Smokeless Tobacco Act directs the FTC to promulgate regulations governing the health warnings on packaging and advertising for smokeless tobacco products. The Commission's regulations specify the placement and rotation of the warnings, and require companies to submit plans to the Commission setting forth their rotation schedules.[8] Finally, the FTC enforces the ban in the Smokeless Tobacco Act on broadcasting smokeless tobacco advertisements on radio and television.

The Commission also publishes periodic reports on advertising and promotion activities in the cigarette and smokeless tobacco industries.[9] Those reports provide information on sales and on expenditures for various categories of marketing expendi-

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[1] The written statement presents the views of the Federal Trade Commission. Oral testimony and responses to questions reflect my views and do not necessarily reflect the views of the Commission or any Commissioner.

[2] *See, e.g., Julep Tobacco Co.,* 27 F.T.C. 1637 (1938) (stipulation prohibiting claims that Julep cigarettes help counteract throat irritations due to heavy smoking and never make the throat dry or parched).

[3] *See* Trade Regulation Rule for the Prevention of Unfair or Deceptive Advertising and Labeling of Cigarettes in Relation to the Health Hazards of Smoking, 29 Fed. Reg. 8324, 8354 (1964).

[4] Pub. L. No. 8992, 79 Stat. 282 (1965), as amended by Pub. L. No. 98474, 98 Stat. 2204 (1984), and by Pub. L. No. 9992, § 11, 99 Stat. 393, 40204 (1985), current version at 15 U.S.C. § 1331 (1994).

[5] *See Lorillard et al.,* 80 F.T.C. 455, 46065 (1972) (consent orders). Under the orders entered into with six tobacco manufacturers, the companies were required to disclose the Surgeon General's warning in identified forms of advertising. The consent orders were modified in 1981, when the Commission sought civil penalties in federal district court against each of the cigarette companies for failure to comply with the 1972 orders. *See United States v. Lorillard,* No. 76Civ. 814 (JMC) (S.D.N.Y. July 13, 1981).

In 1982, the Bureau of Consumer Protection notified the House Committee on Energy and Commerce that the staff supported a new system of rotational health warnings. Letter from Timothy J. Muris, Director, Bureau of Consumer Protection, *Federal Trade Commission,* to The Honorable John D. Dingell, Chairman, Committee on Energy and Commerce, *U.S. House of Representatives* (Sept. 1, 1982). In May 1984, the Commission sent letters to Congress endorsing the concept of federal legislation to require a system of rotational health warnings that would appear in cigarette advertisements and on cigarette packages. Shortly thereafter, Congress amended the Cigarette Act to require rotational warnings for both advertising and package labeling.

[6] 15 U.S.C. §§ 4401-4408.

[7] Although the Commission administers the Cigarette Act, the Department of Justice enforces it.

[8] 16 C.F.R. § 307.

[9] In addition, the Commission issued a report on cigar advertising and promotion in 1999.

tures. The Commission issued its first report on the cigarette industry in 1967 and on the smokeless tobacco industry in 1987.

In addition to its administrative and law enforcement responsibilities under the Cigarette Act and the Smokeless Tobacco Act, the Commission also has authority under Section 5 of the FTC Act to prevent unfair or deceptive acts and practices in connection with the marketing and sale of tobacco products. Pursuant to that authority, the Commission has taken a number of law enforcement actions against unfair or deceptive tobacco advertising and promotional practices. For example, in 1983, the Commission sued the Brown &Williamson Tobacco Corporation over ads that continued to describe Barclay as a 1 mg. of tar brand, even though the Commission had revoked Barclay's 1 mg. rating because the cigarette's unusual design prevented the cigarette test method from measuring Barclay's yields on a basis comparable to other cigarettes.[10] Moreover, in 1997, the Commission issued a complaint against the R.J. Reynolds Tobacco Co. alleging that the company's Joe Camel advertising campaign caused or was likely to cause many young people to begin or continue to smoke, thereby exposing them to significant health risks.[11] In 1999 and 2000, the Commission entered into consent agreements with several cigarette manufacturers, resolving charges that their advertisements implied that their "no additive" cigarettes were safer than otherwise comparable cigarettes because they did not contain additives.[12] In 2000, the Commission also entered into a consent agreement with a company claiming reduced health risks for its herbal cigarettes.[13]

Testing for the tar and nicotine yields of cigarettes is also conducted by the tobacco industry under a methodology adopted by the Commission in 1967. For the past several years, the FTC has also actively sought the views of the Federal government's public health agencies about what changes should be made in that methodology.[14] The agency has also recommended to Congress that authority for cigarette testing be given to one of the government's science-based public health agencies [15] and we renew that recommendation here.

"REDUCED RISK" TOBACCO CLAIMS

As with other products, the Commission's primary role for tobacco products is to ensure that products are marketed in a manner that is truthful, not misleading, and adequately substantiated. The Commission does not prescreen advertising claims for tobacco or any other product. Instead, the agency addresses deception in the marketing of tobacco largely through postmarket law enforcement actions targeted against specific false or misleading claims or unfair practices, just as it does for other products.

Despite coordinated efforts of the government and the public health community, tobacco use in the United States continues to cause substantial health risks. Products that could significantly reduce those risks could provide a substantial health benefit. For example, products that satisfy a smoker's craving for nicotine with substantially fewer risks to health than cigarettes would have the potential to benefit consumers. At the same time, consumers may be injured if advertisers make harm reduction claims that turn out to be untrue or that exaggerate the benefits or safety of their products.

There are currently a variety of products being developed or already in test markets that are intended to reduce the risks associated with smoking. These products include Eclipse (an R. J. Reynolds Tobacco Company product that heats, rather than burns, tobacco) and Accord (a Philip Morris USA system in which special cigarettes

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[10] *F.T.C. v. Brown & Williamson Tobacco Corp.,* 580 F. Supp. 981 (D.D.C. 1983), *aff'd in part, remanded in part,* 778 F.2d 35 (D.C. Cir. 1985).

[11] *R.J. Reynolds Tobacco Co.,* 127 F.T.C. 49 (1999). The Commission's complaint was issued on May 28, 1997. On January 26, 1999, the Commission dismissed the complaint without prejudice because the relief sought had been achieved through, *inter alia,* the master settlement between the major tobacco companies and the attorneys general for 46 states.

[12] *Santa Fe Natural Tobacco Co.,* Docket No. C-3952 (2000) (consent); *Alternative Cigarettes, Inc.,* Docket No. C-3956 (2000) (consent); *R.J. Reynolds Tobacco Co.,* Docket No. C-3892 (1999) (consent).

[13] *Alternative Cigarettes, Inc.,* Docket No. C-3956 (June 14, 2000) (consent). *See also Alan V. Phan,* 116 F.T.C. 162 (1993) (consent order settling allegations that advertisements misrepresented the health risks of smoking certain nontobacco cigarettes).

[14] Letter from Donald S. Clark, Secretary, *Federal Trade Commission* to the Honorable Donna E. Shalala, Secretary, *Department of Health and Human Services* (Nov. 19, 1998).

[15] *Federal Trade Commission Report to Congress For 1998 Pursuant to the Federal Cigarette Labeling and Advertising Act* 6 (2000) ("the Commission strongly recommends that Congress give cigarette testing authority to one of the Federal government's science-based, public health agencies"); *Federal Trade Commission Report to Congress For 1997 Pursuant to the Federal Cigarette Labeling and Advertising Act* 5-6 (1999).

are smoked in an electronic lighter); cigarettes and other tobacco products with reduced levels of nitrosamines (one category of constituents in tobacco that have been classified as known carcinogens), such as that developed by Star Scientific, Inc.; and Omni, which Vector Tobacco, Inc. has marketed as "the first reduced carcinogen cigarette."

There are also products termed "nicotine replacement therapies" ("NRT") that the Food and Drug Administration currently allows to be marketed for smoking cessation purposes: nicotine gums, transdermal patches, lozenges, inhalers, and nasal sprays. These nicotine delivery devices have been studied and approved only for short-term use to help smokers quit smoking, rather than for long-term "harm reduction" use by people who are unable or unwilling to quit smoking.

Finally, in February 2002, the United States Smokeless Tobacco Company ("USST") petitioned the Commission for an advisory opinion regarding the acceptability of communicating in advertising a harm reduction claim for smokeless tobacco. USST withdrew the petition in August 2002, stating that it would provide the Commission with information from two upcoming scientific conferences that would be addressing issues relevant to the petition. On May 9, 2003, USST provided this additional information to the Commission, and asked that the Commission place this new information on the public record and hold a "public forum" to discuss these issues.

In considering advertising or other marketing claims by potential reduced risk tobacco products, the Commission would consider whether harm reduction claims may be deceptive using the same legal framework that it uses for all consumer products under Section 5 of the FTC Act: whether the advertising conveys a message that is likely to mislead reasonable consumers to their detriment, including claims for which the advertiser did not have adequate substantiation. The Commission's experience suggests that harm reduction claims are likely to raise difficult questions of advertising interpretation, as well as complex scientific and public health issues.

In examining a harm reduction claim, the first question that the Commission would address is what messages consumers take away from the advertising in question. Taking into account the full context of the advertising in which the claim appears,[16] the Commission would seek to identify the range of messages—both express and implied—that consumers would take from the advertisement. These would include: (1) whether claims about a reduction in carcinogens and toxins in the product conveys risk reduction messages; and (2) whether consumers might take away from a harm reduction representation the message that a product containing known carcinogens was not just safer than cigarettes, but that it poses no risk or only a minimal risk.

Once the Commission has determined what messages consumers take away from a particular ad, the next issue is whether those claims are truthful and substantiated. The FTC Act requires that objective claims about products and services be substantiated before the ad is disseminated. When the advertisement does not claim to have a specific level of substantiation supporting its claims, the Commission determines what constitutes a reasonable basis for those claims by analyzing the so-called "Pfizer factors": the type of claim; the benefits if the claim is true; the consequences if the claim is false; the ease and cost of developing substantiation for the claim; the type of product; and the level of substantiation experts in the field would agree is reasonable. *Pfizer, Inc.,* 81 F.T.C. 23 (1972). In the context of safety claims, the FTC has typically required a substantiation standard of "competent and reliable scientific evidence."

Analyzing the evidence whether any particular tobacco product is safer than traditional cigarettes, or whether a reduction in exposure to known carcinogens is associated with reduced health risks, requires expertise in biology, chemistry, toxicology, and epidemiology, among other fields. Moreover, the scientific issues raised by purported reduced risk products are often not only extremely complex, but may take years to develop.[17] The Commission brings a unique market-based expertise to its

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[16] The messages consumers take away from a particular statement in an advertisement depend on the overall context in which that statement appears. Accordingly, the Commission ordinarily evaluates each advertisement in its entirety. It is difficult to determine what messages consumers take away from a generic statement about a particular class of products without placing that statement in the context of an actual advertisement.

[17] The history of low tar cigarettes provides an example. One recent survey of current evidence concludes that although low tar cigarettes were initially marketed as safer alternatives than regular cigarettes, recent evidence suggests that they may convey no such benefit. See National Cancer Institute, *Risks Associated with Smoking Cigarettes with Low Machine-Measured Yields of Tar and Nicotine,* Smoking and Tobacco Control Monograph No. 13, at 9 (2001) ("When all of the epidemiological evidence is considered in the context of what is currently known about cigarette design and compensation, it does not support the conclusion that a reduction in disease

scrutiny of consumer protection matters and our work often requires review and analysis of scientific literature. Because the Commission is an agency of lawyers and economists, however, and not a science-based agency, we rely on assistance from other experts in evaluating scientific evidence.[18] Just as the Commission has requested the assistance of the Department of Health and Human Services in connection with the test method that produces cigarette tar and nicotine ratings, the Commission would require similar assistance in evaluating the substantiation for advertising claims made for reduced-risk tobacco products.

Finally, although a determination that an individual risk reduction claim is truthful and substantiated would end the Commission's deception inquiry, broader public health issues may remain.[19] For example, some commenters on the USST petition focused on the overall impact on public health from the marketing of these products; these comments argued that smokeless tobacco promoted as a reduced risk product might degrade overall public health, depending on how consumers react.[20] Similarly, some commenters questioned whether such advertising and promotion might promote more widespread use of smokeless tobacco, rather than just as a replacement for smoking.[21] Others, however, believe that notwithstanding this empirical question, the potential harm to public health is not clear enough to justify depriving individuals of information they might use to reduce risks to their own health.[22] This debate on the public health effects of these alternative tobacco products is an important one the appropriate science-based agencies of the government need to address.

Health claims in advertising, including tobacco advertising, are of particular importance to the Commission. The Commission welcomes the Committee's interest in the role that this agency will play in ensuring that the marketplace works efficiently to provide consumers with information that may enable them to reduce their risks of smoking-related disease, while protecting them from claims that are not sup-

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risks has occurred in the population of smokers due to the design changes that have occurred in cigarettes over the last 50 years.").

[18] Tobacco is not the only category of products for which the Commission turns to other federal entities that possess specialized scientific expertise. For example, the FTC works closely with the Food and Drug Administration in the dietary supplement field, and with the Environmental Protection Agency in the areas of energy conservation, gasoline marketing, and claims for pesticides.

[19] *E.g.,* Institute of Medicine, *Clearing the Smoke: Assessing the Science Base for Tobacco Harm Reduction* 6 (2001) (potential reduced-exposure products "are potentially beneficial, but the net impact on population health could, in fact, be negative. The effect on public health will depend upon the biological harm caused by these products and the individual and community behaviors with respect to their use.").

[20] *E.g.,* Letter from Matthew L. Myers, President, *Campaign for Tobacco-Free Kids* to The Honorable Donald S. Clark, Secretary, *Federal Trade Commission* (Feb. 25, 2002) (comparative health claims made for smokeless tobacco must not only be truthful, but should promote the public health); Letter from Henry A. Waxman, U.S. House of Representatives and Senator Richard J. Durbin, United States Senate to The Honorable Donald S. Clark, Secretary, *Federal Trade Commission* (June 4, 2002) (noting that the potential health benefits that might result from smokers switching to smokeless tobacco were offset by the risks that some smokers who would have quit might, instead, switch to smokeless tobacco; that smokeless tobacco might become more attractive to nonsmokers; and that some of those nonsmokers—once addicted to nicotine—might switch to cigarettes). *See also, e.g.,* WHO Scientific Advisory Committee on Tobacco Product Regulation, *Recommendation on Smokeless Tobacco Products* 3 (2003) (listing arguments against the use of smokeless tobacco for purposes of harm reduction).

[21] *E.g.,* Letter from Matthew L. Myers, *supra* note 17 (despite USST's stated interest in making harm reduction claims to addicted adult smokers, FTC approval of petition would permit it "to disseminate these claims in ads whose primary appeal could be to young non-tobacco users"); Letter from Dileep G. Bal, M.D., Chief, Cancer Control Branch, *State of California Health and Human Services Agency—Department of Health Services* to The Honorable [Donald] S. Clark, Secretary, *Federal Trade Commission* (March 8, 2002) ("While USSTC [sic] claims that this health advisory is mean to claim harm reduction for the benefit of addicted adults, it would allow USSTC [sic] and other companies to market their products with this claim to young, non-tobacco users as well).

[22] L. Kozlowski, *Harm reduction, public health, and human rights: Smokers have a right to be informed of significant harm reduction options,* Nicotine & Tobacco Research S55-S60 (2002) (noting that nicotine replacement therapies and snus [Swedish moist snuff] are much safer than cigarettes; that there is a basic human right to information that affects one's health; and that when the health risks from a product are relatively small, "the level of increased use needed to maintain a public health equilibrium (no changes in population-level problems) becomes very high.") (citation omitted). *See also* Tobacco Advisory Group of the Royal College of Physicians, *Protecting smokers, saving lives: The case for a tobacco and nicotine regulatory authority* 2-5 (2002) (supporting comprehensive regulatory approach to tobacco in order to promote public health and noting that emergence of reduced risk products presents multiple challenges for regulators; smokeless tobacco is "10-1,000 times less hazardous than smoking, depending on the product" but its potential marketing as a harm reduction option raises various questions that must be addressed, including minimizing its use as a starter product for young smokers).

ported by sound scientific evidence. The agency is committed to reviewing advertising for potential reduced risk tobacco products on a case-by-case basis to try to ensure that the information consumers receive about reduced risk products is truthful and non-misleading.

CONCLUSION

The Commission thanks this Committee for focusing attention on this important and evolving public health issue, and for giving us an opportunity to present our views.

Mr. STEARNS. I thank the Chairman, and we welcome the U.S. Surgeon General.

STATEMENT OF VICE ADMIRAL RICHARD H. CARMONA

Mr. CARMONA. Thank you, Mr. Chairman, distinguished members of the subcommittee. Thank you for the opportunity to participate in this important hearing.

My name is Richard Carmona, and I am the Surgeon General of the United States.

Let me start with a few statements that were once accepted throughout society that have now been relegated to the status of myth.

Men do not suffer from depression.

Domestic violence is a family or private matter.

The HIV/AIDS epidemic is of no concern to most Americans.

All of us here know that these three statements are very dangerous public health myths. My remarks today will focus on a fourth public health myth which could have severe consequences in our Nation, especially amongst our youth. Smokeless tobacco is a good alternative to smoking. It is a myth. It is not true.

As the Nation's Surgeon General, my top responsibility is to insure that Americans are getting the best science based information to make decisions about their health. So I very much appreciate the opportunity to come before this subcommittee today and help refute this dangerous idea.

First, let me emphasize this. No matter what you may hear today or read in the press reports later, I cannot conclude that the use of any tobacco product is a safer alternative to smoking. This message is especially important to communicate to young people who may perceive smokeless tobacco as a safe form for tobacco use.

Smokeless tobacco is not a safe alternative to cigarettes. Smokeless tobacco does cause cancer. Our Nation's experience with low tar cigarettes yields valuable lessons for the debate over smokeless tobacco.

Tobacco use is the leading preventable cause of death in the United States. Each year 440,000 people die of diseases caused by smoking or other forms of tobacco use. That is about 20 percent of all deaths in the United States.

The office I lead as Surgeon General has long played a key role in exposing the risks of tobacco use. In 1986, the Surgeon General's report, the Health Consequences of Using Smokeless Tobacco, reached four major conclusions about the oral use of smokeless tobacco.

First, smokeless tobacco represents a significant health risk.

Next, smokeless tobacco can cause cancer in a number of noncancerous oral conditions.

Third, smokeless tobacco can lead to nicotine addiction and dependence.

And, fourth, smokeless tobacco is not a safe substitute for cigarette smoking.

Recognizing these serious health consequences, Congress passed a Comprehensive Smokeless Tobacco Health Education Act in 1986. This law required the placement of Surgeon General's warnings on all smokeless tobacco products.

Mr. Chairman and members of this subcommittee, I respectfully submit that smokeless tobacco remains a known threat to public health just as it was when Congress acted in 1986. Time has only brought more disease, death, and destroyed lives.

A national toxicology program of the National Institutes of Health continues to classify smokeless tobacco as a known human carcinogen, proven to cause cancer in people. As Surgeon General, I cannot recommend use of a product that causes disease and death as a lesser evil to smoking. My commitment and that of my office to safeguard the health of the American people demands that I provide information on safe alternatives to smoking where they exist.

I cannot recommend the use of smokeless tobacco products because there is no scientific evidence that smokeless tobacco products are both safe and effective aids to quitting smoking.

Smokers who have taken the courageous step of trying to quit should not trade one carcinogenic product for another, but instead could use Food and Drug Administration approved methods, such as nicotine gum, nicotine patches, or counseling.

While it may be technically feasible to create a reduced harm tobacco product, the Institute of Medicine recently concluded that no such product exists today.

When and if such a product ever is constructed, we would then have to take a look at the hard scientific data of that particular product. Our Nation's experience with low tar, low nicotine cigarettes is instructive to the issue at hand. Low tar, low nicotine cigarettes were introduced in the late 1960's and widely endorsed as a potentially safer substitute for the typical cigarette on the market at that time.

Within a decade the low tar brands dominated the cigarette market. Many smokers switched to them for their perceived health benefits.

Unfortunately, the true health effects of these products did not become apparent for another ten to 20 years. We now know that low tar cigarettes not only did not provide a public health benefit, but they also may have contributed to a natural increase in death and disease among smokers.

This has taught us that we must move cautiously in recommending any supposedly safer alternative for people trying to quit smoking because now with more knowledge and the benefit of hindsight, the science does not support early recommendations on low tar cigarettes.

Mr. Chairman, in the interest of time I will shortly ask that the remainder of my statement and the scientific information contained in it be considered as read and made part of the record.

Mr. STEARNS. Without objection, so ordered.

Mr. CARMONA. But before I do that, I would like to ask for this subcommittee and the Congress to help in getting the message out about the dangers and myths of smokeless tobacco.

All of us in this rom are very concerned about our Nation's youth. Kids growing up today have a tough time of it. In addition to the normal struggles of puberty, many kids are facing a host of other challenges. Many, especially minority kids, must struggle to find their way in unsafe neighborhoods.

So the temptation to engage in behavior that is not healthy and the opportunity to do so is very hard for our young people to resist. According to a 2000 survey by the Substance Abuse and Mental Health Services Administration, SAMHSA, and this is the national household survey on drug abuse, about 1 million kids from ages 12 to 17 smoke every day. Another 2 million kids smoke occasionally.

And we know that smoking is often not a stand-alone risk behavior. It travels with others. The SAMHSA found that youth who were daily cigarette smokers or heavy drinkers were more likely to use illicit drugs than either daily smokers or heavy drinkers from other age groups. More than half of 12 to 17 year olds who were daily smokers had also used illicit drugs within the past month.

Every day more than 2,000 kids in the U.S. will start to smoke, and more than 1,000 adults will die because of smoking. We have to get youth to stop starting, but the answer is not smokeless tobacco. We have evidence to suggest that instead of smokeless tobacco being a less dangerous alternative to smoking, just as smoking is a gateway to other drugs, smokeless tobacco is a gateway to smoking.

So we must redouble our efforts to get our youth to avoid tobacco in all forms.

We have some real work to do on the culture of smokeless tobacco, which is glamorized by some sports stars. Chicago Cub Sammy Sosa, who has made a public commitment to avoiding smokeless tobacco, is a great example for kids. Past baseball great Joe Garagiola is now Chairman of the National Spit Tobacco Education Program and regularly lectures young players against the dangers of smokeless tobacco.

As Members of Congress, you can lead by example, too, not just in legislation, but in your own lives. I encourage you to avoid tobacco in all of its forms. Do not fall for the myth, a very dangerous public health myth that smokeless tobacco is preferable to smoking.

Do not let America's youth fall to this myth either.

Mr. Chairman, I ask that my written testimony be made part of the record and I thank you and I would be happy to answer any questions.

[The prepared statement of Richard Carmona follows:]

PREPARED STATEMENT OF RICHARD H. CARMONA, SURGEON GENERAL, U.S. PUBLIC HEALTH SERVICE, ACTING ASSISTANT SECRETARY FOR HEALTH, DEPARTMENT OF HEALTH AND HUMAN SERVICES

Mr. Chairman, distinguished members of the Subcommittee, thank you for the opportunity to participate in this important hearing. My name is Richard Carmona and I am the Surgeon General of the United States of America.

Let me start with a few statements that were once accepted throughout society that have now been relegated to the status of myth.

- Men do not suffer from depression.
- Domestic violence is a "family" or "private" matter.

• The HIV-AIDS epidemic is of no concern to most Americans.

All of us here know that these three statements are very dangerous public health myths.

My remarks today will focus on a fourth public health myth which could have severe consequences in our nation, especially among our youth: smokeless tobacco is a good alternative to smoking. It is a myth. It is not true.

As the nation"s Surgeon General, my top responsibility is to ensure that Americans are getting the best science-based information to make decisions about their health. So I very much appreciate the opportunity to come before this Subcommittee today and help refute this dangerous idea.

First, let me emphasize this:

- No matter what you may hear today or read in press reports later, I cannot conclude that the use of any tobacco product is a safer alternative to smoking. This message is especially important to communicate to young people, who may perceive smokeless tobacco as a safe form of tobacco use.
- There is *no* significant scientific evidence that suggests smokeless tobacco is a safer alternative to cigarettes.
- Smokeless tobacco *does* cause cancer.
- Our nation's experience with low-tar cigarettes yields valuable lessons for the debate over smokeless tobacco.
- Tobacco use is the *leading* preventable cause of death in the United States.

Each year, 440,000 people die of diseases caused by smoking or other form of tobacco useCthat is about 20 percent of all deaths in our nation.

The office I lead as Surgeon General has long played a key role in exposing the risks of tobacco use. In 1986, the Surgeon General's Report *The Health Consequences of Using Smokeless Tobacco* reached four major conclusions about the oral use of smokeless tobacco:

1. Smokeless tobacco represents a significant health risk;
2. Smokeless tobacco can cause cancer and a number of non-cancerous oral conditions;
3. Smokeless tobacco can lead to nicotine addiction and dependence; and
4. Smokeless tobacco *is not* a safer substitute for cigarette smoking.

Recognizing these serious health consequences, Congress passed the Comprehensive Smokeless Tobacco Health Education Act in 1986. This law required the placement of Surgeon General's warnings on all smokeless tobacco products.

Mr. Chairman and Members of the Subcommittee, I respectfully submit that smokeless tobacco remains a known threat to public health just as it was when Congress acted in 1986.

Conversely, time has only brought more disease, death and destroyed lives.

The National Toxicology Program of the National Institutes of Health continues to classify smokeless tobacco as a known human carcinogenCproven to cause cancer in people.

As Surgeon General I cannot recommend use of a product that causes disease and death as a "lesser evil" to smoking. My commitment, and that of my office, to safeguard the health of the American people demands that I provide information on safe alternatives to smoking where they exist.

I cannot recommend the use of smokeless tobacco products because there is no scientific evidence that smokeless tobacco products are both safe and effective aids to quitting smoking.

Smokers who have taken the courageous step of trying to quit should not trade one carcinogenic product for another, but instead could use Food and Drug Administration -approved methods such as nicotine gum, nicotine patches, or counseling.

While it may be technically feasible to someday create a reduced-harm tobacco product, the Institute of Medicine recently concluded that no such product exists today. When and if such a product is ever constructed, we would then have to take a look at the hard scientific data of that particular product.

Our nation's experience with low-tar, low-nicotine cigarettes is instructive to the issue at hand. Low-tar, low-nicotine cigarettes were introduced in the late 1960's and widely endorsed as a potentially safer substitute for the typical cigarette on the market at that time. Within a decade, the low-tar brands dominated the cigarette market. Many smokers switched to them for their perceived health benefits.

Unfortunately, the true health effects of these products did not become apparent for another 10 to 20 years. We now know that low-tar cigarettes not only did not provide a public health benefit, but they also may have contributed to an actual *increase* in death and disease among smokers.

First, many smokers switched to these products instead of quitting, which continued their exposure to the hundreds of carcinogens and other dangerous chemicals

in cigarettes. Second, to satisfy their bodies" craving for nicotine, many smokers unwittingly changed the way they smoked these low-tar cigarettes: they began inhaling more deeply, taking more frequent puffs, or smoking more cigarettes per day.

In fact, we now believe that low-tar cigarettes may be responsible for an increase in a different form of lung cancer, adenocarcinoma, which was once relatively rare. This cancer is found farther down in the lungs of smokers, indicating deeper inhalations, and appears linked to a specific carcinogen particularly present in low-tar brands.

We must learn the lessons of the low-tar cigarette experience. Not only did they fail to reduce an *individual's* risk of disease, but they also appear to have increased *population* risk by delaying quitting and potentially contributing to initiation among young people. This has taught us that we must move cautiously in recommending any supposedly safer alternative for people trying to quit smokingCbecause now, with more knowledge and the benefit of hindsight, the science does not support early recommendations on low-tar cigarettes.

Mr. Chairman, in the interest of time I will shortly ask that the remainder of my statement and the scientific information contained in it be considered as read and made part of the record. But before I do that, I would like to ask for this Subcommittee and the Congress' help in getting the message out about the dangers of the myth of smokeless tobacco.

All of us in this room are very concerned about our nation's youth. Kids growing up today have a tough time of it. In addition to the normal struggles of puberty, many kids are facing a host of other challenges. Many, especially minority kids, must struggle to find their way in unsafe neighborhoods.

So the temptation to engage in behavior that is not healthy, and the opportunity to do so, is very hard for our young people to resist.

According to a 2000 survey by the Substance and Mental Health Services Administration (SAMHSA) (The National Household Survey on Drug Abuse), about 1 million kids from age 12-17 smoke every day. Another 2 million kids smoke occasionally.

And we know that smoking is often not a "stand-alone" risk behavior; it travels with others. The SAMHSA survey found that youth who were daily cigarette smokers or heavy drinkers were more likely to use illicit drugs than either daily smokers or heavy drinkers from older age groups. More than half of 12-17 year olds who were daily smokers had also used illicit drugs within the past month.

Every day, more than 2,000 kids in the U.S. will start to smoke, and more than 1,000 adults will die because of smoking. We have to get youth to stop *starting*. But the answer is not smokeless tobacco.

We have evidence to suggest that instead of smokeless tobacco being a less dangerous alternative to smoking, just as smoking is a gateway to other drugs, smokeless tobacco is a gateway to smoking.

So we must redouble our efforts to get our youth to avoid tobacco in all forms.

We have some real work to do on the "culture" of smokeless tobacco, which is glamorized by some sports stars. Chicago Cub Sammy Sosa, who has made a public commitment to avoiding smokeless tobacco, is a great example for kids. Past baseball great Joe Garagiola is now Chairman of the National Spit Tobacco Education program, and regularly lectures young players against the dangers of smokeless tobacco.

As Members of Congress, you can lead by example too, not just in legislation, but in your own lives. I encourage you to avoid tobacco in all its forms. Do not fall for the myth—a very dangerous public health myth—that smokeless tobacco is preferable to smoking. Do not let America's youth fall for it, either.

From the perspective of individual risk, the cumulative effect on smokers of switching to smokeless tobacco is simply not known. But we clearly know that use of smokeless tobacco has serious health consequences. Overall, smokeless tobacco products have been classified as a known human carcinogen. And limited scientific data indicate that former smokers who switch to smokeless tobacco may not have as great a decrease in lung cancer risks as quitters who do not use smokeless tobacco.

From the perspective of population risk, there are even more unanswered questions. Even if there was some decreased risk for smokers who switch to smokeless tobacco, that benefit may be more than offset by increased exposure of the overall population to this known carcinogen.

The marketing of smokeless tobacco as a potentially safer substitute for cigarettes could lead to:

- More smokers switching to smokeless tobacco instead of quitting tobacco use completely;

- A rise in the number of lifetime smokeless tobacco users if more youth begin using smokeless tobacco;
- A rise in the number of cigarette smokers as a result of more youth starting to use smokeless tobacco and then switching to cigarette use; and
- Some former smokers returning to using tobacco if they believe that smokeless tobacco is a less hazardous way to consume tobacco.

Concerns about youth initiation are especially troubling. The scientific evidence is clear that use of smokeless tobacco is a gateway to cigarette use. Young people may be especially attracted to smokeless tobacco if they perceive it to be safer than cigarettes. Studies show that more than one in five teenage males have used smokeless tobacco, with age 12 being the median age of first use. Surveys also show that more than two in five teenagers who use smokeless tobacco daily also smoke cigarettes at least weekly. Finally, independent research and tobacco company documents show that youth are encouraged to experiment with low-nicotine starter products and subsequently graduate to higher-level nicotine brands or switch to cigarettes as their tolerance for nicotine increases.

Finally, we simply do not have enough scientific evidence to conclude that *any* tobacco product, including smokeless tobacco, is a means of reducing the risks of cigarette smoking. At this time, any public health recommendation that positions smokeless tobacco as a safer substitute for cigarettes or as a quitting aid would be premature and dangerous. With the memory of our experience with low-tar cigarettes fresh in our minds, we must move extremely cautiously before making any statement or endorsement about the potential reduced risk of any tobacco product.

Finally, my strong recommendation as Surgeon General is a call for sound evidence about tobacco products and their individual and population based health effects. We need more research. We need to know more about the risks to individuals of switching from smoking to smokeless; and we need to know more about the risks to the entire population of a promotion campaign that would position smokeless tobacco as a safer substitute for smoking.

Until we have this science base, we must convey a consistent and uncompromised message: there is no safe form of tobacco use.

Thank you. I would be happy to answer any questions.

Mr. STEARNS. Again, without objection, so ordered.

I will start the questions, and Admiral, I think I will start with you.

The European Union has a policy on smokeless tobacco, and it has been written by the leading tobacco control public health advocates in the European Union, and they stated that on the average that "Scandinavian and American smokeless tobaccos are at least 90 percent safer than cigarettes."

Now, I respect your position. It is a lot different than all of ours, but do you agree with the European Union policy that what they said, 90 percent safer than cigarettes? I mean just yes or no.

Mr. CARMONA. No, sir, I do not.

Mr. STEARNS. Okay. We know that the Institute of Medicine report states that smokeless tobacco, "the overall risk is lower than for cigarette smoking and some products, such as Swedish snus may have no increased risk."

Now, this is the Institute of Medicine report. So I ask you: do you agree with the Institute of Medicine?

Mr. CARMONA. That particular statement, no.

Mr. STEARNS. Okay. You know, the heart of our hearing today is smokeless as an alterative for people who cannot stop smoking, and I will give you an example. Let us say your son just turned 16 and he had to drive a car, and you had a small sports car in your garage and you also had a brand new Volvo. And I think all of us in this room would agree that the Volvo is safer than a very small sports car.

And you knew your son was just starting out and you had to look at the two products. Would you not say the Volvo is a lot safer for your 16 year old son to drive than a very small sports car?

Mr. CARMONA. I think it is actually an unfair analogy, sir. In most cases, probably so.

Mr. STEARNS. Yes. But, I mean, they both are dangerous, but you know, what we are trying to do is just see if there are degrees here, and then work off of the Institute of Medicine report, as well as some of the European Union policy positions.

Chairman Muris, how does the FTC evaluate an advertising claim? For example, if there is dueling science like there might be here, and a great respect for the Surgeon General, how do you actually reach a conclusion when there is this advertising claim and you have dueling science involved?

Mr. MURIS. Well, the first thing that we do is look to see the message the advertising claim communicates to a reasonable person in the intended audience, and that is a very, very important step because, depending on how the various disclosures would be made, it would not surprise me if an audience understood them differently. I have not seen copy testing of such particular advertising claims. I do not know that they exist, but they would be viewed by the intended audience quite differently.

Once we understand what we call the take-away is, then we would look in terms of substantiation at what we thought was competent and reliable scientific evidence, and again, it partly depends on what the claim is.

If the claim is one that is unqualified, it would not surprise me if people interpreted it as something close to a scientific consensus or at least the majority scientific view. So that would be relevant.

We also look at what we call the Pfizer factors. Pfizer was an FTC opinion about the substantiation doctrine about 30 years ago. One of the crucial factors in that case trying to balance the impact of making mistakes, and you can make two sorts of mistakes here. You can make the mistake of allowing false advertising or preventing truthful advertising, and we try to look at the consequences of those mistakes.

Mr. STEARNS. The FTC has brought a number of cases against companies making health claims related to cancer treatments, weight loss, and cures for HIV/AIDS, arthritis, hepatitis, Alzheimer's disease, diabetes, and many other diseases. How has the FTC proceeded on those cases and how do these cases differ from advertising claims made by tobacco companies?

Mr. MURIS. Well, most of the cases that we brought involve fraud where there is no scientific controversy. In weight loss advertising, for example, we have—and the Surgeon General has helped us in this area—we have a very aggressive campaign against deceptive and fraudulent weight loss advertising. We held a workshop at which we both participated last November, where one of the things we were trying to do is to get advertisers or—I am sorry—the media to police some of the more obviously false claims.

So it is an area in which we spend a lot of resources, but it is an area in which we do not have to make difficult scientific choices.

Mr. STEARNS. Just to conclude, Admiral, let us say we all know that smoking is the leading cause of preventable death in the

United States, but I have seen some people here in the House, Members of Congress, who cannot seem to stop smoking. What do we do?

I mean, a person cannot stop smoking. How do we approach those people?

Mr. CARMONA. Well, I think there is a wide range of possibilities that include substitution therapy, as I mentioned in my opening remarks, behavioral therapy and behavioral modification, and of course, we need to continue to do research in that area.

But I think what we do not do is substitute one carcinogen for another.

Mr. STEARNS. Okay. Thank you.

The ranking member.

Ms. SCHAKOWSKY. Thank you, Mr. Chairman.

You referred to the Institute of Medicine, and I have that report in front of me, and I would just like to read Conclusion Five for Dr. Carmona.

It says, "Regulation of all tobacco products, including conventional ones as recommended in IOM 1994, as well all other PREPs.," and PREPS. stand for potential reduced exposure products; so we are talking about spit tobacco, "is a necessary precondition"—we are talking about regulation—"is a necessary precondition for assuring a scientific basis for judging the effects of using PREPs and for assuring that the health of the public is protected."

So they are making their conclusions by stating that all tobacco should be regulated. And so I am wondering then if in terms of the IOM report if you find any contradictions in what they say and if you would find anything in what they say as, in fact, recommending the use as a harm reduction alternative.

Mr. CARMONA. No, ma'am. The IOM report I think is a very good report, and I think one of its conclusions that is most important is that they found that there really were no products that were available today that had been scientifically tested, such as smokeless tobacco products that would be safe to recommend or use.

So I think their study was a very good one overall.

Ms. SCHAKOWSKY. Thank you.

Mr. Muris, if the FTC were to regulate the advertising of spit tobacco and such an advertising campaign had an incidental appeal to minors, would the FTC be able to regulate the advertisements on that basis alone?

Mr. MURIS. Well, first of all, the FTC has two bases to proceed. One is on the basis of deception, and we would obviously need to know a lot more. So this answer is necessarily very, very qualified.

I think in terms of appeal to youth, the Commission would be much more likely to proceed as it did in the Camel case, based on its unfairness jurisdiction. At least in that case the allegations were that the appeal to youth was far more than incidental.

I think, again, I would have to know a lot more, but that fact, the fact if the appeal was just incidental, would make it very hard to use the unfairness jurisdiction.

Ms. SCHAKOWSKY. Right, and if such an advertising campaign were to result in more people using smokeless tobacco in addition

to cigarettes rather than instead of using cigarettes, would the FTC be able to regulate the advertisements on that basis alone?

Mr. MURIS. It would be very hard for us to make public health judgments outside of the context of whether the advertising was deceptive or not. That is primarily what we do.

On the other hand, clearly when you are balancing my answer to the Chairman's question, when you are balancing the two kinds of risk, the consequence here of allowing advertising that is, in fact, fraudulent, that is part of those consequences. So we would consider it in that sense.

Ms. SCHAKOWSKY. If such an advertising campaign were to result in a dramatic reduction in the number of people who quit tobacco completely, would the FTC be able to regulate the advertisements on that basis alone?

Mr. MURIS. Again, I think my answer is identical. We would not look at this in the first instance under our statutes in terms of a simple public health calculation. However, that would be a very important fact in terms of weighing the consequences of the substantiation, as I just indicated to the last question.

Ms. SCHAKOWSKY. And would that be true then of such an advertising campaign were to result in a dramatic increase in the number of new tobacco users; would the FTC be able to regulate advertisements on that basis alone?

Mr. MURIS. I think my answer would be the same, and I would direct you in more detail to our testimony, particularly page 9 where we discuss some of those issues.

Ms. SCHAKOWSKY. So despite the fact that the advertisements were not directly aimed at children, despite the fact that they said that you should use it as a substitute, if negative consequences occurred, you are saying that, in fact, you could?

I do not read your mandate that way.

Mr. MURIS. Well, first of all and most importantly, and asking any question does not provide a full context of what the advertising campaign would look like, and that full context would be essential and possibly dispositive in what we could do.

It is true, as our testimony states, that—let me just quote it to you. "Although a determination that an individual risk reduction claim as truthful and substantiated would end the Commission's deception inquiry, broader public health issues may remain," and that is the sense in which I was talking about how we do not under our statutes make simply a public health determination, if that determination could ever be simple.

It is true, however, in looking at substantiation that the Pfizer factors require a balance of what statisticians call Type 1 and Type 2 errors, which, as I explained, we try to look at the consequences of us making a mistake, and the factors that you are talking about are consequences of a mistake. We would certainly consider those, and the presence of those factors would require us to want a higher level of substantiation before we allowed the claims.

Ms. SCHAKOWSKY. Thank you.

Mr. STEARNS. The gentlelady's time has expired.

The Chairman of the full committee, Mr. Tauzin.

Chairman TAUZIN. Thank you, Mr. Chairman.

Let me see if I can do something that I have tried with my staff to understand. I have got the best experts in the country here in front of me now.

Dr. Carmona, first of all, let me thank you for your strong and, I think, extraordinary advocacy to help Americans understand the dangers of smoking tobacco. I do not think anybody quarrels with you on those issues today.

What we are focusing on, obviously, is a question of whether or not there are other options other than the quit or die option that Americans unfortunately are faced with when it comes to tobacco.

In regard to that, I have tried to have an understanding with my staff on the nature of nicotine. I am not a smoker. So I have never had this addiction problem for nicotine. My body does not crave it. I do not desire it. I do not smoke, and I do not want to smoke. And so I am trying to understand it as a non-smoker.

And I am trying to place nicotine in the category of substances that are addictive that I do understand. I understand cocaine and heroin and what it does to lives in my district and in this country. I understand that when people start on these kinds of addictive substances it can ruin their lives, and they crave it to the point where it can even kill them.

I am a caffeine addict. I drink coffee all day long. I confess. I know what that addiction feels like. I know I have to have my cup of coffee in the morning, and I have got to have it all day long to keep me going.

But I also know that caffeine is not likely to kill me in the sense that cocaine and heroin might kill me. It might not be good for me. It might make me overactive. It might make me hypertensive. I do not know what, but it is not likely to do the damage that cocaine and heroin do.

Where do you place nicotine in that scale? Is it closer to caffeine or is it closer to cocaine and heroin?

Mr. CARMONA. It is hard to put it in a scale in that comparison, but although they are both addictive, they have different mechanisms of action, and the caffeine works by modifying certain enzymes, xanthene oxidase, I think, specifically, and it works through phosphodiesterase mechanism they call it, and what it does is it works on your cardiovascular system. It will speed up your heart, and it will have cardiovascular effects that you become dependent on.

And so——

Chairman TAUZIN. How about nicotine?

Mr. CARMONA. Nicotine works by a different mechanism, but nicotine has direct adverse cardiovascular effects that are tied to accelerating cardiovascular disease. It has bad effects on your heart, bad effects on the blood vessels and can accelerate atherosclerotic disease, and so on.

So that we are not just talking about cancer here. We are talking about other effects on the body that can be found.

Chairman TAUZIN. It has other negative effects.

Mr. CARMONA. Yes, sir.

Chairman TAUZIN. Does it have any positive effects? I was told by staff that there is at least some scientific evidence that it has

some positive effects on some categories of human conditions. Is that true or false?

Mr. CARMONA. Well, only if you are talking about, you know, biochemistry of the body, but——

Chairman TAUZIN. How about Tourette's syndrome?

Mr. CARMONA. Oh, you are talking about as a treatment.

Chairman TAUZIN. Yes.

Mr. CARMONA. As a treatment now.

Chairman TAUZIN. That is what I am saying. Isn't it used positively in some cases, like treatments of——

Mr. CARMONA. I have never used it, and if it is, then it is probably not very common, but I would imagine in the literature people have tried to use it.

Chairman TAUZIN. Here is where I am going and I want your feedback on it. If Americans who have become accustomed to, addicted to the habit of getting nicotine into their body were able to get it into their body in some other fashion other than the use of tobacco, would that be a positive social development in America in terms of the Nation's health or would it be a negative one?

Mr. CARMONA. Well, again, you know, I am less inclined to comment on social developments than I am on science.

Chairman TAUZIN. Well, on science then. Would it be good for Americans' health, for people who need nicotine or believe they have to have it or are addicted to it to get it in some other fashion other than to having to burn tobacco to get it?

Mr. CARMONA. Well, we have mechanisms presently available through nicotine products that——

Chairman TAUZIN. I know we do. I am asking you is that good.

Mr. CARMONA. It is an option that is available. I mean, the best of all options obviously is not to smoke at all and not to become addicted.

Chairman TAUZIN. Nobody disagrees with that.

Mr. CARMONA. Okay.

Chairman TAUZIN. But if the option is quit or die, and what I am saying is if you have to get nicotine in your system because you are addicted to it and you cannot quit—I mean, the quit rate is like 2 to 3 percent a year in this country, and we know people are having a pretty difficult time quitting. Recognizing that, knowing that we are going to lose an awful lot of people to the effects of not quitting, if these folks can get their nicotine in some other way other than burning tobacco and sucking all of the nitrosamines and all of the other substances into their lungs, would that be a positive thing for the health of the country?

Mr. CARMONA. Well, yes, and it already is where you have patch. We have gum. We have mechanisms that have been tested and found to be safe and effective means.

Chairman TAUZIN. Right. Let me turn to the FTC Chairman.

If, in fact, people come up with products, tobacco products or non-tobacco products that can, in fact, deliver nicotine to folks who have been addicted to it and cannot seem to quit using it, is your department the right agency to regulate the truth of those ads?

Mr. MURIS. Our mission is certainly to evaluate the truthfulness of and including substantiation of advertising. That can require us, and in this case it would, to work with scientists both in and out

of the government because the issues here in the substantiation arena are issues on which their experts——

Chairman TAUZIN. Yes, you get thrown into the health arena here.

Mr. MURIS. And we are not, right.

Chairman TAUZIN. Yes, and you are not health officials. But nevertheless, your agency's function is to examine the truthfulness or lack of truthfulness of advertising of American products. Is that part of your agency's mission?

Mr. MURIS. Yes, but what I am saying is the substantiation issues here turn on scientific issues to which we——

Chairman TAUZIN. Therefore, you would have to turn to people like——

Mr. MURIS. [continuing] seek help.

Chairman TAUZIN. [continuing] Health Department officials to help you.

Mr. MURIS. Absolutely.

Chairman TAUZIN. And if science was available to help you understand whether or not an advertisement was, in fact, truthful or not truthful, that gave people in America better information about options that might be available to them when it comes to getting nicotine, would it not be in the interest of this country for you and our health officials to conduct some public forums and to see whether or not all of this is a good avenue to approach or not?

Mr. MURIS. Well, in the abstract, Mr. Chairman, I certainly think that is a good idea. Again, because the issues are ultimately scientific, they would need to take the lead, the scientific agencies.

Chairman TAUZIN. Well, except they tell us it should be your lead because you end up being the one to say yes or no on the truthfulness of the ads. If they can help you understand that and help you conduct forums that all of us in America, scientists, consumers, advocates, pro and con, all kinds of people can come and debate it and discuss it. Why wouldn't you want to help create that type of forum for us?

Mr. MURIS. Well, that is a different issue than taking the lead. I would certainly think that we would—I know, speaking for myself. Obviously my colleagues would have to vote—be willing to participate in such fora not just to talk about particular products, although that would be important, but to talk about what endpoints, what kind of scientific evidence is relevant.

I mean, I agree with the premise here that we have somewhere near 50 million people who smoke, and it is a very addictive product. I obviously defer to the scientists on that, but it obviously is a very addictive product. Many people have difficulty quitting, and I think there are potential—and the key word is "potential"—public health benefits from addressing that issue, and it is one of——

Chairman TAUZIN. Well, we at least ought to hear about it and talk about it.

Mr. Chairman, my time is up. I just want to make the point. If you do not take the lead and the Health Department says you should take the lead and they do not want to take the lead, we never get these forums going. Somebody has got to take the lead to organize it, and I do not know whether you or Tommy Thomp-

son. We need to put you in a room together, and you all can flip a coin to see who calls the meeting.

But my guess is it would help us immeasurably in this country if one or both of you would take the lead.

Thank you, Mr. Chairman.

Mr. MURIS. I understand. Thank you.

Mr. STEARNS. I thank the Chairman.

The gentlelady, Ms. McCarthy is recognized for her questions.

Ms. MCCARTHY. Thank you, Mr. Chairman. I pass.

Mr. STEARNS. The gentlelady passes.

Mr. Whitfield.

Mr. WHITFIELD. Thank you, Mr. Chairman.

Mr. Muris, it is my understanding that UST, U.S. Tobacco, had asked your agency, I guess back in February 2002, for an advisory opinion to make certain statements in its advertising about their smokeless tobacco products. Is that advisory opinion still pending or what is the status of that?

Mr. MURIS. Well, it is not what they asked us to do. They did not give us advertising on which they asked an opinion. They gave us a general statement without the context of advertising, and as explained in our—I cannot obviously talk about non-public proceedings in a public forum—but as explained in our testimony, generically presenting something to us in that manner caused us problems.

They withdrew the petition. They have recently sent us additional information and asked that we hold a public forum, but the petition has been withdrawn.

Mr. WHITFIELD. Now, what would be the purpose of the public forum?

Mr. MURIS. I think, although they can speak for themselves, my understanding is the public forum would involve some of the issues, many of the issues I was just discussing with Chairman Tauzin.

Mr. WHITFIELD. One of the statements made evidently in their letter to your agency was that the Surgeon General in 1986 concluded that smokeless tobacco is not a safe substitute for smoking cigarettes. While not asserting that smokeless tobacco is safe, many researchers in the public health community have expressed the opinion that the use of smokeless tobacco involves significantly less risk of adverse health effects than smoking cigarettes.

Now, does your agency have the capability to render a decision on whether or not advertising based on that type of a statement would be accurate or truthful?

Mr. MURIS. The question with such advertising would be whether it was substantiated. We do not have expertise to evaluate the substantiation, the scientific evidence. We would turn to scientific experts within and without the government.

I cite a few very briefly. We cite in our footnotes to our testimony just very brief introductions to some of the scientific evidence, but that is where we would have to turn.

Mr. WHITFIELD. And you would be able to do that?

Mr. MURIS. Sure. We would be able to ask for cooperation and assistance. Obviously it would be in the discretion of the people we asked as to how much they participated and what they told us.

Mr. WHITFIELD. And going to the scientists to come up with a scientific analysis of the claims under the current system that you would do that, you would feel comfortable with the conclusion said? I mean the process.

Mr. MURIS. Well, let me, again, put the process in context. When you have advertising, we look to see if the advertising in the first instance is deceptive. Advertising of this nature would almost certainly be advertising that contained an explicit or implicit claim that there was substantiation for the risk reduction.

We, again, are not experts on the science necessary to evaluate that claim. So that is why we would turn to the scientific community. I have confidence in the process in general. How it would work in this particular case, you know, we would have to see.

Mr. WHITFIELD. Yes. Admiral Carmona, would you support the abolition of all tobacco products?

Mr. CARMONA. I would at this point, yes, sir.

Mr. WHITFIELD. So you would support a law in Congress that all tobacco products would be illegal?

Mr. CARMONA. No, sir, I did not say that. You asked me would I support banning or abolishing tobacco products. Yes.

Legislation is not my field. If Congress chose to go that way, that would be up to them, but I see no need for any tobacco products in society.

Mr. WHITFIELD. But if Congress were to pass legislation making tobacco an illegal product, you would be comfortable with that?

Mr. CARMONA. I would have no problem with that.

Mr. WHITFIELD. Okay. Now, the purpose of this hearing today, if oral tobacco is to play a role in harm reduction, would you agree it is not necessarily to show that it does not cause cancer, but it simply needs to be substantially less hazardous than smoking?

Mr. CARMONA. If I understand your question correctly, sir, I would say that we already know it is a carcinogen, one. And if we were looking to test any other theories, certainly the fact that it is a carcinogen would be important, and in my mind, you do not need to do any further testing. If you already know it is a carcinogen, it would not be an acceptable substitute.

Mr. WHITFIELD. So whether or not it is less harmful would not make any difference to you then?

Mr. CARMONA. I if there are those who are doing research in this area and they have thought of unique ways that this can be helpful, I am always willing to listen to research.

Mr. WHITFIELD. Okay.

Mr. CARMONA. But right now substituting one carcinogen for another, I do not see a benefit.

Mr. WHITFIELD. Okay, and I understand that, but you are saying if there is scientific evidence there that shows that it is less harmful, that that is something that you would be willing to look at.

Mr. CARMONA. I would always be willing to look at any scientific evidence, sir.

Mr. WHITFIELD. Okay. Now, the Royal College of Physicians in December 2002, which is England's oldest medical institution, and among its functions is to advise the government, the public, and the medical community on health care issues, stated that as a way

of using nicotine, the consumption of noncombustible tobacco is of the order of 10 to 1,000 times less hazardous than smoking.

Would you agree with that or not?

Mr. CARMONA. I would not, sir.

Mr. WHITFIELD. Are you aware of any scientific data that would disagree with that statement?

Mr. CARMONA. Sir, not so much disagree, but I do not think they have enough scientific data to justify making that statement.

Mr. WHITFIELD. You do not think they have enough data to justify it?

Mr. CARMONA. That statement, yes.

Mr. WHITFIELD. And you have read this report that they have rendered?

Mr. CARMONA. Yes, I have, sir.

Mr. WHITFIELD. Now, on this issue of smokeless tobacco as a gateway to increased smoking, do you have any evidence to show that it is a gateway to increased use of tobacco products?

Mr. CARMONA. Yes, sir. There are studies to demonstrate that it does act as a gateway and can eventually increase smoking in all individuals.

Mr. WHITFIELD. Now, what about there was reference earlier to this European Union study about smokeless tobacco, and in that study, they make all sorts of statements. They said Sweden has the lowest level of tobacco related mortality in the developed world by some distance, approximately half the tobacco related mortality of the rest of the European Union. Sweden has the lowest male smoking prevalence in Europe. Half of the tobacco in Sweden is now consumed as a smokeless tobacco product, and this share has steadily grown since 1970.

They go on and on and on, and they make all sorts of arguments that one of the reasons that there is less mortality in Sweden is because of these so-called smokeless products, and I am sure you have read those reports as well.

But do you have any scientific evidence that would refute that report?

Mr. CARMONA. Well, on those reports, sir, I think there are many potential confounding factors that have not been fully looked at. People smoke or chew for a variety of reasons, and to assume that a decreased morbidity and mortality in a population is solely due to the fact that somebody is chewing tobacco, I am sure they all drink milk also or have a cup of coffee, and you could equally attribute changes to other variables that maybe have not been looked at.

So it is a much more complex problem.

Mr. WHITFIELD. I see my time has expired.

Mr. STEARNS. The gentleman's time has expired.

The gentleman from Texas, Mr. Green.

Mr. GREEN. Thank you, Mr. Chairman.

Admiral Carmona, during the previous Congress members of this committee have introduced legislation which would give the FDA a broad authority to regulate tobacco products, including strong restrictions on advertising and marketing tobacco products, protection for young people against exposure to environmental tobacco smoke and tough company specific surcharges to encourage compa-

nies to reduce youth smoking. Do you think it is important for our Congress this time to enact legislation to give the FDA that authority to regulate these tobacco products?

Mr. CARMONA. Well, sir, I appreciate the question, but not being in the regulation business, I think it is important that Congress looks at this and makes determination if it is something that they want to move ahead with that would be in the best interest of the protection of the American public.

Whether or not the FDA does it, I think strong oversight and scrutiny is important by whatever mechanism you all choose to do.

Mr. GREEN. Okay. Thank you.

I understand the position you are in, and I appreciate the best answer you could give.

Mr. Muris, one of the rotating warnings on packages of smokeless tobacco reads "Warning, this product is not a safe alternative to cigarettes." Let us say that you are a cigarette smoker who saw an ad promoting smokeless tobacco as a product with reduced risk, if that was allowed, and you go to your local convenience store and decide to try it out.

Yet ripping open the top of it, you read the warning that this product is not a safe alternative to cigarettes. Would you feel as if you received a mixed message as to the health benefits of that package of smokeless tobacco?

Mr. MURIS. Well, it obviously depends—and this is just to preface this. This is a very important part of what we would do, is to look at the take-away as to what a reasonable person in the intended audience understood. It obviously depends on what the advertising said.

It is quite possible that even though couched in the language of "safer," that people would receive, you know, depending on how it was written and what all was in the ad and the totality of the circumstances, it is possible that people would receive a message of safe in which case they would be conflicting.

Mr. GREEN. Okay. Thank you.

The Federal Trade Commission Act provides that an act or practice is illegal if it "causes or is likely to cause substantial injury to consumers which is not outweighed by countervailing benefits to consumers or to competition."

Even if we were to assume that scientific evidence were true that smokeless tobacco use can reduce the number of deaths associated with smoking, in your opinion does this outweigh the substantial injury caused to consumer?

Mr. MURIS. Well, you are now turning to a second part of our statute, which is unfairness, and I talked about this briefly a little while ago.

In the context that we would be looking at, and this is part of balancing in a different way than I was mentioning before, but similarly of balancing the benefits and the costs, and that is what that part of the statute requires.

I think it is a factual question on which, you know, we would have to seek evidence.

Mr. GREEN. Thank you, Mr. Chairman.

And I yield back my time.

Mr. STEARNS. The gentleman yields back the balance of his time.

The gentleman from New Hampshire, Mr. Bass.

Mr. BASS. Thank you, Mr. Chairman.

As I mentioned in my opening statement, we have heard comments about young men using smokeless tobacco as a right of passage. We have heard a possible connection between health problems with the former Speaker of the House and chewing tobacco, although I do not know whether that is true or not.

The Surgeon General has recommended that perhaps Members of Congress need behavioral modifications. I would definitely agree with that.

But the real issue here today is a narrow one, and my first question is for Chairman Muris.

Understanding, sir, that the FTC has a difficult mission protecting consumers from deceptive and misleading advertising, it involves judgment calls, and reasonable person standards. Given that you already do this currently for weight loss products and other such items based on a comparative advantage, which is the subject of this hearing, could the FTC establish guidelines that would offer needed protection and more accurate information, in your opinion?

Mr. MURIS. Well, in general I think you have to take advertising in its context and as you find it. There is the issue I was just mentioning, the issue of how consumers understand claims, and then there is the issue on which we spent most of the time in the questions you have asked me about the substantiation.

Because one of the claims that would be in these ads would be an explicit or an implicit claim that there is scientific substantiation for a risk reduction claim.

I think we would have to emphasize both things. I do not think we are ready to do guidelines particularly involving the second issue because we would need to have a much greater discussion with the scientific community about what risk reduction claims mean, about the appropriate endpoints for measuring them, about evidence from around the world, about a whole host of issues.

Mr. BASS. But it is perfectly legitimate or reasonable for the FTC to conduct studies involving comparative advantages of one product over another. It does not have to be an absolute.

Mr. MURIS. There is nothing in principle that prevents comparative claims. The Commission with my predecessor, one of the best things he did more than 30 years ago when he was at the FTC, he got the networks to eliminate their restrictions on comparative advertising.

Comparative claims are important kinds of claims.

Mr. BASS. Okay. Admiral Carmona, I appreciate your testimony, and my colleague from Kentucky, Mr. Whitfield, brought up the issue of the English or the British report that in essence drew a conclusion regarding the relative benefit or whatever of smokeless tobacco versus cigarettes.

I would be interested in if you would be willing to provide the subcommittee with a further explanation as to exactly what scientific evidence you find in that report invalid.

I will say now I have never heard of it, and I have not read it, but you have basically disputed the claims that are made in this report and said they are invalid and they are not based upon adequate science and if you were an officer, you would be willing to

analyze those claims and explain exactly what mistakes they made that led to that particular conclusion.

I would be interested to read about it.

Mr. CARMONA. We would be happy to provide you with the information, sir, and generally it is not that it is invalid. We felt that there was not enough information to support their thesis, that more research needed to be done before you could come to that conclusion.

Mr. BASS. Okay. I do not think anybody here is suggesting, sir, that you recommend one product over the other, but suppose, but I do not like to use hypotheticals, but would you agree that advertising that explains the mortality rates of one product over another, that infers a conclusion that smokeless tobacco was less harmful than cigarette smoking, would that fairly describe an aspect of the harm reduction that we are all seeking?

Mr. CARMONA. Well, we are all seeking harm reduction. I do not think that fairly describes quite a complex problem because where you might be able to argue that a product has one component that may reduce risk, when you look at the product broadly and all of its risk factors, there may be more harm or less harm than others.

So I do not think, sir, it is as simple as just describing that because there are many variables that we are looking at in these comparisons.

Mr. BASS. Mr. Chairman, my time has expired, and the point that I am trying to drive at in this line of questioning is that there is no perfect product for any problem, and there is probably no substance in this country or no issue or product that is more controversial, with the possible exception guns, than tobacco.

However, within the context of this debate if a public good is being achieved, albeit not a perfect one, is it not a good idea for policymakers and agency heads to examine this realistically and objectively because ultimately we are all seeking the same goal, which is reduction in deaths due to this particular substance.

And I will yield back.

Mr. STEARNS. And I thank the gentleman, and we have had a hearing dealing with guns, too.

Mr. BASS. I know.

Mr. STEARNS. The gentleman from Massachusetts.

Mr. MARKEY. Thank you, Mr. Chairman, very much.

I do have a bias in this field. My father died from lung cancer, and he died 3 years ago. And although he smoked two packs of Camels a day from the age of 12 until 67, it never caught him until he was 89, and then it just showed up even though he was otherwise perfectly healthy, and then he died from lung cancer 3 years ago, although the doctor had said, until it showed up, that he was going to live to 100.

So that is a big loss in our family to have a guy in perfectly healthy condition mentally and physically to die because of it.

But what I remember most is that when I was 13, he told me because I was the oldest, that he started smoking at 12 and that he knew I would be starting in the next couple of years because every boy smoked, all right, but that he should not expect him to pay for the Camels; that I was going to have to earn the money. Just do not take the money out of his pockets or anything.

But he knew that we would all smoke. That was his message to me when I was a 13 year old boy.

So because of the Surgeon General's decision in the mid-sixties and the continuation of public education, we have been partially at least able to stem that tide of the inevitable deaths that occur from young boys and girls starting to smoke because they feel like they have to.

So one of my concerns here from a public health perspective is the secret additives that are included not only in cigarettes, but also in the smokeless tobacco kind of products that are sold, and I know that HHS is one of the only entities to have the secret list of ingredients.

Do you think that it would be helpful for there to be a release of the secret additives to the public so that even if smokeless tobacco is advertised as being safer than smoking tobacco that the public would then still be able to see what the additives were and to be able to judge that it is still much too big of a risk to undertake at all and help mothers and fathers to convince their kids not to start?

Doctor?

Mr. CARMONA. Sir, I am not aware of the legal complexities involving the release of such information, but I know that our scientists have looked at it, and in aggregate they have published information as to many carcinogenic agents, as well as other factors that are contained within smoke products that can cause not only cancer, but other disease.

But as far as the release of that, I think that it is out of the scope of my practice, sir, and I am not sure of the legalities of that, but certainly——

Mr. MARKEY. If it was within our power, would you make the list of the secret additives public?

Mr. CARMONA. I think that I would ask my colleagues who were actually at the bench doing the research to ascertain if there was any benefit, additional benefit to that that would be released within the research, and then I would make my decision on that.

Mr. MARKEY. Any additional benefit?

Mr. CARMONA. Knowing the specifics, yes.

Mr. MARKEY. If the public knew what the additives were and it was determined that they would be more likely not to start using it if they knew, would you then be supportive of releasing the additive information?

Mr. CARMONA. Again, sir, that is one of the factors I would consider, but also looking at the entire context of how this information is being used by our scientists and if there was some health status that could be achieved by releasing this information, then certainly that would move me in that direction.

Mr. MARKEY. So there are carcinogens in these additives. You also mentioned other diseases caused by these additives. What are they?

Mr. CARMONA. Well, chronic obstructive pulmonary disease, acceleration of cardiovascular disease, you know, stroke, heart attacks, things like that. So not all necessarily cancer related, but very significant diseases also.

Mr. MARKEY. So let me ask you, Chairman Muris. If the public does not have access to information about secret ingredients and additives in smokeless tobacco, aren't claims regarding the potential health benefits of smokeless tobacco likely to be deceptive or misleading because the information about the additives that are in the smokeless tobacco are not available for the public to make that determination themselves?

Mr. MURIS. Well, let me preface with two general statements.

One, I have never looked explicitly at what this information is, but from the standpoint of what we do, there would obviously be a heavy presumption in favor of more information and not less, and someone would have to make a very good argument, and you know, not having looked at it, I do not know what that argument might be, to withhold information.

Mr. MARKEY. Thank you.

Mr. STEARNS. The gentleman's time has expired.

Mr. Shimkus. No, Mr. Shadegg. Mr. Shadegg.

Mr. SHADEGG. Thank you, Mr. Chairman, and thank you for holding this hearing.

I will tell you I am mystified by it all, and I kind of wonder where it is taking us.

Let me start with the issue of your jurisdiction at the FTC. As I understand it, you have jurisdiction arising out of the concept of deception and the concept of unfairness; is that correct?

Mr. MURIS. Yes.

Mr. SHADEGG. On the concept of deception, as I understand your testimony, before you could allow a label to say this product is safer than, that is, smokeless tobacco is a safer alternative to cigarette smoking, you would have to have evidence which substantiated that point; is that correct?

Mr. MURIS. Among other things, yes, sir.

Mr. SHADEGG. Okay. Dr. Carmona, it is your belief that while there have been studies done on that point, they simply are not sufficient, that is, not enough studies or not enough subjects, not enough contrasting information to reach that conclusion; is that right?

Mr. CARMONA. In the particular instance of smokeless tobacco?

Mr. SHADEGG. Yes, to reach the conclusion that smokeless is safer than.

Mr. CARMONA. Yes, that is correct, sir.

Mr. SHADEGG. Okay. So you believe the FTC could not, in fact, substantiate that first threshold criteria of whether or not it is safer than; is that right?

Mr. CARMONA. That is right, sir.

Mr. SHADEGG. The whole topic puzzles me. For example, this is a can of smokeless tobacco. This particular can has the warning that says, "This product may cause gum disease and tooth loss."

One of the issues I hear in the testimony here today is a relative one, which is if we say or if we allow the claim to be made that smokeless tobacco is safer than cigarettes, which you believe cannot be substantiated, but others believe could be substantiated, are we then deceiving people into using smokeless tobacco as a safe alternative?

Now, we know that one of the labels that is already on smokeless tobacco says this product is not a safe alternative to cigarettes. That raises the issue of, okay, what is the truth. If you give less than all of the truth, are you somehow deceiving people?

And, Dr. Carmona, that is your concern, is it not?

Mr. CARMONA. Yes, sir. My concern is that, you know, that definition of the word "safer" as it relates to these products, that, in fact, if you take one piece out of context and make an assumption that, well, because there is less of a certain chemical, therefore, it is safer where the science is not there to support it, and we ignore the fact that, as you just pointed out, sir, gum disease, tooth problems and so on are also problematic, it is very difficult to say that, and that is why I view that substitution argument as oversimplified for a very complex problem and one that I could not support because it is still detrimental to the American public.

Mr. SHADEGG. Let me ask you both. As I read the information I am provided, right now although the warning on cigarettes is a Surgeon General's warning and the warning on smokeless tobacco is not a Surgeon General's warning, it just says a warning; both are as a result of congressional actions and neither are as a result of FTC action standing alone or Surgeon General action standing alone; is that correct?

Mr. CARMONA. I believe so, sir.

Mr. MURIS. Yes. The FTC got the ball rolling, but then Congress stepped in 40 years ago or almost 40 years ago.

Mr. SHADEGG. And so it is going to be our job to try to spell out at least currently what should be specified on the label, if anything.

Dr. Carmona, if the Congress does not step in and specify what should be spelled out, do you have the jurisdiction to issue your own warning?

Mr. CARMONA. Well, I think that one of the things I have probably that is most important is the so-called bully pulpit. I can certainly speak out regularly on the hazards of all tobacco products, and I would certainly intend to do that along with my colleagues where the scientific basis allows me to do so.

Mr. SHADEGG. and I suppose it would be your position that if someone were to propose that they wanted to advertise smokeless tobacco as safer than cigarettes, you would want to add "but not, in fact, safe" because of these other dangers; is that right?

Mr. CARMONA. I would be opposed to such advertising.

Mr. SHADEGG. And you would like to see the Congress, if the Congress were to step into this field and specify what had to be put on claims about smokeless tobacco, to make sure if anyone had wanted to make a claim that smokeless tobacco was safer than cigarettes, but they would go beyond that and say, "But, however, still not safe because it causes all of these issues, the potential for mouth cancer, potential for gum decay, tooth disease, other things"; is that right?

Mr. CARMONA. Well, sir, my intent would never be to attempt behavioral modification on the Congress.

Mr. SHADEGG. But we look to you for expertise and we should.

Mr. CARMONA. But what I would strongly support is that Congress take into account all of the scientific evidence before us, some

of which you have completely outlined right now, in making their decision to protect the American public.

Mr. SHADEGG. One of the things that concerns me is that of the three labels Congress has specified for smokeless tobacco, and I understand they rotate. So my understanding is that one third of all cans would have to contain one of these; one third the second; and one third the third. One of them, quite frankly, I think you could make the claim that it is deceptive precisely because it does not go far enough.

One of the three labels is, "This product may cause gum disease and tooth loss." I would suggest that if I were a young kid picking up this can and read this particular can, which says it may cause gum disease and tooth loss, I would be a lot less concerned about its use than if read, "This product may cause mouth cancer," which raises the next question of, well, why does it say mouth cancer. Why doesn't it say this product may cause cancer? Because if you want to scare somebody and you warn them this product may cause cancer, I suggest that is going to have a greater impact on them than perhaps any of the other three alternatives that are there.

So one of my concerns is what we will have when we start down the slippery slope, when it is the U.S. Congress that decides what the precise wording of any warning ought to be.

Mr. CARMONA. Well, we are certainly concerned, my colleagues and I, sir, that any references to "safer" that are not clearly spelled out, are not scientifically justified may, in fact, just do that, cause young people to start earlier and feel that it is a safe thing to do; that there is relatively little risk; and as you have pointed out, the whole story is not being told.

Mr. SHADEGG. Let me go back to the FTC on the issue of, okay, one issue would be the issue of deception, and that is would it be deceptive to claim that smokeless tobacco is safer than cigarettes.

Your second element of jurisdiction is that of unfairness. Under the second rubric, unfairness, would you consider it necessary to go on and provide the disclosure however not safe?

Mr. MURIS. Well, the Commission has rarely, and I mean rarely, used unfairness to evaluate advertising. It almost always uses deception. There is a tremendous First Amendment problem from saying an advertisement is truthful, yet we can stop it. So we would much more likely use on the unfair—I mean our deceptive authority.

It is clear that in any of these ads we would be concerned with the take-away. By that I mean an understanding by the intended audience that no matter what the word said, that a lot of people thought that it meant safe, and that would be a big concern.

Mr. SHADEGG. You would be concerned that an implication that safer might cause somebody to conclude it was safe.

Mr. MURIS. Sure, depending on, you know, how the disclosure was made and what else was in the end.

Mr. SHADEGG. Before my time expires, I simply want to conclude by pointing out that according to the information that I have in 1981, the FTC issued a report to Congress that concluded that health warning labels had little effect on public knowledge and attitudes about smoking. So it says public labels do not do anything.

Congress responded by enacting a law requiring health warning labels. I think it is quite interesting what we do here.

Thank you very much.

Mr. STEARNS. The gentleman's time has expired.

Mr. Davis is recognized.

Mr. DAVIS. Thank you, Mr. Chairman.

Chairman Muris, in reviewing your written statement on page 8, you suggest that in the context of safety claims, the FTC has typically required a substantiation standard of competent and reliable scientific evidence. In my opinion, this issue ultimately boils down to respect. How much respect are we going to have for our consumers, for our citizens in terms of how high the standard we set as far as judging the accuracy and truthfulness of any disclosure you would approve or this Congress would approve so people can make safe decisions, not necessarily the right decision.

Can you elaborate a little bit as to exactly how high the standard is you would employ if you were to find yourself in a proceeding judging the marketing of smokeless tobacco?

Mr. MURIS. Well, yes, sir. The first question obviously turns on what the ads would say in their full context and, therefore, what the take-away from consumers would be. The more qualified the take-away that the consumers received, the lesser the substantiation.

On the other hand, as I mentioned, the so-called Pfizer factors before, because I personally believe, again, just speaking for myself—obviously my colleagues could have different views—because the consequences of making a mistake here are so serious in terms of, you know, the potential adverse effects on public health, people who might otherwise have quit, what the effects might be on children; that would indicate that the bar should be very high.

Mr. DAVIS. The debate here today seems to center upon the word "safer." It seems to me as a lay person that by its very nature in whatever context the word "safer" is used, and it invariably is a vague term; it is not a qualitative connotation.

Under what circumstances could safer ever constitute a sufficiently acceptable standard under this very high standard you have just described?

Mr. MURIS. Well, again, there are two questions that I think you really have to keep distinct. One is how consumers understand the words, and I believe it is possible to communicate safer as opposed to safe, but then the second question is about the scientific evidence.

And the scientific evidence, I believe, would have to be very high, but we do not even know. I mean, again, we are not scientists. The scientific community, I think it would be very useful for them to do more work on issues involving what sort of evidence is it that they would want, what sort of evidence that they would look at.

Because I do agree with the general premise that some members have made that we do have upwards of 50 million people who smoke. Many of them find it very difficult to quit. The simplest place to start, if I could just end, I believe, and I would like to explore with the FDA, the potential for broader-based claims for the gums and the patches that the Surgeon General mentioned.

Right now those can only be used for very narrow purposes. They can only be marketed as part of quitting. They cannot be marketed as sort of a long run replacement. It seems to me, again, it would be up to the FDA ultimately because they regulate this, but it would seem to me that there are very large potential benefits from being able to tell people about the longer run possibility.

Mr. DAVIS. And I commend you on that. I do not think we should be afraid of the risk reduction. The Surgeon General has said that. I think we need to be painfully objective about this.

But it just seems to me as a lay person that the question is not whether a safer type of marketing could ever be acceptable under this very high standard, but that it really would be a disclosure as to how much safer or how less safer, don't you think?

Mr. MURIS. Oh, well, absolutely you would need to understand the question of quantity in that sense, not just the question of a qualitative difference, and I agree with that.

It even may be true, a complication of the nicotine products, the gums and patches, and why I used the word "potential" is there is some evidence, and, again, I am not a scientist. The scientists would have to explore it. There is some evidence of potential dangers from nicotine itself beyond addiction.

Mr. DAVIS. In the Footnote 17 on page 8, you seem to acknowledge the possibility that evidence that is presented to you that you rely upon for approval later proves to be faulty. That is a problem.

Do you have the authority to go back and revisit any approval of the disclosure that has been made on a product if subsequent scientific evidence reveals it is not sufficiently accurate?

Mr. MURIS. Absolutely, and the basis of the substantiation doctrine by its very nature recognizes that when the science changes, then the ability to make the claims changes.

Mr. DAVIS. I would like to give the Surgeon General an opportunity to comment on any of these points if he would care to.

Mr. CARMONA. Well, sir, simply I agree with where you are going with this. I think there is qualitative and quantitative aspect to the word "safe" or "safer," and certainly quantitatively we have to be able to define that, but also in its entirety as I alluded to earlier in my remarks.

Taking one variable out of context and simply stating that there is an improvement or it is simply safer does not address the spectrum of risk, of which there are many variables.

So I think it is to the public's benefit that we are very clear on how that word is used.

Mr. DAVIS. Thank you, Mr. Chairman.

Mr. STEARNS. The gentleman's time has expired.

Mr. Issa.

Mr. ISSA. Thank you, Mr. Chairman.

I might preface this by saying I am a recovering smoker of 13-plus years. So I am very aware and every day think about the error of my smoking in my youth and my not so youth judging from when I finally quit, but I do have some questions because I do not think we are dealing with tobacco here. We are dealing with the question of a blank substance relative to other blank substances, claims, interpretation for whether or not they are allowed versus other claims.

And hopefully we can forget the word "tobacco" in the discussion today for purposes of thinking about whether or not safer, which does seem to be the key word, is appropriate or inappropriate to be considered.

And what I would like to, first of all, do is ask the Surgeon General one question, which is what is the health benefit of butter.

Mr. CARMONA. Let's see. There are nutrients within butter.

Mr. ISSA. Butter is basically fat; is that right?

Mr. CARMONA. No, no.

Mr. ISSA. What are the benefits of fat then perhaps is a better question.

Mr. CARMONA. Fat is necessary. It is essential to our growing everything from making steroids in your body to new cells require fats.

Mr. ISSA. And isn't the excess consumption of fat the No. 1 health problem in America, in combination with not enough exercise.

Mr. CARMONA. It certainly contributes to obesity, sir. Yes, sir.

Mr. ISSA. Okay, and yet the low fat butters and the alternate butters appear to be able to claim that they are better and safer. I have read enough packaging to get this idea that this plasticized butter that tastes marginal at best, not margarine, but marginal, gets to make that claim.

And, Chairman Muris, I guess the question is: how do they get to make the claim that they are better if essentially the difference is less fat, which the Surgeon General has said is okay? It is essential.

Mr. MURIS. Well, health claims are regulated by a statute that Congress passed in 1991, the NLEA, and there are a variety of hoops through which you have to jump. So even though we are involved in that area and, in fact, Dr. McClellan, the head of the FDA, and I made an announcement last year where he is hoping, given the way science is changing, he is hoping that advertising and labeling can keep up with the changes in science.

But there is a special, you know, regulatory regime for those.

Mr. ISSA. Okay. So the fact that butter is essentially not bad and fat is not bad, then if you have less of it claiming that it is better would be probably inappropriate on the face of it all, forgetting about the taste of butter, forgetting about what we all put on. Then, in fact, we have a different standard for tobacco than we have for fat.

Doctor, I guess my next question is you support banning tobacco. Does that allow you to be an honest broker in the question of less bad and more bad?

I would personally say that I would have a hard time if I supported outright banning something. We would be happy to see Congress passing a law that would do that.

And then I was asked: well, are we going to allow the good instead of the perfect if the good might, in fact, perpetuate consumption of this for a while?

I would probably inherently say, "Well, geez, I do not want to have anything that might lower a little bit the health risk, but perpetuate the consumption."

Is that something that you are having to deal with in your testimony today?

Mr. CARMONA. Well, no, sir, and let me elaborate. First, I want to respectfully disagree with your analogy with butter because it is much more complex than is presented, and I think it is an unfair analogy.

Second, I am not having any problem with it because the driving factor in what I have testified to is that the substance we are talking about is a proven carcinogen. It causes cancer. So that——

Mr. ISSA. Reclaiming my time from the witness, I guess the problem we have is we are talking about less and more and trying to understand whether or not less or more is an honest statement, and that is why I am trying to get to the bottom of this.

It appears to me as though other than tobacco we have this theory that you are innocent until proven guilty. In tobacco you are guilty until proven innocent, and so for the Chairman, I guess, my question to you would be, because my time is evaporating here, we have made a big point in this country, and accurately so, that we are concerned about second hand smoke, sufficiently that, in fact, it has been found to be something that one has to get rid of, and that is why we ban smoking in public areas in State after State.

If, in fact, second hand smoke is clearly bad, then aren't you better if you have no second hand smoke because you have no first hand smoke? The risk to people around a smokeless tobacco consumer is by definition zero versus whatever you have with cigars, pipes and cigarettes.

Would that not meet the first threshold of a claim?

Mr. MURIS. Well, sure, but now you are addressing a different question. If smokeless tobacco made a claim based on no secondhand smoke, you know, we would evaluate that on it its merits. That is obviously different than the earlier claim we were talking about.

Mr. ISSA. So just one last follow-up. So what I am hearing is that even though there is no smoke and anybody could figure out that it must be safer, you are saying that if they made that claim, then you would think about evaluating it. Do we need science to determine——

Mr. MURIS. Well, no. I am saying——

Mr. ISSA. [continuing] that smoke has no second hand smoke claim?

Mr. MURIS. The evaluation could be very quick, but obviously if someone asks us, let us go back to the premise. The premise was we were asked about these claims. I cannot give an answer without an evaluation, even if the evaluation occurs in a twinkling of an eye.

Mr. STEARNS. The gentleman's time has expired, and the gentlelady from California, Ms. Solis.

Ms. SOLIS. Thank you, Mr. Chairman.

Thank you, Dr. Carmona for being here. It is good to see you. I know on occasion we talked about some of these chronic illnesses that face our communities, especially minority communities and the Latino community.

And I wanted to ask you, and I do not know if this has come up, what the cost is in terms of prevention for tobacco use now that

you know of in terms of government trying to combat the use, trying to get youth to stay out of, you know, going into that bad habit of smoking.

Mr. CARMONA. I do not have a dollar amount for you. I certainly can get that, but whatever it is, I know that when we look at prevention across the board, we spend far, far too little on all prevention activities in this country.

Ms. SOLIS. Would you say that the number of youth, particularly minority youth in terms of smoking, has gone up in the last 10 years or it has gone down?

Mr. CARMONA. I think it has slightly increased where other areas or other subsets have decreased. This is still a population that is at greater risk.

Ms. SOLIS. I saw some information regarding, I guess, a percentage decrease for young Latinas in terms of smoking. I kind of understand why that is happening, because more women at least are going in for prenatal care and are being advised of low birth weight that their child would experience if they continue to smoke.

Is that something that your office is also advocating?

Mr. CARMONA. Well, the epidemiology and demographics of smoking are tracked very carefully by CDC on a routine basis, and they have all of those numbers broken down, again, by ethnicity, by geographic location, by age, and so on.

So it really depends which group you are speaking of. In some areas it has plateaued out, but in some there are still subgroups, Latinos specifically, who are at slightly increased risk, and every once in a while we see a little increase.

Ms. SOLIS. One of the explanations that we were given is that, in fact, if you were advocating for use of smokeless tobacco, that that probably or could lead to use of tobacco, cigarettes. What is your opinion on that?

Mr. CARMONA. Yes, we do look at smokeless products as being a gateway to smoking. It can be still a sense of security that, again, as I have said earlier, this is a lesser threat. It is a safer means to get your nicotine and chew, and we are definitely concerned about that for the reasons I have already mentioned.

Ms. SOLIS. One of the other questions I have is women, I think, overall, my understanding is that the rate has actually gone up; is that correct, in terms of cigarettes?

Mr. CARMONA. It depends on the age group, and I would have to look at that data, but the aggregate, if it has, it is very slightly in aggregate. But, again, breaking down the populations, minority populations' age and demographics you will have peaks and leveling off periods that are different than the aggregate data when you just lump all women together, for instance nationally.

Ms. SOLIS. The information I have is that women account now for about 39 percent of all smoke related deaths in the U.S.

Mr. CARMONA. That is correct.

Ms. SOLIS. I guess one of the questions I would have is if we are trying to get women to stop smoking and using an alternative measure here, in this case smokeless tobacco, I cannot think of too many women who would want to chew tobacco, you know, and I would love to hear more about that. Because I think that is a real

issue that we are really skirting the issue here, and how do you deal with that?

Mr. CARMONA. Well, I think that is, you know, a social and cultural part of our society where young men embrace that and most women reject it.

Ms. SOLIS. Well, wouldn't that have an impact on modifying maybe their behavior?

Mr. CARMONA. Oh, yes, ma'am. Absolutely, yes.

Ms. SOLIS. So I am still very skeptical about the direction of where we are going with all of this because I know that in our community, and especially in California, the State of California is pretty progressive in terms of prevention, tobacco smoking and all of that, and restricting where you can use cigarettes.

In fact, we have an initiative that was passed, Prop. 10, that you are probably aware of that is a dedicated source of funding strictly for prevention.

So my question goes to while we are spending a lot of money to try to treat the illness, cancer, respiratory, emphysema, at the same time we are raising revenue to try to tell youth to give them the message and young people not to smoke.

Mr. CARMONA. Yes.

Ms. SOLIS. And then we are saying, on the other hand, well, it is okay to chew tobacco when, in fact, studies, I guess, are not clear on how severe that might be.

My question is, you know: where are we going with this in terms of giving accurate information that smokeless tobacco may be harmful, could be maybe in different degrees obviously. Maybe you do not get cancer in 10 years. Maybe you suffer from tooth decay a lot faster, which we see in our community, by the way.

And I would ask, you know, what your opinion is on that.

Mr. CARMONA. Congresswoman, my opinion is that, as I have stated, irrespective of the debate here today, I see no scientific evidence to support the use of smokeless products for any reason, and they are hazardous to your health, from causing cancer to causing oral disease, including gingivitis, tooth decay, as well as a host of other diseases.

So without further evidence to refute that, I could not support its use in any fashion.

Mr. STEARNS. The gentlelady's time has expired.

Ms. SOLIS. Thank you. Thank you very much.

Mr. STEARNS. Mr. Fletcher.

Mr. FLETCHER. Thank you, Mr. Chairman, and thank you for conducting this hearing.

Let me say first having spent most of my adult life up until the political side of things encouraging people to stop smoking and using tobacco products, I think it is interesting that we come to today where we are talking about relative risk of different products.

There is no question as we look at the IOM report, 180,000 deaths from the cardiovascular disease, 150,000 from cancer, about 85,000 from respiratory disease related to tobacco use, and so there is no question that if we had a perfect world, that no one would smoke or use products that are harmful to their health.

But, in fact, that is not the case. We do have a free society, and I think in a free society it is very important to remember that a couple of things are important.

One, I think it is extremely important to be intellectually honest with the population so that they can make choices. Some people choose to smoke even though they know the risk is there. I think 75 percent of the people that are smoking would like to quit. That means there is 25 percent that do not even want to quit.

So outside of prohibition, which even though some may support that, I think we probably have it nigh to impossible to control and regulate. We went through prohibition in the early part of the last century with some abysmal results.

But given that, let me look, and I want to present a couple of things. I have looked over these reports, and I know the Surgeon General has commented on that. One was the Royal College of Physicians of London, and these are, you know, pretty reputable folks. In fact, they have been around a lot longer that probably most of our even Harvard and some of our early medical institutions. I mean these are folks that spend their life doing research.

And they come up and say a way of using nicotine, the consumption of noncombustible tobacco is on the order of 10 to 1,000 times less hazardous than smoking, depending on the product. Some manufacturers want to market smokeless tobacco's harm reduction option for nicotine users, and they may find support for that in the public health community.

But the bottom line is it is a pretty big spectrum. So the science is pretty unclear. It is 10 to 1,000 times. Even 10 is pretty significant if that is the low balling side.

Now, I do not support and have certainly found it intolerable that companies in the past have made marketing attempts toward younger individuals and maybe not always been truthful in what they said they would market and things. And so I think it is clear that we have some sort of guidelines for advertising, for marketing a product.

But I also look at given the fact that Royal College is 10 to 1,000 times less, there is also the European. These are some pretty reputable people, too, that have spent a lifetime just in research. They said oral tobacco may play a role in harmful reduction. It is not necessary to show that it does not cause cancer. It just needs to be substantially less hazardous than smoking, even allowing for the cautious assumption about health impact.

So that is what you were talking about, the European, I guess. The smokeless tobacco and other oral tobaccos are a very substantially less dangerous way to use tobacco than cigarettes, and it goes on to talk about a number of different other things, but it does at least acknowledge, and this is a study of some physician researchers that smokeless tobacco has reduced health.

Now, the Scandinavian study—and I know the Surgeon General mentioned that some of the factors were not controlled—there was one of those studies where they were controlled fairly well. Let me read those to you.

This was a Lagergin study. It was a case controlled study, patients with adenocarcinoma of the esophagus, gastric, cardio, and esophageal squamous cell carcinoma. It said many potential con-

founders were considered, including age, sex, education, cigarette smoking, alcohol consumption, dietary intakes. It did not mention coffee specifically. Dietary intakes of fruit and vegetables and energy intake, BMI, reflux symptoms, physical activities.

It talked about the substantial reduction. I agree that the science is not totally—I mean there are a lot of studies that can be done, and the science is not totally complete in this area. But one of the questions I have got for both of you is if we could have certainly an initiative for regulating tobacco products, whether it be FDA or whether it be FTC on the marketing of it, and it was marketed in such a way that it was very clear to not use the word "safe" or "safer," but say you had a relative scale from 1 to 10, and say you could say, well, given the current knowledge that we have, you know, filterless cigarettes, maybe a 10; smokeless, somewhere less there.

And, by the way, I come from a district that produces burley, which is for cigarettes, not for smokeless tobacco.

Given the fact that we live in a free society and it is important to get information out, and given the fact that I know some people feel that this gateway issue may promote more people, but wouldn't it be incumbent upon us to provide that information to them, that there is a relative risk?

And I say that because I have got a brother that I tried to get to stop smoking. He was smoking. We got him to stop. He started dipping snuff. Finally when we could not get him to stop altogether, we just kind of quit, and, yes, he went back to smoking. But I never told him about reduced risk.

And I just wonder that given the fact that even second hand smoke causes some injuries of what we might do if we give the public intellectually honest information about the relative risk, and I would just like both of you to comment on that.

Mr. CARMONA. Well, if I might, I will just comment on the science first, and then I will pass off to my colleague on the advertising.

I certainly respect your opinions as a colleague, as a fellow physician, sir, but the Swedish study, I know that they looked at an endpoint of oral cancer risk and not cardiovascular disease or other causes of mortality in a more broad sense. So it is only one endpoint.

So I think variables also in outcome, as well as the inputs for the research I think are equally important.

Mr. FLETCHER. May I interrupt you just to ask you a question?

Mr. CARMONA. Yes, sir.

Mr. FLETCHER. Do you believe that smoking has the same cardiovascular risk as smokeless tobacco, say, the Swedish smokeless?

Mr. CARMONA. I would have to review the data more specifically, but I know there is risk. If it is the same or lesser, then we get into that issue again of is it safer.

Mr. FLETCHER. Yes, relative risk. That is what studies are about. There is no absolute there.

Mr. CARMONA. Yes, and so the other issue is when we are talking about the amount of nicotine, for instance, and you do not also talk about carcinogenicity, then you just negate the fact that we know that these are cancer causing compounds, and so if you just ad-

dress the issue of, well, is this a safe way of using this to withdraw somebody from their nicotine addiction.

Well, again, my premise is that if I know that this is a carcinogen, then I really could not in good faith recommend it for any other use when I know no matter what else you are using it for——

Mr. FLETCHER. I agree. We do not recommend it for use, period, but I am talking about a relative scale, just getting information out to the public. It is kind of like on HPV and cervical cancer. You know that. We talk about the use of condoms does not totally prevent HPV and cervical cancer, but it reduces the risk, and there are a lot of folks on different sides of the aisle that have a different approach to that.

Mr. CARMONA. Yes, I understand, and I can understand where you are coming from and some of the research is looking at this a little bit different as a matter of policy. But, again, it comes back to the cancer causing effects or carcinogenicity of this for me, that when you say on a relative risk and you say, "Okay. Well, smoking let us say is a ten and maybe this product is a five, but it still causes cancer."

So if you say the relative risk is lower, all right, I cannot argue with you if we show that statistically, but it is still a cancer causing agent, which is why I am concerned.

Mr. FLETCHER. I agree.

Mr. Chairman.

Mr. STEARNS. The gentleman's time has expired.

The gentlelady, Ms. Cubin.

Ms. CUBIN. Thank you, Mr. Chairman, and thank you for calling this hearing today.

I was one of those members that did request because I believe that knowledge is power, and I want to point out that we are not here today talking about the ills of smoking. We all know that. We all believe it, and we accept it.

We are also not talking about marketing tobacco products to children. If I had three wishes and I found the bottle on the shore and the genie popped out, I would probably wish for enough money to take care of myself and my family and meet our needs until we die. I would probably ask for good health for myself and my family. And the third thing would be that I would wish for all children to make decisions that were beneficial to their bodies as far as health is concerned.

So, you know, I am a mother, and I actually have a son that chews smokeless tobacco, and I hate it. When I was a little girl, my grandfather chewed smokeless tobacco. I am from Wyoming, and probably we have as many people that use smokeless tobacco as anyone.

But what I am thinking about are the 10 million adults that are going to die in the next 10 years or the next two decades I should say, that are going to die from actions related to smoking, conditions related to smoking.

I have a degree in chemistry, and whenever we would be arguing an issue in science, the first thing we would always do is challenge the studies that were cited by—I was also in debate—the studies that were challenged by the other side.

And so, Dr. Carmona, you do not accept as valid because it is not comprehensive enough the study by Britain's Royal Academy of Medicine; is that correct? Was that the reason you gave during your questioning and statement?

Mr. CARMONA. Yes. Not that it was invalid, but that to make a decision you need much more information, and my colleagues also who study this——

Ms. CUBIN. Yes. Okay. Well, then does it follow that the same level of comprehensiveness must be followed to support the statement you made that smokeless tobacco is a gateway to smoking? Is there a study that you can cite that has more comprehensive basis than the Royal Academy's?

And if so, would you please furnish that?

I would like a comparison actually of the studies themselves and why the study that you are quoting as far as the gateway to smoking is concerned is superior to the basis of this study by the Royal Academy. Would you provide that to us?

Mr. CARMONA. Yes, ma'am.

Ms. CUBIN. Thank you.

Mr. CARMONA. I did not mean to imply that it was superior, but I would be happy to provide the information to you.

Ms. CUBIN. Sure. You did not say it was superior, but you base your opinion on something, and I am just curious to know how you substantiate that in your own mind, and I would appreciate it if you would provide that to us.

Another point that I wanted to bring up is that science is changing. Mr. Muris brought that up earlier in response to a question that science is changing. In the 1986 Comprehensive Smokeless Tobacco Health Education Act, Congress ordered that three messages be alternated on snus cans. You notice I call it snus because that is what my grandpa always called it. That is politically correct to me.

Anyway, one of those statements is this product is not a safe alternative to cigarettes. Well, since your agency did not come up with that language that it is not a safe alternative to cigarettes, Mr. Muris, I wonder if you have a responsibility.

I mean, obviously the Congress did that, but trying to decide who has a responsibility to get this information forward, I mean, it is your agency's responsibility that the correct information be out there. This language was done in 1986. Isn't there information that would cause you to at least look at that and make a recommendation to the Congress if they are the ones to do the language, which I do not think, frankly, that Congress should be doing that? I think it should be done in your agency.

Mr. MURIS. Well, the history of this issue is many, many years ago, in the mid-1960's, my agency tried to do something, and Congress immediately stepped in, and my agency has had the wisdom since the to——

Ms. CUBIN. To stay out?

Mr. MURIS. Well, we have issued reports and we have done other things, but we have not tried to by rulemaking do something that Congress has made it pretty clear that it wants to do.

Look. In the bigger——

Ms. CUBIN. But that is really not my point. My point really is if this statement is factually wrong, I mean, if we cannot make the statement that non-tobacco products—well, let me see. Where did I write this down? I wish I could keep track.

Go ahead and answer what you were going to say.

Mr. MURIS. Well, in the very large context, and I do not want to lose sight of that here in the specifics, this hearing is very important because potentially—and that is obviously the key word—there are very large public health benefits to be made from addressing the problem of people who cannot or will not quit smoking.

And that is why I said a place to start where I think we can do more, and again, it is potential, and the FDA already regulates this, and that is why I said I would obviously need to talk to them, is with the non-tobacco risk reduction products, the gums and the patches.

They right now can only be marketed for a very limited purpose. So consumers cannot be told about their potential for that group of smokers who are unwilling to go off of nicotine entirely.

Ms. CUBIN. So what I have drawn from this hearing today so far is that if more people were using snus instead of smoking cigarettes, that our national health care bill would be lower; that there would not be people suffering from second hand smoke from other smokers; that improvement would be seen in our national health picture.

And I just think it seems to me, General, or I mean Admiral—excuse me.

Mr. CARMONA. No problem.

Ms. CUBIN. But it is something that we should consider. I do not think anyone is saying that the use of snus is a healthy thing to do, but I certainly do not think that we can say that it is not a healthier thing to do than smoke cigarettes.

So my time is up, and if you would like to respond to that, that would be great.

Mr. CARMONA. I think my remarks, ma'am, have been directed to the science that we have at hand today, that there is no evidence at this point to use that as a substitute. What we do know about the product is that it can cause cancer and other diseases.

I also stated earlier though if there is research to the contrary, if there is research that can define some role, my colleagues and I are always happy to look at that to see if there is a possibility, but as of this date we have seen none.

Mr. STEARNS. The gentlelady's time has expired. The gentleman from Idaho, Mr. Otter.

Mr. OTTER. Thank you, Mr. Chairman.

And I along with the rest of the panel want to thank you very much for calling this most important hearing.

I have always been adverse to putting the fist of government into the glove of courtesy. I know many times when I was in my State legislature we passed no smoking in public places even though it was not a government building or was not a government called meeting, and I always voted against those kind of bills because I felt that I had a personal responsibility, if I did not want to be in part of that environment, that I should go to the restaurant owner

and say, "I am not going to eat here any longer as long as you do not have a no smoking section or as long as I cannot avoid second hand smoke."

But I want to make an admission like my colleague from California, Mr. Issa, that I, too, am a recovering smoker. I quit for my son's first birthday 34 years ago, and it is probably one of the smarter things that I have ever done, but I did it because I recognized that it is personal responsibility.

And it is unfortunate that so many of the things that we do in Congress, and I have only been here a little over 2 years and a few months, but so many of the things that we do here in Congress is we try to substitute the national consciousness and the national Treasury for personal choice, and of course, I have to look right back on the immediate past of the tobacco lawsuits that we had.

And even when I did smoke 35 years ago, I never bought a pack of cigarettes that probably did not have that warning on it. And I say "probably" because I doubt if I read it more than once or twice, only as a novelty, I guess, when it first appeared.

But I made that choice. I made that choice to smoke, and I watched as the generation just before us, as many of the folks in my generation watched as that generation just before us that had smoked 10 years more than we had started suffering the consequences of that behavioral choice.

Well, I think we have sent a far more dangerous message to our youth about smoking or not smoking or choosing to use tobacco in any form or not to use it when we have substituted the national Treasury and the national consciousness through Congress action, through the Judiciary Department's action of bringing a lawsuit against the tobacco companies.

They were warned: do not smoke. Then we go back and sue them anyway and say we are going to hold you responsible. That is past history. I disagree with that.

I suspect when I was in the military, and you could have called me General, Barbara, I was in the armored calvary, and it was not unusual for us during training or during OJT or AIT to stop the column and break and say, "Smoke them if you have got them."

And sometimes they were supplied in our food packets. Anyway, I suspect that got a lot of people smoking.

But anyway, what I would like to ask, I guess, both of you, it has not been unusual for the government, as Congresswoman Cubin made the point earlier, that knowledge is power, and one of the responsibilities this republic, this government does have to its citizens is to make them as knowledgeable as possible and then stay out of their way and allow them to use that knowledge for choices.

And it seems to me that if there is evidence and whether or not you disagree with these early on reports, it has not been unusual, Mr. Muris, for the FTC to allow cigarette makers to say, "This new filter that we have got on here allows for less tars and less nicotine. This new cigarette is a little less of this and a little less of that," and thereby enhancing the possibility that it is probably not as dangerous as the one without a filter or is the one referred to earlier, and I don't want to pick on any particular company, but the Camel cigarette.

And I know when I first stated smoking if you could smoke a camel, you were tough. You know, you probably got off a little easier with something with a filter on it, but my point is: why isn't it your responsibility to make people more knowledgeable and, therefore, more free to make the right decision by adding up and subtracting the causes and the amount of danger there is in different products?

We do it all the time, less salt, less sugar, less fat. We hear it all the time. Why isn't that our responsibility irrespective of your feeling and the Admiral's feeling about all of them being bad?

And with that I will yield back.

Mr. STEARNS. The gentleman's time has expired.

Would you like to answer the question, Mr. Chairman?

Mr. MURIS. Sure, if you want.

Mr. STEARNS. Sure, go ahead.

Mr. MURIS. I do believe in the importance of knowledge, and as I mentioned just a few minutes ago, in the potential of public health benefits from risk reduction products. There are obviously important attributes here. This is a product that used as intended causes you great damage, and I think everybody recognizes that.

And our experience with the tar reduction has not been a particularly happy one because of the phenomenon called compensation by which people smoke the cigarettes harder and, therefore, get more damage than if they smoked them on some relative level. So that just shows us that we need caution.

Mr. CARMONA. I would just briefly comment that I agree with your premise, sir, as far as the right of people to choose, and in a perfect world, we would hope that armed with the appropriate information that people would make the right decisions, but often their individual decisions have impact on a population at large, and sometimes I think where markets fail or common sense fails regulation sometimes is essential.

We do it with speed laws because we know people drive too fast, and we have been able to demonstrate that by slowing them down there are less accidents.

We know that seatbelts save lives, and in many states people felt it was their right not to wear one. Yet the impact to the population and the cost of health care on the whole was significant. So we had regulation for that and helmets and a number of other things.

And I think, again, in a perfect world I would agree with you that it would be nice that people would make prudent decisions based on the information before them, which is part of my job to bring that scientific information forward. However, they do not always make the right decisions. And their poor decisions can adversely impact the population as a whole.

Mr. STEARNS. The gentleman's time has expired.

The gentleman from Ohio, Mr. Brown, is recognized for 5 minutes.

Mr. BROWN. Thank you, Mr. Chairman.

I first would like to recognize Dr. Carmona, whom I shared a podium with at the American Public Health Association meeting in Philadelphia and was very impressed with his words then and all that he shared with us.

Mr. Chairman, I would like to yield my time to Mr. Waxman, who has alerted Americans to the dangers of all forms of tobacco more than anyone in this body. So Mr. Waxman, if I could.

Mr. WAXMAN. Thank you very much, Mr. Brown.

Thirty years ago the FTC was fooled by the tobacco companies into allowing them to advertise low tar and light cigarettes, and as a result millions of Americans switched to those products because they thought it would protect their health.

As a result of that, millions of American died because they were not safer products. In fact, they were not even what they claimed to be.

Now I think what we have before the FTC is another attempt by an industry to commit a fraud on the American people, and that is to try to present smokeless tobacco as a safer alternative. Now, the first question is: is it a safer alternative?

And, Dr. Carmona, you have been so clear on every question that has been raised on that point, the safer alternative. Is that a fair statement?

Mr. CARMONA. Yes, sir.

Mr. WAXMAN. Now, let us say for argument purposes it was safer, slightly, harmful but safer. Well, it is only safer if people will use it instead of smoking, not if they use it in addition to smoking.

Is there any evidence that anybody can show that people will give up cigarette smoking because they have got a safer alternative? I submit there is no evidence at all, none.

Now, another theory. If you advertise this product as a safer alternative to cigarettes, kids might start using this product. In fact, I think this is what this is all about. Kids are not using this smokeless tobacco as much because they have caught onto the fact that it does them a great deal of harm. When it says cancer of the jaw, kids start picturing what cancer of the jaw means, and more and more of them are giving up smokeless tobacco.

But if they are told it is a safe alternative, they might say, "Well, I will try this safer alternative."

But we do have evidence, don't we, Dr. Carmona, that people who use smokeless tobacco are starting to get the nicotine habit and then they can move on to cigarettes? Isn't that an accurate statement?

Mr. CARMONA. Yes, sir, there is scientific evidence to support that.

Mr. WAXMAN. So the question that Mr. Muris said is is there a potential public health benefit. Well, it is hard for me to see that there is a potential public health benefit.

So the FTC allows this advertising. We will have to see 20 years down the road what harm we have done because the FTC operates to allow advertising, unlike the FDA, which would screen any kind of claim in advance.

I really am struck by the fact that it has been a long time since the Congress has held any hearings about tobacco. Today two committees are holding hearings on tobacco. We are not looking at the Institute of Medicine recommendations, which said that they had a strategy. This was an HHS advisory committee, that they thought could lead to a cessation of smoking and lead to 3 million lives being saved. Five million people could quit within 1 year.

Instead, what the two committees of Congress are looking at is what the industries want. Today we are looking at what U.S. Tobacco would like. This afternoon we are going to look at what U.S. Tobacco and Philip Morris would like.

That is what the Congress has come to. We respond to the industry pressure to bring this issue up. Mr. Muris, this is a hearing for you. This is a hearing to impress you that a lot of Members of Congress would like you to be receptive to U.S. Tobacco's attempt to rejuvenate their market.

Well, I would hope that we rely on science, and the science is not there. The science is not there. The politics may be because tobacco is rich and powerful, but the science is not there, and I would hope that you look at the science very, very carefully.

And I am awfully nervous when a bunch of lawyers are making the decision on science when it ought to be up to something like the FDA or the Surgeon General or the Institute of Medicine to make the decision. I know you will consult with them.

I do not know if you are aware, either of you, that Philip Morris once surveyed 85 former users of smokeless tobacco and found that 53 were now smoking, and I would like to introduce for the record Philip Morris' report on how people who were using smokeless tobacco didn't wean themselves off from cigarette smoking, that they are either back to smoking or moved on to smoking, and I would hope we can get that in the record.

Mr. STEARNS. Fine. By unanimous consent, so order.

[The report appears at the end of the hearing.]

Mr. WAXMAN. Mr. Chairman, I appreciate the opportunity you have afforded me to participate in this hearing, and I just hope that people do not get fooled a second time the way the FTC was fooled 30 years ago and then we look back 20 years from now and think about all of the people that got cancer of the jaw and moved on to cigarettes and used cigarettes and smokeless tobacco, and rather than the potential public health benefit, we ended up with a potential public health disaster.

Mr. STEARNS. The gentleman from Ohio's time has expired.

Mr. Shimkus is recognized.

Mr. SHIMKUS. Thank you, Mr. Chairman, and I am going to be brief. We have already been here a long time, and I think we are going in cyclical debates on this issue.

I will just say that we have a debate over words, and basically it is an agreement that there is a risk to smokeless tobacco, but the real question is: is there a lower risk than smoking and whether that is second hand smoke or whether that is all of these other things?

Have we considered—and I would think I would go to Dr. Carmona first—have we as a country considered commissioning our own study that would address many of the questions that were broached today to insure that we have factual, scientific evidence?

And if we have not so far, would we consider doing so? And if not, why?

Mr. CARMONA. Well, sir, there are many studies that have been done in the literature. I mean literally hundreds of studies on a broad range of issues regarding smoking cessation and so on and including smokeless products, and there are ongoing studies now

both at CDC that are ongoing as we speak and programs that are funded throughout the United States at universities and other areas that NIH funds that are addressing many of these questions.

Now, if there are specific questions that are not being answered or that you felt that needed to be addressed, certainly we would be willing to entertain that, and I would pass it on to my colleagues who are doing the research.

But there is a broad range of research that has taken place and continues to take place on these subjects.

Mr. SHIMKUS. So I guess the question for me is based upon the current research that you have available to review, and obviously you do not have the information from the ongoing research, nothing that has been said with respect to the IOM report—that still does not provide enough information to make a determination whether there is any significant benefit for someone going from tobacco used in cigarettes versus smokeless?

Mr. CARMONA. Well, I think the IOM report was fairly clear and said that there was no evidence and there are no products on the market today to advocate for that type of substitution. So the IOM report is fairly clear, I think, in its conclusion.

Mr. SHIMKUS. That is all I have, Mr. Chairman.

Mr. STEARNS. I thank the gentleman.

I want to thank both of you for your patience, and we appreciate your testimony.

Mr. WHITFIELD. Mr. Chairman, may I just ask unanimous consent? I would like to submit one other question to Admiral Carmona relating to the Center for Disease Control.

Mr. STEARNS. Unanimous consent request is granted.

Mr. WHITFIELD. Thank you.

One minute? Oh, submit it for the record, oh, by unanimous consent.

I would say in just conclusion that Mr. Waxman talked about a study that suggests that smokeless tobacco is a gateway to cigarettes, but I think also he should have been fair and pointed out that there is also a study that refutes that gateway theory stating that the gateway study that was made was flawed.

And Mr. Waxman, of course, will be in the second hearing this afternoon on the same subject.

So we welcome now the second panel. The second panel consists of Dr. Robert Wallace, M.D., Institute of Medicine, Vice Chair, Committee to Assess the Science Base for Tobacco Harm Reduction.

Dr. Scott L. Tomar, editor, Journal of Public Health Dentistry, University of Florida College of Dentistry, Division of Public Health Services and Research.

Dr. Brad Rodu, professor, Department of Pathology, University of Alabama at Birmingham.

Mr. Steven Burton, Vice President of Smoking Controls Strategic Development and Switch, Glaxo SmithKline Consumer Health care.

Mr. Richard H. Verheij, Executive Vice President, U.S. Smokeless Tobacco Company.

Mr. Matthew L. Myers, President and CEO, National Center for Tobacco Free Kids.

And Mr. David T. Sweanor, Counsel, Non-smokers Rights Association.

I urge the members to stay for the second panel because if we are talking about the science, then we have people who can actually speak to that science, and so it would be very helpful for members if they can to come back to continue our discussion.

We have an order in my witness list that I will use if you do not mind, and so I am going to ask Dr. Wallace to start off with his opening statement. Five minutes, and if you want to take less and make your opening statement part of the record, obviously that would be appreciated. We have a large panel here.

So we will start off with you, Dr. Wallace, and welcome and thank you.

STATEMENTS OF ROBERT B. WALLACE, VICE CHAIRMAN, COMMITTEE TO ASSESS THE SCIENCE BASE FOR TOBACCO HARM REDUCTION, INSTITUTE OF MEDICINE; SCOTT L. TOMAR, EDITOR, JOURNAL OF PUBLIC HEALTH DENTISTRY, UNIVERSITY OF FLORIDA COLLEGE OF DENTISTRY, DIVISION OF PUBLIC HEALTH SERVICES AND RESEARCH; BRAD RODU, PROFESSOR, DEPARTMENT OF PATHOLOGY, UNIVERSITY OF ALABAMA AT BIRMINGHAM; STEVEN L. BURTON, VICE PRESIDENT, SMOKING CONTROLS STRATEGIC DEVELOPMENT AND SWITCH, GLAXO SmithKLINE CONSUMER HEALTH CARE; RICHARD H. VERHEIJ, EXECUTIVE VICE PRESIDENT, U.S. SMOKELESS TOBACCO COMPANY; MATTHEW L. MYERS, PRESIDENT AND CEO, NATIONAL CENTER FOR TOBACCO FREE KIDS; AND DAVID T. SWEANOR, COUNSEL, NON-SMOKERS RIGHTS ASSOCIATION

Mr. WALLACE. Thank you, Congressman.

I was the Vice Chair of the committee that put the Clearing the Smoke report together, and just for the record, I am a professor of epidemiology and internal medicine at the University of Iowa.

I am going to paraphrase my remarks, and I would like them to be entered into the record, along with the report itself.

Mr. STEARNS. Your opening statement will be part of the record. By unanimous consent, so ordered.

Mr. WALLACE. Thank you.

Let me first say in part because I responded to the earlier testimony this morning that we dealt with a range of harm reduction products and tobacco and not particularly related to smokeless tobacco. In fact, we did consider smokeless, but we also considered other tobacco devices and delivery systems, and we also considered nicotine replacement therapy as well.

We basically had four conclusions in our report, and one is that we think that for many diseases attributable to tobacco use reducing the risk by reducing exposure to tobacco toxicants is, in fact, feasible.

However, while we think that manufacturers of these products should have an incentive to make claims, this incentive could only be done in the context of a comprehensive national tobacco control program that has emphasized abstinence oriented prevention and treatment and only if the harm reduction assessment has been thoroughly scientifically vetted.

We also concluded that these potential reduced exposure products have not yet been evaluated, as others have said, and certainly not comprehensively enough to provide a scientific basis for concluding that they are associated with reduced risk compared to convention tobacco use.

We concluded that regulation of all tobacco products is necessary in order to assure a scientific basis for judging the effects of particular products versus others.

We concluded also that from a public health perspective, and it has been said several times this morning that it is very important to understand the public health impact of introducing new products and making claims about products, and therefore, the health and behavioral effects of all of these products must be monitored on a continuing basis.

We suggested a regulatory framework. It is long and detailed, and I would just highlight just four of the many principles. They included disclosure of product ingredients, toxicity testing, pre-market approval of claims, and issues relating to labeling, advertising, and promotion, and also post marketing surveillance so that, in fact, we can find out what happens to Americans when these products are released both in terms of their behaviors and with respect to these products and in terms of their health.

Finally then I just have three public health messages that I have culled from the report. One is that the committee strongly felt that the best strategy, of course, is to never use tobacco at all, and if you are using it, to quit and I think that needs emphasis.

Second, with appropriate and comprehensive research, surveillance, education, and regulation, we do feel that these products could possibly, emphasize "possibly," reduce the some of the risk of tobacco related disease, but the net health impact, again, is unknown, and although the products may be risk reducing for an individual, they may, in fact, increase the risk to populations.

And then finally, our third public health message is that we pled for a comprehensive and verifiable surveillance system being the crucial link to understand the relationship between the availability of these products and reduced risk both to individuals and reduced harm to the public health in general.

So I very much appreciate your willingness to hear me out, and I would be happy to answer questions.

[The prepared statement of Robert Wallace follows:]

PREPARED STATEMENT OF ROBERT B. WALLACE, VICE-CHAIRMAN, COMMITTEE TO ASSESS THE SCIENCE BASE FOR TOBACCO HARM REDUCTION, INSTITUTE OF MEDICINE/ NATIONAL ACADEMY OF SCIENCES

Good morning, Mr. Chairman and members of the Committee. My name is Robert Wallace. I am Professor of Epidemiology and Internal Medicine at the College of Public Health, University of Iowa. I served as Vice-Chairman of the Committee to Assess the Science Base for Tobacco Harm Reduction of the Institute of Medicine. The Institute of Medicine operates under the 1863 charter by Congress to the National Academy of Sciences to advise the government on matters of science, technology, and health.

The work of the committee was conducted under a contract initiated by the Food and Drug Administration. The committee began its work in December 1999 and released its report, *Clearing the Smoke: Assessing the Science Base for Tobacco Harm Reduction,* in February 2001. For the purposes of this report and in keeping with general definitions, tobacco harm reduction refers to decreasing the burden of death and disease, without completely eliminating nicotine and tobacco use. The com-

mittee was asked to provide a framework for the assessment of tobacco and pharmaceutical products that might be used for tobacco harm reduction. However, the committee did not review specific products.

I'd like to emphasize several of the committee's principal objectives, conclusions and recommendations.

1. For many diseases attributable to tobacco use, reducing the risk of disease by reducing exposure to tobacco toxicants is feasible. Therefore, manufacturers should have the necessary incentive to develop and market products that reduce exposure to tobacco toxicants and that have a reasonable prospect of reducing the risk of tobacco-related disease.

This incentive is the ability of manufacturers to make exposure-reduction or risk-reduction claims. However, I must note that the report is supportive of such claims only if made in the context of a comprehensive national tobacco control program that emphasizes abstinence-oriented prevention and treatment, and if under the harm reduction assessment and regulatory framework outlined by the committee, such as illustrated in my next three points.

2. These potential reduced-exposure products have not yet been evaluated comprehensively enough to provide a scientific basis for concluding that they are associated with a reduced risk of disease compared to conventional tobacco use. Consumers therefore should be fully and accurately informed of all the known, likely, and potential consequences of using these products. The promotion, advertising, and labeling of these products should be firmly regulated to prevent false or misleading claims, explicit or implicit.

3. Regulation of all tobacco products is a necessary precondition for assuring a scientific basis for judging the effects of using the potential reduced-exposure products and for assuring that the health of the public is protected.

4. Finally, and most importantly, the public health impact of these products is all but unknown. They are potentially beneficial, but the net impact on population health, or public health, could, in fact, be negative. Therefore, the health and behavioral effects of using these products must be monitored on a continuing basis. Basic, clinical, and epidemiological research must be conducted to establish their potential for harm reduction for individuals and populations.

The committee outlined several general principles for regulating these products. These principles address, for example:

- disclosure of product ingredients,
- toxicity testing,
- premarket approval of claims, and issues related to labeling, advertising, and promotion, and
- postmarketing surveillance.

I'd like to conclude my testimony by summarizing three key public health messages about the potential for improving health in the face of the availability of the potential reduced exposure products:

1. The committee unanimously and strongly held that the best strategy to protect human health from the dangers of tobacco is to quit—or not to start tobacco use in the first place.

2. With appropriate and comprehensive research, surveillance, education, and regulation, these products could possibly reduce the risk of tobacco-related disease. However, the net health impact is all but unknown. Claims of reduced risk to the individual may well not translate into reduced harm to the population. Although a product might be risk-reducing for the individual using it compared to conventional tobacco products, the availability of these products might increase harm to the population. This could occur if:

- tobacco users who might otherwise have quit do not,
- former tobacco users resume use, or
- some people who would have not otherwise initiated tobacco use do so because of perceptions that the risk with these "new" products is minimal and therefore acceptable.

3. A comprehensive and verifiable surveillance system is the crucial link between the availability of reduced exposure products and reduced risk to the individual and reduced harm to public health. It is imperative that we understand what the American people are doing with regard to these products and what is happening to their health.

I thank you for the opportunity to address you on this important topic. A copy of my testimony and a copy of the report, *Clearing the Smoke,* have been submitted for the record. I am happy to answer any questions about the report.

Mr. STEARNS. I thank Dr. Wallace.

Dr. Tomar.

STATEMENT OF SCOTT L. TOMAR

Mr. TOMAR. Good morning. My name is Scott Tomar, and for the record, I am an associate professor with the University of Florida College of Dentistry.

I thank you for the opportunity to testify on the issue of marketing smokeless tobacco as a potential harm reduction strategy for cigarette smoking. I think this is an important public health area, but it represents a tobacco industry marketing strategy that is both highly flawed and potentially dangerous, and I will outline these.

First, smokeless tobacco causes cancer and is addictive. It is a mistake to promote it as safer, as a safer alternative to smoking while safe sources of nicotine are available, such as gum and path.

In the mid-1980's, the U.S. Surgeon General and the International Agency for Research on Cancer concluded that snuff use causes oral cancer, gum disease, and nicotine addiction. Based on available evidence, UST's products are still carcinogenic.

More recent research suggests that snuff use may increase the risk of cardiovascular disease, including heart attack. Smokers should be encouraged to use proven, safe sources of nicotine to quite smoking and not snuff.

Second, U.S. Smokeless Tobacco Company has a long history of marketing oral snuff to young males with no history of tobacco use, including promotion of low nicotine starter products. Allowing them to make safety claims may increase nicotine addiction among youth.

Heavy promotion of oral snuff led to huge increases in use by young males from the early 1970's until the mid-1990's. Between 1970 and 1991, the prevalence of snuff use among men 18 to 24 years old increased more than 8-fold. This increase was no accident, but was the result of a sophisticated marketing campaign that developed, advertised, and promoted use of oral snuff starter products with low levels of free nicotine as part of a graduation strategy that encouraged new users to move up to brands higher in nicotine as tolerance developed.

The high nicotine brands are highly addictive and high in cancer causing nitrosamines.

Public health groups work aggressively to educate young people on the dangers of oral snuff. In 2001, 14.8 percent of male high school students reported current use of smokeless tobacco, which is down from 20.4 percent in 1993.

That decline was accompanied by an increase in the proportion of high school students who perceive that regular use of smokeless tobacco carries great risk of harm. Allowing UST to make claims that these products are relatively safe could reverse this trend and result in an increase in use by youth.

Third, UST has failed to protect consumers by failing to inform, by not lowering known cancer causing agents in its product or informing consumers about their toxic and addictive properties.

Oral snuff contains dangerously high levels of cancer causing agents called tobacco specific nitrosamines, to TSNAs. USDA does not acknowledge or inform their consumers that conventional oral snuff causes cancer or is addictive.

In addition, UST refuses to report brand specific product content, nicotine dosing, or the levels of TSNAs. A recent study conducted by the American Health Foundation found that snuff brands manufactured by UST had TSNA levels that were 15 to 23 times higher than those found in a popular Swedish brand, and that TSNA levels in UST's products, such as Copenhagen, increased as much as 137 percent after the products were stored at room temperature for 6 months.

In contrast, no significant changes were observed in the TSNA levels of brands made by Swedish Match. That study demonstrates that it is technologically feasible to produce oral snuff products that are significantly lower in TSNAs than those that are currently ont he market. UST has the manufacturing technology to reduce the level of nitrosamines in all of its brands, yet has not done so.

UST has refused to voluntarily reveal the amount of free nicotine in its products. When I was an epidemiologist with the Office on Smoking and Health, we asked the company to provide this information to the American people. They flatly refused and denied that they were able to manipulate the nicotine dosing properties of its snuff products.

UST's contentions are strongly contradicted by peer reviewed science and by sworn depositions of its own chemists.

When Massachusetts passed a law requiring brand specific disclosure of additives that affect toxicity and addiction, UST and the other tobacco companies sued the state.

Fourth, promotion of oral snuff as a safer alternative to smoking may have unintended public health consequences. I recently published two studies on this topic. The first looked at smoking initiation among U.S. males age 12 to 17 and found that young males who were not smokers at baseline but used smoker's tobacco were three times more likely than young males who never used smokeless tobacco to be smokers 4 years later.

In contrast, only 2.4 percent of current smokers and 1.5 percent of "never smokers" became smokeless tobacco users by the 4-year follow-up.

The second study looked at adult male tobacco users and found that U.S. men were 2.5 times more likely to be former snuff users who now smoked than to be former smokers who currently use snuff. One in 5 males who were daily snuff users also smoked, as were 40 percent of occasional snuff users.

These studies suggest that smokeless tobacco may be a gateway for adolescent smoking. Males in the United States are far more likely to switch from snuff to cigarette smoking than vice versa, and many men who use snuff are still smoking.

In UST's current advertising for Revel, the brand is marketed as a complement to smoking, not as a complete substitute or as way to quit smoking. The product is marketed for use in settings when smoking is barred and, therefore, undermines the impact of clean indoor air laws on smokers' decision to quit.

UST uses similar marketing messages for its Skoal products. These products can actually delay or prevent smoking cessation.

Fifth, there is no evidence that the oral snuff use is effective in helping smokers to quit either in the United States or in Sweden.

Not a single randomized controlled trial has been reported that shows——

Mr. STEARNS. Dr. Tomar, your time has expired. You are over by a minute. You are welcome if you can to finish up.

Mr. TOMAR. I will save the rest for questions.

Just concluding that smokeless tobacco causes cancer; that its promotion might actually increase cigarette use, and many states in the United States have actually been able to reduce both smoking and smokeless tobacco use without promoting one substitute for the other.

[The prepared statement of Scott L. Tomar follows:]

PREPARED STATEMENT OF SCOTT L. TOMAR, EDITOR, JOURNAL OF PUBLIC HEALTH DENTISTRY

1. Smokeless tobacco causes cancer and is addictive. To promote it as a "safer" alternative to smoking while safe sources of nicotine (patch and gum) are available is a mistake.

Oral snuff is a finely cut, processed tobacco that the user typically places between the lip and gum. Nicotine is released from the tobacco and absorbed by the membranes of the mouth. In 1986, the US Surgeon General concluded that use of this product causes oral cancer, gum disease, and nicotine addiction. More recent research suggests that snuff use increased the risk of cardiovascular disease, including heart attack. Swedish research shows that male snuff users have twice the rate of cardiovascular death as non-users. Smokers should be encouraged to use proven, safe sources of nicotine to quit smoking not be encouraged to use snuff. There is no evidence that smokers who switch to oral snuff use have a lower risk of disease or death; they are still exposed to high levels of carcinogens.

2. USSTC has a long history of marketing oral snuff to young males with no history of tobacco use including promotion of low nicotine "starter" products. Allowing them to make "safety" claims may increase nicotine addiction among youth.

Use of oral snuff has risen dramatically among young men. From 1970 to 1991, the prevalence of snuff use among men aged 18 and older rose from 1.5% to 3.3%; among men 18-24 years old, it increased more than eightfold from 0.7% to 6.2%, making this age group the heaviest users of the product among those surveyed.

In the 1980s, USSTC operated a college marketing program on over 200 campuses. The company continues to routinely sponsor fraternity and college events today. In 1998, U.S. Smokeless Tobacco Company (USSTC) signed the Smokeless Tobacco Master Settlement Agreement (STMSA) settling lawsuits against USSTC and agreed not to directly or indirectly target youth in their advertising and promotion. USSTC continued to heavily advertise in youth magazines after signing the STMSA and USSTC annual advertising expenditure rose from $5.4 million pre-STMSA to $6.1 post. It was only after the Attorney General threatened legal action did the company drop ads in youth magazines. When Massachusetts banned smokeless tobacco advertising in 1999 near schools and playgrounds, USSTC and other tobacco companies successfully sued the state.

A 1989 National Collegiate Athletic Association (NCAA) survey of college athletes found a 40% increase (from 20% to 28%) in smokeless tobacco use from 1985 to 1989. Among NCAA baseball players, an alarming 57% were users. There is new evidence that suggests that these increases are no accident, but the result of a sophisticated marketing campaign that developed, advertised, and promoted use of oral snuff starter products with lower levels of free (un-ionized) nicotine as part of a graduation strategy that intended new users to move up to brands higher in nicotine as tolerance developed. The high nicotine brands are highly addictive and high in cancer-causing nitrosamines.

Public health groups aggressively worked to educate young people on the dangers of oral snuff. In 2001, 14.8% of male high school students reported current use of smokeless tobacco, down from 20.4% in 1993. According to the University of Michigan, that decline was due to an increase in their knowledge about the dangers of smokeless tobacco. Allowing USSTC to make claims that these products are "safer" than cigarettes could reverse this and result in an increase by youth.

3. USSTC has failed to protect consumers by failing to inform by not lowering known cancer-causing agents in its products or informing consumers about their toxic and addictive properties.

Oral snuff contains dangerously high levels of cancer casing agents called tobacco specific nitrosamines (TSNAs). Unlike the major cigarette companies, who now admit that their products cause cancer and are addictive, USSTC doesn't acknowledge or inform their consumers that conventional oral snuff causes cancer or is addictive. In addition, USSTC refuses to report product content, nicotine dosing, or the levels of TSNAs by brand. In 2000, the Massachusetts Department of Public Health contracted with the American Health Foundation to determine how new and existing technologies affect the levels of tobacco specific nitrosamines in six brands of oral snuff. The Department obtained brands of snuff sold in the state as well as one brand, Ettan, sold in Sweden. The America Health Foundation research found that the Swedish Match brand and its U.S. subsidiary brand had total TSNA levels between 2.8 ug/g (Ettan) and 7.5 ug/g (TimberWolf). These levels were far lower than that found for the standard brands available in the state. UST, Swisher and Conwood brands ranged from16.6 ug/g to 127.9 ug/g. The same study examined the effect of product aging over two, four and six months. Product aging involves placing the tobacco product on a shelf at room temperature and retesting the TSNA levels at the specified time periods. The study found that certain U.S. brands had large increases in TSNA levels. Copenhagen increased 137% over the six-month time period and Skoal increased 20%. Silver Creek increased 9% over a four month time period. No significant changes were observed in the levels of Swedish Match or its subsidiary brands.

The study shows that the levels in the brands manufactured under new technologies were significantly lower than levels of TSNAs in those brands that were produced under the standard manufacturing processes. Also, brands that employed the new processes show no increase in TSNAs when aged. The study demonstrates that it is technologically feasible to produce oral snuff products for adults that are significantly lower in TSNAs than many of those currently on the market.

USSTC has the manufacturing technology to reduce the level of nitrosamines to the same level as those found in Swedish products in all of their brands, yet they have not done so. According to the 2000 Surgeon General's Report, "if a new technology exists that can significantly reduce levels of known carcinogens in a tobacco product, then that technology should be used." Before manufacturers make claims that oral snuff is a "safer" alternative to cigarette smoking, TSNA levels should be lowered to the maximum extent possible for all products. Biomarkers should also be developed to determine if a reduction in TSNAs actually reduces cancer risk and the research and any claim of reduced harm approved by an independent health regulatory agency.

USSTC has refused to disclose the levels of TSNAs in their brands, warn consumers about possible TSNA formation and aging or voluntarily reveal the amount of free nicotine (additive potential) in their product to consumers. I met with USSTC attorneys and representatives several years ago, when I was an epidemiologist with the Office on Smoking and Health, and asked the company to provide to this information to the American people; they not only refused to provide it, they denied that they are able to manipulate the nicotine dosing properties of their snuff products. It has been firmly documented in the scientific literature that USSTC can, and does, control the nicotine dosing properties of its products, and has used that ability to promote addiction among young people. When Massachusetts passed a law requiring the disclosure by brand of additives that effect toxicity and addiction, USSTC and the other tobacco companies successfully sued Massachusetts.

4. Promotion of oral snuff as a "safer" alternative to smoking may have unintended public health consequences.

I recently published two studies on this topic. The first looked at a smoking initiation among U.S. males aged 12-17 and found that young males who were not smokers at baseline but smokeless tobacco users were three times as likely to be smokers four years later (23.9% vs. 7.6%) as young males who never used smokeless tobacco. In contrast only a 2.4% of current smokers and 1.5% of never smokers became smokeless tobacco users by follow-up.

The second study looked at adult male tobacco users and found that U.S. men were 2.5 times more likely to be former snuff users who now smoked than to be former smokers who currently used snuff. One in five males who were daily snuff users also smoked. This combined use of tobacco products may undermine the impact that smoke-free policies have on quitting smoking. This research suggests that smokeless tobacco may be a gateway for adolescent smoking and males in the

United States are far more likely to switch from snuff to cigarette smoking than vice versa.

In USSTC's current advertising for its low TSNA snuff brand, Revel, the brand is marketed as a complement to smoking, not as a complete substitute or as a way to quit smoking. There is no information included in the ads or packaging on the dangers of smoking including lung cancer, no advice on how to quit smoking or information about smoking cessation programs. Rather the product is marketed for use in settings when smoking is barred and in doing so result in undermining the impact of clean indoor air laws on smokers' decision to quit. USSTC use similar marketing messages for its SKOAL snuff products. These products can actually delay or prevent smoking cessation.

5. There is no evidence that oral snuff use is effective in helping smokers to quit, either in the United States or Sweden.

Not a single randomized controlled trial has been reported that shows that oral snuff is effective in helping smokers to quit. Such evidence is required before the manufacturers of any other drug can make health claims about their products. In contrast, USSTC has presented no credible evidence that their products are effective smoking cessation devices, yet their proposed marketing strategy clearly implies that smokers can switch to their snuff products. USSTC's proposed marketing strategy amounts to a widespread, unregulated experiment on human populations. Such an experiment may have very serious negative side-effects, including promotion of tobacco initiation by young people and reduced rates of smoking cessation among adult smokers.

Even in Sweden, where claims have been made that oral snuff use is responsible for its declining smoking rates, there is no evidence that snuff played a major role. In fact, careful examination of the data from Sweden reveals the following: (1) per capita consumption of cigarettes remained constant in Sweden during the 1970s while snuff use was rapidly increasing, suggesting that the growth in snuff use was not the result of substitution of cigarettes for snuff; (2) nearly all of the growth in oral snuff use in Sweden since the 1970s has been among males who started using these products when they were 16-24 years old, the group that also had the lowest smoking cessation rates in Sweden, and not among adult smokers trying to quit; (3) the prevalence of daily smoking has been declining among men and women in Sweden since 1980, although less than 2% of Swedish women use snuff and the prevalence of daily snuff use among men has remained relatively constant; (4) several large studies that followed cohorts of Swedish adults over time found that smokers who also used snuff were no more likely than smokers who did not use snuff to quit smoking; (5) a very small proportion of Swedish smokers who quit did so by switching to snuff; and (6) tobacco control measures implemented in Sweden, including bans on all tobacco advertising in periodicals and electronic media, prohibition of free products and industry sampling practices, dissemination of health information about smoking, increased taxation on cigarettes, and widespread clean indoor air policies are probably responsible for most of the decline in smoking in Sweden.

6. Major health bodies have carefully looked at this issue and recommended that smokeless tobacco not be promoted as reduced harm products until more research is done and the research and claims are approved by a health, regulatory agency.

The Institute of Medicine (IOM) and the World Health Organization have both reviewed this issue and have concluded that smokeless tobacco should not be promoted as a "safer" alternative to smoking. IOM concluded that more research is needed and according to IOM, research and claims on "reduced" harm products, including smokeless tobacco, should be reviewed and approved by an independent health regulatory agency before they are marketed.

Sweden has lowered smoking rates but this is due to the Swedish comprehensive tobacco control program and not the availability of snuff. Massachusetts and California have reduced male smoking far below that of Sweden (14% MA, CA daily smoking vs. 18% Sweden). This has been done without promoting snuff as a safe substitute to smoking. In fact, we have been able to reduce the use of cigarettes and snuff among young people and adults in the United States in the past decade. Safe forms of nicotine are available including nicotine gum and patches that have been approved as effective smoking cessation medications by the Food and Drug Administration. These should be promoted as ways to quit smoking, not smokeless tobacco.

7. Research on the advertising for other "reduced risk" tobacco products shows that advertising may be deceptive and misleading.

The Massachusetts Tobacco Control Program (MTCP) has conducted two studies on advertising claims for other "safer" tobacco products. The first was R.J.R's

Eclipse cigarette, which made a claim that there was no cigarette like Eclipse based on a comparison of smoke carcinogens between Eclipse and a "typical" ultralight cigarette, Merit Ultra Light. RJR claimed that the level of carcinogens was 80% lower than Merit. MTCP commissioned research comparing Eclipse to two other ultra light cigarettes, Now and Carlton, and found that Eclipse actually had higher levels of certain carcinogens. Eclipse had 734% more acetaldehyde than Now and 475% more acreolein. Also, as RJR redesigned this product from its 1988 predecessor, Premier, to present, levels of NNK increased by 1200% from 2.4 ng/g to 32 ng/g and NNN increased 160%. Based on this research, MTCP has concluded that the claim by RJR that "There is No Cigarette Like Eclipse" is deceptive since MTCP found two existing brands, Now and Carlton, that had similar levels of smoke carcinogens.

A second study MTCP commissioned was a Mall Intercept Survey of 600 smokers who reviewed ads for Omni and ADVANCE cigarette brands compared to ads for regular and light cigarettes. The Institute of Medicine has called these products PREPS, potential reduced exposure products. Study results are based on a convenience sample of 600 smokers 18-65 years old. Respondents were asked to examine selected advertisements for Regular cigarettes, Light cigarettes, and the new tobacco products (ADVANCE, Eclipse, and Omni) and answer questions regarding their perceptions of the products advertised and the messages conveyed by the specific advertisements.

In side-by-side comparisons, smokers indicated that they thought PREP products posed fewer tobacco-related health risks, lower levels of carcinogens, and lower tar levels. Specifically:

- Smokers perceived PREP tobacco products as having lower health risks than Light or Regular cigarettes.
- Smokers perceived PREP tobacco products as having a lower level of things that might cause cancer than Light or Regular cigarettes.
- Smokers perceived PREP tobacco products as having a lower level of tar than Regular cigarettes, and a similar level to Lights.
- Perceptions of PREP tobacco product's health risks relative to Light cigarettes were generally consistent across subgroups of the study population.
- Men, people with lower educational attainment, and white non-Hispanic individuals were more likely than others to perceive that PREP tobacco products pose lower health risks than do Regular cigarettes.

Prior to participating in this study, only a few smokers had seen advertisements for or had smoked PREP tobacco products. For the vast majority, the primary source of information for assessing PREP tobacco products' properties, including their health and safety, were the advertisements viewed during the study. Their opinions regarding the advertisements included the following:

- Most smokers interpreted the PREP tobacco product advertisements as conveying positive messages about health and safety.
- Many smokers interpreted the PREP advertisements as saying that these products would be helpful in quitting smoking.
- Most smokers believed that claims made in cigarette advertisements must be approved by a government agency.

In conclusion, smokeless tobacco causes oral cancer, and if promoted as a "safer" alternative to smoking may actually increase cigarette use. Florida, Massachusetts, and California have reduced smoking rates without promoting smokeless tobacco and safe forms of nicotine such as gum and patch already exist. These should be promoted as ways to quit smoking as part of comprehensive tobacco control campaigns.

Mr. STEARNS. Okay, and I thank you very much, especially coming from the University of Florida, which I represent. So I certainly welcome you and appreciate your participating.

Dr. Rodu.

STATEMENT OF BRAD RODU

Mr. RODU. Mr. Chairman and members of the committee, I am honored to appear here today.

Despite limited success, the 40 year old American anti-smoking campaign is an astounding failure in one crucial respect. It has helped too few adult smokers to quit.

National statistics reveal the magnitude of this failure: 404,000 deaths a year. The campaign fails inveterate smokers in two ways. First, they are counseled merely to change their behavior. For example, a government smoking cessation manual tells doctors to recommend ineffective coping tips, such as "keep your hands busy, doodle, knit, type a letter."

"Keep a daydream ready to go."

Second, smokers are told that they must achieve nicotine abstinence in order to quit. They are advised to use nicotine medications temporarily. These medicines are expensive and unsatisfying.

As a result, they rarely work. A recent review reported a 7 percent success rate for over-the-counter nicotine medications. The authors called this result "modest" and even "efficacious."

We call programs with 7 percent success rates abject failures.

Over the past decade we have developed an alternative quit smoking strategy for inveterate smokers based on permanent nicotine maintenance. Nicotine is addictive, but can be consumed as safely as caffeine. It is tobacco smoke that kills. Eliminate the smoke, and you eliminate virtually all the risk.

We recommend that smokers permanently switch to other products containing nicotine, including smokeless tobacco. Ours is a harm reduction strategy because we are focused on reducing disease and deaths instead of tobacco and nicotine abstinence.

We recommend smokeless tobacco because it has three attributes for long-term maintenance. First, smokeless delivers nicotine nearly as rapidly and as efficiently as smoking. Yes, it is just as addictive as smoking, which is why it is an effective substitute.

Second, smokeless is 98 percent safer than smoking. Our research documents that the average smoker loses 8 years of life. The average smokeless user loses only 15 days. The only consequential risk from long-term smokeless tobacco use is mouth cancer. Even this risk is very low, proven by more than 20 epidemiologic studies over the past 50 years. In fact, the risk of death from long-term smokeless use is about the same as that from automobile use.

Third, smokeless actually works for smokers. In 1998, we published the first clinical trial testing smokeless as a cigarette substitute. Most of our subjects had failed repeatedly to quit using gum and patches. Twenty-five percent of them quit with smokeless.

We have 7 years of follow-up now, and the substitution is sustainable.

Population studies from Sweden prove that smokeless is an effective substitute. For 50 years Swedish men have had the lowest smoking rate and the highest smokeless usage rates in Europe. The result, rates of lung cancer, the sentinel disease of smoking, among Swedish men are the lowest of 20 European countries.

Not so for Swedish women whose lung cancer rate ranks fifth highest in Europe. I understand tobacco use patterns in Sweden. I lived there for 6 months last year, conducting research on this subject. I published two studies with Swedish colleagues that clearly demonstrate that smokeless was primarily responsible for a decline in smoking among men from 19 percent in 1986 to 11 percent in 1999.

Throughout this entire period, men smoked less frequently than women, a pattern different from that of every other society in the world where men invariably have higher smoking rates.

Our strategy has evoked criticisms that are inaccurate, irrelevant, or both. The usual complaints involve protecting children. We emphasize that our strategy is tailored to adult smokers. This is not a children's issue. Eliminating children's access to tobacco is important, but the 10 million Americans who will die from smoking over the next two decades are now adults. Withholding life saving information from these adults in the name of protecting children is shortsighted, even immoral.

For 10 years we have been portrayed as lone advocates of our harm reduction strategy, but now good company has joined us. Last year Britain's Royal College of Physicians reported that products like smokeless are safer than cigarettes. Their report stated, "As a way of using nicotine, the consumption of noncombustible tobacco is on the order of 10 to 1,000 times less hazardous than smoking, depending on the product." The report suggested that some smokeless manufacturers may want to market their products "as a harm reduction options for nicotine users, and they may find support for that in the public health community."

A growing number of public health experts now agree with our harm reduction strategy because the antiquated quit or die approach is increasingly recognized as insufficient. For 48 million American adults cigarette smoke is the problem. To answer the question posed by this hearing, smokeless tobacco can be part of the solution.

[The prepared statement of Brad Rodu follows:]

PREPARED STATEMENT OF BRAD RODU, PROFESSOR, DEPARTMENT OF PATHOLOGY, SCHOOL OF MEDICINE, UNIVERSITY OF ALABAMA AT BIRMINGHAM AND PHILIP COLE, PROFESSOR EMERITUS, DEPARTMENT OF EPIDEMIOLOGY, SCHOOL OF PUBLIC HEALTH, UNIVERSITY OF ALABAMA AT BIRMINGHAM

The Centers for Disease Control and Prevention report that 440,000 Americans die from smoking-related illnesses every year. However, even this enormous number does not adequately describe the extraordinary burden that cigarette smoking imposes on American society. Our research provides additional perspective: If smoking-related lung cancer did not occur, cancer mortality rates in the United States would have declined continuously since 1950 (Figure 1).[1] Thus, for the past 50 years the American cancer "epidemic" has primarily consisted of one disease, cancer of the lung, and has been due to one dominant lifestyle factor, cigarette smoking. It is compelling evidence that the anti-smoking campaign in the United States, now nearly 40 years old and of ever-increasing intensity, has failed to help adult smokers to quit.

Conventional approaches to cessation have failed because they offer smokers only behavioral therapy. An excellent example is a 1993 NCI smoking cessation manual, *How to Help Your Patients Stop Smoking,* which advises physicians to recommend coping tips such as "Keep your hands busy—doodle, knit, type a letter;" "Cut a drinking straw into cigarette-sized pieces and inhale air;" "Keep a daydream ready to go."[2] Such advice has little effect on adult smokers because they need nicotine. Conventional programs also fail because they offer adult smokers only temporary nicotine replacement. But these products are expensive and provide low doses of nicotine at doses too low to prevent craving and withdrawal. A recent review of over-the-counter nicotine medications revealed that their success rate is 7%.[3] The authors characterized this result as "efficacious" and "modest." We characterize programs with 7% "success" rates as abject failures.

All these programs are failures because they require smokers to quit nicotine completely. This is incorrect, as well as ineffective. Over the past decade we published epidemiologic and clinical studies that provide the scientific foundation for a new smoking cessation strategy. It involves permanent nicotine maintenance using prod-

ucts other than cigarettes.[4,5,6,7,8]) Our strategy is based on the fact that nicotine, while addictive, is about as safe as caffeine, another widely consumed addictive drug. It is tobacco smoke, with its thousands of toxic agents, that leads to cancer, heart disease and emphysema. Eliminate the smoke, and you eliminate virtually all of the risk.

We recommend many types of nicotine delivery systems, including smokeless tobacco (SLT) products. These products are well suited to replace cigarettes because they have four key characteristics: 1) They provide nicotine levels similar to those from smoking; 2) They are vastly safer than smoking; 3) They are socially acceptable and are cost-comparable to cigarettes; and 4) there is evidence that they help smokers quit. No other products have this combination of features to help smokers quit now.

Nicotine Delivery: SLT rapidly delivers a dose of nicotine comparable to that from smoking (Figure 2). Thus, smokeless tobacco satisfies smokers, a necessary criterium for any agent intended as a permanent substitute. In comparison, nicotine medications provide only about one-third to one-half the peak nicotine levels of tobacco products, which is unsatisfying for many smokers.

Safety: SLT use has been the subject of intensive research for over 50 years. The only consequential adverse health effect from long-term SLT use is oral cancer. However, more than twenty epidemiologic studies over the past 50 years have established that this risk is very low.[9] Our research documents that SLT use imposes only about 2% of the mortality risk of smoking.[4,7] We found that the average reduction in life expectancy from SLT use is only 15 days.[5] In contrast, the average smoker loses almost 8 years. For further context, the risk of death from long-term use of smokeless tobacco (12 deaths in every 100,000 users per year) is about the same as that from automobile use (15 deaths in every 100,000 users per year).[10]

Social Acceptability: Opponents of our strategy often argue that smokers will never use disgusting "spit" tobacco. That term is insensitive and inappropriate when used by health professionals. First, it is demeaning and degrading both to current SLT users and to smokers who may wish to try this strategy. Second, and more importantly, the term is incorrect, because new SLT products can be used invisibly and are more discreet than chewing gum.

Evidence that SLT products work: In 1998 we published the first trial assessing SLT substitution as a quit-smoking method.[11] After one year 25% of inveterate smokers, most of whom had failed repeatedly to quit even with prescription nicotine gum or patches, had successfully substituted SLT for cigarettes. We have followed this group for seven years, and our results suggest that SLT substitution is sustainable (manuscript submitted).

Data from Sweden support the role of SLT in harm reduction at the population level. For 50 years men in Sweden consistently have had the lowest smoking rate and the highest SLT usage rate in Europe. The result: Rates of lung cancer—the sentinel disease of smoking—among Swedish men have been the lowest in Europe for 50 years. World Health organization statistics reveal that Swedish men have the lowest rates of lung cancer among 20 European countries (Figure 3). Not so for Swedish women, whose lung cancer rate ranks fifth highest in Europe (Figure 4). One of us (BR) is very familiar with tobacco use patterns in Sweden. He lived there for six months last year conducting research on this subject, resulting in two published studies with Swedish colleagues that demonstrate that SLT was primarily responsible for a decline in smoking among men from 19% in 1986 to 11% in 1999 [12,13] (Figure 5). This figure reveals the lower rate of smoking among men than among women for the entire period of study. We emphasize that this is the reverse of the pattern seen in virtually every other society in the world, where men invariably have higher smoking rates than those of women.

Our strategy has evoked criticisms that are inaccurate, irrelevant or both. The usual complaint is that providing risk information about SLT to adults will prompt children to use these products. We painstakingly point out that our strategy is tailored to adult smokers. This is not a children's issue. Eliminating children's access to tobacco is important, but the 10 million Americans who will die from smoking over the next two decades are now adults. Withholding life-saving information from these adults, in the name of children, is shortsighted, even immoral.

An extension of the children's theme is that SLT could serve as a gateway to smoking. This notion never had a sound basis, and current research shows it to be wrong. Furthermore, and most unfortunately, for twenty years the dominant public health message has been that SLT use and smoking are equally risky. In fact, this erroneous message is reinforced by the mandated warning on packages of SLT ("This product is not a safe alternative to cigarettes"). Regrettably, surveys show that 80% of smokers believe that smokeless tobacco is as dangerous as smoking, and

continue to smoke. This message may also cause some SLT users to switch to cigarettes, an unfortunate and lethal behavior.

Finally, for ten years we have been portrayed as lone advocates of a flawed public health strategy. But now good company has joined us. Last year Britain's Royal College of Physicians, one of the world's most prestigious medical societies, issued a report on tobacco regulation in the United Kingdom called "Protecting Smokers, Saving Lives".[14] This report marked the first time a major health organization acknowledged that products like smokeless tobacco are safer than cigarettes. The report stated "As a way of using nicotine, the consumption of non-combustible [smokeless] tobacco is on the order of 10-1,000 times less hazardous than smoking, depending on the product." The report continued with an even bolder statement, acknowledging that some smokeless tobacco manufacturers may want to market their products "as a 'harm reduction' option for nicotine users, and they may find support for that in the public health community."

A growing number of public health experts now agree with our harm reduction strategy, because the antiquated quit-or-die strategy is increasingly recognized as a failure. Cigarette smoke is the problem for 48 million adult smokers. To answer the question posed by this hearing, smokeless tobacco can be part of the solution.

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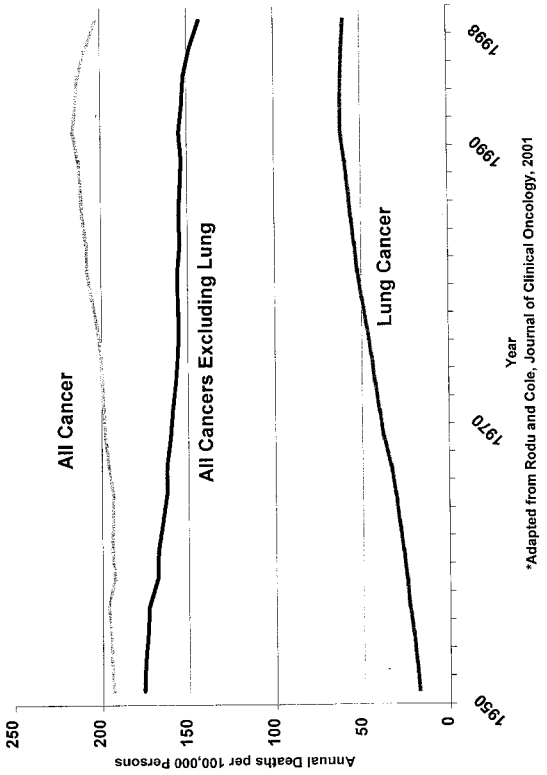
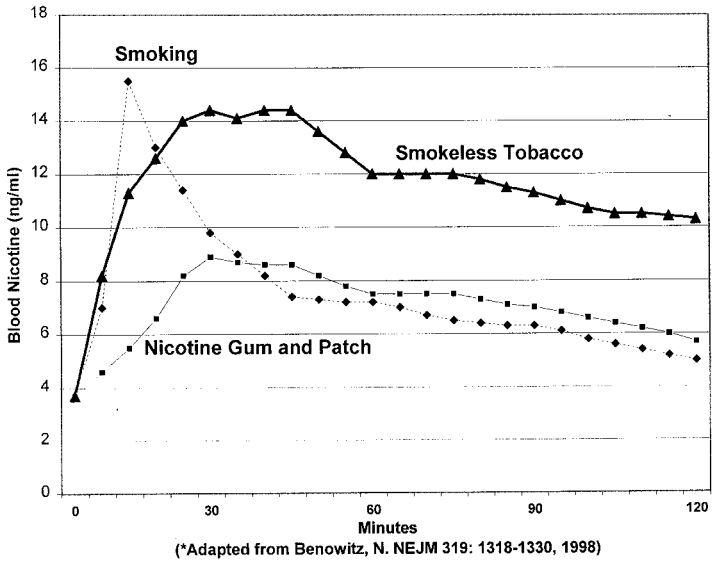
Figure 1. Mortality from Cancer, United States 1950-1998*



*Adapted from Rodu and Cole, Journal of Clinical Oncology, 2001

Figure 2. Nicotine Concentrations Following Use of Tobacco Products and Nicotine Medications*



(*Adapted from Benowitz, N. NEJM 319: 1318-1330, 1998)

Figure 3. Lung Cancer Mortality Among Men Age 40+ in European Countries, 1996

WHO-IARC Worldwide Cancer Mortality Database

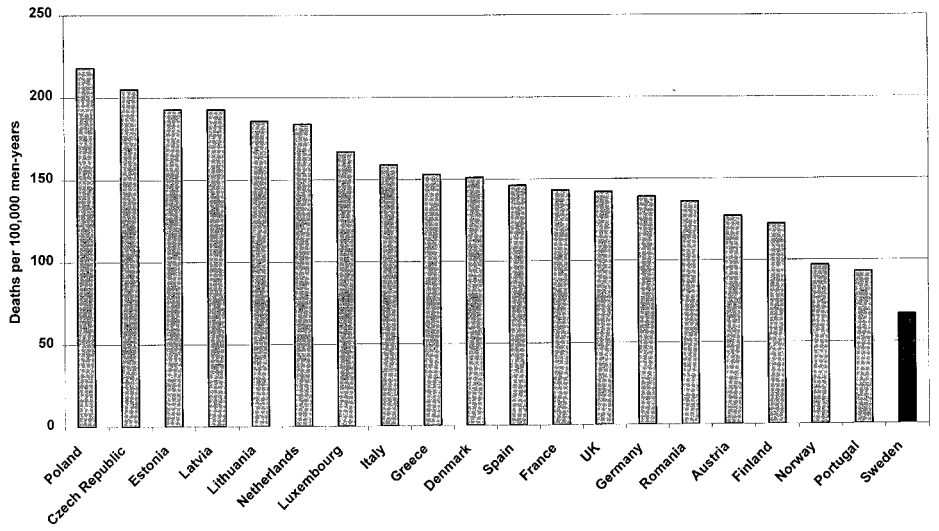


Figure 4. Lung Cancer Mortality Among Women Age 40+ in European Countries, 1996

WHO-IARC Worldwide Cancer Mortality Database

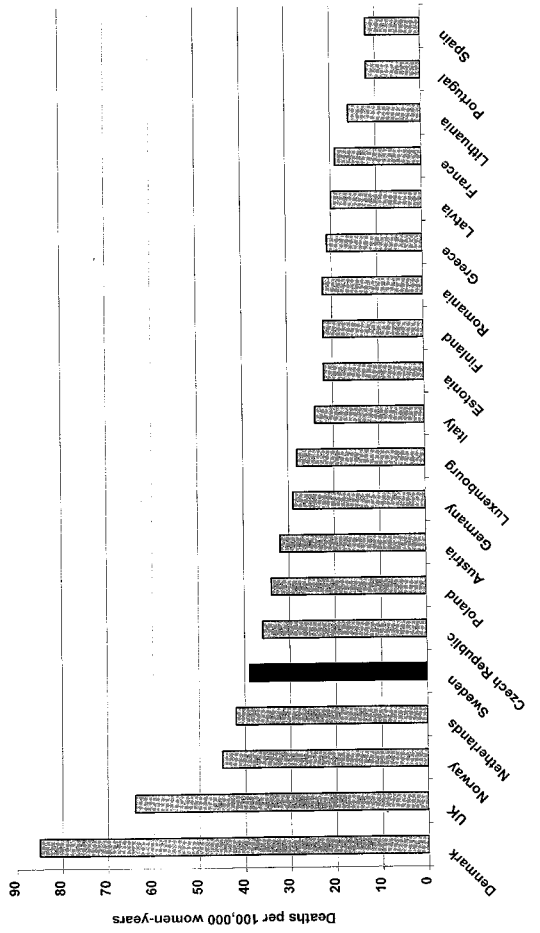
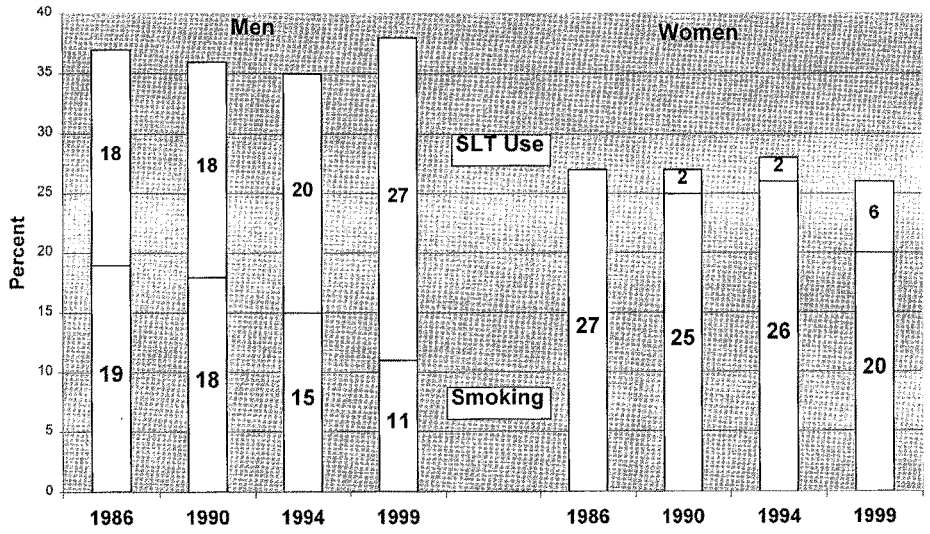


Figure 5. Prevalence of SLT Use and Smoking in Northern Sweden*



*Adapted from Rodu et al, Journal of Internal Medicine, 2002

Mr. STEARNS. Thank you Dr. Rodu.

At this time, Mr. Burton, would you give your statement, please?

STATEMENT OF STEVEN L. BURTON

Mr. BURTON. Thank you, Mr. Chairman.

My name is Steve Burton, and I am responsible for the over-the-counter stop smoking aids that are marketed by Glaxo SmithKline Consumer Health Care. I have been involved in this field since 1996, and currently our products include the Niccoderm nicotine patch, Nicorette gum, and more recently the Commit lozenge.

GSK's chief concern is that unproven health claims for tobacco products threaten efforts to help smokers quit. The distinction between so-called reduced risk products and FDA approved medicines could not be clearer to us.

The reduced risk products are designed to perpetuate tobacco use and our products are designed to end tobacco use, and the emergency of novel tobacco products must not obscure the fact that there is only one proven way today to reduce the harm of tobacco use, and that is to quit completely.

I have heard the term today about the committed smoker, and I have to tell you that in my experience with consumers and the research that we have done, we do not have very many committed smokers. Over 70 percent of smokers want to quit at any one point in time, and nearly all smokers have tried to quit. And over the past decade we have made substantial progress in reducing the prevalence of smoking.

Prevention efforts have stopped millions of our young people from starting to use tobacco, and courageous and motivated smokers who make multiple quit attempts on their way to becoming tobacco free are also heros in the fight against tobacco use.

Our plea today is to reject the policy that would discourage smokers from quitting. We do not accept the proposition that smokers do not want to quit and that more cannot be done to increase the acceptance and effectiveness of the quitting options.

As we have already heard today, and I am not going to repeat comments from other members of the panel, there has been no reduction in the death and disease burden from tobacco from the use of light cigarettes, and the same may be true of the so-called reduced risk products that are before this panel today.

As we learned with lights, the way in which consumers actually use a tobacco product in the real world largely determines its risk, as much or more than the product's inherent toxicity.

For example, it is very plausible that smokeless products would be used in addition to existing cigarette consumption rates that would delay quitting, leading not to a decline, but an increase in risk.

In fact, dual use of cigarettes of cigarettes and smokeless tobacco products has apparently been one of the marketing objectives of the smokeless tobacco industry.

Our own market research of Eclipse, one of the so-called reduced risk products, brings this point home. In a consumer survey, GSK found that most a quarter, 24 percent of smokers considered Eclipse to be completely safe, with 3/4 expecting that Eclipse would reduce health risks by at least 50 percent.

After hearing about Eclipse, there was a net decrease of 19 percent in smokers who were contemplating quitting within 6 months and 15 percent of young adults who had recently quit smoking were interested in buying Eclipse.

Thus, with the emergence of so-called reduced risk tobacco products ex-smokers may start smoking again, and likewise those who never smoked, particularly adolescents, may take up smoking for the first time. And millions of smokes who otherwise might have quit completely could delay or miss opportunities to become tobacco free.

In light of these threats we need a regulatory body that evaluates the public health impact of so-called reduced risk products before they enter the market. That agency must have the in-house scientific expertise to determine the appropriate design and evaluation of the studies to be done before approval. That regulatory body is the Food and Drug Administration.

It should decide whether there is an adequate scientific basis to support the so-called reduced risk claims that tobacco manufacturers seek sot make.

As to the treatment of tobacco dependence, we have certainly not exhausted our opportunities collectively to innovate in this area. Addiction experts agree that the appeal and effectiveness of currently marketed treatments could be enhanced dramatically. FDA should encourage sponsors to develop new indications and uses for current products and work flexibly with sponsors to accelerate development of new and innovative treatments.

Promising drugs should, for example, be fast tracked under FDA's existing authority, and there are new treatments on the way.

On the tobacco side, GSK welcomes tobacco based products proven to meaningfully reduce the risks of smoking. Of course, health claims, either express or implied, must be approved by FDA before being exposed to the most vulnerable within our society: those who have recently quit, or are highly motivated to quit or are tempted to begin smoking.

At GSK we stand ready to assist the subcommittee today in any way that we can. We thank you for the opportunity to appear before you today, and I would certainly be happy to answer any questions that you may have for me later.

Thank you.

[The prepared statement of Steven L. Burton follows:]

PREPARED STATEMENT OF STEVEN L. BURTON, VICE PRESIDENT, SMOKING CONTROL, STRATEGIC DEVELOPMENT AND SWITCH, GLAXOSMITHKLINE CONSUMER HEALTHCARE

INTRODUCTION

Thank you, Chairman Stearns. My name is Steve Burton and I am the Vice President of Smoking Control, Strategic Development and Switch for GlaxoSmithKline Consumer Healthcare (GSK). I have had responsibility for marketing over-the-counter nicotine replacement therapy products (Nicorette gum, NicoDerm CQ patch, and most recently the Commit lozenge) since they were switched from prescription status in 1996. On behalf of GSK, let me thank you and members of the Subcommittee for the opportunity to participate in this important hearing and to share GSK's views on the matter before Congress and the public health community at large. GSK applauds the subcommittee for holding this hearing titled "Can Tobacco Cure Smoking—A Review of Tobacco Harm Reduction." My testimony will concentrate on what can be done to help smokers who are concerned about their health

and interested in reducing the risk of smoking. In particular, I want to offer what we have learned through our research with consumers to help illustrate what they expect novel tobacco products to provide and how they might be used in a real world setting. I will also comment on the adverse public health consequences that could arise when smokers have the new choice to use novel tobacco products instead of FDA approved medicines and other scientifically proven methods of quitting. We believe that an understanding of consumer beliefs and behavior can play a critical role in the design and effective implementation of public health programs and that will be our principal contribution today.

SMOKING AS THE LEADING CAUSE OF PREVENTABLE DEATH AND TOBACCO CONTROL POLICY PROGRESS TO DATE

You are familiar with the staggering statistics associated with the use of tobacco. 440,000 Americans die prematurely each year because of tobacco use (CDC 2002a). More than 6 million of our children alive today will die prematurely later in life because of their use of tobacco (CDC 2002b). The use of this deadly and addictive product constitutes the leading preventable cause of death and disease in the United States each year. While we need to accelerate our progress in reducing the harm of smoking, we should be proud of the fact that millions of smokers have been able to quit completely, youth initiation has been on the decline, and overall prevalence of smoking is slowly trending downward. These significant public health gains are the result of a combination of environmental factors and changes in public health policy led by our elected officials, our regulatory community and the public health field. Examples of these efforts include higher tobacco taxes, restrictions on smoking in the workplace and public places, greater availability of proven treatments, and successful state-based and national youth prevention programs. These and other factors have encouraged more smokers to make serious quit attempts and to be more successful in achieving a smoke free status. GSK has played a small but important part in the overall effort to help adult smokers become tobacco free, and our primary mission remains to reduce the mortality and morbidity associated with smoking by offering smokers proven methods of quitting completely—the ultimate way to reduce risk.

NEW CHALLENGES TO RECENT PROGRESS IN HELPING SMOKERS QUIT

It is well established that overcoming an addiction to tobacco is one of the most daunting and enduring medical challenges an individual can face. In fact, it usually takes multiple attempts for most smokers to become abstinent, and each effort takes a high degree of motivation and personal courage to overcome the psychological and physiological effects of withdrawal from the highly addictive and often socially rewarding use of a cigarette.

To overcome this powerful addiction, smokers need encouragement and support to promote quit attempts and to convert these attempts into positive health outcomes. This includes making effective use of available treatments. Smokers receive this encouragement in a number of ways—from their friends, their health care professional, and also from their government and other public institutions. The decision to quit is easily influenced by smokers' beliefs in their own ability to quit and by their understanding of the alternatives they have to mitigate the risks of smoking. Our research with smokers suggests that the unregulated availability of so-called reduced risk products could lead millions of smokers to delay or reconsider quitting. A perception that novel tobacco products have the endorsement of our public institutions would discourage smokers' commitment to quitting and introduce the confounding and potentially very deceptive notion that smokers can now reduce their risk or even "quit" by continuing to smoke with these novel tobacco products, a so-called "harm reduction" approach. While the health benefits of a harm reduction approach have yet to be proven and remain largely theoretical, the risks of unregulated access to novel tobacco products are clear and present dangers that could undo years of progress by Congress, the FDA and the public health community of which we are a part.

As you no doubt have heard, the great fear held by many public health experts is that these new tobacco products may be nothing more than a scientifically sophisticated version of the "light" cigarette. The introduction of "light" and "ultra light" cigarettes is an object lesson in how policy decisions can unwittingly mislead the public and undermine cessation. Public health officials now believe, many decades too late to be of any help to the health-concerned smoker who switched to lights over the last thirty years, that lights appear to have been deliberately designed so as not to reduce tar and nicotine deliveries when smoked by human beings.

As the National Cancer Institute recently stated, in the definitive study from the federal government on the deception linked with "lights," "Marketing this illusion of risk reduction would have been of concern even if the target for these brands had been confined to continuing smokers. Instead, these brands were targeted at those smokers who were thinking of quitting in an effort to intercept the smokers and keep them smoking cigarettes." (USDHHS, 2001, page 5)

Due in large part to the deliberate design of "lights," there was no reduction in the death and disease burden from tobacco as a result of the marketing of "light" cigarettes. NCI concluded that "The absence of meaningful differences in smoke exposure when different brands of cigarettes are smoked and the resultant absence of meaningful differences in risk make the marketing of these cigarettes as lower-delivery and lower-risk products deceptive for the smoker. The reality that many smokers chose these products as an alternative to cessation—a change that would produce real reductions in disease risks—makes this deception an urgent public health issue." (USDHHS, 2001, page 1)

Thirty years ago, well-intentioned public health officials encouraged health-concerned smokers who could not quit smoking to switch to "lights." At all costs, we must avoid repeating the mistakes with today's products that were made thirty years ago with "lights."

CONSUMER UNDERSTANDING OF RISK OF AND INTEREST IN NOVEL TOBACCO PRODUCTS

At the outset, one critical fact must be recognized. Complete abstinence is the only method that reduces the future health risk of smoking to almost zero, and allows for an ex-smoker to achieve a long-term prognosis essentially equivalent to a never smoker after 10-15 years of abstinence (USDHHS, 1990). The emergence of novel tobacco products does not change this fact. Novel tobacco products have not been studied with the same rigor of smoking cessation medicines and methods. Nor have the studies that have been conducted on these products been submitted to FDA for evaluation. There is only one proven way to reduce the harm from tobacco, and that is to quit.

On the other hand, consumers are all too willing to grasp at the belief that novel tobacco products are indeed safe and effective alternatives to smoking their current cigarettes. As an example, we fielded a large consumer survey that exposed the Eclipse concept (a novel cigarette design that is claimed to primarily heat rather than burn tobacco) to 1000 smokers and 499 ex-smokers. In the survey, after hearing a brief account of claims for Eclipse, almost all current smokers (91.4%) thought Eclipse was safer than Regular cigarettes. Moreover, almost a quarter (23.9%) considered Eclipse to be *completely* safe. On average, participants expected that Eclipse would reduce smoking risk by 62.1% compared to Regular cigarettes, with three quarters (75.9%) expecting that Eclipse would reduce health risks by at least 50%. Eclipse was also regarded as significantly safer than current Light or Ultra Light cigarettes. Compared to the 23.9% who regarded Eclipse as completely safe, only 9.4% and 11.3% regarded Lights and Ultra Lights, respectively, as completely safe. The fact that consumers perceive novel tobacco products to carry less health risk than smoking even light or ultra light cigarettes should be troubling to those who are concerned with the death and disease caused by tobacco products.

We know that approximately 70% of smokers are interested in quitting (CDC, 2002c). GSK's mission is to reduce death and disease by inspiring more smokers to become tobacco, and ultimately, nicotine free. The scientific data behind our treatments, such as Nicorette gum, NicoDerm CQ patch, the Commit lozenge, and the prescription smoking cessation drug Zyban, has been evaluated and approved by the Food and Drug Administration. These products have been approved as being both safe and effective for use in trying to quit. With the help of our products and those of other treatment providers, millions of smokers in this country have successfully stopped smoking and eliminated all of the risk of continued tobacco use.

UNINTENDED CONSEQUENCES OF NOVEL TOBACCO PRODUCTS—CONSUMER PERSPECTIVE

From a public health perspective, we should be concerned about the new crop of tobacco products bearing unproven claims to reduce exposure and risk. The greatest danger is that these products may pose a significant threat to cessation efforts—regardless of whether a smoker would have used one of our products in a quit attempt or chosen another quit method. Smokers who see the claims for products like Eclipse may now think that a safer cigarette genuinely exists. This may make them less interested or inclined to try to quit smoking entirely.

There is the added concern that ex-smokers may start smoking again, thinking that they can now safely consume tobacco products. Likewise, those who never

smoked, particularly adolescents, may take up smoking for the first time, using one of these new products under the assumption that a safe cigarette exists.

The consumer survey data commissioned by GSK on smoker and ex-smoker attitudes towards Eclipse, one of the new generations of tobacco products sold by R. J. Reynolds, confirms these concerns (Shiffman, Pillitteri, Burton, et al, unpublished manuscript). Reynolds makes explicit health claims about reductions in disease risks for Eclipse, including "less risk of cancer," and "a lower risk of chronic bronchitis, possibly even emphysema" (www.eclipse.rjrt.com, December 2002).

The survey found that 57.4% of smokers said they were "somewhat likely" or "very likely" to purchase Eclipse within the next six months. Most importantly, after hearing about Eclipse, there was a net decrease of 19% in smokers who were contemplating quitting within 6 months. Furthermore, 15% of the young adults who had recently quit smoking were interested in buying Eclipse.

In a second study focusing on a novel smokeless tobacco product among smokers interested in quitting, similarly high levels of purchase interest were reported. Around 41% of the sample were very or somewhat likely to want to use the novel smokeless product. Purchase intent (46%) was higher in consumers with an interest in using nicotine replacement therapy to quit, a surrogate for smokers more likely to actually commit to a serious quit attempt. When asked how they would use these smokeless products, 15% of the sample reported they would use the smokeless tobacco product as a substitute for cigarettes at times when they could not smoke, 29% as a way to reduce their smoking rate, and another 36% as a way to cut back on their smoking in preparation for quitting.

These results suggest that Eclipse, and its new brethren of tobacco-based products that have not been proven to reduce the risk of smoking in any meaningful way, are a threat to cessation and risk converting ex-smokers back to their deadly addiction.

Do these products genuinely reduce exposure and risk? We do not know because exposure and risk are determined by the overall pattern and years of use by smokers in real world conditions, not just by physical makeup of the product. Nor do we know how these products perform in the laboratory. But here are a few observations that should be of profound concern to the public health community of which you are a part. Eclipse advertising declares that exposure to carbon monoxide may be higher than traditional cigarettes. Eclipse has been shown to contain filaments of glass particles not found in traditional cigarettes that would be inhaled deeply into the lungs (IOM 2001). The new Quest cigarette offers a program claiming to reduce levels of nicotine consumption while keeping the level of cancer-causing tar *unchanged*—and the tar levels are *higher* than the majority of low tar brands consumed today. Many experts would argue that, as was the case with "light" cigarettes, smokers of Quest would consume a greater number of the reduced nicotine cigarettes in order to avoid withdrawal and maintain the reinforcing effects of their nicotine addiction. These smokers could end up consuming more tar with the reduced nicotine cigarette than their traditional brand of cigarette.

SCIENTIFIC PERSPECTIVE—THE RISK/BENEFIT EQUATION FOR NOVEL TOBACCO PRODUCTS

I expect the scientific community and tobacco control experts to provide their view on the potential risks and benefits of expanded use of novel tobacco products. They believe the tobacco industry's motivation is to perpetuate the use of tobacco-based products by introducing a new generation of tobacco products. By offering promises of reduced exposure to toxins in tobacco smoke, and even making claims to reduce the risk of cancer and other diseases, these products raise profound and troubling public health policy questions for our partners in the tobacco control community.

We should consider carefully the recent findings published in the *American Journal of Epidemiology,* that reductions in cigarette use, as measured by daily smoking rates, had no impact on health risks from smoking among a large population of heavy smokers (Godtfredsen et al, 2002). Smokers who attempt to reduce the harm of smoking by cutting down on the number of cigarettes they smoke compensate in the same way that smokers of so-called light cigarettes compensated by smoking each cigarette more deeply. Smokers who attempt to reduce their smoking rates *without* the support of pharmacotherapy experienced the same degree of harm as smokers who did not reduce their smoking rates.

The novel tobacco products take various forms. Some burn tobacco or employ novel technologies to burn or heat tobacco. Others are tobacco-based but do not burn. The combusting products include Omni and Advance, and promise to reduce or eliminate exposure to a subset of toxins in tobacco smoke. The novel products include Eclipse and Accord, and claim to reduce toxin levels or secondhand smoke.

The non-combusting (i.e. smokeless) products include Ariva, Revel, and Exalt, promise tobacco satisfaction in situations (e.g. at work or on a plane) where smoking is not possible or permitted.

Whether they combust or not, all of these products are aimed squarely at the health-concerned smoker. They have entered the marketplace in the absence of any independent scientific evaluation of their claims, and without any governmental scrutiny of the products or their claims.

Equally troubling are the claims for the smokeless products, like the Ariva tobacco lozenge. In isolation, one could argue that a tobacco-based product that does not burn tobacco leaf has a lower risk profile than one that does. But this could be a short-sighted view to take given the historical behavior of the smokeless tobacco industry operating outside of a credible regulated environment. Reviews of past marketing practices report that this industry deliberately targeted young males, particularly athletes, in the 1970s and revived lagging sales by promoting use of smokeless among teenage boys who had not previously used tobacco. Further, these same reports note that this industry specifically designed and promoted products with varying levels of nicotine delivery, perceived strength and a range of flavors (including "candy-like" flavors) so as to facilitate early use by adolescents and their progression to more addicting, higher nicotine products (FDA Proposed and Final Rule, 1995 and 1996; Bonnie and Lynch, 1994).

Furthermore, the health benefits of products like Ariva presumably result in part from the assumption that Ariva would be used to completely replace all cigarette use and thus overall exposure to toxins would decrease. It is equally plausible that smokeless tobacco products would be used in addition to a smoker's typical level of cigarette consumption, and this is precisely the type of real world consumer behavior that must be assessed prior to market entry, not years after this unfortunate consequence has been documented retrospectively.

Smokers who might have otherwise been inclined to try to quit, may latch on to a smokeless product bearing an "Anytime. Anywhere." or a "WHEN YOU CAN'T SMOKE" claim, and use it to perpetuate their smoking through the dual use of combusting and non-combusting tobacco. In fact, the United States Smokeless Tobacco Company expressed the view in their 2000 annual report that the dual use of cigarettes and smokeless tobacco "represents great potential for future expansion of the business" (UST, Inc, Annual Report, 2000, page 9).

In the absence of public health-based regulation of these products, and well controlled studies of actual patterns of consumer use completed prior to market entry, we have no way of knowing whether this new generation of products will reduce exposure and risk in any meaningful way when used by smokers under normal or typical conditions of use. Nor do we understand the impact on quitting behavior amongst those smokers who otherwise would have achieved complete abstinence when they are exposed to the unsubstantiated claims of these novel tobacco products. Even more of a concern, we will not know what effect this marketing will have on the possibility of young people initiating tobacco use. The unfettered access to the marketplace for these products has created a massive, uncontrolled clinical trial, with commercialization and hefty promotion and advertising preceding a scientifically credible demonstration that there is adequate proof to support the marketing claims and expected public health outcomes of these products.

REGULATORY APPROACHES FOR NOVEL TOBACCO PRODUCTS: RECOMMENDATIONS

The most appropriate way to assess the potential risks and benefits of these products is through a regulatory system that assures the public of comprehensive regulation of all tobacco products; a system where a public health-based regulatory agency evaluates products and claims *before* they enter the marketplace. As this Subcommittee goes forward with its consideration of the role of tobacco-based products in a harm reduction framework, we need to ensure that an appropriate degree of scientific and regulatory accountability is brought to bear on any tobacco products that purport to reduce exposure or risk. One way to achieve this accountability is by insisting that no product or claim should appear in the marketplace until it has been evaluated by an independent, public health-based regulatory authority. Such an agency, and we believe it should be FDA, should decide whether there is an adequate scientific basis to support whatever claims the manufacturer seeks to make.

Whereas the tobacco-based products are carefully designed to perpetuate tobacco use, or at least could have that real world effect, in contrast GSK and other providers of treatment interventions offer quitting programs rigorously studied and evaluated for their safety and efficacy by FDA prior to appearing in the marketplace. We are proud of the collaboration we entered into with Congress, the FDA and the public health community in the mid-1990s to expand access and utilization

of nicotine replacement therapies by marketing them as over-the-counter medications starting in 1996. , , , . We have been encouraged by the evidence that offering treatments directly to consumers can significantly increase utilization of these products to support quit attempts.

Yet, we have not exhausted our opportunities to innovate in the area of tobacco dependence treatment through the use of pharmaceuticals and other public health interventions that expand utilization while also improving outcomes, as recent success in the area of quit lines have shown. We believe it should be the policy of our government to encourage sponsors to develop new indications and uses for current products, and to work with sponsors to accelerate development of a range of novel treatment products. GSK has a number of new products that offer the promise of more consumer acceptable formulations and regimens and a range of experimental drugs are in development within industry and academia. For instance, over-the-counter nicotine replacement therapy products are limited to up to 12 weeks of use as compared to six months or more under their former prescription status. Addiction experts have argued that the appeal and effectiveness of currently marketed treatments could be enhanced dramatically should we consider new uses and indications such as combination therapy, use of intensive behavioral interventions alongside pharmacotherapy, reduction of cigarettes alongside a gradual increase in medicinal nicotine administration, and use of NRT for relapse prevention and long term maintenance of cessation. Promising drugs and interventions like these should be fast tracked when judged by the FDA to qualify for such status.

Finally, GSK welcomes scientifically validated and regulated claims for tobacco-based products. It is not our position that novel tobacco products cannot be marketed today under existing tobacco regulations or that it is unconceivable that such products might make a public health contribution. Our position is that any health claim, expressed or implied, should be scientifically demonstrated and reviewed by FDA before such claims are exposed to the most vulnerable within our society—those who have recently quit, are highly motivated to quit, or are tempted to begin smoking. For a marketplace flooded with unproven and unregulated health claims for novel tobacco products will not only undo years of progress in the tobacco control effort but also damage our capacity to bring even more effective and consumer accepted treatments to the millions of consumers who want and deserve meaningful improvements in their health status.

Today half of ever smokers have become former smokers. Our challenge and yours is to ensure that successful quitters are not lured back to smoking and the vast majority of smokers who can and will eventually quit completely are not discouraged from reducing the harm of smoking to zero. As to the remainder of smokers who may not be able to quit, and we would argue that we have many opportunities yet before us to reduce this number further, we need to find interim and credible solutions to reducing harm to their health. The current cadre of novel tobacco products, if allowed to remain in the market absent scientific evidence of a positive health impact within the population, should nonetheless be prohibited from making implied or expressed claims of health improvement until such time as adequate proof and public health regulatory approval has been obtained.

At GSK, we stand ready to assist the Subcommittee in any way that we can on these critically important and challenging questions of how to reduce the extraordinary death and disease toll caused by the use of tobacco products.

Thank you for the opportunity to appear before you today. I would be happy to answer any questions that the subcommittee might have.

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Mr. STEARNS. Thank you, Mr. Burton.

And at this time, Mr. Verheij, if you would give your opening statement.

STATEMENT OF RICHARD VERHEIJ

Mr. VERHEIJ. Good afternoon, Mr. Chairman and members of the committee. I am Richard Verheij, Executive Vice President, External Affairs, for U.S. Smokeless Tobacco Company.

I would like to thank this committee for convening this hearing to examine the issue of tobacco harm reduction. We see this hearing as a significant step in the country's ongoing efforts to address the issues raised by the continued use of tobacco products by millions of Americans.

Indeed, 50 million Americans smoke. The Institute of Medicine has predicted that a significant proportion of those individuals will continue to do so despite a multitude of approaches with the ultimate objective of total tobacco cessation. This prediction has prompted the public health community to consider new complementary strategies, including tobacco harm reduction.

As we proceed today, it is helpful to keep a couple of things in mind. First, this debate is not about whether smokeless tobacco is considered to be safe. Rather, it is about the increasing consensus in the public health community that smokeless tobacco is significantly less harmful.

Second, this debate is not about whether smoking cessation is the best public health strategy. Rather, it is about whether there are complementary strategies which public health advocates believe will save millions of lives.

We are here today because of the millions of adult smokers who do not quit and do not use medicinal nicotine products. Many in the public health community believe that a harm reduction strategy based on communicating to adult smokers truthful information about other options can have a significant impact on both those individual adult smokers and public health generally. Simply stated, many researchers have expressed the opinion that use of smokeless tobacco is significantly less harmful than cigarette smoking. Based

on that judgment, these same researchers advocate that adult smokers who do not quit and do not use medicinal nicotine products switch completely to smokeless tobacco.

There is increasing consensus on this crucial issue among members of the public health community some of whom are testifying before this committee today. However, despite this increase in consensus, it is documented that the vast majority of adult smokers are unaware of this information.

One researcher has stated that "until smokers are given enough information to allow them to choose products because of lower health risks, then the status quo will remain."

Our company, along with those public health advocates, believes that it is crucial that this information be made available to adult smokers. Such communication will help adult smokers make more informed choices.

We look forward to discussing the real question: how best to communicate this important information. We know there are a variety of opinions on this topic. We welcome a serious and open dialog that brings to the table all relevant parties to express their viewpoints and concerns.

That is why we urge the Federal Trade Commission to initiate a forum that would bring together all of these parties to examine the most appropriate means for communicating this important information to adult smokers.

Let me state clearly for the record that U.S. Smokeless Tobacco Company is committed to restricting tobacco use to adults only. This commitment is not just rhetoric. It is backed by concrete action.

In 1997, we were the only smokeless tobacco company to support the proposed tobacco resolution. When that proposal failed, we became the only smokeless tobacco company to enter into the smokeless tobacco master settlement agreement with Attorneys General of 45 states and various territories.

We are providing more than $100 million to the American Legacy Foundation for programs to reduce youth usage of tobacco. Our company is committed to proceeding in a responsible and deliberate manner that reflects the current state of the science and addresses the concerns of the public health community.

This debate presents a broad societal question. How should we collectively communicate information to adult smokers that many in the public health community believe will prolong and save lives. this is truly an unprecedented opportunity. Public health advocates, researchers, tobacco control activists, and tobacco product manufacturers all agree on the fundamental principle that a harm reduction strategy could represent an important component of a comprehensive public health policy on tobacco.

There may be disagreement on how best to implement this strategy. Nevertheless, given the stakes, this issue deserves serious consideration. We believe this hearing represents a significant step in that process Thank you for holding this very timely hearing. May I ask that U.S. Smokeless Tobacco Company's written statement, which was submitted to the committee on May 30th, be incorporated in its entirety into the hearing record after my statement today?

Mr. STEARNS. By unanimous consent, so ordered.
[The prepared statement of Richard Verheij follows:]

PREPARED STATEMENT OF RICHARD H. VERHEIJ, EXECUTIVE VICE-PRESIDENT, U.S. SMOKELESS TOBACCO COMPANY

U.S. Smokeless Tobacco Company ("USSTC") welcomes the opportunity to participate in this hearing regarding tobacco harm reduction. This issue is of immense importance to the 50 million adult tobacco consumers in the United States, to the public health community, to medical practitioners and to tobacco manufacturers.

For decades, the public health community in the United States has asserted that cigarette smoking is the most deadly epidemic of modern times. For almost as long, the message of the public health community to cigarette smokers has been monolithic: stop all use of tobacco. Over the past several years, however, an increasing number of public health advocates have voiced doubts about what some have called the "quit or die" approach to smoking cessation.

Rather than rely entirely on programs intended to achieve total cessation of tobacco use, this segment of the public health community is urging that a more pragmatic goal be adopted—that of tobacco "harm reduction." One method of achieving tobacco harm reduction, according to a growing number of researchers, is to encourage those cigarette smokers who do not quit and do not use medicinal nicotine products to switch completely to smokeless tobacco products. This strategy, however, is complicated by the fact that the vast majority of adult cigarette smokers in the United States—despite the generally accepted scientific view to the contrary—believe that cigarette smoking and smokeless tobacco use involve the same risk of adverse health effects.

The issue of tobacco harm reduction and the potential role of smokeless tobacco products in that effort is at a crossroads. The debate is no longer about whether smokeless tobacco is considered by the scientific community to be a significantly reduced risk alternative compared to cigarette smoking. The question now is whether that information should be communicated to adult cigarette smokers or whether it should be suppressed.

Set forth below is a brief description of USSTC and its smokeless tobacco products, followed by a review of some of the more significant issues relating to smokeless tobacco in the context of tobacco harm reduction.

I. USSTC

USSTC is the leading U.S. producer and marketer of moist smokeless tobacco or moist snuff. Copenhagen and Skoal—two of USSTC's brands—are America's best-selling moist snuff products. Two other brands—Rooster and Red Seal—were introduced within the last five years, and hold established positions in the marketplace. A new pouch product—Revel—has been test marketed. USSTC maintains manufacturing and processing facilities in Franklin Park, Illinois; Hopkinsville, Kentucky; and Nashville, Tennessee.

In 1997, USSTC was the only smokeless tobacco company to support the proposed tobacco resolution. When the proposal failed to pass the Congress, USSTC became the only smokeless tobacco company to enter into the Smokeless Tobacco Master Settlement Agreement ("STMSA") with Attorneys General of various states and U.S. territories. Pursuant to the STMSA, USSTC is providing up to $100 million (plus an inflation adjustment), over a 10-year period, to the American Legacy Foundation for programs to reduce youth usage of tobacco and combat youth substance abuse, and for enforcement purposes.[1] Moreover, USSTC agreed to limitations on its adver-

[1] Youth usage of smokeless tobacco, as reported in surveys conducted by various federal government agencies and by the University of Michigan, has declined substantially in recent years. For example, in 2001 the authors of the report on the University of Michigan's Monitoring the Future national survey noted that "[t]he use of smokeless tobacco by teens has been decreasing gradually from recent peak levels in the mid-'90s, and the overall declines have been substantial." Johnston LD, O'Malley PM, Bachman JG. (2001) *Monitoring the Future national results on adolescent drug use: Overview of key findings 2000.* (NIH Publication No. 01-4923). Bethesda, MD: National Institute of Drug Abuse, at p. 34. More recently, these same authors reaffirmed their earlier findings, noting that the overall declines in teen use of smokeless tobacco have been "substantial" and that "teen use of smokeless tobacco is down by about one-half from the peak levels reached in the mid-1990s." Johnston LD, O'Malley PM, Bachman JG. (2003). *Monitoring the Future national results on adolescent drug use: Overview of key findings, 2002.* (NIH Publication No. 03-5374). Bethesda, MD: National Institute on Drug Abuse, at p. 34.

tising and marketing efforts, even though this put USSTC at a competitive disadvantage with other smokeless tobacco manufacturers.[2]

As these facts and the remainder of this statement will make clear, USSTC is truly a "distinctly different" tobacco company. Annexed as Attachment A to this statement are copies of excerpts from UST Inc.'s (USSTC's parent company) annual reports for 2000, 2001 and 2002 that discuss the ways in which USSTC is a "distinctly different" tobacco company.

II. SMOKELESS TOBACCO IN THE CONTEXT OF TOBACCO HARM REDUCTION

A. Introduction

Since the Surgeon General's Report in 1964,[3] there has been substantial public health discussion about the potential health effects of tobacco use. Various public health organizations have identified the risks of cigarette smoking as including cancer (*e.g.,* lung, oral cavity, esophagus, larynx, pancreas, bladder, kidney), chronic obstructive pulmonary disease, myocardial infarction, and stroke.[4] The Centers for Disease Control and Prevention ("CDC") estimates that cigarette smoking caused approximately 442,000 premature deaths in the United States in 1999.[5] The Surgeon General has indicated that the ideal way to avoid such health risks is to abstain from cigarette smoking.[6] Nonetheless, 47 to 50 million adults in the U.S. continue to smoke cigarettes. This number represents approximately 25 percent of all U.S. adults.[7]

The Surgeon General reached a judgment in 1986 that use of smokeless tobacco products "can cause cancer."[8] Federally-mandated rotating warnings on smokeless tobacco product packaging and advertising state:

> WARNING: THIS PRODUCT MAY CAUSE MOUTH CANCER
>
> WARNING: THIS PRODUCT MAY CAUSE GUM DISEASE AND TOOTH LOSS
>
> WARNING: THIS PRODUCT IS NOT A SAFE ALTERNATIVE TO CIGARETTES.[9]

Numerous methods have been suggested by public health advocates for achieving tobacco harm reduction, including urging cigarette smokers to smoke fewer cigarettes, developing "less hazardous" cigarettes and creating alternative sources of nicotine, such as nicotine inhalers. A growing number of tobacco harm reduction proponents, however, are arguing for an additional method for achieving their goal. Based on the generally accepted view in the scientific community that smokeless tobacco use involves significantly less risk of adverse health effects than cigarette smoking, they would encourage those cigarette smokers who do not quit and do not use medicinal nicotine products to switch completely to smokeless tobacco products.

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[2] These restrictions include, among other things, eliminating outdoor advertising of smokeless tobacco products, such as billboards and signs in arenas, stadiums, shopping malls, video-game arcades, and on public transit. In addition, USSTC voluntarily limited itself to one brand-name sponsorship in any 12-month period, and agreed to discontinue distribution to the public of non-tobacco merchandise, such as caps and T-shirts, bearing the brand name, logo, or trademark of any smokeless tobacco product.

[3] U.S. Department of Health, Education and Welfare. *Smoking and Health. Report of the Advisory Committee to the Surgeon General of the Public Health Service.* 1964.

[4] Stratton K, Sherry P, Wallace R, Bondurant S (eds.). *Clearing the smoke. Assessing the science base for tobacco harm reduction. Institute of Medicine.* National Academy Press, Washington, D.C., 2001, at pp. 367-68.

[5] Centers for Disease Control and Prevention. Annual Smoking-Attributable Mortality, Years of Potential Life Lost, and Economic Costs—United States, 1995-1999. MMWR 2002; **51**: 300-303.

[6] U.S. Department of Health & Human Services, *Preventing Tobacco Use Among Young People: A Report of the Surgeon General* (1994); *see also Smoking As A Health Hazard,* American College of Cardiology Position Statement, available at http://www.acc.org/clinical/position/72565.pdf.

[7] The National Center For Chronic Disease Prevention and Health Promotion estimates that 47 million adults in the United States smoke cigarettes. *Targeting Tobacco Use: The Nation's Leading Cause of Death,* Tobacco Information and Prevention Source (2001). The U.S. Department of Health and Human Services estimates that more than 57 million Americans currently smoke cigarettes. *Preventing Death and Disease From Tobacco Use,* Fact Sheet (Jan. 8, 2001). Other reports suggest that the number of smokers in the United States is between 46.5 and 50 million. *Cigarette Smoking Among Adults-United States, 1999, MMWR Highlights* (Oct. 12, 2001) Vol. 50, No. 40; Treating Tobacco Use and Dependence, U.S. Public Health Service, Fact Sheet (June 2000).

[8] U.S. Department of Health & Human Services, *The Health Consequences of Using Smokeless Tobacco: A Report of the Advisory Committee to the Surgeon General* (1986).

[9] Comprehensive Smokeless Tobacco Health Education Act of 1986, 15 U.S.C. §§ 4401-4408.

B. The IOM Report

A logical starting point for discussion of smokeless tobacco in the context of tobacco harm reduction is the 600 page report issued in 2001 by the Institute of Medicine ("IOM") entitled: *Clearing the Smoke. Assessing the Science Base for Tobacco Harm Reduction* ("IOM Report"). The IOM was established in 1970 by the National Academy of Sciences to examine policy matters pertaining to public health, and acts under the Academy's congressional charter to be an advisor to the federal government and to assess issues relating to medical care, research and education. The IOM tobacco harm reduction project was undertaken at the request of, and was supported by, the U.S. Food and Drug Administration. The IOM Report explains the need for a tobacco harm reduction strategy as follows:

> Despite overwhelming evidence and widespread recognition that tobacco use poses a serious risk to health, some tobacco users cannot or will not quit. For those addicted tobacco users who do not quit, reducing the health risks of tobacco products themselves may be a sensible response. This is why many public health leaders believe that what has come to be called "harm reduction" must be included as a subsidiary component of a comprehensive public health policy toward tobacco.[10]

Tobacco "harm reduction" is defined in the IOM Report as follows:

> *For the purposes of this report, a product is harm-reducing if it lowers total tobacco-related mortality and morbidity even though use of that product may involve continued exposure to tobacco related toxicants.* Many different policy strategies may contribute to harm reduction. However, this report focuses on tobacco products that may be less harmful or on pharmaceutical preparations that may be used alone or concomitantly with decreased use of conventional tobacco. (Original emphasis). [11]

It is clear from this definition of "harm reduction" that, in the view of the IOM, it is not necessary to demonstrate that a product is "safe" or "harmless" in order for that product to play a role in tobacco harm reduction.

The IOM Report had the following to say with respect to smokeless tobacco products:

> Smokeless tobacco products are associated with oral cavity cancers, and a dose-response relationship exists. However, the overall risk is lower than for cigarette smoking, and some products such as Swedish snus may have no increased risk. It may be considered that such products could be used as a PREP [Potential Reduced-Exposure Product] for persons addicted to nicotine, but these products must undergo testing as PREPs using the guidelines and research agenda contained herein.[12]

There has been criticism of the IOM Report's recommendation that all products proposed for use in the context of a tobacco harm reduction strategy require substantial and elaborate scientific testing to demonstrate their harm reduction benefits. For example, Clive Bates, former Director of the United Kingdom's Action on Smoking and Health, has made the following comments:

> The report places very substantial evidential requirement on those seeking to bring PREPs to the market with a health related claim. The easiest approach for the public health and regulatory community is to demand near complete certainty before approving the marketing of any PREPs. At first sight this appears prudent, but it is actually a transfer of risk from the regulator to the smoker. With insurmountable evidential hurdles in place, the regulator may sleep easy in a cocoon of professional skepticism.[13]

The IOM Report's focus on the need for further research and demonstration of harm reduction benefits may be understandable in the context of new or novel tobacco products or so-called "safer" cigarettes. When it comes to smokeless tobacco, however, there is considerable agreement in the scientific community that the use of smokeless tobacco involves significantly less risk of adverse health effects than cigarette smoking.

As Professor Lynn Kozlowski, Head of the Pennsylvania State University Department of Biobehavioral Health, has stated in a commentary published last year in the journal *Nicotine and Tobacco Research:*

> The failure of governments to establish any effective regulation of tobacco products can be seen as arguably the greatest failure of public health policy for the past 100 years. I have recently been in a meeting with several distinguished

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[10] Stratton K, et al. (2001) at p. 201.
[11] *Id.* at p. 2.
[12] Id. at. p. 434.
[13] Bates C. Clearing the smoke or muddying the water? (Editorial) *Tobacco Control* 2001; **10**: 87-88.

scientists and opinion leaders interested in smoking-related public policy and regulation. The majority of these individuals expressed an unwillingness to express any public opinion about would-be harm reduction products for tobacco, until such time as proper regulatory/evaluation systems were in place to unequivocally judge the degree of harm reduction afforded by the products as used by society. (This might be viewed as in keeping with the position of the Institute of Medicine report.) Clearly the best of all possible research has not yet been done on snus or medicinal nicotine, but, equally clearly, it is wrong to assume that we lack practical scientific bases for estimating that there will be harm reduction to individual smokers from these products. *Though it is important to attain proper regulation over tobacco and harm reduction products, this goal is logically and ethically independent of the need to provide smokers today with what information we do have about the risks of various products.* (Emphasis supplied).[14]

C. There is General Agreement in the Scientific Community Regarding the Comparative Health Risks of Cigarette Smoking and Smokeless Tobacco Use

USSTC's February 5, 2002 Request to the Federal Trade Commission ("FTC") for an advisory opinion [15]15, which is discussed below, contains excerpts from 50 scientific publications, many of which were peer-reviewed, that assert or support the proposition that the use of smokeless tobacco involves significantly less risk of adverse health effects than cigarette smoking. Additional scientific information and publications that became available subsequent to February 5, 2002 is reviewed in USSTC's May 9, 2003 submission to the FTC, which is also discussed below. Two of the publications referenced in that supplemental submission reflect the generally held view in the public health community regarding the comparative health risks of cigarette smoking and smokeless tobacco use. Those publications can be expected to have a significant impact on the tobacco harm reduction debate, and therefore merit some discussion.

i. Royal College of Physicians Report

In December 2002, the Royal College of Physicians ("RCP") issued a landmark report entitled *Protecting Smokers, Saving Lives,*[16] which assessed various issues relating to future tobacco regulation in the United Kingdom. The RCP is England's oldest medical institution; among its main functions is to advise the government, the public and the medical profession on health care issues.

The 2002 RCP Report recognized that tobacco harm reduction must be an essential element of any tobacco regulation program:

> A tobacco and nicotine regulatory authority should have a clear objective:
> *. . . to reduce the overall burden of tobacco-related disease by contributing to a reduction in smoking prevalence and by regulating to reduce the harm caused to continuing nicotine users."* (Original emphasis) [17]

The 2002 RCP Report also recognized that smokeless tobacco would be a key component of any tobacco harm reduction strategy:

> Smokeless Tobacco:
> As a way of using nicotine, the consumption of non-combustible tobacco is of the order of 10-1,000 times less hazardous than smoking, depending on the product. Some manufacturers want to market smokeless tobacco as a 'harm reduction' option for nicotine users, and they may find support for that in the public health community.[18]

The issuance of the RCP's 2002 Report is not the first time that the RCP has led the way on tobacco and health issues. In March 1962, the RCP issued a report on smoking and health which concluded that cigarette smoking caused lung cancer. Shortly after the issuance of that report, the U.S. Surgeon General, Dr. Luther L. Terry, established the Surgeon General's Advisory Committee on Smoking and

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[14] Kozlowski LT. Harm reduction, public health, and human rights: Smokers have a right to be informed of significant harm reduction options. *Nicotine and Tobacco Res* 2002; **4 Suppl 2**: 55-60 at p. 58.

[15] Throughout this statement reference will be made to USSTC's February 5, 2002 and May 9, 2003 submissions to the Federal Trade Commission and attachments thereto. Those documents and their attachments can be found at: http://www.ftc.gov/os/otherpubliccomments.htm and http://www.ussmokeless.com. Hereafter, documents that are part of these submissions will be indicated as follows: "See Website."

[16] Tobacco Advisory Group of the Royal College of Physicians. *Protecting smokers, saving lives.* Royal College of Physicians of London, 2002. See Website.

[17] Id. at p. 24.

[18] *Id.* at p. 5

Health to produce a similar report for the United States. That report was released in January 1964 and is generally referred to as the 1964 Surgeon General's Report. Its conclusions were similar to those of the 1962 RCP Report.

ii. White Paper on European Union Smokeless Tobacco Policy

In February 2003, a group of tobacco and health researchers and public health advocates from the United Kingdom, Sweden and Austria published a white paper entitled *European Union policy on smokeless tobacco. A statement in favour of evidence-based regulation for public health.*[19] The authors recommend that the current European Union ban of smokeless tobacco be replaced with a regulatory program based on the recognition that smokeless tobacco is substantially less harmful than cigarette smoking and could play a significant role in tobacco harm reduction. The group summarized the "public health case" favoring smokeless tobacco as follows:

> We believe that the partial ban applied to *some* forms of smokeless tobacco in the European Union should be replaced by regulation of the toxicity of *all* smokeless tobacco. We hold this view for public health reasons: smokeless tobacco is substantially less harmful than smoking and evidence from Sweden suggests it is used as a substitute for smoking and for smoking cessation. To the extent there is a "gateway" it appears not to lead to smoking, but away from it and is an important reason why Sweden has the lowest rates of tobacco-related disease in Europe. We think it is wrong to deny other Europeans this option for risk-reduction and that the current ban violates rights of smokers to control their own risks. For smokers that are addicted to nicotine and cannot or will not stop, it is important that they can take advantage of much less hazardous forms of nicotine and tobacco—the alternative being to 'quit or die'. . . and many die. (Original emphasis)[20]

Among other points made in the white paper are the following:

> [F]or oral tobacco to play a role in harm reduction it is not necessary to show that it does not cause cancer—it just needs to be substantially less hazardous than smoking. Even allowing for cautious assumptions about the health impact, snus—and other oral tobaccos—*are a very substantially less dangerous way to use tobacco than cigarettes.* Smokeless tobaccos are not associated with major lung diseases, including COPD and lung cancer, which account for more than half of smoking-related deaths in Europe. If there is a CVD risk, which is not yet clear, it appears to be a substantially lower CVD risk than for smoking. Smokeless tobacco also produces no environmental tobacco smoke (ETS) and therefore eliminates an important source of disease in non-smokers and children. These are very substantial benefits in reduced risk to anyone that switches from smoking to smokeless tobacco and we believe the public health community has a moral obligation to explore this strategy. It is likewise ethically wrong to actively *deny* users the option to reduce their risk in this way.[21]
>
> * * *
>
> The risk to the user arising from use of a smokeless tobacco product varies by product and is to some extent uncertain—notably in the area of heart disease (though at *worst* the heart disease impact appears to be substantially less than smoking). However, we are confident that the evidence base suggests that it is reasonable to formulate the overall relative risk as follows: *on average Scandinavian or American smokeless tobaccos are at least 90% less hazardous than cigarette smoking.* In a spectrum of risk, snus is *much* closer to NRT [nicotine replacement therapy] than it is to cigarette smoking. (Original emphasis)[22]

D. Individual Risk Versus Population Risk

One concern raised by some in the public health community with respect to "reduced risk" tobacco products is that, while a product might reduce the health risk to an individual, the aggregate public health impact on the population might be negative. Thus, for example, it is argued that if a "safer" cigarette reduced the health risks associated with cigarette smoking by 10 percent, but resulted in a 20 percent increase in cigarette use (either through new smokers or by causing some smokers who otherwise would have quit to continue smoking), the aggregate public health

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[19] Bates C, Fagerström K, Jarvis M, Kunze M, McNeill A, Ramstrom L. *European Union policy on smokeless tobacco. A statement in favour of evidence-based regulation for public health.* February 2003. See Website.

[20] *Id.* at p. 2.

[21] *Id.* at p. 3.

[22] *Id.* at pp. 3-4.

impact would be negative. Professor Kenneth E. Warner of the University of Michigan gives the following example:

> [C]onsider the implications of Star Enterprise's advertising that its new cigarette, Advance, yields fewer nitrosamines than conventional cigarettes. Informed that most cigarette smoke contains nitrosamines and that nitrosamines are carcinogenic, would smokers preparing to quit flock to the new cigarette instead, believing that it would greatly reduce their risk of smoking-induced lung cancer? The net health consequences are unclear: for those smokers who would have continued smoking anyway, switching to Advance might well reduce risk. For smokers who would have quit, or former smokers induced to start smoking again by the availability of this purportedly "safer" product, the active marketing of a low-nitrosamine cigarette clearly would increase risk. The net impact would depend on the unpredictable balance between such effects.[23]

Professor Kozlowski has developed a "risk/use equilibrium" chart[24] to assess the issue of individual risk reduction versus aggregate population impact. The chart compares the "decrease in danger (%)" displayed on the horizontal axis to the "multiplier to achieve equal risk" on the vertical axis.

According to Professor Kozlowski's analysis, a tobacco product that reduces risk by only 10 percent raises a difficult public health issue because an 11 percent increase in use of the product would offset the risk reduction in the population as a whole, and an increase in excess of 11 percent would result in a negative public health impact on the population as a whole. On the other hand, a tobacco product that results in a reduced risk in excess of 90 percent presents a relatively easy public health issue since the increase in usage necessary to offset the reduction in risk is so substantial—more that 1,000 percent—that it is highly unlikely to occur.

Given the predominant view in the public health community that the risk of adverse health effects associated with smokeless tobacco products is slight compared to that of cigarette smoking, researchers believe it is highly unlikely the public health benefit of cigarette smokers switching to smokeless tobacco would ever be offset by increased usage of smokeless tobacco.

Professor Kozlowski expressed his agreement with this conclusion in a recent publication entitled *Harm Reduction, public health, and human rights: Smokers have a right to be informed of significant harm reduction options,* in which he applied his "risk/use equilibrium" analysis to smokeless tobacco:

> When risks from a product are relatively small, the level of increased use needed to maintain a public health equilibrium (no changes in population-level problems) becomes very high (Kozlowski, Strasser, Giovino, et al., 2001)... For a product like snus, if the risk is even 1% that of cigarettes, use would have to increase 100 times to equal the problems from cigarettes. If the risk from snus were as much as 5% that of cigarettes, use would still have to increase an unlikely 20 times for the public health problems to equal those from cigarettes.[25]

E. The Swedish Experience

Proponents of encouraging "inveterate" cigarette smokers to switch to smokeless tobacco products point to the history of cigarette smoking and smokeless tobacco use in Sweden as support for their view. Swedish males have the highest rate of smokeless tobacco use and the lowest rate of cigarette smoking of any Western country, and the daily use of smokeless tobacco by Swedish males now exceeds that of cigarettes (18.2 percent daily smokeless tobacco users versus 17.1 percent daily cigarette smokers).[26] The following chart illustrates the changing pattern of tobacco use in Sweden during most of the past century, including the fact that smokeless tobacco use has overtaken cigarette smoking in recent years for the first time since World War II.[27]

Tobacco and health researchers have linked Sweden's low rate of "tobacco-related mortality" to its high prevalence of smokeless tobacco use and low prevalence of cigarette smoking:

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[23] Warner KE. Reducing harm to smokers: Methods, their effectiveness and the role of policy. In: Regulating Tobacco. Rabin RL, Sugarman SD (eds.) Oxford University Press, Oxford. 2001. Chapter 5, at pp. 133-134.

[24] Kozlowski L, Strasser AA, Giovino GA, Erickson PA, Terza JV. Applying the risk/use equilibrium: use medicinal nicotine now for harm reduction. (Editorial). *Tobacco Control* 2001; **10**: 201-203.

[25] Kozlowski LT (2002) at p. 58.

[26] Henningfield JE, Fagerström KO. Swedish Match Company, Swedish snus and public health: a harm reduction experiment in progress? *Tobacco Control* 2001; **10**: 253-257, at p. 254.

[27] Adapted from Swedish Match's Third Quarter Results, October 23, 2001, as posted on Company's web site. The figures cited reflect reported taxable shipments of snuff and cigarettes, measured in tons.

> Sweden, with a long tradition of smokeless tobacco use (16% of adult males use smokeless tobacco daily) and the highest penetration of NRT [nicotine replacement therapy] use, is the only European country that has reached (19%) the World Health Organization's target of 20% smokers in the adult population by the year 2000; about 35% of all nicotine consumed comes from nonsmoked deliver[y] forms. The tobacco-related mortality in Sweden is by far lower than in any other European or North American country, although nicotine consumption may not be lower than in other countries.[28]

In 2001, a *New Scientist* article summarized the Swedish experience in the context of tobacco harm reduction:

> [S]mokers [in Sweden] aren't faced with the quit-or-die dilemma. Instead of using a nicotine replacement therapy with the aim of quitting both smoking and ultimately nicotine, they can continue using tobacco as a recreational drug, safe in the knowledge that it probably won't kill them. It's all down to a product called 'snus,' a form of moist ground tobacco that you pop between your lip and gum.[29]

* * *

> The 'Swedish experiment,' as it has come to be known, has inspired some health campaigners to press for a more enlightened approach to the smoking epidemic. It's a concept they call 'harm reduction.' 'If you look at Sweden, we have a living example of the concept in action,' says Clive Bates, director of ASH.[30]

Also of interest is Swedish survey data regarding the use of smokeless tobacco as a smoking cessation aid presented at two scientific conferences in late 2002. At the *3rd International Conference on Smokeless Tobacco: Advancing Science and Protecting Public Health,* held in Stockholm, Sweden in September 2002, Dr. Lars M. Ramström, Director of Stockholm's Institute for Tobacco Studies, reported on a recent nationwide survey of a representative sample 6,700 adults in Sweden sponsored by the Swedish National Institute of Public Health. Dr. Ramström reports the following in the press summary of his presentation:

> "Among males snus is the most commonly used and most effective smoking cessation aid." In support of this conclusion, Dr. Ramström cites survey data indicating that "76% of male Ever Daily Smokers have made at least one attempt to quit smoking. Around 40% of the "triers" report that at their latest attempt they have used some kind of smoking cessation aid. 36% of these males have used nicotine gum, 20% nicotine patch and 55% have used snus as a smoking cessation aid. No other kind of cessation aid has been used by as much as 10%.[31] The proportion of those who have succeeded to quit smoking completely is 50% for gum users, 34% for patch users, 65% for snus users." [32]

At the *4th European Conference of the Society for Research on Nicotine and Tobacco: Improving Knowledge and Treatments of Nicotine Addiction,* held in Santander, Spain in October 2002, Clive Bates made a presentation entitled "Harm Reduction and Smokeless Tobacco." One of the points made was that "snus is an important factor in the low smoking prevalence in Sweden. It is used for cessation and as an alternative to smoking." He cited data from a 2001 survey commissioned by the Swedish Cancer Society reporting that, among 1,000 ex-smokers, 33% used snus as a smoking cessation aid, compared to 17% who used nicotine replacement therapies.[33]

The European Union white paper also points to smokeless tobacco as the explanation for Sweden's low rate of tobacco-related mortality:

> Evidence from Sweden suggests snus plays a positive public health role as a substitute for smoking and as an aid to smoking cessation. It is impossible to be definitive about this, because it is impossible to run a controlled trial on a whole nation.
>
> However, consider the following:
>
> • Sweden has the lowest levels of tobacco-related mortality in the developed world by some distance—approximately half the tobacco related mortality of the rest of the EU.

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[28] Balfour DJK, Fagerström KO. Pharmacology of nicotine and its therapeutic use in smoking cessation and neurodegenerative disorders. *Pharmacol Ther* 1996; **72**: 51-81, at p. 71.

[29] Wilson C. My friend nicotine. *New Scientist* 2001; **10**: 28-31, at p. 29.

[30] *Id.* at p. 30.

[31] Dr. Ramström noted that the total exceeds 100% because some smokers used more than one aid.

[32] Ramstrom L. Press summary entitled: Snus as a substitution for smoking—the Swedish Experience. See Website.

[33] Bates C. Presentation: Harm reduction and smokeless tobacco. See Website.

- Sweden has the lowest male smoking prevalence in Europe (16% daily) and low female (c. 22%) prevalence.
- However, it has comparable male *tobacco* prevalence and total consumption to neighbours Norway and Denmark—suggesting the big difference is in the type of tobacco used, rather than overall propensity to use tobacco or consume nicotine.
- About half of tobacco in Sweden is now consumed as snus—this share has steadily grown since 1970s.
- 33% of ex-smokers report use of snus—almost twice the number that report use of a pharmaceutical treatment (17%). Among males who have used a single aid to stop daily smoking, and succeeded to do so, some 70% had used snus and some 30% had used some kind of NRT.

Some have raised a question as to whether the Swedish experience is applicable to the United States, asserting that Swedish moist snuff products contain lower levels of so-called tobacco-specific nitrosamines (some of which have been reported to be laboratory carcinogens) than U.S. moist snuff products. For example, Professor Newell Johnson in an article published in 2001 entitled "Tobacco Use and Oral Cancer: A Global Perspective" conceded that "on present evidence, snuff habits as they exist in Scandinavia and probably in the United States carry lower risk of serious health hazards"[34] than cigarette smoking, but also made the following comment:

> In Scandinavia it is clear that local snuff is not a major risk factor: two recent case-control studies of oral cancer cases in Sweden have failed to show an association. This is because Swedish snus is not fermented and contains much lower nitrosamine levels than fermented tobaccos. The view that smokeless tobacco use may be associated with a lower risk of oral cancer in the United States has led to a movement to advocate the practice as a less dangerous alternative to smoking and an aid to nicotine withdrawal in those addicted to smoking.[35]

In fact, there is currently no significant difference in tobacco-specific nitrosamine (TSNA) levels in U.S. moist snuff products compared to Swedish moist snuff. Data reported in scientific literature by researchers from the American Health Foundation, together with data published by Swedish researchers,[36] show that the average levels of TSNAs in the major U.S. the moist snuff products decreased 77% between 1980 and 1994 (the last time that data for both of these products was reported in the scientific literature), and that currently there is no significant difference between the levels of TSNAs in those products compared to Swedish moist snuff products. A chart depicting this data follows:

> This view is supported by a report issued in 1997 by the Swedish National Board of Health and Welfare, which concluded:

Recent data suggest that the differences [in TSNA levels reported in American and Swedish moist snuff] have grown smaller, and that it is now questionable to make a sharp distinction between use of American and Swedish moist snuff when assessing risks—at least where TSNA content is concerned.[37]

F. The Gateway Issue

One argument relied upon by those who oppose the use of smokeless tobacco as a component of a tobacco harm reduction strategy is that smokeless tobacco may be a causal "gateway" to cigarette smoking, that is, smokeless tobacco use may cause consumers to later take up cigarette smoking.

The authors of the EU white paper reject the notion of a causal "gateway" from smokeless tobacco to cigarette smoking based upon their assessment of empirical data from Sweden and their analysis of the studies relied upon by those who argue that there is a "causal" gateway effect. Indeed, the authors of the EU white paper conclude that the Swedish data suggest that smokeless tobacco prevents rather than promotes cigarette smoking:

> **Gateway effects.** There is concern that smokeless tobacco will function as a lead-in to smoking for people that would not otherwise smoke. Such 'gateway

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[34] Johnson N. Tobacco use and oral cancer: A global perspective. *J Dent Educ* 2001; **65**: 328-339, at p. 328.

[35] *Id*., at pp. 332-333.

[36] Andersson G, Bjornberg G, Curvall M. Oral mucosal changes and nicotine disposition in users of Swedish smokeless tobacco products: A comparative study. *J Oral Pathol Med* 1994; 23: 161-167 (1993 Swedish data); Djordjevic MV, Brunnemann KD, Hoffmann D. The need for regulation of carcinogenic N-Nitrosamines in oral snuff. *Food Chem Toxicol* 1993; 31: 497-501 (1992 U.S. data and all earlier data); Hoffmann D, Djordjevic MV, Fan J, Zang E, Glynn T, Connolly GN. Five leading U.S. commercial brands of moist snuff in 1994: assessment of carcinogenic N-Nitrosamines. *J Natl Cancer Inst* 1995; 87: 1862-1869 (1994 U.S. data).

[37] Ahlbom A, Olsson UA, Pershagen G. Health hazards of moist snuff. *SoS Report* 1997; 11:3-29, at p. 7.

effects' are always contentious, and they are hard to demonstrate for the simple reason that we do not know what smokeless users would have done in the absence of smokeless tobacco—they may have simply moved straight to smoking. Gateways can act in the opposite direction too—they can be 'exits' rather than 'entrances'. Smokers may move to smokeless tobacco or use smokeless tobacco to quit, where they would otherwise have continued to smoke. Starters on smokeless tobacco may continue as smokeless users but otherwise have started with cigarettes, so that smokeless tobacco is a diversion from smoking. In both the US and Sweden, most smokeless tobacco use cannot be a gateway to smoking, either because smokeless users never started smoking or because they started smoking first. For the minority who started using smokeless before cigarettes they may or may not have had their smoking caused by smokeless use. **Exit or entrance gateway?** Understanding the order in which tobacco users take up different products is an important and necessary factor in establishing a gateway effect and whether the gateway is an exit from or entrance to smoking, but it is not in itself sufficient to establish a gateway from smokeless to cigarettes. The basic problem is that it is difficult to know whether those that start with smokeless tobacco would otherwise have started on cigarettes in the absence of smokeless tobacco. The data from Sweden suggest that the gateway is more likely to be an 'exit' from smoking than an 'entrance'. Among Swedish males with a primary use of snus no more than 20% ever started smoking, while 45% of other males did become smokers. In addition to this compelling evidence from the pattern of transitions, Sweden has the lowest rate of male smoking in Europe, combined with high levels of snus use. There is no other credible explanation for such low male smoking prevalence than the displacement and cessation of smoking through smokeless tobacco use. In total therefore, the Swedish data suggest that uptake of snus use prevents rather than promotes smoking and therefore contributes a net public health benefit. There have been studies in the United States that claim to show a gateway effect from smokeless tobacco use to smoking for a minority of smokeless users. However, these studies or related commentary have generally drawn causal inferences based on observation of transitions between often poorly defined categories of tobacco use, and sometimes from groups that are unrepresentative of the general population, such as the military. Psychosocial predictors of smoking initiation (school performance, parental smoking, risk taking etc.) can be used to assess which smokeless tobacco users might otherwise have been smokers. When these confounding factors are taken into account, the data do not show that initial smokeless tobacco use adds to the propensity to become a smoker.

Additional data from Sweden contradicting the theory of a causal "gateway" from smokeless tobacco to cigarette smoking was recently published by Rodu et al. in a paper entitled *Evolving patterns of tobacco use in northern Sweden*.[38] The researchers report on their analysis of data from a prospective follow-up study of approximately 3,400 men and women in northern Sweden, and describe the evolving patterns of tobacco use in this population over the period 1986 to 1999. While the researchers conclude that "the use of snus played a major role in the decline of smoking rates amongst men in northern Sweden,"[39] some of their data is of particular relevance to the "gateway" issue. They report that among men who used moist snuff but had never smoked at the beginning of the study, not a single person switched to cigarette smoking during the follow-up period of 5 to 13 years, and only 1 percent of these men used both moist snuff and cigarettes during the follow-up period.

G. Cigarette Smokers' Misperception that Smokeless Tobacco and Cigarettes Involve Equal Health Risks and Their Right to Accurate Information

At the November 2001 meeting of the National Conference on Tobacco or Health in New Orleans, Louisiana, Dr. K. Michael Cummings of New York's Roswell Park Cancer Institute, and his colleagues, presented results of a survey of a nationally representative sample of over 1,000 adult cigarette smokers regarding their beliefs about tobacco products. Of particular interest was the fact that 82% of adult cigarette smokers responded that they believed smokeless tobacco was just as likely to cause cancer as smoking cigarettes.[40]

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[38] Rodu B, Stegmayr B, Nasic S, Cole P, Asplund K. Evolving patterns of tobacco use in northern Sweden. *J Intern Med* 2003; **253**: 660-665.

[39] *Id.* at p. 660.

[40] Presentation by Dr. K. Michael Cummings at the National Conference on Tobacco or Health in November 2001.

Given these survey results, it was not surprising that in a 2002 publication, Dr. Cummings made the following comments regarding the comparative health risks of smokeless tobacco and cigarettes, and the need to provide adult cigarette smokers sufficient information to permit them to make informed choices regarding the tobacco products they choose to use:

> Competition to produce more consumer-acceptable medicinal nicotine products would be helped by educating consumers about what factors in tobacco products really contribute to disease risk. Ironically, many smokers do not perceive much difference in health risk between smokeless tobacco products, nicotine medications and cigarettes. Yet if all nicotine products were put on a risk continuum the actual difference between smokeless and nicotine medications would be seen as fairly minor compared to the difference in disease risk between smoked and smokeless products (Stratton *et al.* 2001). *Until smokers are given enough information to allow them to choose products because of lower health risks, then the status quo will remain.* Capitalism, and not governmental regulation, has the greatest potential to alter the world-wide epidemic of tobacco-related disease. (Emphasis supplied) [41]

Professor Kozlowski has also commented recently concerning the urgent need to provide cigarette smokers with information regarding risk reduction options and their right to receive such information:

> Cigarettes kill about half of those who smoke them . . . It is urgent to inform smokers about options they have to reduce risk. This needs to be done in ways that inform smokers as fully as possible that never starting and complete quitting as soon as possible are the best choices to promote health, while also indicating that snus or medicinal nicotine (the latter more than the former) would be preferable to continued smoking. Also, complete substitution of these products should be encouraged over mixing them with continued smoking. The harm reduction message will be complex. There will be many ways to give it. Some will misinterpret even the most artfully framed message. Notwithstanding, public health policy in this instance lacks compelling justification to override the human rights of the individual. Individuals have the right to such health relevant information.[42]

H. USSTC's Request for FTC Guidance

On February 5, 2002, USSTC filed a request with the FTC seeking issuance of an advisory opinion regarding the acceptability of communicating in advertising that smokeless tobacco products are considered to be a significantly reduced risk alternative as compared to cigarette smoking (See Website). USSTC noted in its request that issuance of an advisory opinion by the FTC would address an issue of significant public interest to adult tobacco consumers, USSTC, and other smokeless tobacco manufacturers. USSTC explained the rationale behind its request as follows:

> USSTC requests that the Commission issue an advisory opinion supporting the use of statements in advertising that provide the public with truthful and substantiated information about the harm reduction that a growing number of public health advocates believe can result from switching from cigarettes to smokeless tobacco products. The benefits of making such information available to consumers would be twofold: it would provide ready access to scientific opinion that otherwise would be difficult or costly to obtain, and it would help adult consumers make better educated choices about the tobacco products they use. As the federal agency with authority over tobacco advertising, the FTC should act affirmatively to provide guidance in this area.
>
> USSTC believes that the types of information it proposes to communicate in advertising are truthful, non-misleading and substantiated. At the same time, USSTC recognizes that cross-category (*i.e.*, smokeless tobacco advertisements directed at adult smokers) comparative advertising of reduced risk tobacco products raises issues which currently are the subject of ongoing public health debate. Providing USSTC with an advisory opinion would inform USSTC and other smokeless tobacco manufacturers of the criteria the FTC will apply when considering such statements. At a minimum, FTC consideration of these issues would advance the public debate on the issue of tobacco harm reduction, and increase the amount of information available to the public regarding reduced risk alternatives to cigarette smoking. Indeed, as part of its consideration of this request, the FTC may wish to hold a public workshop or similar forum to facilitate a full exchange of views on the issues involved.

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[41] Cummings KM. Can capitalism advance the goals of tobacco control? Addiction 2002; **97**: 957-958 at p. 957.

[42] Kozlowski LT. (2002) at p. 59.

USSTC's request made clear that any statement USSTC made would be truthful and non-deceptive, and gave an example of the type of statement contemplated:

> USSTC proposes to disseminate advertisements with the following or similar statements:
>
> > *The Surgeon General in 1986 concluded that smokeless tobacco "is not a safe substitute for smoking cigarettes." While not asserting that smokeless tobacco is "safe," many researchers in the public health community have expressed the opinion that the use of smokeless tobacco involves significantly less risk of adverse health effects than smoking cigarettes. For those smokers who do not quit, a growing number of researchers advocate switching to smokeless tobacco products.*

Following the submission of its request to the FTC, USSTC representatives met with FTC staff representatives on May 21, 2002 in order to present an overview of various issues relating to its request, as well as to answer any questions that might be raised by the FTC staff. Following the presentation and discussion, USSTC provided to the FTC staff additional information and documentation responsive to their requests. A similar meeting was held with representatives of Department of Health and Human Services public health agencies on May 30, 2002. Copies of the presentation materials relating to these meetings are annexed as Attachments B and C.

In the spring and summer of 2002, smokeless tobacco and tobacco harm reduction was the topic of discussion and debate at various scientific conferences and public policy forums in the United States and abroad. On May 16, the subject was discussed at a scientific conference in London entitled *Harm Reduction, Smoking and Smokeless Tobacco;* on May 29, the issue was the subject of a forum entitled *Marketing Highly Regulated Products* at Northwestern University in Chicago; on June 20 through 22, the issue was discussed at the *Third European Conference on Tobacco or Health* in Warsaw, Poland; on June 26, the issue was debated at a seminar sponsored by the American Council on Science and Health in New York City; and on July 16, the issue was the subject of debate at the CATO Institute in Washington, DC.

In the summer of 2002, USSTC became aware of the scheduling of two very important scientific conferences that would include a public debate directly relevant to USSTC's request. On September 22 through 25, 2002, the Centers for Disease Control, the National Cancer Institute, and the Stockholm Center of Public Health, Center For Tobacco Prevention, would sponsor the *3rd International Conference on Smokeless Tobacco: Advancing Science & Protecting Public Health,* in Stockholm, Sweden. The conference would bring together leading experts on smokeless tobacco, and feature a session on tobacco harm reduction. Similarly, the *4th European Conference of the Society for Research on Nicotine and Tobacco* was to be held on October 3 through 5, 2002, in Santander, Spain. This conference would also include discussion and presentations of research findings on current scientific issues relating to smokeless tobacco, including harm reduction. In view of the pendency of these scientific conferences, on August 12, 2002, USSTC temporarily withdrew its request for an advisory opinion so that it would have the opportunity to provide for the FTC's consideration significant new information expected to be presented at these conferences.

On May 9, 2003, USSTC submitted to the FTC information regarding smokeless tobacco as a reduced risk alternative to cigarette smoking that had been presented or published subsequent to the August 2002 temporary withdrawal of its request for FTC guidance. As expected, the Stockholm and Santander conferences produced important new information relevant to USSTC's request. More significantly, however, two publications had appeared in late 2002 or early 2003 that will have a major impact on the public debate regarding smokeless tobacco in the context of tobacco harm reduction. Those publications, discussed above, are a report from London's Royal College of Physicians and a white paper prepared by a group of European tobacco and health researchers and public health advocates. In addition, several other scientific publications or documents had appeared that were relevant to USSTC's request for FTC guidance.

Significant new information from the above-referenced scientific conferences and publications was reviewed in USSTC's May 9, 2003 filing, submitted together with copies of the referenced materials (See Website).USSTC suggested in its submission to the FTC that the Commission may wish to consider holding a workshop or other forum to address the appropriateness of conveying tobacco harm reduction information as part of smokeless tobacco advertising. USSTC continues to believe that such a workshop would afford all of the participants in this public health debate an opportunity to present their views in a constructive and productive manner. It might also help form a consensus as to how we move forward on this important public

health issue and could provide guidelines to ensure that any comparative risk communication is directed at adult smokers to avoid any unintended consequences.

III. CONCLUSION

Some tobacco control activists have taken the position that USSTC should be prevented from communicating to adult cigarette smokers the prevailing view in the scientific community regarding the comparative health risks of tobacco products. Interestingly, they also believe that neither the federal government nor the public health community has any responsibility to undertake that task.

On the other hand, some in the public health community believe that communication of that vital information could have a significant positive impact on the lives of adult cigarette smokers. Indeed, some in the public health community believe that USSTC must confront the question of whether it has a responsibility to step forward and communicate this critical information to adult cigarette smokers in light of the vacuum created by the federal government and the tobacco control activists.

Mr. VERHEIJ. Thank you.

Mr. STEARNS. Mr. Myers.

STATEMENT OF MATTHEW MYERS

Mr. MYERS. My name is Matthew Myers. I am the President of the Campaign for Tobacco Free Kids, and I am here today representing my organization.

Today this committee has bene given a false choice. It is not about whether more should be done to reduce the harms of tobacco but how. This committee and its members do not face the Hobsean choice, do nothing or choose to use smokeless tobacco. The choice is not quit or die.

Every one of the major public health organizations in this nation have an agenda for how we can reduce the death toll of tobacco. This committee, if it is serious about reducing the death toll of tobacco, has a prominent role to play.

Let me start out by saying there are constructive things that we can and should do together. Despite the rhetoric, this nation has never funded a sustained, national, preventive public education campaign aimed at tobacco, either at children or to help people quit. If we want to reduce the number of people who smoke, States like Massachusetts, California, and Mississippi have shown we can do a great deal that we are not doing.

Two, the Department of Health and Human Services Interagency Council on Smoking and Health have come up with a comprehensive report on smoking cessation. If we want to help those smokers quit, the answer is not to throw up our hands, as Mr. Rodu suggested. We have learned in states that have adopted aggressive programs with quit lines and access to smoking cessation programs that we can dramatically reduce the number of people who smoke.

We all say that there are people out there who cannot quit, and there are, but there are many people out there who can quit who we have not helped.

Three, there are proven smoking cessation products out there that have been shown to be safe and effective. We are doing far too little to encourage their broader use for harm reduction, to encourage their development in a manner that will make a major difference.

And, fourth, our organization and every one of the major organizations in this nation have come before this committee before and have urged this committee to grant the Food and Drug Administra-

tion comprehensive regulatory authority over all tobacco products. If we want to do harm reduction based on science, not rhetoric; if we want to make the truism that knowledge if power, then we will insure that there is a government agency that has regulatory authority over the product so that we will know and consumers will know what is in that product; so that we will know and consumers will know truthfully not just what the manufacturers want us to know but the truth, the full truth about the relative harmful effects of those products.

We will be in a position where we will be able to control the advertising. So we will not have to have a rhetorical debate in the abstract about whether marketing of relative health claims will make a difference in terms of the number of people who start or stop. We will have the authority of the agency to accomplish the goal we set out in this case.

So that if this committee is truly serious about reducing the harms caused by tobacco, let me suggest there are three things we can do right off the bat. Let me also ask that we have this debate today about the use of smokeless tobacco in the real world, and the real world is this.

As Dr. Carmona has said, smokeless tobacco as used in the United States has been conclusively shown to be a cancer causing agent. Smokeless tobacco as used in the United States is different than smokeless tobacco as a produce used in Sweden. It has far higher levels of nitrosamines, and in my testimony I have provided you specific studies that have been done that demonstrate that smokeless tobacco in the United States has infinitely higher levels of nitrosamine. The two most popular products, both made by UST fall into that category.

Second, smokeless tobacco product or snus, as Congressman Cubin referred to it, in Sweden is controlled for other things. It is controlled for cadmium, lead, arsenic, nickel, chromium, benzopyrene. It is controlled for none of those things in the United States.

If Sweden has a different experience, it is because they have a different regulatory regime. They have a different product.

Three, Sweden is different for another reason that we need to think about seriously. Sweden bans tobacco advertising. Smokeless tobacco companies in Sweden did not make health claims on advertisements. That is not what happened. The scientific community communicated accurate, helpful information to consumers in the absence of consumers being bombarded by uncontrolled advertising, and that is what I really want to talk about here.

In the United States today, in the absence of FDA regulation over this industry and this product, what are we really talking about when we are talking about this. Well, let me show you the reality of where we will see advertisements for smokeless tobacco products with claims that they are safer.

Off to my left are two ads. The first ad on the far right is "Cock-a-Doodle Freakin' Do." When we met with U.S. Smokeless Tobacco and said is this the kind of advertisement that under current law you would be permitted to make this claim in, the answer was yes.

When we asked would the FTC have the authority to prohibit you from making such a claim in that ad if you got what you want-

ed, the answer to that was no. They did say, however, that that ad embarrassed them because of its obvious appeal to kids, and on February 28, 2002, wrote to us to say that ad would never appear again.

Well, it did not. The ad on the left did. The reality is in the absence of meaningful regulation over tobacco marketing, it is not a guess. It is a virtual guarantee that we will do the same thing that we did in the 1980's, use this kind of advertising to expand the number of children who use tobacco products.

And let me suggest when it is a child who uses smokeless tobacco, we are not talking about reduction of risk. We are talking about a cause of cancer.

Now, a second thing that is very important and a very real concern——

Mr. STEARNS. I just need you to sum up.

Mr. MYERS. And I will.

The risk of using smokeless tobacco to discourage quitting of those who cannot is also very real. Two thousand, the President of UST in describing his marketing strategy explicitly said the goal is dual use.

For people who might otherwise quit because of clean indoor air restrictions, we want them to be able to use this product. For people who switch to dual use, they increase the risk of disease.

And let me just finish with one critical last point. It is nice to have this debate in the abstract. We have to have it in the reality. There may be a place to discuss the role of smokeless tobacco, but it should take place only after this committee has worked with the rest of the Congress to grant the Food and Drug Administration the kind of regulatory authority to accomplish the goals you have all talked about.

We heard a great deal today about 400,000 people dying. There is much we can do to solve that problem.

[The prepared statement of Matthew Myers follows:]

PREPARED STATEMENT OF MATTHEW MYERS, PRESIDENT, CAMPAIGN FOR TOBACCO-FREE KIDS

Good morning Mr. Chairman, and members of the Committee. My name is Matthew Myers. I am the President of the National Center for Tobacco-Free Kids, a national organization created to protect children from tobacco by raising awareness that tobacco use is a pediatric disease, by changing public policies and by actively countering the special interest influence of the tobacco industry.

Mr. Chairman, I want to thank you for inviting me to testify on the question of whether tobacco, and specifically smokeless tobacco, can cure smoking. The question seems simple and straightforward enough, and so deserves a simple and straightforward response. The answer today is the same as it was almost twenty years ago when the House Energy and Commerce Committee last held hearings on the health effects of smokeless tobacco products. In the absence of the kind of meaningful regulation of both the content and marketing of smokeless tobacco products that could be provided by the Food and Drug Administration (FDA), the answer is no.

SMOKELESS TOBACCO IS A CAUSE OF SERIOUS DISEASE

Let us start with a basic premise: smokeless tobacco products as sold in the United States have been found to increase the risk of oral cancer and other serious diseases. The Surgeon General, the National Cancer Institute, the American Cancer Society, the American Dental Association, the Scientific Advisory Committee to the World Health Organization and numerous other scientific bodies have all determined that there is conclusive evidence that smokeless tobacco products as sold in

the United States increase the risk of serious disease. This conclusion is no surprise. Scientists have identified twenty-eight cancer-causing chemicals in these products.

Today we are seeing history repeat itself. Just as we had the last time this committee met to discuss smokeless tobacco, we have a smokeless tobacco industry that refuses to acknowledge the health effects of its products seeking government approval to use health-related claims in advertising whether or not that advertising's primary appeal is to children. In 1985 the then President of the Smokeless Tobacco Counsel testified before this Committee "it has not been scientifically established smokeless tobacco is a cause of any human disease." In April 1999, a spokesperson for the United States Smokeless Tobacco Company, a subsidiary of U.S. Tobacco (UST) was quoted in the *Providence Journal* as claiming that it has not been "scientifically established" that smokeless tobacco is "a cause of oral cancer." This statement resulted in the Rhode Island Attorney General suing UST for violating the multi-state settlement agreement's prohibition on making false statements about the health effects of its tobacco products. UST was required to pay $15,000 to the Attorney General's office to fund efforts to prevent youth tobacco use and to formally acknowledge that the Surgeon General and other public health authorities have concluded that smokeless tobacco is addictive and can cause oral cancer.

Just last year, UST claimed in a letter to the Federal Trade Commission (FTC) that "smokeless tobacco has not been shown to be a cause of any human disease." UST would have this committee think that it is new evidence that has motivated it to seek approval to market its products as a safer alternative to cigarettes. The unfortunate reality is that this is a company that has never acknowledged that its products cause harm. How can you have a meaningful discussion about the potential to use a cancer-causing product to reduce the harm from smoking with an industry that won't acknowledge that its products cause harm and hasn't agreed to meaningful government regulation?

SMOKELESS TOBACCO ADVERTISING HAS INCREASED YOUTH USE

There is a second basic point about which there can be no dispute. Twenty-five years ago few young people in this country used smokeless tobacco products. However, in large part in response to a massive marketing campaign that in part portrayed smokeless tobacco use as safer than cigarette smoking, the number of people who used these products and the demographics of who used these products changed in the early 1980's. Smokeless tobacco usage among young males rose dramatically. As a nation we experienced a sixty percent upswing in smokeless tobacco use among young men resulting from a decade of smokeless advertising. The lesson is clear: in the absence of meaningful government regulation, our children are vulnerable to smokeless tobacco marketing that portrays smokeless tobacco use in a manner that kids find acceptable. Largely because the major smokeless tobacco manufacturers have fought FDA regulation of both their products and their marketing, our kids are as vulnerable today as they were 25 years ago.

Was it an accident that smokeless tobacco use rose in the 1980's even as the leading smokeless tobacco companies argued that they didn't market to kids? The answer from their own documents is no. According to internal company documents, UST developed a graduation strategy some time ago for hooking kids as new smokeless tobacco users. As one document states:

> *"New users of smokeless tobacco attracted to the product for a variety of reasons are most likely to begin with products that are milder tasting, more flavored, and/or easier to control in the mouth. After a period of time, there is a natural progression of product switching to brands that are more full-bodied, less flavored, have more concentrated 'tobacco taste' than the entry brand."*

UST has also used the addition of flavorings to increase the appeal of its products to children. In 1993, cherry flavoring was added to UST's Skoal Long Cut, an entry or starter product. A former UST sales representative revealed that, "Cherry Skoal is for somebody who likes the taste of candy, if you know what I'm saying."

Many had hoped that when the United States Smokeless Tobacco Company signed its settlement agreement with the states in 1998 its marketing practices would change dramatically. It did not happen because UST has apparently interpreted the broad prohibition against targeting youth as not requiring it to change the kind of advertising and youth oriented imagery that it has previously used that has made its products so appealing to children. A May 2002 study by the Massachusetts Department of Public Health found that UST's overall magazine advertising increased 135% from 1997 to 2001. The study also found that UST's advertising in magazines with high youth readership increased 161% during the same time period. For the period 1997-2001, UST's expenditures in youth magazines increased from $3.6 million to $9.4 million. Thus, smokeless tobacco advertising that appeals to

children has continued unabated. One only has to look at the images projected by this advertising to understand its appeal to children. While UST may increase or decrease its advertising in certain magazines for its own purposes when it chooses, the evidence is that the MSA has not provided the legal club that was anticipated. In addition, although the multi-state settlement agreement has limited UST's ability to continue to do brand name sponsorships of some events and teams, UST continues to be a promotional sponsor of both professional motor sports and rodeo and bull riding.

There is a legitimate concern that in the absence of meaningful government regulation of smokeless tobacco products, and how they are marketed the disastrous experience of the early 1980's could be duplicated again today. If that occurred, more lives would be needlessly lost as the result of an effort that started out seeking to reduce the harm caused by tobacco products.

NOT ALL SMOKELESS PRODUCTS ARE ALIKE

There is a third fundamental point—not all smokeless tobacco products are alike. UST has continued to market products far higher in one cancer-causing class of agents—nitrosamines—than its counterparts in Sweden, despite the technical ability to produce low nitrosamine products. Data concerning Swedish snus is often cited by UST in support of its desire to market its products—all of its products, including its products with very high nirtrosamine levels—as a way to reduce the risks of tobacco use because of some data that indicates that it has not been associated with an increase in cancer in Sweden.

Swedish smokeless products are much lower in cancer-causing nitrosamines than U.S. products. In 1995 the average Tobacco Specific Nitrosamines (TSNA) in Swedish Snus was approximately 5 mg/kg. By 2000 that number had been reduced to 2 mg/kg. An independent study conducted for the State of Massachusetts by the American Health Foundation in 2001 found, in contrast, that while the Swedish snus it tested contained 2.8 ug/g TSNA's, UST's two largest selling products—Skoal and Copenhagen contained 64 ug/g and 41.1ug/g TSNA levels, respectively.

Even more disturbing, a new study just conducted by the American Health Foundation for the Massachusetts Department of Health that examined nitrosamine levels in snuff over the last three decades found that nitrosamine levels actually rose in one of the two most popular American brands in 2003 after declining in 2002. The American Health Foundation found that the TSNA levels in these brands this year were 22.0 and 27.9 ug/g respectively—levels far higher than those found in Sweden at any time in the last thirteen years. These findings are critical to the Committee's consideration because TSNA's are widely accepted as the most serious carcinogens in oral snuff made in the United States.

The American Health Foundation discovered another distinction between American smokeless tobacco products and Swedish snus. The nitrosamine levels of U.S. smokeless products increase once they leave the manufacturing plant and continue to increase the longer they sit on the shelf, in one case by an amazing 137 percent over six months. Swedish snus does not. It is clear that American manufacturers like UST know how to produce low nitrosamine smokeless tobacco products, but have chosen not to do so in their most popular products.

Nitrosamines are not the only harmful component in smokeless tobacco products and this is another distinction between American smokeless tobacco products and those in Sweden. Swedish snus is also controlled for heavy metals found in smokeless tobacco products, like cadmium, lead, nickel and chromium, as well as substances such as arsenic, BaP's, and pesticides. None of those controls apply to American products. It is for these reasons that organizations like the Scientific Advisory Council to the World Health Organization in November 2002 distinguished between the evidence that it found conclusively linked U.S. smokeless tobacco products and oral cancer and the evidence that it found that the health effects of Swedish Snus were more uncertain.

There is a third distinction between what is described as the Swedish experience and the likely result in the U.S. The marketing and advertising of smokeless products in the United States and Sweden is completely different. Sweden forbids the marketing and advertising of all tobacco products, and no claims in advertising about relative safety of these products are permitted. In the United States there are few restrictions on the advertising and marketing of smokeless tobacco products, and UST wants to make explicit claims about the relative safety of its products.

The difference in the laws governing marketing in the two countries is critical. When our organization met with representatives of UST and asked if they believed that there was anything to prevent UST from using ads featuring roosters with what we perceived to be youth oriented slogans placed in youth oriented magazines

to promote their products as less hazardous than cigarettes, they were quick to say no. They went further. UST said that if they were given permission to claim that their products were less hazardous than cigarettes, it was their belief that the FTC did not have the legal authority to tell them what kinds of ads or magazines those claims could appear in.

CLAIMS OF REDUCED RISK COULD DISSUADE SMOKERS FROM QUITTING

There is a fourth fundamental point. Another potential risk to permitting smokeless tobacco to be marketed as a harm reduction mechanism in the absence of meaningful government regulation is that claims of risk reduction could lead smokers who would otherwise quit not to do so. The risk is real. In August 2001, UST announced plans to market a new smokeless tobacco product called Revel. UST is marketing the new product as a way to consume tobacco in places or situations when smoking is not allowed or is not socially acceptable. Many smokers quit after the enactment of restrictions on smoking in the workplace. There is legitimate concern that in the absence of any regulation of where and how smokeless tobacco products are marketed, some current cigarette smokers who would otherwise quit will switch instead to Revel or other smokeless products. This concern is compounded by studies that show that claims of reduced risk can lead consumers to falsely underestimate the relative benefits of quitting versus switching.

THERE IS MUCH THE FEDERAL GOVERNMENT CAN AND SHOULD DO TO REDUCE THE HARM OF TOBACCO PRODUCTS

My fifth point: There is a great deal that can and should be done to reduce the harm caused by tobacco. It is a misplaced priority to focus so much attention on smokeless tobacco in the current environment when there is so much that everyone agrees on that will make a real difference. Let me highlight some of the actions this Congress and the executive branch could take that will reduce the harms currently being caused by tobacco use in our society.

1) The federal government is doing far too little to fund programs or adopt policies that have been proven effective in reducing tobacco use. Comprehensive tobacco prevention programs have been proven to work in every state that has tried them. Yet, the federal government has not funded a meaningful national sustained public education campaign.

2) The federal government is doing far too little to fund cessation programs or to promote and make available the cessation tools that have been proven to help smokers quit. A recent Report conducted at the request of the Department of Health and Human Services laid out a comprehensive plan to encourage and assist smokers to quit. It should be adopted and implemented.

3) The FDA already has authority over FDA approved medicinal nicotine products. These products have been proven to be safe, at least for short-term use, but little has been done to encourage their improvement or to explore their long-term use and potential for harm reduction. Before we turn to a cancer-causing agent as a tool to reduce the harms caused by tobacco, shouldn't we first make sure we have done everything we can to maximize the potential role of safe products that our government has already reviewed and approved? FDA can initiate a review of the use of nicotine replacement products without the need for further legislation, and it should do so.

COMPREHENSIVE REGULATION OF TOBACCO PRODUCTS BY THE FDA IIS A NECESSITY

My sixth and, perhaps, my most important point: The single most important action this Congress can take to reduce the harm that current tobacco products are causing is to provide the FDA with meaningful authority over all tobacco products. In case we needed further proof, a study conducted by scientists at the Centers for Disease Control and Prevention published in the journal *Nicotine & Tobacco Research* just last Friday demonstrated once again that without a federal agency that has oversight over tobacco products consumers are being deprived of critical information about the risks of individual products and are being sold products that contain more toxins than are necessary. The study found that even while tar levels in Marlboros have gone down over the last several decades, nitrosamine levels in Marlboros have increased and are higher, in fact, than most locally produced popular brands in other countries throughout the world.

The high nitrosamine levels may provide at least a partial explanation for why cancer rates have not declined as expected when tar levels declined. Don't be confused; the importance of this study is not that we can save lives if we just reduce nitrosamine levels in Marlboros. The real importance of this study is that there are dozens of known carcinogens and toxic substances in current tobacco products that

we are not controlling and about which the public is not being informed. This study proves that the reduction of any one toxin may have little impact if you don't control the level of other toxic substances, and that you cannot count on manufacturers on their own to provide this information truthfully and completely to consumers. The lesson is clear—what you don't know will kill you. In the absence of government regulation tobacco manufacturers—smokeless and cigarette—will not produce the least hazardous product possible and consumers will not have the type of complete information needed to make a truly informed choice.

The latest study reminds us that in the absence of a governmental agency with the authority to require manufacturers to test and disclose the toxic substances in their products, claims that any tobacco products reduce the risk of tobacco-related disease should not be trusted or permitted. Our experience with both light and low tar products demonstrates why this is so important. For decades tobacco manufacturers have advertised light and low tar products in a manner that they knew led consumers to believe that these products were safer than traditional cigarettes. The evidence is now conclusive that these light and low tar products have not in fact reduced the overall risk of disease. This public health tragedy could have been avoided if tobacco manufacturers had been required to disclose to the FDA the levels of different toxins in their products and their knowledge about the actual levels of tar and other harmful substances that consumers were receiving.

Mr Chairman, this hearing dramatically underscores the pressing need for Congress to give the Food and Drug Administration the authority to regulate tobacco products effectively. A discussion about harm reduction has to begin with a discussion about providing the FDA with the kind of authority that is necessary to protect consumers, verify claims, and require that all reasonable steps are taken to reduce the harm caused to smokers. Is there a role for smokeless tobacco in a comprehensive effort to reduce the death toll from tobacco overseen by the FDA? No one has the information to make that decision today. The FDA should be open to all strategies that are scientifically based and that will save lives. The decision about what role smokeless tobacco plays in that overall scheme is a decision that can only be made by the FDA after it has all of the relevant information before it.

Why the FDA? The FTC lacks both the authority and the expertise to do the job by itself. I worked at the Federal Trade Commission and was responsible for that agency's tobacco-related activities. The job of the FTC is to stop false, deceptive or misleading advertising. It is not a science-based agency. It lacks the authority to restrict smokeless tobacco marketing that appeals to children or to prevent claims of reduced risk to be used to make these products more attractive to children. It further lacks the authority to evaluate different smokeless tobacco products for relative safety, to require smokeless tobacco manufacturers to disclose to it changes in the product that could impact its relative harm or to require smokeless tobacco manufacturers to lower the level of toxic substances in their products. The FTC is most effective when it is able to work with the FDA with regard to products over which both have jurisdiction. If FDA is given this authority over tobacco products, the two agencies working together could make a very positive difference.

Mr. Chairman, if UST and the other smokeless tobacco companies are serious about reducing the harm caused by tobacco and about assuring that the marketing of its products as less hazardous contributes to public health, they would support giving FDA the strong authority it needs to regulate tobacco products as outlined by the major public health groups. I have no doubt that FDA would have had this authority already but for the opposition of the major cigarette and smokeless tobacco manufacturers. They should not now be rewarded for their opposition to meaningful government regulation by being permitted to make health-related claims that we lack the ability to verify only because of the lack of such regulation.

Mr. STEARNS. And I thank the gentleman.

Mr. Sweanor.

STATEMENT OF DAVID SWEANOR

Mr. SWEANOR. Thank you very much, Mr. Chairman.

I am David Sweanor. I am a lawyer based in Canada. I spent the last 20 years working full time on a broad range of tobacco control activities both in Canada, where I am very pleased with a lot of what we have accomplished, including the last 12 months. We appear to have knocked per capita consumption down by over 12 percent, which is a world precedent setting rate of decline.

I have also been very involved in activities globally, although the views I express today are going to be those of mine and not for any of the organizations I have worked for.

The public policy goal, public health goal of tobacco control is important to keep in mind. What we are trying to do is to reduce death and disease, and there is three broad ways we can do that. We can reduce tobacco onset. We can facilitate cessation, and we can reduce toxicity for those who use the product.

This is important because the status quo is truly horrible. We have got a product that dominates the market that kills half of its long term users. Among these long term users we have people who believe that nicotine itself is what causes cancer. Many people do not want to use medicinal nicotine products because of the fear of cancer. They are less likely to use them. They will not use them as long as they should or as much as they should.

They believe smokeless tobacco causes cancer at least at as great a rate as smoking. And perhaps most importantly, they believe light cigarettes are significantly less hazardous.

Well, what do we do with a mess like this? And I think that a key part of understanding potential solutions is to recognize that though nicotine is a primary reason people would be smoking, combustion is a primary reason that they are dying.

So that in theory at least reduced risk products make a tremendous amount of sense, and I think properly regulated by a body like FDA, these products have the potential to complement the other aspects of what we are doing in tobacco control of supporting what we are doing to prevent onset and to encourage cessation.

But this is not merely theoretical. We do have examples of elsewhere in the world where medicinal products are given a broader range of indicated uses. We have examples of people who have used medicinal products for years with no apparent ill effects.

We do have the example from Sweden where there has been a massive transformation in their market from one dominated by cigarettes to one dominated by smokeless tobacco, with a concomitant decline in the rates of disease that follows smoking. It does not follow tobacco use.

In theory at least, there is a spectrum of risk here, and there would be the ability to offer products with information so that consumers get to decide where in that spectrum they want to be. I think to work though, you do need to have some form of comprehensive regulation. Without it, you cannot guarantee public health. You cannot give consumers protection, and I would argue you cannot effectively allow the operation of a marketplace because there is a whole lot of questions that come out, such as how do we know that a product really does reduce risk on a one for one basis compared to a standard cigarette.

I would say that is fairly easy. There is no problem dealing with that dealing with medicinal nicotine. I don't think there is any problem with that dealing with low nitrosamine smokeless tobacco. The Surgeon General clearly does.

How would we know that a product might only reduce some or what would be the impact if it only reduces some of the cigarettes somebody might otherwise smoke? Where does the product fit on that spectrum of risk? How does it impact on things like cessation

and youth uptake, and how do you communicate a message to the public?

Because one of the problems we have now is that even totally truthful communications from a tobacco company will probably not be believed. There has to be some way that people can get honest communications that are believable so that they are in a position to do something that their own health.

I think these are very difficult issues, but I think that there is also a need for prompt action. You have got roughly 1,300 Americans dying every day as a direct result of cigarette smoking. What do we do?

Well, we do need that broad regulatory framework for all tobacco products, and in the meantime, we need to look at things like what should we do with medicinal nicotine. I mean, one of the clear consensuses that I have been hearing here today is that everybody seems to think we should have broader access to these products.

Well, surely there can be some way that your committee can alert the FDA and the FTC that you want them to do that. You want them to examine the role of these products in harm reduction. While they are at it, what can they do to set something in place that allows the manufacturers of smokeless products to come forward and say, "Here is what we have got on offer as well."

There ought to be more discussion about this. There needs to be a way that people can dialog and discuss what is happening because I do not think it is any longer a question of will there be alternative products or should we give information to consumers. It is a question of how are we going to evaluate those products and how are we going to get truthful information to consumers in a way that is actually going to allow them to make more informed decisions about their own health.

Thank you.

[The prepared statement of David Sweanor follows:]

PREPARED STATEMENT OF DAVID SWEANOR, COUNSEL, NON-SMOKERS' RIGHTS ASSOCIATION

Thank you very much for the opportunity to appear before this committee to talk about a truly critical issue for global public health.

My name is David Sweanor, and I am counsel to the Non-Smokers' Rights Association [NSRA] in Canada, an organization I have worked for for over 20 years. NSRA has been a primary driver for a very full range of public health policies aimed at reducing the toll from tobacco. These include health-oriented tobacco tax policies, restrictions on tobacco sales, comprehensive restrictions of tobacco advertising and promotion, detailed package-based heath information—including picture-based warnings covering 50% of packages and package inserts giving additional health information, comprehensive disclosure of additives and sales data, and regulatory authority over tobacco manufacturing standards. These policies have played a key role in very significant drops in Canadian tobacco consumption, which have outpaced US declines. Last year alone, and largely due to very significant cigarette tax increases, per capita consumption in Canada fell by 8%. I believe that this is two to three times the rate of decline in the US.

In addition to my work in Canada I have, for many years, been very involved in tobacco control issues in this country, and globally. It is because of my interest in global public health, combined with the policy interactions between Canada and the United States, that I welcome the opportunity to speak to you today.

THE PUBLIC HEALTH GOALS FOR TOBACCO POLICY

It is possible to articulate a concise view of the public health goals of tobacco control activities. The ultimate goal is to reduce death and disease as much as is practically possible within the constraints of law and with respect for human rights. To

achieve this goal there are essentially three broad areas of intervention. We can expand current efforts to prevent smoking onset and that encourage and facilitate cessation but we must also reduce the toxicity for those who continue to use tobacco.

While many nations have done much to try to prevent onset of smoking, far fewer have made significant strides in promoting and facilitating cessation, and almost none have moved significantly on issues of toxicity reduction. This is a major concern to me since preventing the uptake of smoking, even when successful, will not have a significant impact on disease rates for another 20-30 years due to the lag between the onset of smoking and the development of the resulting diseases. To put this into an American perspective, the World Health Organization estimates that roughly 10 million Americans will die as a direct result of cigarette smoking in the next 20 to 25 years. All of these people are currently smokers, most say they'd rather not be smoking, and only cessation and toxicity reduction can impact on this unfolding tragedy.

In short, the status quo is horrible. Cigarettes dominate the market, and will kill roughly 50% of their long-term users. Few consumers turn to FDA approved Nicotine Replacement Therapies such as the patch, oral inhaler, and lozenge. FDA-approved products have slowly increased in sales but consumers currently have far too few choices to replace their cigarettes and inadequate information to facilitate changes in their delivery system. The development of long-term replacement products appears to have been stymied by the FDA, and there has been no meaningful consideration of using these products for long-term harm reduction. It makes no sense that so little consideration has been given to how to better use products that the FDA has reviewed and approved as safe—at least for short term use—to address the broader problems of how best to help more people quit and how to help about smokers who have tried to quit and can't. It also makes no sense that there has not been more discussion about whether or under what conditions smokeless tobacco products might be used to reduce the disease risk for smokers who cannot quit. The fact that prestigious bodies such as the Royal College of Physicians have pointed out that smokeless tobacco can be between 90% and 99.9% less hazardous than cigarettes cries out for serious examination of how these products can be used as part of an overall effort to reduce tobacco's health toll.

THERE MAY BE A WAY OUT OF THIS MESS.

Nicotine is the primary reason for tobacco use. It provides various pharmacological effects sought by many smokers. But it is also, especially when delivered through cigarette smoking, highly addictive. Yet nicotine itself is apparently responsible for only a very small part of the health damage caused by tobacco use. The reason smokers are dying in such great numbers is that they are obtaining their nicotine through the repeated inhalation of smoke. Nicotine provides the demand for tobacco, but it is combustion that is the principal reason for the morbidity and mortality.

Simply put, cigarettes are an exceedingly "dirty" delivery system for the drug nicotine. If Americans got their nicotine by brewing tobacco leaves and their caffeine by smoking tea leaves we would be looking at a very different national disease profile, with tea likely responsible for hundreds of thousands of deaths per year and tobacco very likely a sidelight on the broader health picture.

Replacing "dirtier" delivery systems with cleaner ones is an obvious measure to take in efforts to reduce toxicity for those who are going to continue using nicotine. Different nicotine delivery devices will have differing levels of risk. Theoretically we could place all these products on a spectrum and look at ways to give information and other incentives that would encourage consumers to move toward the lowest risk products that can still meet their needs. And one could also imagine a system of incentives that would encourage manufacturers to work to create products with lower and lower toxicity levels.

But, like most seemingly straightforward public policy solutions it gets rather complicated in the real world. If it were truly easy to prevent a half million deaths a year in this country I am sure these hearings would not even be necessary since the corrective measures would have been taken many years ago.

THE COMPLICATING ISSUES

We need to avoid making or reinforcing the mistakes of the past. Millions of smokers smoke "light" and "mild" cigarettes in the false believe that they are actually safer. It took years for independent scientists and governments to discover that these products are actually part of a massive consumer deception on relative risk. An effective harm reduction strategy must begin with an end to all forms of deception on relative risk and comprehensive science based regulation of all tobacco prod-

ucts and the marketing for those products. There needs to be a governmental agency that knows the whole truth about the relative health risks of different products and that is in a position to insure that consumers are provided the whole truth in a non-misleading way that promotes the overall public health. Without comprehensive regulation both the government and consumers cannot be sure they have complete information or the tools to best protect the public health.

Regulation is only a first step, and is not an end in itself. It needs to be based on clear goals. Here, briefly, are some of the issues I think we need to consider when looking at potential reduced-risk products:

1. **What is the degree of certainty that we want to have that a product truly does reduce risk compared to standard cigarettes?** On a one-for-one basis this is not a difficulty when looking at medicinal nicotine products such as the patch and nicotine gum that are already fully regulated. It should also not be a difficulty with low nitrosamine smokeless tobacco, given the massive differences in potential disease risk compared to cigarettes, if there was a mechanism that could stipulate the actual level of nitrosamines and other harmful substances in these products. If all cigarette use were simply replaced by medicinal nicotine and low nitrosamine smokeless tobacco products the death rates would be massively lower. But there are many products, especially combustion-based products, where the degree of risk reduction is by no means understood. There needs to be some system in place that can credibly evaluate the relative risks of all tobacco products.
2. **What about the risk from a product that only replaces some cigarettes?** It is quite possible that a product could be far less hazardous than cigarettes, but replace so few of the cigarettes that someone smokes that it would have no appreciable impact on risk. Yet if smokers believe such a product to have significant health benefits they are, once again, being deceived. How can we develop guidance on issues of "smoking reduction"?
3. **How can we effectively place various current and future products on a "continuum of risk" so that we can communicate to users the information they need to make fully informed decisions?** Many smokers believe that "light" cigarettes are significantly less hazardous than regular cigarettes, which is perhaps the greatest consumer deception of our time. Consumers also believe that the "tar" and nicotine listed on ads is what they actually get from smoking various cigarettes. As shown in Appendix 1, many also believe that nicotine causes cancer and that using smokeless tobacco is as deadly as smoking. In addition most harbor misunderstandings about the workings and potential risks from medicinal nicotine that only serve to keep them from availing themselves of these proven safe and effective means of quitting smoking. This level of confusion about such a critical public health issue is truly alarming, and could possibly even worsen as new and unregulated products hit the market.
4. **How can we prevent efforts at toxicity reduction from undermining our efforts on cessation and prevention of uptake?** The main planks of good public policy should be complementary rather than adversarial. If the promise of toxicity reduction reduces quitting or encourages more people to enter [or re-enter] the market the unintended consequences could negate any potential health gains from the intervention. This is the reason that meaningful regulation of both claims and how potential harm reduction products are marketed is critical.
5. **Who should communicate messages to the public?** One of the realities of the present environment, and one borne out by the history of foods and drugs prior to the existence of the FDA, is that without strong government oversight those with a vested interest in selling products should not be trusted to communicate full and truthful information. With foods and pharmaceuticals there are now stronger grounds to believe claims due to the intervention of a credible, objective and expert third party. Such third party validation is as important to tobacco companies as it is to public health. Even a tobacco company that tried to tell the truth about a massively reduced-risk product would probably not be believed in today's environment. It is critical that FDA be given effective authority over all tobacco products in order to ensure that consumers are not misled about the relative risks of different products, including reduced risk tobacco/nicotine products.
6. **How can we be assured that the messages conveyed to the public are being appropriately interpreted?** What if smokers believed that smokeless tobacco was something they could switch to after they developed a smoking related disease like lung cancer? What if they believed that all smokeless tobacco [including, say, that sold in Sudan or Central Asia] had the same risks? There

appears to be a strong need for an institutionalized form of post-marketing surveillance, both to assess attitudes and behaviors.

7. **How do we stay on top of what could be a rapidly changing environment?** Approximately 45 million Americans spend roughly $80 billion a year buying a dirty drug delivery system that is killing over 400,000 of them—and tens of thousands of non-smokers—annually. If this market were subject to effective FDA regulation that actually promotes competition based on good science and marketing that is not misleading, private enterprise and informed consumers would cause a marketplace revolution. Just as did the legal reforms on foods and drugs in 1906 and 1938.

These are tough issues. But the need to address them is truly monumental. Your fellow citizens are dying from tobacco use, but they are also dying for want of truthful information on relative risks and from a lack of viable alternatives to cigarettes. There is a need for prompt action. The FDA and FTC already have authority over medicinal nicotine. I would hope that they would begin an immediate examination of how they might use their existing authority to expand the availability of these products and to explore their potential for harm reduction. Smokeless tobacco products could also be a key part of a harm reduction strategy if a federal agency were given the authority to regulate the content of these products and how they are advertised. I would hope that this, too, could be done quickly.

There are no easy answers. There is, instead, a need to balance potential risks and benefits. There is a need to assess the science behind new products and the best way to communicate relevant information to consumers, and how best to regulate a market in order to give maximum protection for consumers. There is also a great need to stimulate discussion on how to proceed. It is no longer a question of whether there will be alternatives to cigarettes or whether truthful information on relative risks should be communicated to consumers. It is, instead, an issue of how to evaluate products and of how to communicate information in a way that complements public health goals and provides consumers with much needed information about the relative risks of alternative products.

Thank you for your time,

Mr. STEARNS. I thank the gentleman.

We are in the process of having three votes. We have about a little over 7 minutes left on the first vote, and we have two 5 minute votes. And I will come back by voting early on the third vote.

So I think we have got about a 15 to 18 minute break. So I appreciate that if you will be patient with us, the committee is going to be recessed for 15 to 20 minutes.

[Brief recess.]

Mr. STEARNS. Will the subcommittee reconvene?

I think at this point we have finished the opening statements. So I will start with some questions. Let me get right to this question.

Dr. Rodu, oral cancer is a risk of using smokeless tobacco products. What is the risk of using such products, and how does that oral cancer risk compare to the use of cigarettes? That is the bottom line.

Mr. RODU. Oral cancer is a risk of smokeless tobacco use. That risk has been well defined by 20 epidemiologic studies. The risk can be quantified and was quantified by a 1981 study in the New England Journal of Medicine.

Of 100,000 long term, that is, above 40 years or so, use of smokeless tobacco, of 100,000 users, 26 of them will develop oral cancer every year. Of that number, about 12 or 13, unfortunately, it is tragic, but they will die.

Now, we also know the risks of smoking, and the risks of mouth cancer from smoking are somewhere in the range of double that risk. So the point I always make is that the smoker who switches to smokeless tobacco also reduces his or her risk for that disease as well.

Mr. STEARNS. You heard the Surgeon General when I tried to talk to him about the degree of risk between cigarette smoking and the smokeless tobacco, and the Surgeon General noted in his testimony that there is no significant scientific evidence that suggests smokeless tobacco is a safer alternative to cigarettes.

And I even tried to push the idea of the Volvo versus the Miata, the very small sports car.

Do you agree with his statement?

Mr. RODU. Quite frankly, I am dumbfounded by his statement. The scientific evidence that is out there both from the 20 epidemiologic studies, from four cardiovascular disease studies in Sweden, from our work over 10 years published in numerous journals, including high quality journals like Nature, American Journal of Medicine; I just do not know how a Surgeon General can come to that conclusion, and in fact, I would be willing to submit a portfolio of research to him for his review and response because I am quite surprised.

Mr. STEARNS. Dr. Wallace, what additional issues need to be researched before you would be comfortable allowing companies to claim reduced risk product, whether it be a cigarette, smokeless product, or a medicinal nicotine?

Mr. WALLACE. Sure. There are many. We laid out in the report a long term research agenda, but some of the things that need to be done more quickly are to begin to understand how it affects the behavior. If you were to make a claim like that, how does it affect children's behavior? How does it affect physician behavior in making recommendations, but most importantly adult behavior?

How does it change their habits? How do they use tobacco products? And what happens to them in the long term?

All of these tobacco products may have outcomes that include things other than cancer, and we have to pay attention to those. So there is a whole menu of things to do. So there is a lot of research left to be done.

A very important bit of the research agenda finally then would be to try to identify indicators in the body that future risks of cancer, heart disease, small fetuses, whatever the outcomes happen to be, in fact, might be different and reliably predict in advance. Otherwise you have to wait a very long time to see the effects of some of these products.

Mr. STEARNS. Dr. Tomar, you have heard Mr. Waxman talk, and in your opening statement we talked about this report that you have. In a study conducted by Dr. Lynn Kozlowski recently published in Nicotine and Tobacco Research, he indicated your gateway theory to be statistically unreliable because he argues you fail to take into account well known psychosocial predictors of smoking initiation, such as below average school performance, depressive symptoms or fighting.

Now, this is your chance to give your side. So how do you respond to what he said about your report?

Mr. TOMAR. Well, there are two approaches. One, in the original paper that Dr. Kozlowski supposedly refuted, the argument I made in that paper is that if there are common psychosocial risk factors that account for moving from one tobacco product to another, wouldn't we expect it to move in both directions?

And in fact, what we found was that 40 percent of young males who were using smokeless tobacco at the beginning of that study 4 years later had either added cigarettes to their use of smokeless tobacco or had switched to smokeless. We found almost no movement from cigarettes to smokeless tobacco.

So that was the first one, and then actually you need to read the reply that has been accepted for publication in that same journal to Dr. Kozlowski's analysis. As I read his analysis using the same variables that he claimed were so critical and that I had omitted, and in fact, when I did the analysis limited to the group that actually uses the products, non-Hispanic white males and those who were under 16 at the beginning of the study, in fact, smokeless tobacco was not only a statistically significant predictor of subsequent smoking. It was a stronger effect than the risk behavior predictors that he felt were such a critical omission.

Mr. STEARNS. I will let someone else. Dr. Rodu, you may want to comment based upon the study from Sweden.

Mr. RODU. Yes. We have a study of tobacco use among adults in Sweden, and we saw, in essence, no effect of gateway from smokeless tobacco use to smoking, and that is among adults. Largely, the predominant public health message in Sweden, of course, is that snus is safer than smoke. I do not think there is anyone that doubts that in the Swedish environment.

In the United States, the dominant public health message is that smokeless tobacco is just as dangerous as smoking, and that is seen in Mr. Sweanor's testimony. And so we have an open gate. It is an open gate for transition back and forth between smoking and smokeless tobacco use based on convenience, not based on health.

So that you know, the other thing about gateway is that it is a convenient issue when you look at smoking is a gateway to smokeless or vice versa and drinking and sex and all kinds of behaviors, when, in reality, these behaviors are all grouped; they are all associated; and they are all present in a small proportion of our teenagers, and it is unfortunate, but it is association instead of causation.

Mr. MYERS. Mr. Chairman, could I just make two quick points with regard to that because I think they are vitally important?

One is Sweden does not permit the kind of advertising I showed before so that the interaction between different products is really quite different because you do not have the same market forces. As a matter of fact, in Sweden, the same company for a long time owned both the major cigarette company and the same smokeless company.

The second, and the reason we have a real life example in the United States is, you know, in the mid-1970's virtually no kids used smokeless tobacco products. The kind of marketing that I showed you that UST was engaging in through 2002 kicked in around the late 1970's, early 1980's, and what we saw was a little explosion of smokeless tobacco use.

And part of the ad themes in those cases was a safer message, implicit safer message. So that when we talk about a concern about kids in this country, we are not talking some sort of ephemeral thing. We are talking about a real life example of what happened here.

Now, we do not have any different kind of regulation today. We had all hoped in 1997 that the master settlement agreement would bring about a change in tobacco marketing by companies like UST, and instead what we saw was a dramatic up-tick in marketing, particular in youth oriented magazines until several Attorneys General threatened them.

When they got out of those magazines, they used carefully the word "we are suspending advertising in magazines like Rolling Stone," not "we are getting out permanently."

So the concern that we all have is that in the absence of government regulation that controls the kind of marketing, that puts in place the kinds of regulations that they have in Sweden, that the effort to promote health reduction will, in fact, result in an explosion in youth smoking.

Is it possible to deal with that? Perhaps if the FDA had full and comprehensive regulatory authority, we could, but that is what we ought to really be talking about here.

Mr. STEARNS. Okay. My time has expired.

The ranking member.

Ms. SCHAKOWSKY. Thank you.

Dr. Rodu, is it not true that in 1999 the University of Alabama at Birmingham received $1.25 million unrestricted research grant from the United States Tobacco Company of Greenwich, Connecticut?

Mr. RODU. That is correct.

Ms. SCHAKOWSKY. And is it also not true that the award supports the UIB Tobacco Research Fund, and you are the principal investigator?

Mr. RODU. That is correct.

Ms. SCHAKOWSKY. I wanted to ask Mr.—I want to say it right—Verheij?

Mr. VERHEIJ. That is right.

Ms. SCHAKOWSKY. Verheij a question. UST has indicated that it is a company that can be trusted not to use health claims for smokeless tobacco to attract children or to deter people from quitting. I want to talk a little bit about the ads, but I would like to ask whether you have told the whole truth today to Congress about levels of carcinogens called tobacco specific nitrosamines in your product.

In your written testimony, you stated today, "There is currently no difference in tobacco specific nitrosamine levels in U.S. moist snuff compared to Swedish moist snuff." However, your testimony only includes data on U.S. brands up to 1994, and if you will look at this chart, which is based on data provided by the Massachusetts Department of Public Health based on research by the Institute for Cancer Prevention, it shows that the levels of tobacco specific nitrosamines in your two leading products doubled between 1994 and today.

The average level in the last 4 years has been 26.7 micrograms compared to an average level of less than 10 in Swedish products for the last 20 years.

Why did you not share any more recent data than 1994 with the committee today?

Mr. VERHEIJ. Well, we would be happy to share recent data. The fact is that products that we have introduced into the market over the past year, they have some of the lowest nitrosamine levels of any product in the world, including as a comparison to Swedish product.

The data you have there is from the State of Massachusetts. We met with the State of Massachusetts with respect to their methodology. In fact, I had a phone call with Dr. Connolly probably 3 weeks ago where he was giving me current data on some of our leading brands.

Our objective——

Ms. SCHAKOWSKY. Are you talking about your moist product?

Mr. VERHEIJ. Yes, indeed, and including two new pouch products that we have introduced.

The fact is I think as we have indicated in our submission, we have reduced nitrosamine levels more than 80 percent in our products over the last 20 years to the point that a Swedish government report in 1997 concludes that the differences were so small at this point that the differences in relative risk were negligible.

Our objective is to reduce nitrosamine levels to the lowest levels possible. In the context——

Ms. SCHAKOWSKY. Let me just say that my understanding is that the 2000 data, which you were given on August 16th, 2001, says that it is now 52.7 micrograms for that year.

Mr. VERHEIJ. And I would have to go back and look particularly at the timing of that. They were taking data 6 months out from when the product was introduced on the shelf. Those products are not on the shelves after 6 months at all.

And in fact, looking at data that we have, and again, I would be happy to provide the committee, in terms of our leading brands, we are talking about levels of 12 to 14 parts per million. We continue to work to reduce those to the lowest level possible.

Ms. SCHAKOWSKY. Did you put any shelf life or expiration data on your productions?

Mr. VERHEIJ. Actually we do. On the Copenhagen product, there is a made date, and within 30 days of that made date that product is either purchased or taken off the shelf by our sales people.

We have guaranteed to be fresh dates on our other products, which indicate the optimum period within which we think consumers should purchase the product. So we do have made dates on it.

Ms. SCHAKOWSKY. So I understand that you refuse to accept a maximum shelf life for your product, that is, any kind of requirement to have a shelf life.

Mr. VERHEIJ. Not at all. We had a good discussion with Dr. Connolly at the time; showed him the fact that our products turn 52 times a year, the most made dates, the most shopped product other than milk in terms of date, and in fact, these products were coming off the shelves, and any significant increase in nitrosamine levels were toward the end of the 6-month period when these products are not available to consumers.

Ms. SCHAKOWSKY. Okay. Let me ask you this. In a letter the company wrote February 5, 2002, it says, "It is UST's position that smokeless tobacco has not been shown to be a cause of any human

disease." That was in a letter from Brian Cave, LLP, to the Federal Trade Commission. That is your submission to the FTC.

Mr. VERHEIJ. And I think we have also made clear in our public filings that based on the scientific literature taken as a whole, the company has not taken the position that the product is safe, and the question on the table in the context of the debate we have all been talking about here is the fact that smokeless tobacco is considered to be considerably less harmful than cigarette smoking, and whether that information——

Ms. SCHAKOWSKY. No, no. That is not what I am asking. "Has not been shown to be a cause of any human disease." Mr. VERHEIJ. I do not think that statement is inconsistent with the position that we have taken, which is that we have not taken a position that the product is safe.

Ms. SCHAKOWSKY. Dr. Tomar, would you respond to that?

Mr. TOMAR. Well, it seems to be contradicted by Dr. Rodgers' earlier statement, where he acknowledged that these products cause cancer. It has certainly been established by the International Agency for Research on Cancer and the U.S. Surgeon General.

Mr. VERHEIJ. If I may follow up on that, the fact is that based on studies that were available in 1986, the Surgeon General reached the judgment that smokeless tobacco can cause oral cancer.

Ms. SCHAKOWSKY. You know, actually I have gone over my time already and want to make one other point.

I just think that this is an astonishing statement given the unanimous actually, including Dr. Rodu's statement about disease.

Now, why anyone would think that this magazine with Britney Spears on the cover might be read by young boys I have no idea, but I just want to say this is December 2001, and in it is an ad showing a fire fighter putting out a fire, clearly one of the heroes of 9/11, "a bit braver, a pinch better," and it is for Skoal.

I just want to say that given that and the ad for Rooster, it is not credible to say that these products are not pitched to children.

Thank you.

Mr. VERHEIJ. Mr. Chairman.

Mr. STEARNS. The gentlelady's time has expired.

Yes?

Mr. VERHEIJ. Mr. Chairman, if I may for 1 second.

Mr. STEARNS. Sure, yes.

Mr. VERHEIJ. I think there has been a lot of focus on old ad campaigns some of which, you know, once certain concerns were brought to our attention like the rooster ads that Mr. Myers showed, we discontinued those once we took a second look.

The fact is what we are talking about in this debate is communications to adults about information that there is an increasing consensus in the scientific community that smokeless tobacco is considerably less harmful than cigarette smoking.

And we are urging a workshop where all of these parties can participate so that we can come up with guidelines that will address everybody's concerns before those communications are made. And, frankly, you could take our company out of it entirely.

That means the remaining issue is to what degree does the government and the public health community have an obligation to

communicate this important information to adult smokers who are not quitting.

Mr. STEARNS. The gentlelady's time has expired.

The Chairman of the full committee, Mr. Tauzin.

Chairman TAUZIN. Thank you, Mr. Chairman.

Mr. Myers, you made the point several times that we tend to be debating this in the abstract and we ought to look at real world information and real life conditions, and I think that is a good point.

One of the things you have pointed out to us, however, was that the story in the Washington Post over the weekend that said smoking is projected to kill a billion people worldwide this century and that one out of two long term users of cigarettes will die, that is not abstract. That is real. And that is pretty awful.

And I think what we are beginning to have here is a debate on whether or not we can do something about those real life statistics.

I want to tell you a real life example and the reason why I have got such an interest in here in this debate and why I want to see this indeed, not just workshops but forums and discussions and more hearings, and I want to see the scientific evidence debated and the policy issues debated.

One of the people I love dearest in my life is the former chief of my local staff who served me four times as chief of staff. He has two sons. One is a Navy Seal and the other is a college student right now, he and his son both addicted to smoking.

They were able to use the product called Revel, which is one of the newest, I think, products you were talking about, the pouch spitless variety of smokeless tobacco. It has made the difference for them. Both of these people used it where they have never been able to quit smoking before, and they quit smoking, and now they have quit using this product, and they are completely off of tobacco.

That is a real life example. I have got a couple of kids I would love to see quit smoking. They try, and they cannot quit, and if there are products like this Revel, if there are products that are being developed that not only are considerably less harmful than the cigarettes my children are smoking——

Mr. MYERS. Mr. Chairman.

Chairman TAUZIN. Let me just finish.

If there are products like that and there are products like that that can be a bridge for people like my dear friend and his son who went from smoking cigarettes to using these products, to using no tobacco products; if there are products like that, doesn't it make sense for us to find some way to allow someone, if not the company, someone to communicate the existence of those products to the adults of this world, the billion people worldwide who are going to die in this century if we do not give them another option?

Mr. MYERS. Mr. Chairman, let me response.

Chairman TAUZIN. Please.

Mr. MYERS. Because the organizations with which I work spend day and night trying to figure out how we can reduce the death toll from tobacco.

Chairman TAUZIN. I know you do.

Mr. MYERS. We do it at all levels. We try to help prevent kids from starting, which is the best way.

Chairman TAUZIN. Yes.

Mr. MYERS. We try to make more funds available to help people to quit. And you know, sadly in most states we are not doing that. So that your friends, your colleagues, your loved ones should have more resources available to you, and I would hope we would work together.

Third, based on your statement this morning, I know you share our concern, that you do not want to see the unintended consequences of this action, and for us to avoid the unintended consequences that will occur by the kinds of ads that I have shown, the only way we can do that and make sure that your loved ones are provided the best tools available to quit, whatever they may be, is to make sure that we have a comprehensive regulatory system.

Chairman TAUZIN. Yes, but I have limited time, Mr. Myers.

Mr. MYERS. Well, let me——

Chairman TAUZIN. No, no. You opened it up. I have limited time.

Mr. MYERS. To ahead.

Chairman TAUZIN. That is a good debate, and we are having it. We have been having that one for years, whether the Food and Drug Administration ought to regulate tobacco, and that debate is going to go on, I suspect, for a long time, but in the meantime my children are smoking cigarettes.

Mr. MYERS. Well——

Chairman TAUZIN. In the meantime there are 400,000 citizens who are going to die because they cannot quit smoking even though they want to.

I have got some examples of what is going on in Europe. These are what is required in the EU on cigarettes. These are the warnings they put out in the EU. "Smokers die younger." "Smoking kills." "Smoking seriously harms you and others around you." "Smoking clogs your arteries and cause heart attacks and strokes." "Smoking kills." "Smoking can damage the sperm and decrease its fertility."

I mean, the EU puts out warnings like we do not even think about putting out on cigarettes, and the EU is now saying, leading tobacco experts in the EU are saying information to us telling us they think they made a mistake when they partially banned smokeless tobacco products because they are looking at Sweden and they are seeing how Sweden is really seriously reducing the deaths from lung cancer to males who have been able to use something other than a cigarette to get their nicotine habit satisfied.

Answer, please.

Mr. MYERS. Two quick points, and they are very important ones.

One, we would welcome to work with you to improve the health warning on tobacco products.

Chairman TAUZIN. Good.

Mr. MYERS. So that it is serious.

Two, the recommendations——

Chairman TAUZIN. Yes, but wait a minute.

Mr. MYERS. Wait, wait. Let me respond.

Chairman TAUZIN. No, no.

Mr. MYERS. Go ahead.

Chauirman TAUZIN. I have got the time, and I am not going to let you do that to me.

I am not telling you we do not have these warnings. I am telling you the EU is telling us these warnings are not working.

Mr. MYERS. No, that is not what they are saying.

Chairman TAUZIN. No, I am reading their report, and they are telling us that they are seriously considering repealing their ban——

Mr. MYERS. No, no.

Chairman TAUZIN. [continuing] because they are looking at the only country in the EU that met the World Health Organization's target of reducing smoking prevalence to 20 percent. The only country was Sweden.

Mr. MYERS. May I just have the opportunity——

Chairman TAUZIN. Where, in fact, they promoted the use of something other than smoking cigarettes.

Mr. MYERS. I think it is very important to understand exactly. The report you are referring to is written by five people for the EU, not the EU. What it recommends, just as the Royal College of Physicians recommends, is that no health claims be permitted in the absence of a comprehensive regulatory system like we are proposing for FDA. That is what the EU recommendation is.

Now, the EU has banned smokeless tobacco, and they said, "We should go back and relook at that." But what they have said about health claims is that health claims should only be permitted within the context of a comprehensive regulatory system so that we do not have the unintended consequences, so that we do not market them to kids, and——

Chairman TAUZIN. My time is up.

Mr. MYERS. [continuing] so that we know what is in them.

Chairman TAUZIN. My time is up.

I accept the fact that we ought to be very, very careful how we regulate these health claims.

Mr. MYERS. But we are not doing that now.

Chairman TAUZIN. But wait, wait. Let me make the point.

But we are never going to get there if the Surgeon General has never ever read some of these reports that look at that there are alternatives that are less harmful than smoking tobacco.

We are never going to get there if the head of the FTC, who has jurisdiction to verify the validity of claims, is not willing to lead a forum, a discussion; if the Health Department in this country is refusing to lead it because they think the FTC ought to lead it.

And if you are going to keep insisting that the Food and Drug Administration ought to do it, we are going to have this debate forever while alternative options that should be discussed, that should be available to my children and to my dearest friend who finally found one of these, used it, and got off of cigarettes, are never even discussed publicly because we are too scared to talk about the truth about where the science is really going.

If the science is really going there, if people in this country can know that there are alternatives for them to use to get off of smoking cigarettes to get the nicotine highs, and they are not finding out about it because we are too afraid, too unwilling to lead and have some open discussions and debates about them to figure out how to regulate it properly to make it work well, then shame on us.

And I agree with you. We ought to have that great debate. Help us have that debate.

Mr. MYERS. Mr. Chairman, my most important point——

Chairman TAUZIN. Yes, sir.

Mr. MYERS. [continuing] is that in the absence of comprehensive regulation your desire to do good will produce a public health tragedy.

Chairman TAUZIN. That is a fair concern.

Mr. MYERS. It will turn into a marketing tool for the tobacco industry.

Chairman TAUZIN. That is a fair concern, and that ought to be part of the debate.

Thank you, Mr. Chairman.

Mr. STEARNS. The Chairman's time has expired.

The gentleman from Texas.

Mr. GREEN. Thank you, Mr. Chairman.

And I appreciate the line of questioning from our Chairman. I think our children or smokers know the alternatives because, like our Chairman, I have had a father-in-law who died of lung cancer and a brother-in-law who died of lung cancer, and they tried everything. And in fact, they even chewed, too, and they still died of lung cancer, but that was because of smoking.

But I think our children know alternatives just like they know alternatives already that we do not want to tell them about the use of condoms, but that is a debate that this committee has had other times.

Let me ask Mr. Sweanor, and having read your testimony where you talk about placing dirtier delivery systems with cleaner systems, and I know we talk about different ways, but obviously you have never sat next to someone who chewed and had to spit in a cup next to you, but let me ask you some questions.

Does Canada recognize smokeless tobacco as a safer alternative?

Mr. SWEANOR. As far as I know, that is a debate that simply has not happened in Canada. Smokeless tobacco is actually rarely used in Canada.

Mr. GREEN. Okay. You mean not even in the western provinces?

Mr. SWEANOR. Alberta actually does have use of smokeless tobacco, and that is now a debate emerging with the Drugs Education Agency in Alberta.

Mr. GREEN. Because we have rodeos in Texas and the Midwest like in Canada and Alberta and other parts. But what tobacco control measures are in place in Sweden that are not in place in the United States? For example, the tax rates; the smoke free indoor air law includes restaurants effective the first of next year in advertising. Is there a difference on how Sweden treats all tobacco products?

Mr. SWEANOR. Yes, in different ways. There will actually be less protection from second hand smoke in Sweden than what I find many places in the United States now, but Sweden does have a ban on tobacco advertising. It has a fairly comprehensive——

Mr. GREEN. Is that both a print ban and an electronic ban?

Mr. SWEANOR. Yes, yes. It is like Canada or the rest of the European Union. It has much larger warnings on packages, further dis-

closure to consumers, restrictions on how the product is displayed at retail.

Mr. GREEN. Okay. Let me go on. Are Swedish customers or consumers told by companies or the government that smokeless tobacco is a safer alternative to cigarettes?

Mr. SWEANOR. I found that to be a very interesting thing because they are——

Mr. GREEN. Is it a program by the companies or the government that allows them to say that it is a safer alternative? Does Sweden do that?

Mr. SWEANOR. No. My experience is that the government has not told them that. The companies have not explicitly told them that, but that information is got to them through the scientific community and through simply word of mouth.

Mr. GREEN. Okay.

Mr. SWEANOR. I think similar to——

Mr. GREEN. Okay. Let me because I only have a couple of minutes left.

Are you aware that Sweden has an active program to reduce snuff tobacco use and that the Swedish Health Ministry aims primarily to get people to quit tobacco entirely?

Mr. SWEANOR. Yes, that is certainly their goal, is to reduce tobacco use entirely.

Mr. GREEN. Okay, and so all of this study that has been talked about the science that we are quoting a Swedish study, even the Swedish health ministry has an active program to reduce snuff tobacco use.

Mr. SWEANOR. It is aimed at overall reduction of death and disease by reducing tobacco use in all forms as much as possible Mr. GREEN. Mr. Chairman, let me introduce into the record and I ask consent to introduce into the record information from the Swedish Health Ministry about their handling of smokeless tobacco, and it is addressed to Mr. Sharfenstein, and it says your question number 1, whether advertising claims on reduced risk are permitted for smokeless tobacco in Sweden and the regulation of tobacco products in Sweden are contained in Tobacco Act, and I will put the whole letter in the record.

It concludes it is not permitted to use advertising claims on reduced risk as the legislation does not permit for advertising for tobacco products as was defined as commercial advertisement, according to the Swedish constitution, and no, that the Ministry of Health and Social Affairs does not have a campaign to switch to smokeless tobacco in the meaning of the product or snuff.

I would like to ask unanimous consent to have that placed in the record.

Mr. STEARNS. Without objection, so ordered.

[The information referred to follows:]

MINISTRY OF HEALTH AND SOCIAL AFFAIRS
SWEDEN
2 June 2003

Dear Mr Sharfstein, I've been appointed by Mr Magnusson to answer your questions on the Swedish tobacco legislation and policy.Your question no (1). Whether advertising claims on reduced risk are permitted for smokeless tobacco in Sweden

The regulations of tobacco products in Sweden are contained in the Tobacco Act. This Act does not distinguish between different tobacco products, no matter which

area of legislation concerned. Therefore the prohibition of the advertising for tobacco products remains the same no matter the product would be a cigarette or any other tobacco products, such as oral tobacco.

To conclude on this matter, it is not permitted to use advertising claims on reduced risk, as the legislation does not permit for advertising for tobacco products in what is defined as commercial advertisement according to the Swedish Constitution. When marketing tobacco products a businessman shall observe particular moderation. In particular, advertising or other marketing may not be invasive, actively seeking new areas of trade nor encourage the use of tobacco.

Your question no (2) and (3)

No, the Ministry for Health and Social Affaires does not have a campaign to switch to smokeless tobacco, in the meaning of the product of snuff.

On the issue of cessation there is a national telephone line The Stop Smoking Line, which is given national resources, in order to offer a national competent advice on cessation. The main focus for this branch of the County of Stockholm is smoke cessation, even though there are a significant number of users of oral tobacco as well who make use of their service.

In a recent Government Bill the government concluded that one of 10 public health goals would be to raise the ambition on tobacco prevention. The main focus are:

—a tobacco free start in life for all children by 2014
—a decrease by half of the groups of adults who are smoking most by 2014
—a decrease by half of children, under 18 according to Swedish legislation, who use tobacco cigarettes or oral tobacco, i.e. snuff at the year of 2014,
—no person should be subjected against his will to smoking by those around him or her.

In the same Bill the Government underlined the need for further research into the health aspects of oral tobacco, and it was also considered that this was already a task for the National Institute for Public Health.

The Government has also directed 30 million Swedish Crowns (cirka 3 800 000 US dollar) to the area of tobacco prevention, each year during a period of 3 year from 2002 to 2004. The Government has also underlined smoking cessation as being one of the areas of prevention where the health care has a specific responsibility. The resources directed to tobacco prevention in the health care sector are managed by the County Council, and as tobacco prevention is an integrated part of the health care system it is difficult to a specified on how much is spent on tobacco prevention.

During the past three years there has been an influx of new and cheaper cigarettes in Sweden. These so called low price cigarettes, which hold a price that has been around 10 Swedish crowns (circa 1.27 US dollar) lower than the most popular tobacco brand in the most sold category of cigarettes, is taxed according to an EC-directive. The consumer price on the most popular brand in the most sold category is 38.50 Swedish crowns, (circa 4.9 US dollar). As the EC-legislation has been changed the Swedish government has taken the opportunity to raise the taxation on this group of cigarettes to 90 percent of the tax on the most popular brand in the category of the most sold cigarettes. The Swedish government has chosen the level of 90 percent as it has been shown in the past that sudden increases in the taxation might affect the level of smuggled goods into Sweden. The reason for the increase was among other things the knowledge that a low price on cigarettes might trigger the consumption. Therefore a survey has also been started on a monthly basis in order to improve knowledge on the consumption of tobacco.

Since 1997 Sweden has an age limit on the sale of tobacco products of 18 years of age, no matter being cigarettes or oral tobacco. There is no sanction according to this legislation on the person under the age limit, as the sanction was to be placed on the seller.

Even though it is prohibited by the law to sell tobacco products to persons under the age of 18, it has been shown that there are still a considerable number of persons under the age of 18 that are able to buy tobacco there has been an introduction of a notification system of sellers of tobacco. This has been introduced in order to improve the compliance of the Tobacco Act. The National Institute for Public Health was according asked to give a report in the beginning of 2004 on the consumption of tobacco by persons under the age of 18 years.

In the Swedish Tobacco Act there is a catalogue of premises that are to be smoke free. In practice the only public premise that is not smoke free is the restaurants and cafés. From January 1, 2003 every restaurant or café have to provide for that a part of the premise is smoke free. The Swedish parliament has also stated that the goal is smoke free restaurants from January 1, 2004. There is a report from the Swedish National Institute on what it takes to fulfill the parliaments goal on smoke free restaurants. This report is no distributed for consultation with national authori-

ties, organizations and other interested parties. Finally, what can be said on the catalogue of smoke free premises in the Swedish Tobacco Act, it does not regulate outdoor environments, except for school playground.

The Swedish Council on Technology Assessment in Health Care has confirmed that the use of nicotine replacement products is a major part of a successful cessation policy. As these are approved as pharmaceutical products these are sold the sales places of the Swedish Pharmaceutical Monopoly.

Yours Sincerely,

ULRIKA LINDBLOM,
desk officer

Mr. GREEN. And with the brief time I have left, Mr. Verheij, UST uses a Swedish study as a foundation for its argument that should be able to advertise that smokeless tobacco is less harmful. However, Mr. Myers points out that snus products in Sweden are very different than the products marketed here. For example, he states that the levels of cancer causing nitrosamines in Swedish products are much lower than the United States.

Could you comment on that in what brief time I have left?

Mr. VERHEIJ. I would be happy to.

The fact is that we have successfully reduced nitrosamine levels in our products to extraordinarily low levels, and some of the products we have introduced recently have levels much lower than any other smokeless tobacco product in the world.

Another reason why we believe the Swedish model is applicable is I think as Mr. Sweanor pointed out, the fact is that culturally and through the public health community, the type of communication we are talking about today is actually reaching adult smokers.

Mr. GREEN. Okay.

Mr. VERHEIJ. That is not happening here in the United States.

Mr. GREEN. Let me talk about it because I think there is a new study, I understood, from the State of Massachusetts which indicates that nitrosamine levels are increased in U.S. products.

Is that you all's products?

And I would like Mr. Myers if he had a brief comment on that.

Mr. MYERS. Sure. Yes, the sad reality is that in several independent studies done by the American Health Foundation for the State of Massachusetts, they found something quite inconsistent with what Mr. Verheij said. What they found was that for the two most popular products from UST, one study done in 2001 found that the comparable Swedish product had 2.8 parts per million of nitrosamines, whereas Copenhagen had 41.1 and Skoal had 64.0. Those products are not comparable by any remote imagination.

And also attached to my testimony is an updated report, again, done for the State of Massachusetts, not done exclusively in Massachusetts. Samples were picked up around the country by one of the most respected labs.

And what it found there, too is that in 2003 nitrosamine levels in the two most popular brands by UST remain about 10 times higher than those that we are comparing in Sweden. It is a very disturbing thing because the numbers for these two are 22.0 and 27.9 compared to under 2 for the comparable products in Sweden.

So we are talking not apples and oranges even, but apples and grapefruits is the difference here. Unfortunately when the State of Massachusetts asked U.S. Tobacco if they would agree to a 10 parts per million, much higher than in Sweden, the answer was no.

I think what it is time for us to do is to compare apples to apples, and if we are really interested in low nitrosamine, what we need to do is have a regulatory agency that can set standards for it so that we can protect consumers and accomplish the goals of this committee.

Mr. GREEN. Thank you, Mr. Chairman.

Mr. VERHEIJ. Mr. Chairman, if I just may——

Mr. STEARNS. Sure.

Mr. VERHEIJ. [continuing] because I think Mr. Myers is comparing apples and refrigerators. The fact is——

Mr. GREEN. I would think more like apples to gasoline maybe.

Mr. VERHEIJ. Well, at least if it is apples at least they are healthful.

No, I think that the fact is the appropriate comparison between the data that Mr. Myers cited from Sweden is comparison to the types of products that Chairman Tauzin was pointing out, which is the Revel product, which has the lowest levels of nitrosamines of any smokeless tobacco product in the world, and that is the appropriate comparison.

Because pouch products are 50 percent of the market in Sweden, unlike here, which is about 3 percent. So the notion is not to compare Copenhagen with a pouch product in Sweden. They should be comparing a pouch product in Sweden with a pouch product in the United States, and, in fact, the levels are comparable or lower.

Mr. MYERS. What is stunning is that UST has demonstrated in Revel that it can produce a low nitrosamine product, but what it sells to most Americans, Copenhagen and Skoal, it has nitrosamine levels multiples of that.

If they can produce it for Revel, why don't they produce for every one of their products? Why should some people be in more jeopardy than others?

Mr. STEARNS. One last word here before we move on.

Mr. VERHEIJ. I appreciate that, Mr. Chairman.

The fact is that we are working to reduce the levels of every product we had. In Revel we are working with a product that was newly introduced last year with new technology. We can now take that technology and start applying it to products like Copenhagen that have been on the market for 180 years, and that does not happen overnight without dramatically changing Copenhagen.

The overall goal is to reduce the levels to the lowest levels possible in the world in such products as Revel.

Mr. STEARNS. The gentleman's time has expired.

The gentleman from Kentucky, Mr. Whitfield.

Mr. WHITFIELD. Thank you, Mr. Chairman.

Mr. Myers, you have made some comments and Mr. Verheij made some products about their product, Revel, and comparing that with snus, and a number of people have indicated in their testimony today that if the U.S. had a similar regulatory system, as they have in Sweden, that that would make a difference.

So is it your position that if the U.S. had a similar regulatory system that you would have no objection to products like snus or Revel?

Mr. MYERS. If the U.S. had a comprehensive regulatory system, then scientists with full knowledge about the product would be able

to make appropriate comparative science claims. We are not in a position to do that.

You know, we just learned how little we really know. There was a recent study done on Marlboro that we thought had reduced tar levels for many years that discovered, in fact, Marlboros have among the highest nitrosamine levels of products anywhere in the world.

What we need is an agency that can control each of the potential toxic substances and then make a scientific decision. We will abide by the science, whatever that is.

Mr. WHITFIELD. Now, do you think that in Sweden and the European Union they have valid science on this issue?

Mr. MYERS. There are widespread disputes about both what the cause of the Swedish experience is and what the impact of the Swedish experience is, but you know, one of the very documents that you cited this morning, the one written by the five scientists to the European Union, had an explicit sentence in it that says, "We do not know if the experience in Sweden would apply anywhere outside of that experience because of the full maze of regulatory mechanisms they have in place and the difference in the product."

What I would be willing to say to you is let us give an agency like the FDA the kind of authority over it so that it can make sure that if these products can, in fact, reduce the harm to disease, then there is an agency to control so that they accomplish the goal.

Step one is giving an agency the authority to do the job.

Mr. WHITFIELD. How many of you on the panel agree that there is sufficient scientific evidence already in Sweden or elsewhere that smokeless tobacco is safer to use than cigarettes?

Mr. MYERS. I would be happy to start that if you want.

Mr. WHITFIELD. Well, I think I know how you——

Mr. MYERS. Well, let me just say because I think it is important. For the——

Mr. WHITFIELD. Let me get——

Mr. MYERS. [continuing] overwhelming majority of Americans.

Mr. WHITFIELD. Let me get Dr. Rodu in on this. Dr. Rodu, you raised your hand.

Mr. RODU. Well, yes, I raised my hand to agree with your statement that smokeless tobacco use is on the order of 98 percent safer than smoking. I think that the epidemiologic research published by others over the last 50 years substantiates that. Our own epidemiologic models substantiate that.

Mr. STEARNS. Will the gentleman yield just for a second?

Dr. Wallace, I understand you are on the first panel of another committee. So we want to thank you for coming, and you are welcome to leave now so that our colleagues can share your wisdom.

Mr. WALLACE. Thank you, Congressman. I appreciate it.

Mr. STEARNS. Sure.

Mr. WHITFIELD. Mr. Sweanor, did you want to make a comment?

Mr. SWEANOR. Certainly my view is on a one-for-one basis, there is no doubt that smokeless tobacco products such as is sold in Sweden or the United States is going to be much, much less risky than getting your nicotine by smoking a cigarette.

Mr. WHITFIELD. Now, Mr. Myers, do you accept Mr. Verheij's statement that Revel has nitrosamines equal to the level of snus or do you have any basis of knowing that?

Mr. MYERS. it is exactly why we need a regulatory agency, so that we can have a regulatory agency that tests it and we do not have to depend on what U.S. Tobacco tells us.

Mr. WHITFIELD. Okay. I notice that in the European Union evidently they recently changed their warnings and they said this tobacco product can damage your health and is addictive as it applies to smokeless tobacco, but they removed the warning about cancer.

Is anyone aware of that?

Mr. MYERS. That is in Sweden, not in the European Union, sir.

Mr. WHITFIELD. That was in Sweden?

Mr. MYERS. Yes.

Mr. WHITFIELD. Okay.

Mr. MYERS. Sweden does not permit the sale of smokeless tobacco. I mean the European Union does not permit the sale of smokeless tobacco.

Mr. WHITFIELD. Mr. Sweanor?

Mr. SWEANOR. Yes, it is an EU role that applies to Sweden, which still has the ability to sell smokeless tobacco. My understanding is it was removed because the evidence simply was not there to substantiate it. The evidence coming out of Sweden could find no conclusive proof that the product was causing cancer at all.

Mr. WHITFIELD. Recently CDC came out with a study about nitrosamines and the content in certain American products, and the bottom line to that is I know since that report has come out or since the beginning of it, the way you dry this tobacco has changed. The technology has been changed.

But would you make the argument that tobacco grown in foreign countries is safer than the tobacco grown in the U.S.?

Mr. MYERS. I am glad you raised that issue. The study done by the CDC was of Marlboros manufactured both abroad and here. So it is an American brand, but it includes foreign made cigarettes under Philip Morris International as well.

What it found was that Marlboro had higher levels of nitrosamines in the vast majorities of countries in which it was sold not matter where it was manufactured. The problem was not American tobacco. It was not American manufacturers. The problem was how Philip Morris chose to manufacture that product, which was particularly disturbing because a study by British American Tobacco showed that when Philip Morris actually enters countries with Marlboro, they initially produce low nitrosamine products equal to the level in the country and then gradually they raise them up so that there is a conscious decision going on, or at least a noncaring decision going on, that has nothing to do with American tobacco.

American tobacco is the best in the world.

Mr. WHITFIELD. Mr.Rodu?

Mr. RODU. Could I make one quick comment about nitrosamines to place it in perspective?

The epidemiologic studies performed between the 1950's and 1980's that show a relative risk of smokeless tobacco mouth cancer

association at about 2 to 4 were conducted in people who were using products where the nitrosamine levels were in the 100's.

Now we are talking about nitrosamine levels in the single digits and teens, and we are arguing differences that are very, very small compared to products used 40 years ago.

Mr. WHITFIELD. I would like to ask Mr. Myers just one other question if I could.

You have been pretty emphatic about this, which I understand. I did not see this, but recently they said on C-SPAN that you replied to someone who called in, and that you made the comment cigarettes are the most dangerous form of tobacco used. Literally one out of two long term users of cigarettes will die from tobacco use. Smokeless tobacco, cigars are harmful but not to the same magnitude.

Did you say that?

Mr. MYERS. It sounds like an accurate quote of what I would have said. The important issue here is whether or not the government is going to put a stamp of approval to make a health claim in an unregulated environment that could have tragic marketing consequences.

The position I take that these claims should not be permitted in the absence of meaningful regulation reflects the absolute consensus of every single major American public health organization, from the American Medical Association to the American Cancer Society, the American Lung Association, to the American Public Health Association, the American Dental Society.

There is no emerging consensus on the other side. This is the view of the public health community.

Mr. STEARNS. The gentleman's time has expired.

I would say to the gentleman from Kentucky I heard Mr. Myers say that U.S. tobacco is the best in the world. So I think you can take that back to your constituents.

Mr. WHITFIELD. Maybe you could go down and visit with my farmers.

Mr. MYERS. I actually do all of the time.

Mr. STEARNS. Mr. Stupak.

Mr. STUPAK. Thank you, Mr. Chairman, and I apologize for being late, but I did catch some of this in between meetings. So just a couple of questions, if I can.

Is there any profile or high risk individuals who should not use tobacco?

Mr. MYERS. Humans.

Mr. STUPAK. Well, I mean besides humans. But I mean is there certain characteristics that you look for? In some drugs there are considered high risk patients for this use. Is there anything like that? No profile like that has been done?

Mr. MYERS. Not to the best of my knowledge. It is true that one out of two long term users of tobacco products will eventually die from the disease. That means that one out of two do not, but it is worse than playing Russian roulette. The real concern is that virtually every one of them start as a child, and what we need to do is break that step.

Mr. STUPAK. Dr. Rodu, in answer to my friend's question over there, you are talking about when the study was done between the

fifties and the sixties that certain parts were in the 100's and you said now it is down to single digits and it really did not make any difference from a health risk area? Can you explain that a little bit more?

Mr. RODU. Yes, okay. Let me clarify that.

When most of the epidemiologic studies were performed it was between the 1950's and the 1980's. They measured smokeless tobacco associated risks in users during that period, and during that period nitrosamine levels were in the range of the hundreds. They were quite a bit higher than they are today.

So we have a relative risk from that period in the range of two to four, and that is what we have based all of our epidemiologic models on.

Now we are talking about products that are substantially lower, and in fact, the American Health Foundation has said that they are at least 70 percent lower than they were in the 1970's. So we are talking about a shift downward in risk from the 1950's through the 1980's. So we go from two to four down. We are going toward one, and one being the risk of a nonuser of tobacco.

Mr. STUPAK. Is it fair to say then, as maybe UST would argue then, that it is safer now than it was in the fifties to eighties?

Mr. RODU. Well, Mr. Verheij can respond for UST. I believe that products are safer now than they were in the 1980's.

Mr. STUPAK. Because of this nitrosamine?

Mr. RODU. Yes, because of nitrosamine level reduction.

Now, when you have a relative risk to start with of around two to four, it is very difficult to show without enormous populations and huge studies any more reduction in risk. So that reduction is going to be very difficult to quantify, but in fact, the safer products can be the better off we all are.

Mr. STUPAK. Okay. Mr. Verheij, UST petitioned the FTC to advertise this as safer, correct? And then that was withdrawn, that petition?

Mr. VERHEIJ. We actually petitioned the FTC for an advisory opinion. We thought that instead of going out and communicating this information to adult smokers who were not quitting that we would get some guidance from the Federal Government. It was unlike anything any other tobacco company had done.

Mr. STUPAK. But did you withdraw the petition?

Mr. VERHEIJ. We have temporarily withdrawn the petition. We have supplemented the record probably 3 weeks ago.

Mr. STUPAK. Okay, and there has been some talk about doing a workshop on this issue now, right, with the FTC?

Mr. VERHEIJ. That is certainly what we are urging, a workshop. We believe this is a process. The Institute of Medicine report was a process. Our filing with the FTC was a process. This hearing today is part of the process, and we think a workshop would be a very important part of the process.

Mr. STUPAK. If you did a workshop, would FDA be invited to that workshop?

Mr. VERHEIJ. Absolutely. We would encourage that.

Mr. STUPAK. The Centers for Disease Control?

Mr. VERHEIJ. Absolutely.

Mr. STUPAK. Should FDA regulate smokeless tobacco then?

Mr. VERHEIJ. Well, there have been a lot of proposals about fda regulating cigarettes and smokeless tobacco. Historically we are opposed to that because the fact was it was going to regulate——

Mr. STUPAK. Right.

Mr. VERHEIJ. [continuing] it as a medical device.

Mr. STUPAK. But if you are talking about it being safer, smokeless tobacco would be safer, and if FDA regulates nicorette and all of this other stuff to help you reduce your smoking, if this is a product that is safer and encourages less smoking, shouldn't they also regulate smokeless tobacco then?

Mr. VERHEIJ. Well, as we have laid out in our public filings, we believe that if there was a regulatory regime that recognized this concept of tobacco harm reduction and the distinct differences between smokeless tobacco and cigarettes, that is something the company would seriously consider supporting.

Mr. STUPAK. But if it is tobacco harm reduction, shouldn't we also know that not only from an advertising point of view but also health point of view, and that is where the FDA, CDC and others, NIH, would come in?

Mr. VERHEIJ. I think that is implicit in the process. I think what you see here along the panel, however, is a difference of viewpoint, is when, in fact, we are going to begin communicating to adults this information about the fact that smokeless tobacco is considerably less harmful. Mr. Myers would say 5 years in the future when we get FDA regulation.

Mr. STUPAK. Sure.

Mr. VERHEIJ. Dr. Rodu says we should have started this 10 years ago. So you see a range of views, and that would be a part of the discussion at the forum.

Mr. STUPAK. But aren't you really saying that we should advertise first and then let the FDA look at it second? Isn't that what you are saying?

Mr. VERHEIJ. Well, I think the broader societal question is as we move through this process, what are we going to communicate?

And I believe Chairman Tauzin raised the concern about what are we doing today. Yes, everyone is moving toward some increased regulation, but I think a number of people on the panel here are saying what should be done today. What type of communication?

And, again, take the company out of it, but what type of communication should come from the public health community to adult smokers who are not quitting today?

Mr. STUPAK. But should the public health concern be addressed before you advertise? I mean, there is advertising for smokeless tobacco in Sports Illustrated, the USA Today's sports page. It seems like the advertising is getting ahead of the health concerns.

Mr. VERHEIJ. And I think, Congressman, that the underlying assumption that there would be some broad based advertising in Sports Illustrated or some publication that has some concern, again, take the company out of it. Say there is no communication from the company.

Mr. STUPAK. Okay.

Mr. VERHEIJ. The remaining question is: what type of communication will come either from the government or from the public

health community about truthful, accurate information about the significant differences between smokeless tobacco and cigarettes.

Mr. STEARNS. The gentleman's time has expired.

The gentlelady is recognized.

Mrs. CUBIN. Thank you, Mr. Chairman.

It troubles me that I have heard today in this hearing that, to paraphrase, we will not even consider a possible action that could benefit smokers unless we have Federal regulation of that. In fact, we will not even consider looking at whether or not a product is beneficial unless we have Federal regulation.

I disagree with that very much. I do not think that the first thing that we ever should do is look to Federal regulation to solve our problems, although there certainly is a point in our society when that is appropriate.

As far as Federal regulation of these tobacco products, tobacco, whether you smoke it or whether you use snus, is a legal product. Now, if this should ever happen that it does become regulated under the FDA, then what is the next thing? Are we going to be regulating cream gravy or white sauce, as it might be called here in the northeast?

It just bothers me that some people think the only way to solve a situation is that the government has to take control. Historically they do not do that good a job.

So I do not think that you can rule out listening to scientists who have done studies. You cannot rule out listening to information and facts that are presented to you simply because the Federal Government does not have regulation over that area.

I would like to start by asking a question, just kind of a general question about truth in advertising. Commercial advertising is protected by the First Amendment, provided that it is truthful——

Mr. STEARNS. Will the gentlelady just move her mic a little closer to her.

Mrs. CUBIN. Oh, yes. Thank you.

—providing that it is truthful and not mislead. The government may regulate commercial speech if it has a compelling interest in doing so and its regulation is reasonably tailored to directly advance that interest.

In relation to the promotion of tobacco reduction products, what compelling State interest is directly advanced by suppressing truthful, reasonably tailored messages to the public?

Do you understand the question?

Mr. MYERS. I will start with you because it is based on a misconception, and that is——

Mrs. CUBIN. No, you will not start. You have talked more here today than everyone, and we know how you feel.

Mr. MYERS. But the government does not——

Mrs. CUBIN. No, sir. I would like to address someone else.

Mr. STEARNS. The gentlelady controls the time.

Mrs. CUBIN. Thank you.

I do not care. The question I want to ask is that the government can regulate commercial speech if it has a compelling interest in doing that and the regulation is reasonably tailored to directly advance that interest that the Federal Government has.

So in relation to the promotion of tobacco harm reduction products, is there then a compelling State interest directly advanced by suppressing this truthful, non-misleading advertising?

Mr. VERHEIJ. Congresswoman, if I may start with that, and then maybe others will chime in.

The fact is we believe there is no compelling interest by the state, particularly when you look at the offsetting potential benefit to public health that people like Mr. Sweanor and Dr. Rodu and many others have articulated, to the fact that this information through some mechanism—and again, I think everyone focuses on our company as proposing we would be the only avenue.

Frankly, we would like to get out of the middle of that fight because of concerns and go back to if we are taken out of the equation, what obligation does the government or the public health community have to communicate this information——

Mrs. CUBIN. Exactly.

Mr. VERHEIJ. [continuing] to adult smokers.

Mrs. CUBIN. Exactly, and there are scientists and researchers that are available that are nonbiased. Like you said, take tobacco out of the equation. They could produce good information that we could base decisions on without Federal oversight and without Federal regulation.

If the information is accurate and fairly presented, doesn't the public have a right to receive that information and evaluate for themselves the usefulness of that information?

Yes, Dr. Rodu.

Mr. RODU. Ms. Cubin, we have tried for 10 years to publish strongly scientifically based research in order to help, and I believe your husband is a practicing physician.

Mrs. CUBIN. That is correct.

Mr. RODU. In order to help people like him help their patients because we believe knowledge is power, and it can help him help patients to make decisions that allow them to lead longer and healthier lives.

Mrs. CUBIN. Thank you.

I do appreciate that, and that is exactly the course that my husband has tried to follow because that is one thing he tells every single patient that comes in there that smokes, carte blanche. You must stop smoking.

And they tell him, "I cannot stop smoking."

And at that point, he needs help in dealing with them when they have tried gum and when they have tried patches. You know, anything else would be a benefit to him and especially to his patients.

Mr. RODU. Ma'am, we would like to say he is in the trenches.

Mrs. CUBIN. Thank you.

Mr. RODU. And the closer you are to real patients and real problems the more likely you are to consider an option like smokeless tobacco.

Mrs. CUBIN. And that is the truth. I agree with you.

Mr. BURTON. Congresswoman, could I weigh in?

Mrs. CUBIN. I do not see who is weighing in.

Mr. BURTON. I am sorry.

Mrs. CUBIN. Yes, you bet, Mr. Burton.

Mr. BURTON. I guess I will come back to a comment that I think I heard the Surgeon General make this morning, which was in the presence of truthful and accurate information, nonetheless consumers might be incapable of making the right decision in their own interest, as well as the interest of the public health.

Mrs. CUBIN. Excuse me. Would you repeat that?

Mr. BURTON. Certainly. I guess the point I am making or want to make is harking back to something that the Surgeon General said, and I think I have this from my own experience in being before the agency, the FDA, on drug applications. One of the burdens we as a drug supplier have to meet is a demonstration that information can be correctly interpreted. Can it be understood by the average consumer and can the net behavior actually be within the bounds of what we expect and what we know to be a safe and efficacious use of that product?

So I think in part my answer and I think part of the answer of the Surgeon General was that even information—and I am not accepting that the information as you framed it is necessarily truthful and accurate—but were it to be found to be so, I think the question is can consumers take that information, interpret it, and act accordingly.

And I think from our research and from what we have heard from other public health experts, it is not only an individual decision, but it is also a public health population impact that we need to be concerned about. If that information is targeted to a different group of people, like young adults who might otherwise not start smoking, upon hearing what may be truthful and accurate information to a so-called committed smoker, if that young adult decides to begin using those tobacco products on the assumption that that is a safe alternative, I think that is a public harm that I think counters the public interest of providing that accurate information.

Mrs. CUBIN. Thank you.

I appreciate that, but that is a very weak response when you consider the 10 million people that are going to die over the next 2 decades because we are worried about children starting to use a tobacco product, when in fact we do not even know—and I have heard no source that quotes that smokeless tobacco is a gateway drug.

Just real quickly.

Mr. STEARNS. The gentlelady's time has expired.

Mrs. CUBIN. Just real quickly. I have been waiting all day.

Mr. STEARNS. Okay. Do you want to take unanimous consent?

Mrs. CUBIN. Well, what are you going to do, Markey?

No, I would like to ask one other question. I would like to ask for unanimous consent for one question.

Mr. STEARNS. The gentlelady has asked for unanimous consent for one question. Is there any objections?

Mr. Myers, I understand you have been waiting patiently and you have to be on this other panel. So I think you are welcome to leave. You have given yeoman's service here since 10 o'clock. So if you have to be on another panel.

Mr. MYERS. I am not on another panel, but I do have an emergency that I have to go to.

Mr. STEARNS. Okay. Well, that is fine. That is fine. We appreciate your staying this long and your patience and so forth.

Mr. MYERS. Thank you.

Mr. STEARNS. The gentlelady is recognized.

Mrs. CUBIN. I do not want to be redundant and most of the questions that I wanted to ask have been asked and answered, but I would like to as Mr. Verheij a question.

Back to the Swedish study that males are reported to have the highest rate of smokeless tobacco use and the lowest rate of cigarette smoking in any Western country, and the daily use of smokeless tobacco by Swedish males now, as has been stated, is that of the use of cigarettes. Tobacco related mortality in Sweden is reported to be lower than any other European or American country.

From the point of view of comparative health risk, comparing cigarette smoking to smokeless tobacco or snus, as we call it, would you describe your company's Revel product and what your marketing plans for that are?

Mr. VERHEIJ. I would be happy to. The fact is that a number of researchers believe that the Swedish model is, indeed, applicable here in the United States. The difference is that, as I think one of the panel members noted, there is a cultural acceptance there as to the fact that smokeless tobacco is considered to be significantly less harmful than smoking.

And, yes, it is not a communication from a tobacco company to consumers in a newspaper, but when I was there in September for a conference on smokeless tobacco, there was a full page ad in the primary newspaper signed by four leading Swedish researchers, talking about this conversion from smoking to smokeless tobacco, and the fact is how fortunate they thought Sweden was to have smokeless tobacco as an alternative for those smokers who do not quit.

So I think that is a good example where the communication does not have to come from a tobacco company.

When we began marketing Revel or at least test marketing Revel, it was advertised as a product for the times: you cannot smoke. The fact is we would prefer to market Revel to adult smokers who are not quitting on the basis of completely switching from smoking to smokeless tobacco because what we have found out in the research is that to convince a smoker to switch to smokeless tobacco, they need a very compelling reason, and they need a very compelling reason because an overwhelming percentage of them have been taught over decades now that smokeless tobacco is as dangerous as cigarette smoking, and so they think they are trading oral cancer for lung cancer.

They are shocked when they are provided truthful, accurate information about research in this country and other countries concluding that smokeless tobacco is significantly less harmful than cigarette smoking.

Once they hear about that research and actually accept it, then they have that compelling reason, and Revel is designed to attract adult cigarette smokers, adult cigarette smokers only, and I think any communication we plan in conjunction to that will be directed to only that audience.

Mrs. CUBIN. Thank you.

Mr. STEARNS. The gentlelady's time has expired.

Mrs. CUBIN. Thank you.

Mr. STEARNS. The gentleman from Massachusetts.

Mr. MARKEY. Thank you, Mr. Chairman, very much.

I do not think anyone is going to debate that it is less dangerous. I think we are going to accept the fact that it is less dangerous, but that is a little bit like saying, well, you know, we have been playing Russian roulette with three bullets in a six-chamber gun and now we are going to reduce it down to only one bullet in the six-chamber gun. So it is obviously a safer game playing Russian roulette with only one bullet rather than three bullets in a six-bullet chamber.

But eventually if you play the game long enough, then enough people are going to get harmed that most people would say that is too dangerous a game to be played. And I think that is, you know, why you have the level of concern that members are indicating, Mr. Verheij, today.

Let me ask this. The Massachusetts Attorney General and others wanted to examine and reveal to the public the additives that are being put into smokeless tobacco products. Why can't the public know what those ingredients are so they can make up their own mind as to whether or not they or their family members would use that product?

Mr. VERHEIJ. As you know, Congressman, under the 1986 act we as a company and an industry are required to report all of our ingredients to HHS, which I think the Surgeon General confirmed this morning indicated that they had an ability to look at that list, and every year we dutifully file that list, and to the extent that HHS has a concern, it is explicitly authorized to report to Congress about the concerns they have.

In connection with that, however, there are measures taken to protect the proprietary interests that the companies have in unique ingredients used in the product.

As for another state, for example, Texas has adopted a similar statute and, in fact, the industry reports its ingredients to Texas.

I think where the difference was in Massachusetts, that in our view and the industry's view, that the statute at the time that was put into place was really not a disclosure statute, but it was really a forfeiture statute where we would have forfeited the proprietary value of the ingredients we used, and the court of appeals agreed with that argument.

Mr. MARKEY. I understand that, but the problem is from a consumer perspective, as the Surgeon General said today, there are carcinogens in your product and those carcinogens also contribute to other types of diseases, cardiac disease in addition to respiratory.

Mr. VERHEIJ. Well, I think now, if I understand your question correctly, we have shifted from ingredients, which are those items that are added to the product by the company, all of which are approved for use in food or food grade, unlike other tobacco products, and I think by your question, I understand you want to switch to constituent levels of nitrosamines.

And as indicated earlier, the Massachusetts Department of Health has conducted at least one survey. We have met with the

department in terms of trying to evaluate that data. Dr. Connolly of your State called me about 3 weeks ago. He was particularly concerned about levels in competitor's product, gave me some idea of the levels of the constituent levels in our product in the current survey. He is very concerned about the fact of being able to continue that testing, although his budget has been cut dramatically.

And we actually engaged in a discussion about industry funding of that survey for him on an annual basis so that the State of Massachusetts can actually do that.

Mr. MARKEY. Well, would U.S. Smokeless Tobacco Company support a regulation which mandates that all smokeless tobacco products contain nitrosamine levels below 10 micrograms per gram if this were implemented in Massachusetts?

Mr. VERHEIJ. Well, I think we had an agreement with Dr. Connolly that everyone was moving in the direction of trying to reduce it to the lowest levels possible. I guess I would have some questions about the level of 10 parts per 1,000,000 because when Dr. Connolly proposed that, when he was advised by a newspaper reporter about the levels of nitrosamines in the Revel product, which is around 2 to 3 parts per million, his response was, "Well, there is no magic about 10."

So I think it would be worthwhile for everyone, the industry in your State and Dr. Connolly to get together and work out some standards that he perhaps as an encouragement to the industry, goals and targets which we would be happy to sit down and work with him to do that.

Mr. MARKEY. I think in general that the American public has become acclimated to knowing what is inside of the products which they purchase. My father late in life became a health food nut. I would have sworn that a guy that used to just put a whole can of sardines and slice off 12 heads at once and then pop them all in his mouth when I was a boy would become a health food fanatic at 70 and 75, 80 and 85, but he did.

And so here is a product thought that——

Ms. CUBIN. Would the gentleman yield?

Mr. MARKEY. I will be glad to.

Ms. CUBIN. Are you supposed to cut the heads off of sardines before you eat them?

Mr. MARKEY. Well, my father thought it was fun if they all squirted toward my brother's head.

Ms. CUBIN. Oh.

Mr. MARKEY. And it was just kind of——

Ms. CUBIN. Being from Wyoming.

Mr. MARKEY. My father was a milkman for the Hood Milk Company.

Ms. CUBIN. Well, thank you.

Mr. MARKEY. And his form of humor was lost on my mother, although my brothers and I thought it was very funny.

Ms. CUBIN. I can relate to that.

Mr. MARKEY. But anyway, I am just saying his eating habits were not the best, but he later just became a fanatic in studying every single ingredient in every single thing that he put into his system, and but for smoking the doctor said he would have gone on indefinitely over the age of 100.

And here is a product though that we know is inherently, you know, dangerous because of the carcinogens that are in it, and the more information which is out there, I think the more likely that there would be an abstinence that was total. That is not to be an unimaginably high goal a generation ago, but the whole culture has changed.

If my father could change, anyone could change, and all I am saying to you is that that information is what you are denying the public under the guise of proprietary information, competitive advantage, but in fact, in my opinion it is to deny the public the knowledge of the danger which their bodies are being exposed to by having these kinds of products put near their bodies.

I thank you, Mr. Chairman.

Mr. VERHEIJ. Mr. Chairman, if I may just respond to that last point, the fact is that I heard the Surgeon General this morning very strongly indicating that, in fact, as these ingredients are reported to the Federal Government, they have mechanisms, including his bully pulpit, if there was a concern to educate the public about ingredients in tobacco products.

We share your concern about educating the public, but in the context of educating the public about the fact that there are dramatic differences between the relative risks between smokeless tobacco and cigarettes, and they are not getting that information either.

Mr. STEARNS. The gentleman's time has expired.

Mr. TOMAR. Mr. Chairman.

Mr. STEARNS. We will allow you to answer. Do you want to reply also?

Mr. TOMAR. Yes. I just wanted to speak to the issue of the additives to smokeless tobacco products. I used to be an epidemiologist with the Office on Smoking and Health, and so I was able to see that list of more than 500 chemicals that are added to smokeless tobacco products. When we were there, we asked them to provide brand specific information on that, and they refused.

They also do not provide any information on concentration or quantity on any of those 500 chemicals, and a number of the chemicals that are added to those products are specifically to affect the nicotine dosing properties of those products. That feeds into their whole graduation strategy of being able to manipulate the nicotine dosing properties. We ask them to provide information on pH. The degree of alkalinity of the product affects the rate of nicotine absorption. They refuse to provide brand specific information.

If the company really wants to disclose truthful information to the public, they can start with what they already have.

Mr. STEARNS. The gentleman's time has expired.

The gentleman from New Hampshire.

Mr. BASS. Thank you very much, Mr. Chairman.

I just want to emphasize that we are here today to talk about relativity, not absolutes, and I do not think any member of this subcommittee believes that smoking cigarettes or the use of tobacco products is good for your health or should be condoned, especially amongst minors, and a lot of the debate today has revolved around accusations that somehow minors are going to get into the business of chewing tobacco or smoking cigarettes, which has always been

a problem, and in my home state, it is a misdemeanor to possess tobacco products of any sort under the age of 18. There are criminal penalties for that, and the local law enforcement community enforces that, and nobody here today is advocating that.

And so the issue is for those individuals that cannot terminate the use of cigarettes, what other options exist, and we have talked about a lot of different opportunities, and the other issue of whether or not the smokeless tobacco industry can advertise or discuss in an advertisement any kind of relative benefit of their product versus any other.

I have two questions, one for Mr. Verheij and another one for Dr. Tomar.

Mr. Verheij, if U.S. Tobacco were to advertise smokeless tobacco products as being less harmful than cigarettes, how would you advertise that fact under government guidelines, without influencing minors to use the product?

Mr. VERHEIJ. Well, we have given that some thought, and there are a number of ways that we communicate directly to adults. We have adult only facilities where people are carded or only 18 and over are admitted. In fact, we get information about the tobacco habits of those particular individuals. We find out if they are smokers, and we could make a communication right there.

There are also direct mail lists of adult smokers. I mean, I think people envision some broad based advertising program, and frankly, it would not be very effective because it would be so diffuse when you are really trying to address adult smokers who are not quitting.

The optimal from our standpoint would be take us out of the equation. If as Dr. Rodu indicated all of those physicians in the trenches, if it was physicians were advised by the government that, in fact, here you have a patient who is a smoker who they have tried the gum, they have tried the patch, and they are not quitting, that they could advise that patient of smokeless tobacco as a significantly less harmful option, then the company would not have to make any type of communication if that is the type of communication the government and the public health community were giving to these adult smokers who do not quit.

Mr. BASS. Dr. Tomar, I understand that you were listed as an expert witness in an action brought by the Washington State Attorney General to recover the health care costs of tobacco use, and that you prepared a report estimating that the health care costs related to smokeless tobacco used were less than 1 percent of those. Is that true?

Mr. TOMAR. I would have to go back and look at the figures, and it has been a number of years. I do not remember the exact figure.

Mr. BASS. Okay. Well, you would be kind enough to check up on that and advise the committee I would be very grateful to you.

Mr. Chairman, I yield back.

Mr. STEARNS. Do you mind yielding the balance to the gentleman?

Mr. BASS. I would like to yield to the gentlelady from Wyoming.

Ms. CUBIN. Thank you very much.

The question I wanted to ask, and maybe, Mr. Burton, you will know or, Mr. Verheij, maybe you will know: are physicians right

now prevented from telling their patients that they believe smokeless tobacco is a healthier alternative, is healthier than smoking, although not a healthy alternative?

And, Dr. Rodu, you may know that answer. Anyone, just speak up.

Mr. VERHEIJ. Well, let me start. Just based on our conversations with physicians, which we do on a frequent basis in terms of trying to identify the issues related to smokeless tobacco, and I believe there have been some submissions for the record from treating physicians and head and neck surgeons, what is taught in public health school is that smokeless tobacco is as dangerous as cigarette smoking, and they are stunned to find out that many researchers believe that smokeless tobacco is significantly less harmful.

Ms. CUBIN. But do you know, Dr. Rodu, is there a prohibition against physicians telling their patients that?

Mr. RODU. No, none whatsoever. It is called informed consent.

Ms. CUBIN. Correct.

Mr. RODU. As long as we provide both the risks and the benefits of any treatment that we recommend, we are fulfilling our obligations as health professionals in letting people make choices.

Ms. CUBIN. And, Mr. Burton, is that the sort of thing that doctors also have to do when they are recommending a prescription that perhaps your company might manufacture when they are prescribing the medication?

Mr. BURTON. Certainly physicians would advise their patients of the risk and benefits of a particular course of action. Certainly I think a significant difference being the fact that when you are talking about pharmaceuticals or medicines, they have been reviewed by the agency, the FDA. They have been proven to be safe and effective, and the physician within that context can go beyond based on his understanding or her understanding of the science to maybe amplify what is in the approved labeling for that particular drug.

Ms. CUBIN. Thank you.

Thank you, Mr. Bass.

Mr. STEARNS. And the gentleman's time has expired, and our hearing has expired, and we are completing.

By unanimous consent, all members will have 5 working days to enter any extraneous material they wish to put in.

I think it has been an excellent debate, and I want to thank the witnesses sincerely for this long afternoon. We need to focus on the science of this debate. The science should lead the way, and if the science tells us that lives can be saved, we need to investigate these options.

I hope the Federal Trade Commission will seriously consider putting together a workshop on tobacco harm reduction. If we can save even a handful of people out of the 400,000 people who die every year, it will be worthwhile to do.

I also want to thank staff for getting all of this balanced, I think a very balanced hearing, and I think the thesis of our hearing has been accomplished, namely, that smokeless tobacco needs to be explored as an alternative for persons who cannot stop smoking, and we need more research on that.

And with that, the subcommittee is adjourned.

[Whereupon, at 3:18 p.m., the subcommittee meeting was adjourned.]

[Additional material submitted for the record follows:]

AMERICAN LEGACY FOUNDATION
June 10, 2003

The Honorable CLIFF STEARNS
Chairman
Subcommittee on Commerce, Trade and Consumer Protection
Energy & Commerce Committee
Washington, DC 20515

The Honorable JANICE D. SCHAKOWSKY
Ranking Member
Subcommittee on Commerce, Trade and Consumer Protection
Energy & Commerce Committee
Washington, DC 20515

DEAR CHAIRMAN STEARNS AND RANKING MEMBER SCHAKOWSKY: I am writing today to clarify the record with regard to testimony offered by U.S. Smokeless Tobacco Company (USSTC) regarding its payments to the American Legacy Foundation as part of the Smokeless Tobacco Master Settlement Agreement. The testimony was offered during a hearing before the Subcommittee on Commerce, Trade and Consumer Protection of the Energy & Commerce Committee on June 3, 2003 entitled "Can Tobacco Cure Smoking? A review of Tobacco Harm Reduction."

The American Legacy Foundation (Foundation) is an independent public health foundation that addresses the health effects of tobacco use on our nation through research, grants, technical training and assistance, youth activism, counter-marketing and grass roots outreach. Our mission is to build a world where young people reject tobacco and anyone can quit. The Foundation is a 501(c)(3) organization and was established in March 1999 as a result of the Master Settlement Agreement (MSA) between the attorneys general in 46 states and five U.S. territories and the tobacco industry. I serve as the Foundation's President and CEO.

During the hearing, USSTC offered testimony regarding its company's smokeless tobacco products. In so doing, it sought to allay concerns members might have regarding the marketing of these products to youth by pointing to USSTC's support of the American Legacy Foundation. Specifically, USSTC testified that:

> "...USSTC became the only smokeless tobacco company to enter into the Smokeless Tobacco Master Settlement Agreement ("STMSA") with Attorneys General of various states and U.S. territories. Pursuant to the STMSA, USSTC is providing up to $100 million (plus an inflation adjustment), over a 10-year period, to the American Legacy Foundation for programs to reduce youth usage of tobacco and combat youth substance abuse, and for enforcement purposes." (citations omitted)

While we commend USSTC for entering into the STMSA, we would like the record to clearly reflect the history and underpinnings of the settlement agreement to which it refers.

Along with the larger MSA reached with the cigarette manufacturers, the STMSA was the result of protracted litigation brought by the states to recoup the billions of dollars the states were forced to spend as a direct result of a wide range of illegal activities undertaken by the tobacco industry. It was the states, and not the tobacco companies, that introduced the concept of the Foundation into the settlement discussions. Moreover, it was the states that earmarked a portion of their recovery to create the Foundation. Indeed, the agreement specifically states that the payments are "made at the direction and on behalf of Settling States." It also states that the manufacturers "do not undertake and expressly disclaim any responsibility with respect to the creation [or], operation..." of the Foundation.

Accordingly, while USSTC quite accurately represents that it entered into the settlement agreement and has made payments pursuant to that agreement, it is not accurate to state that USSTC is funding the American Legacy Foundation or to suggest that it is responsible for its successes in reducing youth smoking or that, because of its connection to the Foundation, members of Congress should not be concerned about smokeless tobacco products being marketed to America's youth.

I would also like to take this opportunity to inform the Subcommittee of the American Legacy Foundation's successes in countering youth tobacco usage. Indeed, on June 4, Legacy was honored to receive both the Gold and Grand Prize EFFIE awards for its **truth**® campaign. The EFFIE Awards recognize advertising campaigns that deliver superior results in meeting the objectives they were designed to

achieve. Legacy was just the second nonprofit organization to earn this top honor in the EFFIE's 35-year history.

With its frank approach and blunt messaging, **truth**® was specifically cited in a recent *Monitoring the Future Report* released by the National Institute on Drug Abuse as one of the reasons behind sharp declines in teen smoking. *See* Johnston, L.D., O'Malley, P.M. & Bachman, J.G. (2002), p. 126-127. *Monitoring the Future national survey results on drug use,* 1975-2001. (NIH Publication No. 02-5106). Bethesda, MD: National Institute on Drug Abuse. Indeed, a table presented during the release of a subsequent report shows a striking trend in the reduction of cigarette use among eighth, tenth and twelfth graders, which corresponds to the launch of our **truth**® campaign, as well as other important tobacco control efforts including increases in cigarette prices, increased prevention activities in a number of states, efforts by the FDA in conjunction with states to reduce youth access to tobacco, and removal of certain types of advertising nationwide, such as billboards. *See* Johnston, L.D., O'Malley, P.M. & Bachman, J.G. (2002). *Monitoring the Future national results on adolescent drug use: Overview of key findings, 2002.* (NIH Publication No. 03-5374). Bethesda, MD: National Institute on Drug Abuse.

Legacy has received what is likely to be its last payment for public education pursuant to the MSA, which could mean that we will forced to scale back or eliminate our **truth**® campaign. States with award winning youth tobacco control and counter marketing efforts are also eliminating these programs because of budget woes. Increasingly, campaigns like **truth**® and state counter marketing campaigns are being challenged in the courts by tobacco companies. Now, more than ever, we urge you and your colleagues to remain vigilant when it comes to our children's health.

We respectfully request that the entire contents of this letter be included in the official record for the Subcommittee.

Sincerely,

CHERYL G. HEALTON. DR. P.H.
President & CEO

cc: Mr. Richard H. Verheij, USSTC
Members, Subcommittee on Commerce, Trade and Consumer Protection,
House Energy and Commerce Committee

FRONTIERS OF FREEDOM
FAIRFAX, VA
May 29, 2003

The Honorable CLIFF STEARNS
House Commerce, Trade and Consumer Protection Subcommittee
2125 Rayburn House Office Building
Washington, DC 20515

DEAR CHAIRMAN STEARNS: Please accept the following testimony for the June 3rd Subcommittee hearing entitled, "Can Tobacco Cure Smoking?—A Review of Tobacco Harm Reduction."

On behalf of Frontiers of Freedom I would also like to take this opportunity to applaud the Subcommittee for looking into this issue and encourage other parts of the government, including the Federal Trade Commission and the Department of Health and Human Services, to work together to explore this issue in further formal settings.

The Frontiers of Freedom Institute has been on the forefront of promoting sound science in public policy. It is our belief that sound science must be the bedrock foundation for public policy decisions. This is particularly true when public health is involved. To divorce sound science from public policy is legislative and regulatory malpractice.

The Institute has reviewed a wide array of studies and experts and it appears that the great weight of the evidence indicates that using smokeless tobacco instead of smoking tobacco provides a better, safer and healthier alternative. Many of these experts have a long history of speaking out against tobacco for health reasons.

It is not our opinion that the use of tobacco in any form is healthy, but if sound science and medicine indicate that using smokeless tobacco instead of smoking cigarettes provides a significant reduction in health risks, the public has a right to know this important fact. This is useful information to those who currently smoke and want to reduce their health risks.

Some argue against permitting the public to have this information and argue that people should simply stop smoking. However, in practice many people have been unsuccessful in their attempts to stop smoking. The adult smoking public should be made aware of their options. To prohibit consumers from having access to this

knowledge is more than bad policy. It is malfeasance. In the corporate world, such a decision would expose executives to untold liability to those who would have benefited from this information but were denied it.

Much has been made of the Enron scandal on grounds that employees, investors, and the public were not given access to the best and most accurate information about the company's financial health. Throughout recent history, there have been a wide variety of scandals when government or corporate officials withheld factually accurate information from the public. Congress should NOT place itself in the center of a future scandal by preventing the public from obtaining accurate and factual information that can help smokers improve their health. Political correctness is no substitute for factual correctness.

For these reasons, the Institute appreciates the attention the Subcommittee is giving this subject, and urges Congress to continue to look into this issue and work to permit consumers to have access to information and scientific studies regarding the potential health benefits of using smokeless tobacco as compared to smoking tobacco.

Sincerely,

GEORGE LANDRITH
President

PREPARED STATEMENT OF ALLIANCE FOR HEALTH ECONOMIC AND AGRICULTURE DEVELOPMENT

GENERAL COMMENTS

The Alliance for Health Economic and Agriculture Development (AHEAD) appreciates the opportunity to submit this testimony to the House Committee on Government Reform as well as to the Subcommittee on Commerce, Trade and Consumer Protection (House Committee on Energy and Commerce). AHEAD was formed shortly following the issuance of the historic report **Tobacco at a Crossroad,** which laid out a series of recommendations for policy changes affecting the production, manufacture and marketing of tobacco products.

The Alliance is an informal coalition of individuals, organizations, business, churches and other interests working cooperatively to implement the principles and recommendations in the commission report. The Alliance builds on nine years of dialogue and discussion between tobacco producers, public health organizations and others and provides a **neutral** setting where non-traditional partners can resolve differences and work together to achieve mutual goals.

Tobacco growers, the public health community and manufacturers are indeed at a crossroads. There are unique challenges and opportunities before us that are going to require that all parties set aside the rhetoric and to focus on substantive issues. On the one hand, the attitude that we have to change everything overnight or not at all is unrealistic. But the attitude on the part of some that nothing should change is not only unrealistic but irresponsible. Dogmatic views, entrenchment and an unwillingness to find solutions must be substituted with open dialogue, discussion and transparency. We need to be able to recognize and work through the things that represent *legitimate* issues and to circumvent those that are used merely to stall what is inevitable and necessary. The Alliance recognizes that no one party alone can solve the challenges confronting us from the use of tobacco.

The future of tobacco and tobacco products will require a more integrated system that encompasses the production, processing, manufacturing, labeling, advertising, and marketing of tobacco. For example, the current tobacco program with its system of quotas must be a replaced with a new system of production controls that brings the growing of tobacco into the 21st century, taking into account technological opportunities and consideration of health and safety issues. These authorities should be based within the USDA and coordinated with the FDA. The future will require a more active research agenda, more effective monitoring and surveillance and an effective regulatory system (FDA) that is flexible enough to be able to deal with unforeseen issues and to take advantage of opportunities when they arise. It should involve incentives for tobacco growers, researchers and responsible manufacturers to develop new methods of production and new products that reduce exposure to tobacco toxicants and which have a reasonable prospect of reducing tobacco related disease. Government, public health organizations, researchers, tobacco growers and even industry must find a way to work constructively and cooperatively to address the challenges and to find meaningful, effective and workable solutions. What we do here in the United States could set an example for the rest of the world in light of the recently approved FCTC.

Tobacco and tobacco products come in a variety of forms. For decades there has been a tendency to equate all tobacco and tobacco products as being equally harmful when in fact this is not the case. There are many types of tobacco leaf that go into making a tobacco product. These include such varieties as burley, flue-cured, dark-fired, and oriental. As with any agricultural plant, most tobacco is treated with pesticides, and cured and processed in different ways. All of these things can and do affect the quality (including health and safety) and composition of the leaf. In addition, as much as 50% of the tobacco used in US manufactured cigarettes (both domestic and foreign export) comes from overseas where there are fewer regulatory controls in place. This alone can result in added and unforeseen risks. Similarly there are many types of manufactured tobacco products—cigarettes, cigars, pipes, and smokeless. Each of these carries their own set of risks—some greater than others. And even within each of these categories there are and can be significant variations of risks. Risk will vary depending on whether the product is burned or not, what type of tobacco is used, how it is treated, where that tobacco came from, and what additives and chemicals are used in its manufacture. Lowering risks from tobacco will also depend on the development of new technologies that are based on science and not public relations gimmicks. The challenge that we face is how to best assess these risks so that the public and consumers of tobacco fully understand the consequences of using tobacco products and understand the relative risks that various products present.

DEVELOPMENT OF LOWER RISK PRODUCTS AND TECHNOLOGIES TO REDUCE RISK

The Alliance believes, as do most others, that risk reduction can be a viable and effective means in reducing the disease caused by the tobacco products currently on the market. Statements by the Surgeon General, the IoM, and other public health authorities all advocate that reducing toxins in tobacco products and "encouraging the development of products that reduce consumer health risks or serve as less harmful alternatives" should be done undertaken. There is enough science to begin to make changes and to recognize that there are technologies in existence that can reduce the levels of toxins that are known to be associated with disease. While clearly unique, tobacco products are consumer products and like other products in society where we consider "risks" we can and should do the same with tobacco. The issue no longer seems to be whether scientifically based lower risk products should be developed and made available, the issue and challenge is *how.* Development of science-based tobacco products that can lower risk through both regulation and competition can also force the more toxic products off the market. We could see a significant shift in not only the development of new products but the removal or replacement of the older ones.

As the **Tobacco at a Crossroad** noted:

> Given the number of Americans who use tobacco today, prohibition would not protect the public health because it would drive many smokers to use unregulated black market products. Therefore, a statutory standard designed to promote the 'public health' rather than one that requires a tobacco product to be "safe" best protects everyone's interests. It also recognizes that the "status quo" for current products is not in anyone's interest if it is possible to reduce the harm that tobacco products cause (p.43).
>
> Independent science based decisions by FDA designed to protect public health by taking *reasonable* steps to reduce the harm of tobacco products now being sold and *promote* the introduction of less harmful products will also create fair standards and will provide predictability to farmers and to industry. (p.43)

The Institute of Medicine Report, **Clearing the Smoke** noted:

> For many diseases attributable to tobacco use, reducing risk of disease by reducing exposure to tobacco is feasible. This conclusion is based on studies demonstrating that for many diseases, reducing tobacco smoke exposure can result in decreased disease incidence with complete abstinence providing the the greatest benefit.

There are obviously many unknowns that will have to be addressed. For example, concerns have been raised that we may find ourselves making the same mistakes that were made in the development and marketing of low tar and low nicotine cigarettes. What was believed to be in the interests of public health turned out to be an abusive marketing tool for the tobacco companies. One of the primary reasons for this was the absence any kind of regulatory oversight. These kinds of mistakes (and others) can be resolved and avoided if the FDA is given the authority it needs to prescribe the labeling and marketing requirements for all tobacco products—including prescribing the manner in which claims can be made and preventing the use of claims that are false or misleading. A science-based regulatory structure can

not only ensure that products are properly labeled and marketed, but it can also serve to stimulate competition to develop new technologies and products that will lower risks associated with tobacco use. These efforts however, must been carried out under an effective regulatory scheme and with greater transparency.

THE CRITICAL NEED FOR AND ROLE OF THE FDA

FDA will provide the level playing field under which all tobacco products should be regulated—governing their manufacture, sale, distribution, labeling and marketing.

FDA's authority must be comprehensive but at the same time flexible enough to be able to deal with what will most likely be a rapidly changing environment. Issues related to risk reduction will be but one component of FDA's authorities. Other things that the agency will need to focus on include:

- Prohibiting and restricting advertising and marketing that is misleading and deceptive(all tobacco products).
- Restricting the sale, advertising and promotion of tobacco products to children and adolescents.
- Disclosing additives, toxins, ingredients, country of origin and other information that adult users of tobacco are entitled to have.

The research and science base will need to be expanded by both the public and private sectors. Industry science must be held to the same level of standards and peer review and transparency that is required in other industries.

Consideration should also be given to undertaking a major educational campaign designed to educate the public about the new regulatory authorities and to help them read and understand the warnings and labeling requirements (not unlike what was needed when food labeling reforms were instituted).

In addition, there will be a need to have a monitoring and surveillance system in place that will allow governmental agencies to effectively track tobacco use by the public and to take the necessary corrective steps if certain goals and objectives are not being met.

Some argue that existing authorities of the Federal Trade Commission are sufficient to ensure effective and proper regulation of tobacco products including lower risk products. We disagree. Although we believe that the FTC should retain its section 5 governing unfair trade practices, the FDA, as a science-based agency, is best suited to deal with the complex scientific and medical issues relating to tobacco "including reduced risk products.

For a more detailed list of what the Alliance believes to be the "Core Principles" of FDA regulation see attached.

CONCLUSION

Reducing risk associated with tobacco and tobacco use must move forward but it must do so carefully and with the full participation of all parties. We believe the Commission report **Tobacco at a Crossroad** represents a blueprint for change—change that must be made and accepted by all stakeholders. Preserving the "status quo", whether its on the part of manufacturers, tobacco growers and even public health is in the best interests of no one. The kind of open dialogue and discussion that resulted in the issuance of a set of **Core Principles** in 1998 between growers and health organizations as well as the commission report, **Tobacco at a Crossroad** (2001) must now be the model upon which we enter the final phase of ensuring effective but fair regulation of tobacco by the FDA.

PREPARED STATEMENT OF NANCIE G. MARZULLA ON BEHALF OF DEFENDERS OF PROPERTY RIGHTS

Mr. Chairman, members of the subcommittee, thank you for allowing Defenders of Property Rights an opportunity to present testimony concerning the impact of communicating to American consumers important health-related information about tobacco risk reduction. I am Nancie G. Marzulla, President of Defenders of Property Rights, the only public interest legal foundation devoted exclusively to constitutionally protected property rights. Defenders of Property Rights was founded in 1991 to counterbalance the governmental threat to private property as a result of a broad range of regulations. We believe that society can achieve important social objectives such as protection of our environment and our health while respecting fundamental constitutional rights like those of private property and freedom of speech. As such, we continue our efforts to protect victims of over-zealous regulations in court, to help government regulators better realize the limits on their power, and to work

closely with elected representatives to ensure that property owners have a say in the laws that govern their ability to make use of their property.

Mr. Chairman, we come before your Subcommittee today to remind you that commercial speech, like all other lawful expression in this nation, is constitutionally protected, a point which is often overlooked in the heat of debate over how best to protect the consumer against false or misleading advertising. We are here to underscore the fact that, just as a manufacturer may not disseminate false or misleading information about its product, neither may Congress prohibit the dissemination of truthful information by that same manufacturer. Because this commercial expression carries First Amendment protection, Congress bears the burden of making certain that any statement it prohibits is, in fact, untrue. If Congress cannot demonstrate, based on sound scientific evidence, that a particular statement is false or misleading, Congress cannot prohibit that statement consistent with the First Amendment.

The Founders understood that the free exchange of commercial information makes free enterprise possible by enhancing competition and educating consumers. Indeed, the origins of our right to free expression are as much commercial as they are political for, in the end, our economic freedoms are the true source of our political freedoms as well. Judge Loren Smith of the Court of Federal Claims rightly observed that:

> Without extensive property rights, jealously defended, only the government would have the resources needed to organize political campaigns or parties of any size. Without property rights, no individual would have a base to run for office other than those who hold governmental power. Without property and contract rights, litigation in the courts would be a very limited and ineffective tool for protecting anything. The judiciaries of every former socialist country are a stark testimony to the weakness and ineffectiveness of a dependent judiciary. Without the right to advertise profit-making products, the free press and media necessary for effective free speech, would be a mere illusion . . . Underlying all of our political and intellectual freedoms which make for a civilized society is a foundation of widely dispersed private property, and all the attributes of that system that Madison so clearly understood: freedom to contract, free markets, and personal security. Without this foundation, political liberty and the ability to exercise those rights guaranteed by the First Amendment would be a mere sham.

Loren A. Smith, *Allen Chair Symposium 1996: The Future of Environmental and Land-use Regulation: Essay: Life, Liberty & Whose Property?: An Essay on Property Rights,* 30 U. RICH. L. REV. 1055, 1060 (1996).

For example, the Constitution places such a strong emphasis on protecting private property rights, among other economic freedoms, because the right to own and use property is critical to the maintenance of a free society. Properly understood, property is more than land. Property is buildings, machines, retirement funds, savings accounts and even ideas. In short, property is the fruits of one's labors. The ability to use, enjoy and exclusively possess the fruits of one's own labors is the basis for a society which individuals are free from oppression. Indeed, there can be no true freedom for anyone if people are dependent upon the state (or an overreaching bureaucracy) for food, shelter and other basic needs. Where the fruits of your labors are owned by the state and not by you, nothing is safe from being taken by a majority or a tyrant. As a government dependent, the individual is ultimately powerless to oppose any infringement of his rights (much less degradation of the environment) because the government has total control over them. People's livelihoods, possibly even their lives, can be destroyed at the whim of the state. Private property thus acts as a barrier to the arbitrary and tyrannical exercise of government power.

With proper appreciation for this strong relationship between our economic and political freedoms, the Supreme Court recently stated that, "so long as we preserve—a predominantly free enterprise economy, the allocation of our resources in large measure will be made through numerous private economic decisions. It is a matter of public interest that those decisions, in the aggregate, be intelligent and well informed. To this end, the free flow of commercial information is indispensable." *See 44 Liquormart, Inc. v. Rhode Island,* 517 U.S. 484, 496-97 (1996) (citing *Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council,* 425 U.S. 748, 765 (1976)). The Court further explained that "a paternalistic assumption that the public will use truthful, nonmisleading commercial information unwisely cannot justify a decision to suppress it." *See id.* at 498. While government may have an interest in consumer protection, regulating truthful, non-misleading commercial information does not serve to protect that interest. Rather, protecting commercial speech empowers consumers to make informed decisions and allows business to compete effectively.

Those who contend that commercial speech is not entitled to First Amendment protection rely on a two-page 1942 decision of the Supreme Court in which the Court disposed of commercial speech in one sentence. *See Valentine v. Chrestensen,* 316 U.S. 52, 54 (1942) ("We are . . . clear that the Constitution imposes no . . . restraint on government as respects purely commercial advertising"). As Judge Kozinski of the Ninth Circuit has pointed out in his penetrating law review article, this opinion "cites no authority". *See* Alex Kozinski and Stuart Banner, *Who's Afraid of Commercial Speech?,* 76 Va. L. Rev. 627, 627 (1990) ("Without citing any cases, without discussing the purposes or values underlying the First Amendment, and without even mentioning the First Amendment except in stating Chrestensen's contentions, the Court found it clear as day that commercial speech was not protected by the First Amendment"). Realizing its folly, the Supreme Court reversed itself 34 years later in *Virginia State Board of Pharmacy,* 425 U.S. 748, 770 (1976), when it then accorded First Amendment protection to commercial speech:

> Virginia is free to require whatever professional standards it wishes of its pharmacists; it may subsidize them or protect them from competition in other ways . . . But it may not do so by keeping the public in ignorance of the entirely lawful terms that competing pharmacists are offering. In this sense, the justifications Virginia has offered for suppressing the flow of prescription drug price information, far from persuading us that the flow is not protected by the First Amendment, have reinforced our view that it is. We so hold.

The Court recognized that commercial expression belonged as much in the marketplace of ideas as did other forms of expression. Producers now convey and consumers now receive information about goods and services without fear of severe restrictions, strengthening the foundations of our free society and our free market economy.

Advocates of regulating commercial speech blithely ignore the important role that commercial speech plays in a free society and in a free market, instead brandishing flimsy rationales for limiting First Amendment protection for commercial speech. None of these rationales withstand scrutiny. For example, the California Supreme Court in *Nike v. Kasky,* a case now pending before the United States Supreme Court, thought it had distilled from the Supreme Court's opinions three reasons for the commercial speech exclusion from full First Amendment protection: (1) that commercial speech was more easily verifiable by the speaker than news reporting or political commentary; (2) that commercial speech was hardier than noncommercial speech in the sense that commercial speakers, because they act from a profit motive, are less likely to experience a chilling effect from speech regulation; and (3) that governmental authority to regulate commercial transactions to prevent commercial harms justifies a power to regulate speech that is 'linked inextricably' to those transactions." *See Kasky v. Nike,* 45 P.3d at 252-53 (citing *44 Liquormart, Inc.,* 517 U.S. at 499; *Virginia State Board of Pharmacy,* 425 U.S. at 771-72 fn. 24)

First, objective verifiability is not a characteristic unique to commercial speech. As Judge Kozinski of the Ninth Circuit also pointed out in his aforementioned law review article:

> [T]here are many varieties of noncommercial speech that are just as objective as paradigmatic commercial speech and yet receive full first amendment protection. Scientific speech is the most obvious; much scientific expression can easily be labeled true or false, but we would be shocked at the suggestion that it is therefore entitled to a lesser degree of protection. If you want, you can proclaim that the sun revolves around the earth, that the earth is flat, that there is no such thing as nitrogen, that flounder smoke cigars, that you have fused atomic nuclei in your bathtub—you can spout any nonsense you want, and the government can't stop you.

Kozinski, *supra,* at 635.

Second, the notion that profit is a stronger motivation to speak than, e.g., religious, philosophical or political conviction, contradicts the history of this nation's founding and the sacrifices of our founding fathers themselves. George Washington and John Adams neglected their farming businesses to serve the revolution, while Benjamin Franklin, James Madison, Thomas Jefferson and the others risked hanging for treason as the price of signing the Declaration of Independence. Pasternak and Solzhenitsyn continued to write, and Shostakovich to compose, under the very real threat of being sent to the Gulag. Humankind throughout the ages has proved that it is not the love of money, but the love of truth and right that appears to be the strongest motivation of our race.[1] See Kozinski, *supra,* at 637 ("History teaches that speech backed by religious feeling can persist in extraordinarily hostile climates; sacred texts survive in places where dire consequences attend their posses-

[1] . . .

sion, consequences that would easily overcome a mere profit motive. Artistic impulses can also cause expression to persist in the face of hostile government regulation").

Third, although government may certainly act to prevent commercial fraud, restrictions on commercial speech often do not link the speech at issue to a proposed or completed fraudulent transaction. Were the speech so linked, First Amendment protections would certainly not obtain because it is the transaction, not the speech, which is unlawful. Restricting fraudulent or misleading speech with no connection to actual resulting fraud abandons the marketplace of ideas for the majesty of the courtroom, placing judges in the role of arbiter of the truth. Advocates of restricting the free flow of commercial information apparently consider the relative merits of laundry detergent or pickup tricks, for example, too important to be left to the consuming public.

Having dispensed with these rationales, it is clear to see that there is no compelling rationale for restricting commercial speech. Indeed, any attempt to distinguish between commercial and noncommercial speech for the purposes of determining the "appropriate" level of First Amendment protection (and the "appropriate" degree of speech restriction) is bound for failure. Commercial motivations are invariably and inextricably intertwined with all forms of expression. See Loren A. Smith, supra, at 1062-63 ("The desire to make a buck and the desire to write a poem appear very similar"). Many motives, including profit, can prompt expression on any issue, and "human motives cannot be separated by any objective test." *See id.* at 1062-63. *See also* John O. McGinnis, *The Once and Future Property-Based Vision of the First Amendment,* 63 U. CHI. L. REV. 49, 55 (1996):

> Moreover, research into our evolutionary heritage confirms that the human faculty of speech evolved to improve economic well-being, both by facilitating the exchange of goods and by creating another product for exchange—namely information itself. Information production of all kinds is thus increasingly seen as directed toward the acquisition of wealth and status . . . Expressive man is economic man.

Indeed, as I noted earlier, commercial speech has played a leading role in the establishment of our right to freedom of expression. In 17th and 18th century England, printers faced loss of income when government suppressed publication. *See* McGinnis, *supra,* at 60 ("Printers [who convinced Parliament to end the licensing system] . . . naturally sought to protect their interests and limit the prerogatives of government [to suppress publication]"). Accordingly, the printers relied on property rights arguments in their successful efforts to convince Parliament to end the licensing system and the general warrants by which government seized printed material. *See id.* at 61 ("The notion of information as property came naturally to printers and played a prominent part in their arguments for freedom"). In defending freedom of the press, these Whig printers couched their arguments in the language of economic rights, rightly understanding that economic motives often drive and enable the dissemination of information on matters political, commercial, and otherwise. *See id.* Accordingly, no court has held that there exists a commercial press exception to the Free Press Clause.

Other forms of expression demonstrate a similarly close relationship between commercial motivations and the resulting expression. *See* Kozinski, *supra,* at 641 (providing example that fully protected music videos promote record sales). Newspapers and broadcast television, the heirs of the aforementioned Whig printers, disseminate information on political affairs with a view to increasing sales, attracting paying advertisers, and generating ratings. In these cases, profit motivation and economic transactions are essential to the transmission of the resulting expression. *See* McGinnis, *supra,* at 91. Excluding "commercial speech" from the ambit of First Amendment protection thus undermines the very foundations of free speech.

Congress must therefore exercise the utmost caution in considering whether to regulate the transmission of commercial information about the health benefits and risks of smokeless tobacco. The First Amendment guarantees our freedom to give and receive information to ensure that we are a self-governing people. A well-informed basis for decision-making, aided by the free exchange of information, is an essential ingredient of that self-government, both at the ballot box and at the supermarket. A well-informed basis for decision-making is even more essential when it comes to making decisions about one's health. Before taking action, Congress should keep in mind the importance of self-government and the role that commercial speech plays in maintaining it.

Thank you for the opportunity to address this important issue here today. I would be happy to answer any questions you may have.

PREPARED STATEMENT OF CARL V. PHILLIPS, ASSISTANT PROFESSOR, UNIVERSITY OF TEXAS SCHOOL OF PUBLIC HEALTH [1]

Cigarette smoking is widely described as the greatest preventable cause of morbidity and mortality. I have always found this a rather tortured definition of "preventable"—after all, if it is so preventable, why do U.S. smoking rates remain high, with the total number of smokers in the world increasing? It is reasonable to say that smoking is *theoretically* preventable. But the current methods—education, warning, regulating sales and advertising, prohibiting smoking in many places, and pharmaceutical nicotine replacements—despite their effectiveness over the last half century, seem to have had most of the effect as they are going to. Even if those methods become even more effective at discouraging people from taking up smoking, the tens of millions of current smokers in the U.S. remain at risk.

Last year, I was retained by U.S. Smokeless Tobacco Company to analyze and give my opinion on what the scientific research had to say about the health risks of using smokeless tobacco (ST). As a professor of public health (Assistant Professor, University of Texas School of Public Health and University of Texas Medical School) specializing in methods for interpreting data and study results, I had much to say about the science. As a public policy analyst (Ph.D. in public policy from Harvard University and Masters in Public Policy from the Kennedy School of Government at Harvard), I find myself particularly interested in the potential life-saving policy of harm reduction.

Like most everyone who has not personally reviewed the science, I believed that ST was a major risk factor for life-threatening illness, perhaps not as risky as cigarettes, but of similar magnitude. It quickly became clear to me that the risk from smokeless tobacco was tremendously lower than that from cigarettes. Indeed, even for the one disease most commonly linked to ST, oral cancer, the evidence of any risk at all was highly equivocal. I was distressed that the public health community, a community I am part of, had perpetuated such misinformation. More than that, I was impressed by the potential to reduce the devastating health effects of cigarettes by encouraging smokers to switch to ST. I came to consider this one of the greatest untapped resources for improving the health of the U.S. population, and have made ST my major substantive area of academic research.

Many areas of health research offer large speculative payoffs, but it is not clear what will really be discovered. Many potential interventions offer great health benefits in theory, but it is not clear they could really be implemented. ST has scientifically proven potential to reduce harm from cigarettes and a proven track record in Sweden, where ST consumption has increased while smoking has dropped dramatically. It is difficult to imagine any other policy as likely to further reduce the health costs of smoking in the U.S., if only policy makers and public health leaders will let it work. This would require no complicated and expensive intervention; it would probably be enough for the government to tell the truth about the risks or allow ST manufacturers to do so.

Much less harmful than cigarettes

The potential of ST use to reduce harms from smoking follows immediately from its role as an alternative source of nicotine and its relative safety. Despite the popular belief to the contrary, there is no genuine scientific disagreement with the claim that ST is much less harmful than cigarettes. Biology and chemistry would tend to predict this (for example, ST does not produce carbon monoxide buildup or cause chemical insult to the lungs), but it is the study of actual results for actual people (the science of epidemiology) that makes it clear. Of the various cancers, cardiovascular diseases, and other life threatening diseases that smoking has been shown to cause, the only persistent claim about risk from ST is for oral cancer (OC). The elimination of clearly smoking-specific hazards—lung cancer and other lung diseases, fires, and environmental ("second hand") tobacco smoke—alone reduce the risks by half. But there has also been no conclusive link to cardiovascular disease and most other cancers. Even for OC, which account for about 1% of deaths attributable to smoking, smoking is associated with greater risk than the worst plausible claims about the risk from ST.

The bottom line is that a cigarette smoker who switches to ST reduces his risk of disease from tobacco use by more than 90%, and quite possibly more than 99%. There is legitimate scientific uncertainty about whether the reduction is 98%, 99.9%, or some other value, but it clear that it is better than 90%. The remaining uncer-

[1] This statement is the scientific opinion of the author, and does not necessarily represent the views of the University of Texas School of Public Health, the University of Texas Health Science Center at Houston or the University of Texas system.

tainty should not dissuade us from acting immediately. One of the most important points I teach my students in my health policy classes is that if you perform a careful scientific analysis of a proposed policy, you will often find that you do not need to resolve the remaining uncertainty about some values. Even though they are somewhat uncertain, you know enough to know that any plausible value leads to the same policy recommendation. In the case of ST, if the reduction in risk of life threatening disease was possibly as low as 50% or even 75% compared to cigarettes, the question might be more difficult. But our current information, that the risk of using ST is much less than 10% of that from smoking, is sufficient to show that telling the truth about ST is a promising harm reduction strategy

How do we know?

The scientific literature fails to establish a link between ST use and any life threatening disease. Scientifically demonstrating that something does not exist, such as showing there is no substantial health risk from ST, is usually more difficult than demonstrating that it does exist. A common observation is that "the absence of evidence is not evidence of absence." This is an important point when evidence is absent because there has been little attempt to find the evidence. But when researchers have looked hard for evidence of a health risk and have not found it, we have compelling evidence that the risk is close to zero. This is the case for ST. This does not mean that the risk from ST for any particular disease is exactly zero—such a thing can never be proven—but it does give the best possible evidence that it is either zero or very low.

The active effort by many organizations and researchers in the health community to show that ST is unhealthy has created attitudes that are a barrier to the suggested harm reduction strategy. But that same active effort is very helpful for drawing scientific conclusions, because we can be confident that if there were any clear associations to be found, they would have been found. The health science literature contains only a few papers that look at risk of diseases other than OC from ST use. One reason for this might be that no one has looked for such associations. However, there are many well-studied datasets that would allow such analyses and there is huge demand for findings that ST is associated with disease. Given that there is demand and potential supply, we can conclude that the lack of findings is not for lack of trying to find something. It is not surprising that there are not a lot of published papers that show a lack of association, because such findings tend to not get published (the phenomenon is called "publication bias"). We can further conclude that if there was a large risk for a disease from ST, it would be noticed; large effects are difficult to miss. Finally, we can observe that the opponents of ST focus almost entirely on the risk of oral cancer, and energetic advocates can usually be counted on to come up with the strongest possible case for their claims, suggesting that even they do not think there is support for the claim that ST causes other diseases.

But even the case for OC risk is not very strong. It is widely reported that there is a causal link between ST and OC, most notably in a Surgeon General's Report [1986]. There is evidence that smokeless products that contain other major ingredients (particularly betel nut in South Asia) are risk factors for OC. There is one large U.S. study [Winn et al., 1981], that found an association between the use of early- and mid-20th century *dry* snuff and oral cancer. (The Surgeon General Report conclusions hinged largely on this study.)

But the dominant product in the industrialized world, modern *moist* snuff, has not been associated with OC. The two major published studies on the topic [Lewin et al., 1998; Schildt et al., 1998] did not find an association, and provide convincing evidence that there is no strong association. Furthermore, my own research (which I will present this June at the Society for Epidemiologic Research meeting, the major U.S. epidemiology meeting) shows that Winn et al. and most others of the few modern studies that purport to find an association of ST and OC have reported their results in ways that tend to exaggerate the association, or make it appear that there is an association in the data when there really is not. In particular, they picked out subgroups of their population (such as only reporting results for non-smoking women, or certain individuals who had used ST for more than 50 years), and reported numbers for them, omitting numbers for other groups who had much lower association or even showed reductions in cancer rates. The conclusion from all this is not that modern American and Swedish ST is proven to not cause oral cancer, but there is clearly no proof that it does cause it.

A (so far) missed opportunity for harm reduction

Even if we accept the main finding from the Winn et al. study about OC risk, the worst case scenario there is any evidence to support, and allow for some small risk of others diseases (so small that it has not been detected), the risk from ST

is only about 1% of that from smoking. Our current scientific knowledge allows us to be *fairly confident* that ST has about 99% less risk of life threatening disease than smoking. We are *as confident as is ever possible* in health research that the reduction is greater than 90%. The implication of that is clear: Anyone who uses ST rather than cigarettes will be much safer, eliminating almost all the risk of life-threatening disease from his or her tobacco use.

Having learned this in the last year, I have found myself thinking about my grandmother, a lifelong smoker, who died a few years ago following a series of smoking-related cancers. She tried to quit using tobacco and failed. The message from the public health community to her and to current smokers was "quit or die." She could not quit. As an Appalachian woman of her age group, the use of ST would not have been unusual or socially unacceptable. Had she gotten the message that she would have been so much safer using ST rather than cigarettes, she might be alive today.

Health authorities in other countries are starting to come around. Most notably, the United Kingdom's oldest medical organization, the Royal College of Physicians [2002], issued a report on tobacco regulation that acknowledged that ST is "10-1000 times less hazardous than smoking" and suggested that a harm reduction strategy might be appropriate. Many public health advocates and researchers are speaking up in favor of using ST as part of a harm reduction strategy. The changes in policy attitudes will come too late for millions who have already died, but millions of others can be saved.

Misleading the public

Why did my grandmother never learn that ST offered such a huge reduction in risk? Why do tens of millions of literate and well-informed smokers not know it now? Why did I, a well-read expert in public health not know this a year and a half ago? The consistent message from public health authorities, including state and federal government agencies, advocacy groups, and medical organizations, is that ST is as unhealthy as cigarettes. Sometimes this claim is stated in so many words, despite being clearly false. More often, the message is that ST is not a safe alternative to cigarettes. When this message is presented without further qualification, people tend to assume that the two products have comparable levels of risk, making the claim clearly misleading.

My colleagues and I just completed a review of the over four hundred public-service-oriented Web sites that were found with a Google search for statements about the health risk from ST. Less than 1% of these say anything about ST offering a major risk reduction compared to smoking or acknowledge that it has not been shown to be very harmful. Many sites contain specific numbers that make their claims more misleading, while giving the appearance of greater accuracy. A fairly common claim is that ST "can lead to a 50-fold increase in oral cancer risk." This result traces to one number reported in Winn et al., for extremely high exposure among a small subgroup of the population, and is not meaningful out of context. This number, the largest reported in the paper for any subgroup or exposure definition, clearly does not summarize the results from Winn et al. Furthermore, having re-analyzed the original unpublished Winn data, I found that the specific statistical choices used to produce that number appear to have been chosen to produce the largest number possible, which is a scientifically invalid method of analysis.

Our major finding from our analysis of the Web sites (which we will also be presenting at the epidemiology meetings) is that most of them repeat the same overstated or false claims, reporting the same few numbers from Winn and the Surgeon General, and ignoring the substantial scientific literature that contradicts these claims. When they attribute their claims to any source, they cite the Surgeon General, the American Cancer Society, and a few other sources, all of which trace their claims primarily to pre-1980 research, which is not up to modern methodologic standards and studies people who used a different product from modern moist snuff. Furthermore, with the exception of two Web sites that deal with harm reduction, the sites that showed up in our search provide no absolute risk number that would allow readers to realize that, even the worst case scenario, ST is tremendously safer than smoking. What looks like a huge amount of mutually-confirming information about substantial risk turns out to be a lot of groups citing each other and repeating the same small body of misleading and often incorrect information.

Given these patterns of systematic misinformation, it is not surprising that when people learn the truth about the risk of ST, they are almost always extremely surprised. Of the hundreds of people, usually highly educated and often health professionals, that my colleagues and I have told this information to, only one (my dentist) already knew the truth. It is little wonder that the harm reduction message, as strong as it is, has not taken off on its own.

Attempts to justify the misinformation

The health advocates who defend the misinforming of the public offer several arguments, all of which seem difficult to defend. No one who hopes to preserve any credibility will deny that using ST rather than cigarettes leads to a dramatic risk reduction. Instead, other arguments are usually offered. They turn out to be equally unconvincing, but more subtly so.

Advocates sometimes argue that honest information about ST should be denied to the public because it might cause tobacco nonusers to take up ST, and their increased risk could exceed the benefit experienced by smokers switching to ST. Simple arithmetic shows this to be wrong. If ST offers a 99% reduction compared to smoking, it would be necessary for 99 tobacco nonusers to take up ST for every smoker who switches. Even if the reduction were as little at 90%, it would require 9 for every 1. It is implausible that such a large increase in tobacco use could occur.

An occasional retort to this arithmetic is that there is an ethical concern when one person experiences a benefit (the smoker who switches to ST) and another suffers a health cost (the nonuser who takes up ST upon learning it is relatively safe—assuming, of course, that ST does create some risk). But a much clearer ethical argument is that it is unacceptable in a free society for public officials to filter information to protect people from their own free choices, especially when someone else (the smoker who never learns the value of switching) pays a high price for it.

A second argument used to justify the misinformation is that even though it is arithmetically implausible that increased ST use could directly cause an increase in the total health impact of tobacco, honest information about ST would lead to more tobacco users, and some of them would take up smoking. If this phenomenon—that ST would act as a "gateway" to smoking—did occur, the net benefits would indeed be reduced. However, even though this possibility can be stated, there is no reason to believe it would actually occur. Several studies have attempted to show that there is a tendency to switch from ST to cigarettes, but they have merely shown that many of the same people who might use one form of tobacco might use another, just as we would expect. But even if a pattern of switching from ST to cigarettes does exist in the U.S. currently, it would say nothing about what would happen if people had good information. Believing that the two products are comparably unhealthy, people might be equally likely to switch in either direction. But when people learn that ST is much less harmful, they will increase their switching from cigarettes to ST and decrease their switching from ST to cigarettes. To claim otherwise is to say that tobacco users do not care about their health, which is clearly not the case.

Furthermore, the logic of the gateway argument is fundamentally flawed. The argument requires that there is a group of tobacco nonusers who are avoiding tobacco because of health concerns, but who would start using ST if they knew it was not very risky. But then, these same people—who were originally motivated to avoid tobacco due to health concerns—somehow decide to switch to cigarettes, which they know are much less healthy. Thus, since honest information about ST would tend reduce the switching from ST to cigarettes, and it is difficult to imagine any new ST users switching to smoking, honest information about ST would tend to *decrease* any role that ST plays as a gateway to smoking. Anyone concerned with the gateway effect should be in favor of honest information about the lower risk from ST.

When the preceding arguments are shown to not hold up, anti-tobacco advocates sometimes offer a third argument that does not depend on logic or science: the goal of our society should be to eliminate all tobacco use, and telling the truth about ST is not compatible with this goal. It is not clear exactly whose goal this is and what justification they have for imposing it on the rest of society. The legitimate goal of health advocates is to improve health, and denying people a great harm reduction opportunity clearly does not do this. It is certainly true that eliminating all tobacco use would improve health (almost all the gain coming from eliminating cigarettes), but this goal, whether legitimate or not, will be unrealistic for many decades.

Conclusions

Advocating the use of ST to reduce the harm from cigarettes is a minority position in the U.S. But scientific truth and ethical duties are not decided by counting votes. The science is clear: ST is much less harmful than cigarettes, and there is no realistic scenario that leads to any increase in health risks by telling the truth. In my opinion, health officials have an affirmative ethical duty to make the truth known, both because it is the truth and because it would save lives. It is difficult to justify keeping the truth from people, even when it might be harmful; it is clearly unjustified when it would be beneficial. In other countries these points have been appreciated at the highest levels in the health community. And many other American health researchers, notably including Professor Lynn Kozlowski of Penn State Uni-

versity, who has presented the ethical arguments in greater detail than I can here, have come to the same conclusions.

It is not clear whether those who would prevent this harm reduction strategy are motivated by an unrealistic vision of eliminating all tobacco use in the short term or by something else. Whatever their motives, there should be a strong burden on them to present some logical argument, based on realistic scientific claims and clearly stated ethical positions, that we should deny people truthful information that could save their lives. In my extensive studies of the scientific and popular literature, I have found no such argument. We are not faced with a need for more scientific information. We have enough information to know that the harm reduction strategy responds to a huge health problem, has the potential for substantial reduction of risks, is likely to be implementable, and has not been shown to be costly or likely to have major unintended consequences. It is difficult to imagine a more compelling case for harm reduction.

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PREPARED STATEMENT OF DAVID W. EISELE, CHAIRMAN, DEPARTMENT OF OTOLARYNGOLOGY-HEAD AND NECK SURGERY, UNIVERSITY OF CALIFORNIA

With this letter, I would like to provide you and your committee with a clinical perspective on the issue of tobacco harm reduction, an issue that is presently being debated amongst public health experts, dentists, and other health care professionals. The scientific information regarding the relative health risks of various tobacco products is important information, which should be made available to tobacco consumers, the public, and the health care community. Dissemination of this information will assist individuals who use tobacco products to make informed decisions regarding tobacco use.

On this issue, I offer you the perspective of a head and neck cancer surgeon with significant experience with the clinical problems encountered by patients who use tobacco products. I am an academic clinician-educator and I presently serve as Professor and Chairman of the Department of Otolaryngology—Head and Neck Surgery at the University of California, San Francisco. I also direct the Head and Neck Oncology Program at the UCSF Mt. Zion Cancer Center, an NCCN Comprehensive Cancer Center. Formerly, I founded and directed the Johns Hopkins Head and Neck Cancer Center at the Johns Hopkins School of Medicine. A copy of my curriculum vitae is attached.

My postgraduate training consisted of residency training in General Surgery and Otolaryngology—Head and Neck Surgery. My clinical practice consists of the care of patients afflicted with head and neck cancer as well as other tumors of the head and neck. I have cared for such patients in three geographically distinct regions of the United States including the Pacific Northwest, the Middle Atlantic region, and the San Francisco Bay Area. These regions of the United States have varied tobacco product usage patterns. It is my understanding that, in particular, the use of smokeless tobacco is especially prevalent in the Pacific Northwest.

In order to supplement my personal clinical experience and perspective, I have reviewed the body of epidemiological literature regarding smokeless tobacco and oral cancer. In addition, I have examined literature relevant to the issue of the potential role of smokeless tobacco in the context of harm reduction. My experience of nineteen years in the care of head and neck cancer patients has demonstrated that approximately 80% to 90% of patients with head and neck cancer are present or former smokers of cigarettes. A smaller proportion are cigar or pipe smokers. On numerous occasions, I have observed benign reversible oral lesions (hyperplasia) in users of smokeless tobacco. To date, however, I have never seen a patient with an oral cancer that can be attributed to the use of smokeless tobacco.

The medical literature supports my clinical observations. The literature clearly demonstrates significant differences in the relative risks for the development of head and neck and other cancers for different tobacco products. Of notable importance is the markedly diminished risk for the development of cancer of the head and neck and the elimination of the risk of cancers in other body locations for smokeless tobacco compared to cigarettes. The medical literature provides clear and undebatable data indicating that smokeless tobacco is a safer form of tobacco use relative to cigarettes.

There is general consensus that physicians and public health authorities have an obligation to inform patients and tobacco consumers regarding the adverse health risks associated with the use of the various tobacco products. Because the health risks associated with tobacco use vary according to their form, this information is additionally relevant and important information that should be disseminated. Patients must have this information in order to make an informed decision regarding tobacco product usage and product choices. In my practice, patients demonstrate interest in understanding these relative risks. For example, cigar smokers will often inquire about the relative risk of smoking cigars compared to smoking cigarettes.

An analogous practice by physicians already exists. Physicians already advise patients regarding the comparative risks of drinking alcoholic beverages. All reasonable physicians acknowledge that excessive consumption of alcohol is deleterious to one's health. Recent data, however, show that alcohol use in moderation has beneficial health effects. A physician can only be effective in the care of a patient who consumes alcohol if the physician understands and transmits this information about alcohol. In addition, those of us in academic medicine have an obligation to our students and trainees regarding the unbiased transmission of this relevant information.

In addition, physicians must understand the data relating to relative risk of tobacco forms in order to fully educate patients regarding tobacco use risks and smoking cessation. Presently, the general public health message to consumers has been that all tobacco products are hazardous to one's health. Although this dictum is generally correct, the various forms of tobacco carry with them significant risk difference with regard to health. These relative risks should be known by patients, physicians, and other health care providers. Public health authorities should disseminate this information to the public so that consumers of tobacco products can make informed, personal decisions.

June 20, 2003

The Honorable CLIFF STEARNS
Chairman
Subcommittee on Commerce, Trade, and Consumer Protection
Committee on Energy and Commerce
U.S. House of Representatives
Washington, D.C. 20515

DEAR MR. CHAIRMAN: Thank you for your invitation to testify on June 3 before the Subcommittee on Commerce, Trade, and Consumer Protection. I appreciate the opportunity to address the Subcommittee regarding the dangers of allowing the tobacco industry to make "reduced risk" health claims absent comprehensive and meaningful regulation of all tobacco products by the Food and Drug Administration (FDA).

We at the Campaign for Tobacco-Free Kids are also grateful for the hard work and many efforts of Committee staff, especially Counsel Kelly Zerzan, to assist us in preparing for the hearing. Below are the answers to the questions submitted by Representative Whitfield for my response.

Q1. Do you believe that as your press release strongly suggests, Marlboro cigarettes are more dangerous than other American blend brands? Then foreign brands?

The first question does not accurately represent what we said in response to the important new study conducted by scientists at the Centers for Disease Control (CDC). I have attached our actual statement on the study and would request that it be included as an attachment to this letter. The study conducted by the scientists from the CDC found that Marlboros have higher levels of nitrosamines than do the most local popular brands in most countries sampled. In response, we said that while most people assume that cigarettes from highly sophisticated manufacturers, such as Philip Morris are "better" than other cigarettes, this may not be true because of the presence of high levels of certain known carcinogens in Marlboro. The thrust of our statements is that consumers should be wary of tobacco manufacturers' representations in the absence of concrete, objective and independent informa-

tion about the actual levels of the many known toxins in tobacco and tobacco smoke. Without this information neither consumers, nor the public health community can know for sure whether one brand is more harmful than others.

The study shows that knowledge of tar levels tells us little about the relative harm of different products. There have been 69 different known carcinogens and hundreds of other harmful substances identified in tobacco smoke. We need to know about the level of each of these harmful substances. We do know that Philip Morris possesses the technology to reduce the level of nitrosamines in Marlboro cigarettes, has had the technology to do so for many years, and should have done so long before now. The real lesson from this study is that consumers will receive accurate and complete information about the different levels of harmful substances in tobacco products only through comprehensive and meaningful regulation of tobacco products by the FDA. Similarly, the study shows that companies such as Philip Morris can be counted on to reduce the level of toxic substances only when their failure to do so becomes public knowledge.

Q2. Keeping in mind that I know your advice is to quit smoking, would you recommend to people who don't quit that, instead of Marlboro, they switch to Winston? To Newport? Camel? Kool? Let me move to some international brands that don't contain much American tobacco, would you recommend that smokers switch to Gauluoise from France? To 555 from the UK? Mild Seven from Japan? Are any of these brands less dangerous than Marlboro?

The lesson of the study described above and our experience with light and low tar is that it has not been shown that any of the tobacco products now on the market significantly reduce the risk of tobacco-caused disease. The recommendations that we would make to a smoker are to quit or to switch to a scientifically proven smoking cessation aid that has been reviewed and approved by the FDA. We do not recommend that Marlboro smokers switch to Winston or that Winston smokers switch to Marlboro. Both are deadly. The same is true with regard to foreign brands.

Q3. How would you feel if you learned that a consumer read your press release, or the misleading headlines that it generated, and switched to another brand from Marlboro, having been convinced that they were making a good decision by switching to a less risky product?

I do not believe that any smoker, based on our press release, would take the course of action implied by the question. Our message is clear: Marlboro and other cigarettes kill one in two long-term users. Smokers concerned about their health should quit in the absence of scientific proof that any alternative dramatically reduces their risk of disease. Anyone concerned about providing smokers who cannot quit a real alternative should endorse the kind of government regulation that we have proposed. Meaningful FDA regulation of tobacco products, including tobacco products claiming to be less harmful, is essential to protect consumers looking for less harmful alternatives. In the interim, we recommend that smokers discuss their individual situations with their doctors.

Q4. Your release concludes by saying that "no company should be free to make a claim that a product is safer simply by reducing a single poison." I agree. By the same token, having just put out a release with the headline of "Marlboro Shows Higher Levels of Key Carcinogens," do you think that advocacy groups such as yours should be able to claim that a product is more dangerous simply because of increased levels of a single poison? If you don't think smokers will take away that message and that there won't be any confusion, why would you have a problem with claiming that a single poison had been reduced?

We agree that no company should be free to make a claim that a product is safer simply by reducing a single poison in it. The Campaign has not stated that one tobacco product is more harmful than others. In fact, the Campaign for Tobacco-Free Kids makes no claims regarding the relative dangers posed by the cocktail of lethal chemicals found, in varying combinations, in currently marketed tobacco products. For decades consumers have assumed that tobacco products low in tar reduce their risk of tobacco-caused disease. New studies show that this assumption was not correct, perhaps in part because some or all of the low-tar products had higher levels of specific toxic substances, such as nitrosamines. The new study by the CDC, combined with our experiences with low-tar should be a caution that without knowing the levels of other toxic substances we cannot assume that the removal of one known harmful substance alters the overall health impact of the product. It also makes clear that we need to know the levels of all of the toxic substances in these products before we will have any reason to believe that we can assess relative risk. Thus, even if Philip Morris lowers the levels of nitrosamines in Marlboros, we will not know if consumers are exposed to fewer toxic substances without knowing the levels of the other toxic substances in the cigarette and its smoke. Our earnest hope

is that the takeaway message of our press release is that if Congress is concerned about ensuring that consumers get the information they need to make rational decisions, Congress should enact comprehensive and meaningful regulation of tobacco products by the FDA immediately.

Q5. Finally, you have been the leading advocate in Washington for unlimited Food and Drug Administration authority over tobacco products, and have repeatedly characterized any effort by members to respond to those of us who are skeptical of this initiative, and concerned about its consequences, by crafting some kind of compromise approach as "worse that nothing." Your "my way or the highway" approach has significantly contributed to the stalemate on this issue for over five years now; according to you, on every day in each of those years, another 3,000 kids have started to smoke. If this problem is in such urgent need of resolution, how can you justify remaining so inflexible? Which is more important to you resolving this issue, or keeping it alive?

We have supported repeatedly, and in various forms, compromise legislation to grant FDA meaningful authority to regulate tobacco products. We have also stated that the enactment of legislation that only provides the illusion of meaningful regulation of tobacco products would indeed be worse than no regulation because it would remove the pressure on Congress to act. Unfortunately, it is our assessment and the assessment of every other major organization in the public health community that the FDA bills supported by Philip Morris would do more harm than good because they are riddled with loopholes that would make it impossible for the FDA to protect consumers effectively. They do not represent a step forward. Instead, they simply remove the pressure for Congress to act. We continue to be willing to work with any member of Congress interested in enacting legislation that will give FDA effective authority over all tobacco products. Progress has been stymied by the unwillingness of the tobacco industry to endorse such legislation.

Mr. Chairman, thank you again for the opportunity to address these issues so important to the nation's, and particularly our children's, health.

Respectfully,

MATTHEW L. MYERS
President, Campaign for Tobacco-Free Kids

Enclosures
cc: The Honorable Edward Whitfield

American Heart Association.
Fighting Heart Disease and Stroke

AMERICAN LUNG ASSOCIATION.

CAMPAIGN for TOBACCO-FREE Kids

IMMEDIATE RELEASE
June 3, 2003

CONTACT: Joel Spivak/Nicole Dueffert
202-296-5469

Statement of American Heart Association, American Lung Association and Campaign for Tobacco-Free Kids
Congress Should Protect Public From Tobacco Industry Deception
By Granting FDA Effective Tobacco Authority

WASHINGTON, D.C. (June 3, 2003) – Today, two U.S. House of Representatives committees – the Committee on Energy and Commerce and the Committee on Government Reform – are holding hearings on tobacco industry efforts to market new and existing products as posing "reduced risk" to consumers without meaningful government oversight of these products and claims. The U.S. Smokeless Tobacco Company (USSTC) wants the Federal Trade Commission (FTC) to allow it to market smokeless tobacco products as less hazardous than cigarettes, while Philip Morris wants a government stamp of approval for its cigarette health claims in the form of ineffective Food and Drug Administration (FDA) regulation of tobacco products. Other tobacco companies are already marketing cigarette products with claims they are less hazardous. It is imperative that Congress remember the tobacco industry's long and continuing history of deception regarding the harm caused by its products and reject these harmful tobacco industry efforts. Instead, Congress should enact real FDA regulation of tobacco products, including the authority to verify and regulate any health claims made about them, in order to reduce the death and disease caused by tobacco products.

Absent meaningful FDA authority over tobacco products, "reduced risk" health claims become a new marketing tool for the tobacco industry to hook new customers, rather than a public health tool to reduce the death and disease caused by tobacco use. The result would most likely be to increase the number of kids who start using these products and reduce the number of current smokers and smokeless tobacco users who would otherwise quit entirely.

History warns us that we cannot trust the tobacco industry or its claims about "reduced risk" products. Thirty years ago, the cigarette companies introduced "light" and "low-tar" cigarettes with clearly implied claims that they are less hazardous than regular cigarettes. But a November 2001 report by the National Cancer Institute found that light cigarettes are just as harmful and that the tobacco companies knew this all along. In fact, a judge in a recent Illinois court case found that two Philip Morris light brands are actually more dangerous than their regular counterparts because of changes in the chemistry of the smoke, and that Philip Morris knew this.

The tobacco industry's deception continues today. Even while seeking to make health claims about smokeless tobacco products, USSTC last year told the FTC that "smokeless tobacco has not been shown to be the cause of any human disease." This statement is contrary to the conclusions of the Surgeon General, the National Cancer Institute and numerous other scientific bodies that smokeless tobacco products increase the risk of serious disease, including oral cancer. In fact, 28 cancer-causing chemicals have been found in smokeless tobacco products. In addition, USSTC continues to market its products in ways effective at reaching children, increasing its advertising in youth-oriented magazines by 161 percent from 1997 to 2001 and using cartoonish images and slogans such as "Cock-a-doodle freakin' do." Allowing USSTC to make health claims regarding smokeless tobacco products would amount to a dangerous reversal of a longstanding federal policy of discouraging smokeless tobacco use to protect the

public health. It would be extremely harmful to public health for Congress to buy USSTC's argument that the way to reduce tobacco-caused cancer is by promoting a cancer-causing tobacco product.

USSTC is not the only tobacco company making or seeking to make irresponsible health claims about deadly tobacco products. Brown & Williamson is marketing Advance cigarettes with the slogan "All of the taste…less of the toxins," while Vector Tobacco's ads for its Omni cigarettes proclaim "Reduced Carcinogens. Premium Taste." RJ Reynolds is launching a national ad campaign for its Eclipse product that, among other things, claims it "may present less risk of certain smoking-related diseases." Philip Morris has announced that it plans to launch a new "reduced risk" product later this year.

Unfortunately, no government agency today has the authority to determine whether these products are actually less hazardous or to ensure that they are responsibly marketed to reduce the overall harm caused by tobacco products. Consumers deciding whether to use so-called "reduced risk" products should be fully protected and informed by a scientifically qualified government agency, the FDA, rather than an industry with a long history of deception. Until Congress grants the FDA real authority over tobacco products, customers relying on cigarette industry claims are essentially human guinea pigs in a deadly science experiment.

Attached is a letter from public health groups to members of the U.S. House of Representatives.

June 2, 2003

On June 3, 2003, the House Committee on Energy and Commerce and the Committee on Government Reform will hold hearings on so-called "reduced risk" tobacco products including smokeless (spit) tobacco. The Partners for Effective Tobacco Policy Coalition and others are writing to express our concerns about these products and the misleading marketing and health claims associated with them. We urge Congress to oppose current efforts by the tobacco companies to acquire governmental approval for its misleading claims.

In November of 2001, the National Cancer Institute (NCI) released a landmark study entitled *Risks Associated with Smoking Cigarettes with Low Machine-Measured Yields of Tar and Nicotine* that clearly demonstrated that light and low-tar cigarettes have not reduced smokers' health risks and have been deceptively marketed by the tobacco industry to discourage smokers from quitting. The NCI study concluded that smokers who use low-tar brands are exposed to the same amount of toxins as those who use full-flavor cigarettes in part because smokers use low-tar brands differently in order to obtain the same amount of nicotine. The NCI study also revealed that despite knowing that low-tar cigarettes delivered the same amount of tar to smokers, the cigarette companies marketed them as reduced risk, especially to smokers thinking of quitting.

Today, 30 years after the introduction of "light" and "low-tar" cigarettes, the tobacco companies would like to see history repeat itself. They are keenly interested in expanding their marketing of a new set of products with claims of reduced risk. In the last couple of years the tobacco companies have introduced a number of so-called "reduced risk" products designed to encourage new tobacco users and discourage current smokers from quitting. Currently, Brown and Williamson is marketing Advance cigarettes with the slogan "All of the taste... Less of the toxins" and Vector Tobacco has embarked on an extensive marketing campaign of Omni cigarettes with ads proclaiming "Reduced Carcinogens. Premium Taste." Philip Morris recently announced that it plans to launch a new "reduced risk" product next year.

The marketing of so-called "reduced-risk" products is not limited to cigarette manufacturers. United States Smokeless Tobacco Company has recently asked the FTC to approve a claim that its products are less harmful than cigarettes despite the fact that similar advertising by this company in the past has led to a large expansion of smokeless tobacco users, many of them young males, with no reduction in the use of cigarettes. The industry makes claims that these products will help smokers quit. However, there has been no independent scientific evidence to support or confirm any of these claims. The U.S. Surgeon General, the NCI and other scientific organizations have determined smokeless tobacco products sold in the United States increase the risk of serious disease, including oral cancer. Smokeless tobacco is simply not a safe alternative to smoking: users are up to 50 times more likely to get oral cancer than non-users and these cancers can form within five years of regular use. Moreover, although

UST and other manufacturers claim otherwise, there is no evidence that smokeless tobacco products help smokers quit.

The lesson to be learned from the NCI report and an Institute of Medicine Report entitled *Clearing the Smoke, Assessing the Science Base for Tobacco Harm Reduction* is that in the absence of effective government regulation, harm reduction has been and will continue to be a fallacy. Without strong and meaningful Food and Drug Administration (FDA) regulation, tobacco product manufacturers do not have to pre-clear claims or scientifically substantiate them. They also do not have to disclose how they make their products, including what they add in during the manufacturing process. Moreover, they do not have to produce any evidence regarding human exposure or data that would justify claims that their products are less harmful because they reduce exposure to one or more toxic substances.

We are calling on the members of the Committee on Energy and Commerce and the Committee on Government Reform to protect the public from these inaccurate and misleading statements. Industry advertising that falsely states that tobacco products are less hazardous is not only misleading but also has a serious public health consequence as it leads smokers to believe that these "reduced-risk" products are a safe alternative to quitting. It also results in more children starting to use these products. In the absence of meaningful FDA authority over tobacco products, we urge you to publicly oppose the tobacco industry's claims that smokeless and low-yield products result in harm reduction to consumers.

We thank you for your attention to our concerns and stand ready to work with you on these critical public health issues.

Sincerely,

Action on Smoking and Health
American Academy of Family Physicians
American Academy of Nurse Practitioners
American Cancer Society
American College of Chest Physicians
American College of Preventive Medicine
American Heart Association
American Legacy Foundation
American Lung Association
American Medical Association
American Medical Women's Association
American Psychological Association
American Public Health Association
Association of Asian Pacific Community Health Organizations
Campaign for Tobacco-Free Kids
Center for Tobacco Cessation
Community Anti-Drug Coalitions of America/Drug-Free Kids Campaign
Hadassah, the Women's Zionist Organization of America
Interreligious Coalition on Smoking OR Health
Latino Council on Alcohol and Tobacco Prevention
Mautner Project
National Association of County and City Health Officials
National Association of Local Boards of Health
National Center for Policy Research (CPR) for Women & Families
National Women's Law Center
Oncology Nursing Society
Oral Health America
Partnership for Prevention
Society for Public Health Education

UNIVERSITY OF MINNESOTA

Twin Cities Campus

Tobacco Use Research Center
Medical School

Suite 201
2701 University Avenue S.E.
Minneapolis, MN 55414
612-627-4900

May 30, 2003

The Honorable W.J. Tauzin, Chairman
Committee on Energy and Commerce
U.S. House of Representatives
2183 Rayburn House Office Building
Washington, DC 20515

Dear Chairman Tauzin,

I am writing in response to the submission made by the U.S. Smokeless Tobacco Company (USSTC) requesting an Advisory Opinion with the Federal Trade Commission regarding the acceptability of advertising smokeless tobacco products as a significantly reduced risk alternative as compared to cigarettes. I understand that there is a hearing on smokeless tobacco products on June 3rd, 2003 and I request that this letter be included in the record for this hearing. Although the USSTC submitted one of my presentations to provide support for a reduced risk claim, I would like to strongly state that I am not in favor of this position. As noted in the abstract that USSTC provided on my talk, I indicate "**superficially**, the use of smokeless tobacco as a cessation tool does not seem unreasonable." Before any advertising claims can be made that smokeless tobacco products are a significantly reduced risk alternative as compared to cigarettes, we need the scientific data to show that making such a claim would not have detrimental effects on public health in the United States.

Smokeless tobacco is addictive and harmful to health. It has been linked to oral and other cancers, other oral pathologies, increased cardiovascular risk factors and fetal toxicity. The amount of toxins in smokeless tobacco products varies across different U.S. brands. Unfortunately, the brand of snuff that contains the highest level of toxins is the most widely used product. Given that the products sold in the United States still confer a significant risk for disease and produce dependence, it is *unknown* whether making claims indicating the relative reduced risk of smokeless products compared to cigarettes would or would not have detrimental effects on public health. The following are my concerns:

- We do not know if advertising smokeless tobacco as a reduced risk product would increase the initiation of smokeless tobacco use, while having no effect on cigarette smoking in the United States. Experience in other countries, such as Sweden, may not generalize to a different cultural and tobacco marketing environment.
- We have no data to know whether more people would choose to continue to smoke or to use smokeless tobacco products rather than quit because they

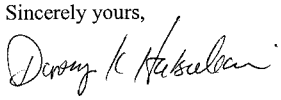
perceive the use of smokeless tobacco product to be safer, thus increasing the total net harm.

- We have no data on the pattern or dual use of tobacco products. It is conceivable that smokers will use both smokeless tobacco products and cigarettes, which may result in greater rather than less tobacco toxin exposure.
- We do not know whether long time smokers would actually experience any reduced risk if they switch to smokeless tobacco. The damage to health may have already occurred. In fact, we have found that smokers who are the most interested in the reduced risk approach tend to be the more highly dependent and experience more medical problems than smokers interested in quitting (Lemmonds et al., in press, *Addictive Behaviors*).
- There is data showing that smokeless tobacco may facilitate the initiation of smoking.

To date, the only scientifically known way to reduce risk for disease is by not initiating tobacco use or by ceasing tobacco use. The use of medicinal nicotine, a product that has undergone rigorous evaluation by the Food and Drug Administration, has a proven record showing relative safety. Therefore, developing more effective cessation medications that undergo extensive testing prior to marketing and that result in the greatest risk reduction will be the most effective method to improve public health.

In summary, to date, whether advertising smokeless tobacco products as a significantly reduced risk alternative to cigarettes would produce negative or beneficial impact on an individual or population level in the United States is virtually unknown. *Before* such claims are made, we need to have in hand evidence-based information, which is collected by scientists independent of a tobacco company to assess potential harms or benefits. Such claims should undergo the same scrutiny by the Food and Drug Administration as conducted with medicinal products.

Sincerely yours,



Dorothy K. Hatsukami, Ph.D.
Professor of Psychiatry

Cc: Congressman Cliff Sterns, Chairman of the Subcommittee on Commerce, Trade and Consumer Protection
Congresswoman Janice D. Schakowsky

Office of the Commissioner
MAJOR LEAGUE BASEBALL

May 29, 2003

The Honorable W. J. Billy Tauzin
Chairman
U.S. House of Representatives Committee on Energy and Commerce
2125 Rayburn House Building
Washington, DC 20515

Dear Congressman Tauzin:

Thank you for the opportunity for Major League Baseball to comment on the dangers of smokeless tobacco.

For decades, chewing tobacco, spit tobacco and other forms of smokeless tobacco have been closely associated with the game of baseball. All baseball fans can picture a large wad of tobacco stuffed in a professional player's cheek, and amateur players at all levels right down to sandlot play have used smokeless tobacco while on the ballfield. This close association between baseball and smokeless tobacco is one that Major League Baseball is assiduously trying to end.

Baseball has for quite some time recognized the medical risks inherent in smokeless tobacco use, and we have done our best to educate players, fans and others connected with

baseball and to eliminate or at least minimize the use of smokeless tobacco by players. Toward those ends, we have taken the following actions:

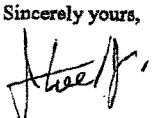
- Beginning in 1993, we have prohibited the use of all forms of tobacco at ballparks and during team travel by minor league players, staff and umpires.

- Throughout the past decade, we have offered cessation counseling and provided educational materials to players about the deleterious effects of smokeless tobacco use, and we have teamed with Oral Health America's National Spit Tobacco Education Program (NSTEP) in an effort to discourage use by all Baseball personnel.

- Also with the help of the NSTEP, Baseball has offered oral screenings to Major and Minor League players during spring training to detect lesions and other evidence of oral cancer.

In short, Major League Baseball would like to end any remaining association it has in the minds of the public with smokeless tobacco and would like the world to know of its serious medical risks. We appreciate any actions that Congress may take in this area and we are grateful for the chance to have our input on this subject considered.

Sincerely yours,



Jimmie Lee Solomon
Senior Vice President
Baseball Operations

TJO/mjr

cc: The Honorable Cliff Stearns
The Honorable Janice D. Schakowski

Extended Testimony of David M. Burns M.D.

U.S. House of Representatives
The Government Reform Committee
Hearing entitled "Potential Reduced Exposure/Reduced Risk Products: An Examination of the Possible Public Health Impact and Regulatory Challenges."
Rayburn Bldg. 2154 2:00 p.m. 6/3/03

My name is David Burns, and I am a medical doctor, professor of medicine and professor of family and preventive medicine at the University of California, San Diego School of Medicine. I was one of two scientific editors for the National Cancer Institute Smoking and Tobacco Control Monograph # 13 entitled "Risks associated with smoking cigarettes with low machine measured yields of tar and nicotine". I am also chair of the scientific advisory group for the Massachusetts Department of Health Services charged with examining the methods by which harm reduction can be evaluated, and I am on the Scientific Advisory Committee on Tobacco for the World Health Organization examining the regulation of new tobacco products. My Curriculum Vitae is attached to this testimony. My testimony today draws heavily on the deliberations of those groups and excerpts from their published reports (SACTob 2003), but I am speaking today as an individual and not as a representative of my university or of any group.

New tobacco products are being introduced for which reduced exposure, reduced toxicity, and reduced health risk claims are being made. These products include cigarettes made with modified tobacco from which established carcinogens were reduced/removed, products designed employing unconventional advanced technologies and a variety of oral tobacco products.

Evaluation of these newer products should be informed by our understanding of, and experience with, so called "light and ultralight cigarettes. Tobacco companies marketed products that claimed lower emissions (Pollay and Dewhirst 2002) but in fact, these cigarettes did not deliver reduced uptake of toxicants or lower risks to those who smoked them (Stratton et al. 2001; NCI Monograph # 13; SACTob 2002). There is no existing regulatory structure to evaluate the scientific validity of current claims for existing or modified tobacco products or to evaluate future claims (Stratton et al. 2001).

The lessons we have learned include:

1. **A simple standardized testing protocol cannot asses the exposure or risk likely to occur with different products.** Human smoking behavior changes when products with different design characteristics are smoked, whereas machines do not change their pattern of smoking in response to the changes in cigarette design. Our error in relying on tar measurement from a single protocol driven machine measurement is not that the parameters of the test were set wrong, but rather that the machine parameters that best mimic actual use are different for different styles of cigarettes. When smokers smoke ultra light cigarettes with larger more intense puffs than full flavor cigarettes, machine measurements using any single puff profile will not match the smoke delivered by these cigarettes as they are actually used by smokers.
2. **Smoke chemistry measurements may be useful to evaluate engineering changes in cigarettes or the characteristics of the smoke produced, but they are not adequate measures of actual human exposure.** Because smokers smoke different products in different ways and may respond to a given design change in an unanticipated manner, human exposure and risk can only be reliably assessed by measurements made in human smokers.
3. **Changes in risk must be evaluated for those smokers who actually use the product rather than being based simply on the characteristics of the product.** Low tar cigarettes were marketed to smokers who were thinking about quitting rather than to smokers who would not or could not quit. Even a product with real reduced toxicity in comparison to conventional cigarettes will not reduce the harm caused by smoking if it is used by those who would otherwise have quit or by those who had not previously smoked.
4. **Claims must be constrained by the data available to support them.** Because of the marketing advantages of reduced harm claims, there is great risk that the claims made will exceed the evidence to support them. For example, using evidence of changes in smoke chemistry to claim reduced exposure or reduced harm is an over statement of the actual evidence available to support the claim. The fact that it is difficult and time consuming to acquire the evidence to establish differences in exposure or reduced harm does not justify making claims for which the evidence to support them does not exist.
5. **Harm reduction cannot be adequately considered without examining the marketing messages used for the product.** Messages communicated to the consumer, the groups targeted by the marketing effort, and the proposed use of the product all define who will use a new tobacco product and how it will be used. Messages that promote initiation of tobacco use, interfere with

cessation or encourage use as a means of preserving and enhancing the level of addiction will cause harm even if the product itself is less harmful than conventional cigarettes.

6. **The meaning of a claim is defined by the understanding of the consumer not the manufacturer.** Marketing messages communicate to the consumer in a variety of ways including the words used, images presented and colors portrayed. It is the message received by the consumer from a harm reduction marketing effort that is important in determining what the consumer believes he or she is receiving when they purchase the produce and how they will use it. Methods exist to determine what consumers will comprehend from various marketing strategies and these methods should be used to prevent the delivery of marketing messages which communicate inaccurate or misleading information.
7. **Absent effective regulatory control of tobacco products, verification of manufacturer's harm reduction claims in time to prevent future consumer deception will be impossible.**

EXISTING SCIENTIFIC KNOWLEDGE

Evaluating the potential for newer tobacco products to cause/reduce harm is complex, even if real changes occur in the emission profile when they are used. Differences in human exposure and injury as well as the influence of the product on cessation and initiation all need to be included in an assessment of potential harm. Extensive reviews of the relative hazard of using existing cigarettes, and the changes in cigarettes over the past several decades, conclude that evidence does not support a difference in disease risks with the use of cigarettes with different levels of machine measured tar and nicotine yields or with product modifiers such as light or mild. (Stratton et al., 2001; NCI 2001; Canadian Expert Panel 2001; SACTob 2002). The evidence available for newer tobacco products is more limited and is largely based on chemical measurements and *in vitro* toxicity assays. The U.S. Institute of Medicine concluded that existing scientific evidence is not sufficient to allow definition of differences between newly engineered tobacco products and currently existing products for human uptake of toxicants, toxicity, or harm (Stratton et al., 2001). They also concluded that a scientific methodology to establish toxicity and harm differences for these products does not currently exist and that a structure for regulatory oversight would be essential to any scientific assessment of claims for reduced harm (Stratton et al., 2001). However, the report also concludes that emerging scientific understanding of disease mechanisms offers the promise of new and more specific methods of assessing tobacco toxicity and harm.

Product characteristics that are important in evaluating the potential for harm reduction include cigarette ingredients (particularly the type and blend of tobacco), design and engineering characteristics of the product, and elements of the manufacturing processes that may alter the ingredients used. Quantities of these ingredients by brand, and the design and manufacturing techniques used for the cigarette brand, are usually not provided by tobacco manufacturers, but they are essential for evaluation of toxicity; and they could be provided without any increased cost to the manufacturer. Patterns of actual use are also important determinants of toxicity, since they influence the delivery of toxicants to the smoker. Compensation leads smokers to use products differently based on the amount, rate and form in which nicotine is provided, making exposure extrapolation from chemical measurements even more difficult (Djordjevic et al., 1995, 2000; Kozlowski et al., 1994, 1998; Kozlowski and O'Connor 2002).

Assessment of differences in human exposure and harm is complicated by differences in the demographic characteristics and intensity of use of those who choose to use different products (Giovino et al1996; Haddock et al., 1999, NCI 2001); by the difficulty in extrapolating from forced switching studies to actual uses exposures (Benowitz 2001); by the reality that how products are marketed determines who uses the product; by what the alternatives are for the person switching to the product, and by the context in which the product is used (Ashley et al., 2001; Health Canada 2002a,b).

Perspectives On Harm Reduction

The major public health rationale for development of new or modified tobacco products is the potential for reducing the harm caused by existing tobacco products. The world health organization has suggested that the harm that may be reduced must be evaluated in at least four contexts (SACTob 2003).

Harm To The User

Harm can be examined within the narrow perspective of effects on the individuals currently using the product. Estimates of the harm reduction that can occur with shifting from one product to another are commonly derived from risk data derived from populations who are lifelong users of the different product;. for example, comparison of the risks of cigarette smokers and cigar smokers as a measure of the risk reduction that might occur if smokers switched from smoking cigarettes to smoking cigars. This approach is deeply flawed by two constraints. First, for the individual, initiation of use of a tobacco product can only increase the harm they are likely to experience in comparison with continued never use of any tobacco product; and therefore, recommending initiation with a less hazardous form of tobacco use cannot be considered a harm reduction approach. It is only the population of individuals who switch to a potentially less harmful product that can experience a reduction in harm. The difference in risk that accrues with switching from one product to another is not well estimated from the risks of those who have only used the less hazardous product. Second, smokers who switch from cigarettes to potentially less harmful products carry with them levels of addiction and patterns of use that may differ from those who have only used the less harmful product. For example, those who have only smoked cigars tend not to inhale and this difference in inhalation is felt to be responsible for much of the difference in risks of lung cancer and heart disease between those who have only smoked cigars and those who smoke cigarettes (NCI 1998). However, cigarette smokers who switch from smoking cigarettes to smoking cigars do tend to inhale eliminating much of the theoretical benefit that might be achieved from switching to smoking cigars.

Difference in toxicity with switching from cigarettes to other tobacco products should be examined by comparing those who switch to those who continue to smoke cigarettes. An alternative behavior that also needs to be part of this examination of potential harm reduction is a comparison of those who switch to those who quit using any tobacco product instead of switching. This comparison defines the maximum benefit available to the user so that the benefits of switching can be placed in appropriate context, bounded by the risks of continuing and the benefits of quitting.

For a purported harm reduction product to benefit the user who switches to it, the product must reduce the intensity of exposure to tobacco or tobacco smoke toxicants, continue that reduced intensity for a sufficient duration, and have a reduction in intensity that is sufficient to more than counterbalance the impact of an increased duration of exposure on disease risks. When estimating the differences in intensity of exposure with switching to a new product, it is necessary to account for compensatory and other changes in the actual use of the new product. For example, in some epidemiological studies the risk of lung cancer declines for smokers of lower tar cigarettes when estimated on a constant number of cigarettes smoked per day basis (Hammond 1980). However, if smokers compensate for the reduced nicotine yield by increasing the number of cigarettes they smoked per day when they switched, the risk could potentially increase.

The frequency and timing of relapse to using the previous tobacco product also need to be evaluated when considering the likelihood that reduced intensity of exposure will be of sufficient duration and magnitude to meaningfully effect disease risks. And finally, the effect of prolonging the duration of exposure needs to be considered when examining the impact of reduced intensity of exposure. Duration is a much more powerful determinant of disease risk than is intensity of smoking for cancer and lung disease (Doll and Peto 1978), and therefore modest prolongation of duration of use may overwhelm the effect of a substantial reduction in intensity of exposure in determining the risk for individual smokers.

Harm To Non-Users/By-Standers

Many new products may claim reductions in environmental tobacco smoke generation and there is clear reduction when shifting from burned tobacco products to products that heat rather than burn tobacco, or to smokeless tobacco use. However, there may be an increase in secondhand smoke exposure if individual smoking duration increases or if new products result in an increase in toxicants present in either sidestream smoke or exhaled mainstream smoke. An additional concern is the reduction in smoke emissions may be used to justify delay or reversal of restrictions on smoking in indoor environments.

Harm To The Population

The harm to the population is the net effect of the changes in harm to the individual users and the changes in number of users who are exposed. A principal concern for all harm reduction products is that their presence on the market will offer alternatives to cessation for those who are interested in quitting. If the only users of a reduced harm product are those who would have quit in the absence of the product, or if the number of smokers whose cessation is delayed or aborted by use of the product exceed the number of those who would never have quit who are using the product, then it is likely that there would be a net increase in harm to the population. This would occur even from the introduction of a product that could actually reduce the harm for those individual smokers who would not otherwise quit. Conversely, it is possible that offering harm reduction products might induce some smokers who would not otherwise have quit to use the product and then begin a path that leads to successful long-term abstinence from tobacco. These products may also play a role in enhancing the cessation success of those who are having difficulty achieving abstinence. The potential benefits described here are theoretical, as no tobacco product has currently demonstrated such benefits.

Population harm, therefore, is the net of the combined effects that harm reduction products and their marketing have on the use of tobacco products and resultant population exposure to toxicants. This calculus involves consideration of who is using the newer products and why; what the users alternative behavior might have been; whether the availability of the new product increases the initiation of tobacco use with that product; and whether, once initiated, users then transition to products with a greater degree of toxicity. These concerns cannot be addressed without considering the marketing approaches and messages utilized for harm reduction products as they are introduced in the marketplace. The experience with so called "light" and "ultralight" cigarettes is not only that their marketing messages were misleading but also that their marketing target included those who were thinking about quitting smoking (Pollay and Dewherst 2002). The risk that marketing messages may be used to intercept smokers who are on the way to cessation, or to increase the initiation of tobacco use, must be part of any estimate of the net harm produced by newer tobacco products. Monitoring of the rates of initiation and cessation are critical elements of any post-market surveillance program.

Harm Due To Marketing Messages

Messages used to market purportedly less harmful tobacco products can create harm not measured by changes in rates of tobacco initiation, use and cessation. Creation of a false perception of safety alters population norms and beliefs about tobacco, may be used by young smokers to continue tobacco use since they can switch to a safer alternative in the future, and may alter the perceived need for regulatory control of products or of smoking behavior. In addition, the offer on the market of purportedly safer products may be used by the tobacco companies as a demonstration that they have changed their corporate behavior and are now acting responsibly, even if there is no meaningful effort to actually market the products. Harm to society may accrue if these marketing messages slow the changes in social norms and the development of regulatory controls that are effective in altering tobacco use.

A Framework For Evaluating New Products

No operational regulatory model exists to adequately address the evaluation of the harm reduction claims being made for products currently on the market or for products that are likely to be introduced in the near future. There is also no scientifically validated testing protocol that would allow comparison of the injury caused by modified (reduced toxicant) cigarettes with that of older more conventional cigarette brands (Stratton et al., 2001). However, WHO has provided a scientific framework of questions that would need to be answered in examining the claims made for newer products (SACTob 2003). The questions vary somewhat for the different types of products.

Modified (reduced carcinogen/toxicant) Cigarettes

The ideal evaluation of any purported harm reduction product would be based on measures of disease outcomes from human epidemiological studies of individuals followed before and after they switched to the new product. For most disease outcomes, such studies would require very large populations followed for long intervals and could therefore only provide information on changes that occurred many years in the past. More timely examination of new products is important for both regulatory oversight and for providing accurate public health advice to consumers. The data upon which this evaluation is made will, of necessity, be more limited than that which would be available from epidemiological and other observations made over long duration of use of the new product. Limitations of the data likely to be available make it useful to conceptualize the evaluation as a set of questions that can be answered in series and which allow a progressively more complete understanding of the actual benefits likely to be experienced by those who switch to a new product. Conceptually this sequence would involve five measures: measures of smoke emissions under conditions reflecting actual use, measures of smoke uptake in actual users of the product, measures of addiction potential of the product, measures of injury from use of the product, and measures of disease outcome.

Careful independent scientific review of existing data for each of these questions allow conclusions to be drawn (and claims to be validated) for each question independently at a point in time when the data are sufficient to support the claim. The separation of the questions, and of the data to support them, will also avoid confusion about the type of claim that can be made from the data presented. For example, data on the emissions generated by a cigarette might allow claims about differences in smoke composition but would not, without measures of injury, allow claims for reduced toxicity. Allowing measures of smoke emissions (machine measured tar and nicotine yields by the FTC/ISO method, or event the Massachusetts and Health Canada methods which prescribe more intense machine smoking parameters) to be extrapolated to enable claims of reduced uptake and reduced harm (light and mild brand designators) resulted in the consumer being misled (SACTob 2002), and this experience should not be repeated with new tobacco products. If claims are to be made by the manufacturer, it should be the responsibility of the manufacturer to provide evidence supporting the claim to an independent scientific review before the claim is made. The claims must be validated by the data presented, and claims that go beyond the data presented should not be allowed. Absence of evidence, or absence of scientific methods to measure toxicity or harm, are not legitimate scientific bases to allow claims of harm reduction from measures of smoke emissions.

The first logical step in examining a product having potential to reduce the harm produced by tobacco use is to examine the characteristics of the product. Consideration of the ingredients used, both quantitatively (type and amounts of ingredients, the blend of tobacco, reconstituted sheet tobacco) and qualitatively (toxicity of burned ingredients), defines likely areas of scientific concern as does a description of the engineering design and characteristics of the product. This information is currently available to the manufacturer and can be provided at no additional cost.

The next step is to examine emissions from the product, again both quantitatively and qualitatively. There are two dimensions to this question. The first is a comparison of the emissions of a product to other products under standardized conditions, and the second is the evaluation of the emissions under conditions of actual use. Smokers may vary in the way they use a single product (Djordjevic et al., 2000), and different products may be used differently by the same smoker, making machine measured values derived using a single set of smoking conditions misleading as an estimate of the smoke emissions actually arriving at the smokers mouth when the product is used (SACTob 2002). A companion concern is quantitative and qualitative measures of second hand smoke emissions.

Smoke uptake by the smoker, rather than smoke emissions, is the measure of intensity of exposure important for predicting disease risk. Measures of uptake with actual (rather than laboratory) use of the product are key to estimating uptake for populations of individuals who are likely to use a product. As they are developed and validated, measures of the biologically effective dose (levels of toxicants in critical target organs or tissues) may offer even more precise measures of smoke uptake for predicting smoke toxicity (Stratton et al., 2001). Additional keys to assessment of differences in uptake that result from differences in actual use of different products are understanding who is using the product and why. Measures of uptake derived from comparisons of groups of users may be misleading if a large fraction of those who switch to a new product are doing so in an effort to quit or cut down the amount that they smoke. Valid comparisons of the differences in uptake attributable to differences in the products used must ensure that the populations studied are using the products with similar intentions for maintaining the intensity of their smoking behavior.

Bioassays for injury related to cancer, lung disease, heart disease, reproduction and development, or neurobehavioral systems are essential to any examination or validation of claims of reduced toxicity. At present, the evidence linking existing biomarkers to ultimate disease outcomes remains incomplete, and no biomarkers have been validated for use in distinguishing the relative injury caused by different levels of cigarette smoke uptake (Stratton et al., 2001). The potential exists for evolving scientific techniques to make a meaningful contribution to the definition of early tobacco smoke related injury, but these approaches remain future rather than current solutions. The absence of existing validated biomarkers of injury from tobacco smoke is a scientific challenge to be overcome, but the absence of measurement tools should not be used to justify claims of reduced injury or reduced harm based on smoke emission or smoke exposure data.

One of the principal harms caused by tobacco use is addiction, and evaluation of the potential to create and sustain addiction is an important component of any consideration of the potential harm that can accrue from new and modified tobacco products.

Rates of disease outcomes following tobacco use are the ultimate measure of harm from tobacco use. The long time period required to generate this information for many of the diseases caused by smoking may preclude its use in making regulatory decisions surrounding the introduction of new tobacco products, but the importance of this information to understanding the harm caused by tobacco use makes collection of this information a scientific imperative. No claim for harm reduction should be allowed in the absence of evidence demonstrating reduced harm. The length of time required to generate such data is a reality that results from the biology of disease, and it is not a justification for allowing claims in the absence of evidence.

Once products are introduced into the market, there is a continuing need to monitor who is using the products and why, changes in the product design/ingredients or marketing approaches after the product is initially evaluated, and the impact of the product on rates of smoking initiation and cessation. Who the target populations are for the marketing messages, what those target populations actually understand those marketing messages to mean, and what the effect is for populations other than the target population, are concerns requiring ongoing monitoring. Many reduced toxicant products may have the potential to either increase or decrease harm depending on who uses them and what are the alternatives to their use. Absent monitoring of these phenomena, it will likely be impossible to determine whether use of reduced toxicant cigarettes by smokers provides a benefit or a cost to the population in terms of the damage and disease caused by smoking.

Products That Allegedly Heat Instead Of Burn Tobacco.

The issues to be examined for products that use processes other than tobacco combustion to deliver nicotine are similar to those for reduced toxicant cigarettes. However, much greater attention is necessary to the technology being employed and how it functions under a variety of smoking conditions. Assumptions that these new technologies will be smoked with the same pattern of puffing as conventional cigarettes, will continue to heat rather than burn the tobacco under all of the puffing conditions likely to be encountered by consumers, or will not contain new constituents with undefined risks are not warranted and must be tested. These products may also have different potential for creating of sustaining addiction than conventional cigarettes.

Oral Tobacco Products (including smokeless tobacco, but not including NRT products already regulated for a therapeutic purpose).

Differences in the process by which tobacco constituents are delivered to the user, sites of delivery and time course of uptake make comparisons of emissions from oral tobacco products and cigarettes difficult. Even comparisons of uptake of the same constituent (e.g. nicotine) can be difficult to interpret. However, the same general concerns described above for reduced toxicant cigarettes also apply for defining the harm reduction potential of oral tobacco products. However, there are some particular concern with oral tobacco products.

It remains to be demonstrated that large numbers of adult cigarette smokers who will not otherwise quit will switch to oral tobacco products. The rate at which adults are willing to switch is important for calculating the net effect for harm reduction of marketing oral tobacco products because of the likely effects of marketing on those not yet using any tobacco product. As a new product is introduced, or an existing tobacco product is marketed as offering less risk for the smoker who is unwilling to quit, the initiation of use of that product among adolescents may increase. Existing data on current use suggests that users of oral tobacco products are much more likely to transition to cigarette smoking than are cigarette smokers to transition to smokeless products (Tomar 2002). Initiation of oral tobacco use also occurs largely among the young raising further concerns about which age groups might be influenced most by marketing messages. A real concern is that a marketing message of lower risk might not change the behavior of adult smokers but might increase the rate of adolescent initiation of oral tobacco use, increasing rather than decreasing the fraction of the population using tobacco products.

A second issue is that the data available on the risks of using oral tobacco products are derived from populations of individuals who use only oral tobacco, and little is known about the magnitude and timing of any change in risk among those who switch from smoking cigarettes to use of oral tobacco. The fraction who switch who might otherwise quit, the fraction who relapse back to smoking, the fraction who continue dual use, and the impact of dual use on disease risks are all unanswered questions in the context of offering these products as vehicles for harm reduction.

A similar concern exists for existing oral tobacco users. Will harm reduction messages reduce cessation or delay cessation attempts?

Oral tobacco products are marketed as temporary alternatives to smoking that sustain nicotine addiction in those circumstances where smoking is prohibited. The potential for these products to sustain a high level of nicotine addiction, or to otherwise reduce the interest in quitting or success in achieving abstinence, are real concerns. These effects, if present, could cause a net harm to the population even if the products themselves have low levels of toxicity.

Conclusion

In conclusion, regulatory oversight of cigarette and cigarette like products should include examination of at least five separate aspects of the new products: physical chemical characteristics of tobacco and tobacco smoke, uptake of toxicants (both by smokers and by non-smokers), toxicity, addiction potential, and disease risk. Demonstration of reductions in smoke emissions or reduced uptake of toxicants alone is not sufficient to support claims or implications of reduced toxicity or harm. No claim should be permitted for any tobacco product absent adequate scientific data. Regulatory oversight, including post market surveillance, is necessary to assess and monitor changes in newly modified tobacco products

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SWEDISH MATCH

For Immediate Release

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SWEDISH MATCH NORTH AMERICA APPLAUDS HOUSE ENERGY AND COMMERCE SUBCOMMITTEE FOR HOLDING TOBACCO HARM REDUCTION HEARING

Expert Witnesses Testify on Alternative Tobacco Concepts

Washington, D.C. June 3, 2003 – Swedish Match North America, a manufacturer of specialty tobacco products based in Richmond, Virginia, today commended members of a House Energy and Commerce Subcommittee for holding a hearing on the issue of reducing tobacco harm, "Can Tobacco Cure Smoking? A Review of Tobacco Harm Reduction." The hearing by the Subcommittee on Commerce, Trade, and Consumer Protection follows increasing interest from the public health community in minimizing tobacco-related death and disease *without* completely eliminating tobacco use.

"Today's hearing is an important step forward in advancing the debate surrounding cigarette harm reduction and I applaud Chairman W.J. "Billy" Tauzin (R-La.) and the subcommittee members for their diligence in hearing both sides of this important issue," said Lennart Freeman, president of Swedish Match North America "It's clear that an increasing number of leading scientists, doctors and members of the health community believe that not all tobacco is the same from a risk perspective and that the quit-or-die approach to reducing cigarette smoking is simply not working."

Swedish Match does not manufacture cigarettes and is focused on reducing or eliminating substances in tobacco deemed harmful or controversial.

The hearing included communication of relative risk to consumers, alternatives for smokers who cannot quit, messages regarding "less harmful" alternatives, the availability of reduced-exposure products and the effects that reduced-harm claims have on tobacco consumers.

"We have a long history of developing safer alternatives to cigarettes and are thrilled that Congress is generating greater public awareness of this issue in an effort to reduce tobacco-related death and disease," said Freeman. "Recognition of this issue is long overdue and we thank the subcommittee members for engaging public health professionals and encouraging people to consider all of the facts in the debate surrounding tobacco-harm reduction."

The hearing can be viewed with Real Player® via Web cast by linking onto the House Energy and Commerce Web site at
http://energycommerce.house.gov/108/hearings/06032003Hearing928/hearing.htm.

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Swedish Match North America, headquartered in Richmond, Virginia, produces niche tobacco products, specifically smokeless tobacco. It is one of the leading U.S. manufacturers of smokeless tobacco with facilities located in Virginia, Alabama and Kentucky. Swedish Match North America traces its roots to the Pinkerton Tobacco Company founded in 1901. Swedish Match is an international group of separate companies based in Stockholm, Sweden that offers a complete range of market-leading snuff and chewing tobacco brands, cigars and pipe tobacco as well as matches and lighters. Swedish Match shares are listed on the OM Stockholm Exchange (SWMA) and NASDAQ (SWMAY).

The Lessons of "Light" and "Low Tar" Cigarettes:

Without Effective Regulation, "Reduced Risk" Tobacco Products Threaten the Public Health

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Prepared for

Rep. Henry A. Waxman
Rep. Janice D. Schakowsky

Minority Staff Report
Special Investigations Division
Committee on Government Reform
U.S. House of Representatives
www.reform.house.gov/min

June 3, 2003

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EXECUTIVE SUMMARY

After the U.S. Surgeon General concluded in 1964 that cigarette smoking causes lung cancer, tobacco companies recognized that health issues concerned millions of Americans smokers. The companies responded by introducing "light," "filtered," "low tar," and "ultra low tar" brands and marketing them as less dangerous than regular cigarettes. Millions switched brands but experienced no health benefits as a result. The "light" and "low tar" experiment was a public health disaster.

Today, the U.S. tobacco industry is marketing a new generation of "reduced risk" tobacco products. These include "low nitrosamine" cigarettes, "heated" nicotine delivery devices, and smokeless tobacco. Companies are claiming they are "safer," have "less toxins," and deliver "reduced carcinogens." An essential question regarding these products is whether history is repeating itself.

At the request of Reps. Henry A. Waxman and Janice D. Schakowsky, this report compares the history of "light" and "low tar" cigarettes to available evidence about the new "reduced risk" tobacco products, including previously undisclosed internal company documents. The report finds striking parallels between current "reduced risk" products and past experience with "light" and "low tar" cigarettes.

- **Marketing to Counter Health Fears**

Starting in the late 1960s, tobacco companies sold "light" and "low tar" brands as important scientific advances that addressed the growing anxiety smokers felt about their health. The companies' claims could be explicit, as when Brown & Williamson marketed Fact, "the low gas, low 'tar'" cigarette that should appeal to "critics of smoking." More frequently, cigarette manufacturers exploited the widespread belief that since nicotine and tar were harmful, cigarettes offering less of these toxins had to be safer. As a result, when Philip Morris relied on machine-based testing of nicotine and tar to declare "Merit Science Works" or Brown & Williamson stated "Latest U.S. Gov't Laboratory test confirms . . . Carlton is lowest," smokers heard a clear message about health. The tobacco industry also sought to enlist health officials in their campaign to promote these products, with one company hoping "to generate statements by public health opinion leaders which will indicate tolerance for smoking and improve the consumer's perception of ultra low 'tar' cigarettes."

The tobacco industry is making strikingly similar claims for its "reduced risk" products today. For example, Brown & Williamson markets its Advance Lights brand as a "revolutionary breakthrough in cigarette technology" that provides "All of the taste . . . less of the toxins." Vector Tobacco has promoted Omni as offering: "Reduced carcinogens. Premium taste." In marketing Eclipse, R.J. Reynolds proclaims that "the toxicity of [Eclipse's] smoke is dramatically reduced compared to other cigarettes." According to internal company documents, Brown & Williamson's parent company has developed a public relations campaign for "lower risk products" based on partnerships with the public health community.

- **Deceiving Consumers**

Even as their advertisements promoted "light" and "low tar" cigarettes as better for health, tobacco companies knew that smokers generally received the same amount of nicotine and other toxins from these products as from their regular cigarettes. In fact, the companies designed cigarettes to score low on machine-based testing but still allow users to inhale their usual amounts of nicotine and tar. To accomplish this, manufacturers took such steps as adding ventilation holes that drew in diluting air on machine testing but were blocked by smokers during actual use. An Illinois judge recently called one company's actions in creating these brands "immoral, unethical, oppressive and unscrupulous."

While new "reduced risk" products are still in their infancy, there are warning signs that tobacco companies may again be deceiving consumers. In 2000, in an internal company email, a senior scientist at Brown & Williamson's corporate parent flatly dismissed the advertised advantages of the company's special "low nitrosamine" tobacco. He wrote to other company officials that the technology to make cigarettes "appreciably less lethal . . . does not exist." He added: "We should tone down future expectations. Firstly, it is not ethical and secondly we shall be asked to explain our failures at some point in the future."

On its website today, R.J. Reynolds claims to have evaluated its "reduced risk" product Eclipse using a rigorous four-step verification process. However, the Department of Justice recently determined that "all R.J. Reynolds did was look at all of the work it already had done to evaluate Eclipse to date, categorize it, and retroactively dub it a 'four step methodology.'" The head of the supposedly "independent" scientific effort reviewing Eclipse has received more than $1.5 million from R.J. Reynolds.

- **Marketing to Deter (or Reverse) Quitting**

Tobacco companies marketed "light" and "low tar" brands to the health-conscious smoker as viable alternatives to quitting. For example, Lorillard's brand True was advertised with the slogan, "Considering all I'd heard, I decided to either quit or smoke True. I smoke True."

There are signals that similarly irresponsible marketing is occurring today. In 1998, Philip Morris introduced Accord as a tobacco product with less secondhand smoke. In January 2003, the Department of Justice determined that "to the extent that Philip Morris has sought to market Accord . . . there is evidence showing that it had its advertising agency assist in marketing Accord to those who want to quit or who have quit and are rejoining the cigarette market."

In 2000, the President of the U.S. Smokeless Tobacco Company wrote that a key company objective was "Promoting Dual Consumption" of smokeless tobacco among smokers frustrated by indoor air laws. Starting in 2001, the company began to market a

new product, Revel, with the slogan "a fresh new way to enjoy tobacco when you can't smoke." This marketing strategy, if successful, could sustain nicotine addiction and make it harder for smokers to quit.

- **Exploiting the Absence of Effective Regulation**

Health officials did not recognize the dangers posed by "light" and "low tar" cigarettes before it was too late. Without full access to information, some government officials even believed that substantial disease reductions were likely among "light" and "low tar" smokers. For decades, cigarette manufacturers advertised the numbers from the Federal Trade Commission's flawed machine-based testing method while simultaneously fighting effective tobacco regulation.

Today, tobacco companies are making a blizzard of health claims about new "reduced risk" products without any significant government oversight. No agency has the authority to assess the claims made by the companies before they are made, routinely review company research and documents, or set standards for what might justifiably pose a reduced risk to consumers. As a result, the unregulated promotion of "reduced risk" products threatens to undermine smoking cessation (which is proven to save lives), cause former smokers to resume their addiction, and even attract young people to tobacco products.

I. INTRODUCTION

For more than 75 years, U.S. tobacco companies have marketed tobacco products to health-concerned smokers using direct or implied health claims that are unsupported by evidence. In the 1920s, for example, American Tobacco claimed that "20,679 Physicians Say Luckies Are Less Irritating."[1] In the 1930s, R.J. Reynolds told the public that Camels "don't get your wind," and Philip Morris declared that "[o]n changing to Philip Morris, every case of irritation due to smoking cleared completely or definitely improved."[2] In the 1940s, Brown & Williamson advertised: "Head stopped up? Got the sneezes? Switch to KOOLS . . . the flavor pleases!"[3]

In the 1950s, as reports on the health effects of smoking increased, tobacco companies competed for market share by promoting the health benefits of "filtered" cigarettes.[4] Not only were the purported advantages of cigarette filters never proven, at least one was made of asbestos.[5] As one Philip Morris report later noted, "[t]he illusion of filtration is as important as the fact of filtration."[6]

In 1964, the U.S. Surgeon General's conclusion that smoking causes lung cancer created anxiety among smokers — and among tobacco companies.[7] To maintain their industry, cigarette manufacturers embraced a decades-long campaign to create doubt about the scientific evidence linking smoking to disease.[8] At the same time, they began to market new "filtered," "light," "low-tar," and "ultra low tar" cigarettes as viable health-conscious alternatives to quitting. As Brown & Williamson's advertising agency noted in 1967:

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[1]Richard Kluger, *Ashes to Ashes*, 75, 77 (1997).

[2]*Id.* at 87, 102.

[3]Institute of Medicine, *Clearing the Smoke: Assessing the Science Base for Tobacco Harm Reduction*, 63 (2001).

[4]*See* National Cancer Institute, *Risks Associated with Smoking Cigarettes with Low Machine-Measured Yields of Tar and Nicotine*, 200 (Oct. 2001).

[5]Richard Kluger, *supra* note 1, at 151.

[6]M.E. Johnston, *Market Potential of a Health Cigarette*, Special Report No. 248, Philip Morris (June 1966), as cited in National Cancer Institute, *supra* note 4, at 206.

[7]*See* National Cancer Institute, *supra* note 4, at 199.

[8]*See, e.g.*, Neil Francey and Simon Chapman, *"Operation Berkshire": The International Tobacco Companies' Conspiracy,* British Medical Journal, 371–74 (Aug. 5, 2000).

> Psychologically, most smokers feel trapped. They are concerned about health and addiction. Smokers care about what commercials say about them. Advertising may help to reduce anxiety and guilt.[9]

Millions of smokers switched brands. According to the most recent data, more than 85% of cigarettes sold are considered "low tar,"[10] and many of those who smoke "light" or "mild" brands believe they are reducing their risk from smoking.[11]

Yet these beliefs are misplaced. Nearly 40 years after the Surgeon General's report, "light" and "low tar" brands failed to reduce tobacco-related disease.[12] In an exhaustive review of available research, the National Cancer Institute recently found that "[t]here is no convincing evidence that changes in cigarette design between 1950 and the mid[-]1980s have resulted in an important decrease in the disease burden caused by cigarette use either for smokers as a group or for the whole population."[13] The National Cancer Institute concluded:

> The absence of meaningful differences in smoke exposure when different brands of cigarettes are smoked . . . and the resultant absence of meaningful differences in risk . . . make the marketing of these cigarettes as lower-delivery and lower-risk products deceptive for the smoker . . . . The reality that many smokers chose these products as an alternative to cessation — a change that would produce real reductions in disease risks — makes this deception an urgent public health issue.[14]

II. THE PURPOSE OF THIS REPORT

Today, tobacco companies are marketing a new generation of "reduced risk" products. Like "light" and "low tar" cigarettes, these new products are being sold as a potentially safer substitute for conventional tobacco products. The new "reduced risk" products include:

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[9]Oxtoby-Smith, Inc., *A Psychological Map of the Cigarette World* (Aug. 1967), prepared for the Ted Bates advertising agency and Brown & Williamson, as cited in National Cancer Institute, *supra* note 4, at 204.

[10]*See* Federal Trade Commission, *Cigarette Report for 2000*, 6 (2002).

[11]National Cancer Institute, *supra* note 4, at 193–97.

[12]*See, e.g.*, National Cancer Institute, *supra* note 4, passim.

[13]National Cancer Institute, *supra* note 4, at 146.

[14]*Id.* at 1.

- **Cigarettes with modified tobacco**. Brown & Williamson sells Advance Lights, a brand advertised with two safety features: a special filter and tobacco that is low in nitrosamines, a type of carcinogen. Vector Tobacco has marketed Omni cigarettes as lower in carcinogens and is selling Quest cigarettes as low in nicotine.

- **Substantially modified cigarettes**. Philip Morris has test-marketed Accord, a product that only burns tobacco on inhalation, and R.J. Reynolds sells Eclipse, a product that primarily heats rather than burns nicotine.

- **Smokeless tobacco products.** The U.S. Smokeless Tobacco Company (UST) has proposed marketing its conventional smokeless tobacco products as posing "significantly less risk" than cigarettes. Star Scientific is selling Ariva, a compressed tobacco product claimed to be low in nitrosamines.

An essential question about these new products is whether history is repeating itself. The tobacco industry asserts that the "reduced risk" products represent a new health "breakthrough." But this is essentially how the industry has promoted "light" and "low tar" cigarettes for decades.

At the request of Reps. Henry A. Waxman and Janice D. Schakowsky, this report compares the history of "light" and "low tar" cigarettes to available evidence about the new "reduced risk" tobacco products, including previously undisclosed internal company documents. The report finds four striking parallels between current "reduced risk" products and past experience with "light" and "low tar" cigarettes: marketing to counter health fears, deceiving of consumers, marketing to deter quitting, and exploiting the absence of effective regulation.

III. PARALLELS BETWEEN "LIGHT" AND "LOW TAR" CIGARETTES AND "REDUCED RISK" TOBACCO PRODUCTS

A. Marketing to Counter Health Fears

1. "Light" and "Low Tar" Cigarettes

Starting in the late 1960s, tobacco companies sold "light" and "low tar" brands as important scientific advances that addressed the growing anxiety smokers felt about their health. As a Brown & Williamson marketing study in 1977 noted, "Almost all smokers agree that the primary reason for the increasing acceptance of low 'tar' brands is based on the health reassurance they seem to offer."[15] Cigarette manufacturers created this reassurance through advertising.

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[15]Hawkins, McCain, and Blumenthal, Inc., *Low "Tar" Satisfaction* (July 25, 1977), Bates Numbers 775036039-6067 at 775036047 (available online at http://legacy.libary.ucsf.edu).

At times, health claims were explicit. In 1972, R.J. Reynolds marketed Vantage cigarettes as offering flavor:

> without the high 'tar' and nicotine. And since it is the high 'tar' and nicotine that many critics of cigarettes seem most opposed to, even they should have some kind words for Vantage.[16]

In 1976, Brown & Williamson launched Fact, "the low gas, low 'tar'" cigarette. Advertisements for Fact claimed that "some critics of smoking say it's just as important to cut down on some of the gases as it is to lower 'tar' and nicotine. No ordinary cigarette does both. But Fact does."[17]

More often, companies exploited the consumer's assumption that since nicotine and tar were health risks, any products offering less of these toxins had to be safer. A 1976 study prepared for Philip Morris found that 74% of smokers cited specific brands as "better for health" on the basis of "less/lower in tar and nicotine" or "less/lower in tar."[18] As the National Cancer Institute concluded in an extensive review of advertisements from the period, "The reductions in tar were marketed as a surrogate for reductions in risk."[19] When Philip Morris declared on the basis of machine-based tar and nicotine readings "Merit Science Works"[20] or Brown & Williamson stated "Latest U.S. Gov't Laboratory test confirms" that "Carlton is lowest,"[21] smokers heard a clear message about health.

As part of their campaign to promote "light" and "low tar" products, cigarette manufacturers courted health officials. For example, in 1982, Brown & Williamson proposed:

> activities designed to generate statements by public health opinion leaders which will indicate tolerance for smoking and improve the consumer's perception of ultra low 'tar' cigarettes (5 mg. or less) . . . Through political and scientific friends, B&W will attempt to elicit . . . statements sympathetic to the concept that

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[16]R.J. Reynolds, Advertisement: *Anyone Who's Old Enough to Smoke Is Old Enough to Make up His Own Mind* (June 25, 1972), Bates Number 502612446 (available online at http://legacy.libary.ucsf.edu).

[17]National Cancer Institute, *supra* note 4, 1976 advertisement reproduced at 215.

[18]The Roper Organization, Inc., *A Study of Smokers' Habits and Attitudes with Special Emphasis on Low Tar Cigarettes* (May 1976), Bates Numbers 2040543437-3734 at 2040543476 (available online at http://www.pmdocs.com).

[19]National Cancer Institute, *supra* note 4, at 70.

[20]*Id.*, 1979 advertisement reproduced at 214.

[21]*Id.*, 1985 advertisement reproduced at 224.

generally less health risk is associated with ultra low [tar] delivery cigarette consumption.[22]

These efforts were at least partially successful. In the 1970s and into the 1980s, some health officials, eager to address a growing epidemic of lung cancer, did express optimism about health benefits from "light" and "low tar" products.[23]

2. "Reduced Risk" Products

Today, the marketing of many "reduced risk" tobacco products is again premised on health reassurance through scientific progress. Brown & Williamson officials, for example, have declared Advance Lights to represent a "revolutionary breakthrough in cigarette technology."[24] The company's advertisements for the product proclaim: "All of the taste . . . Less of the toxins."[25]

Other companies are making similar claims. R.J. Reynolds has claimed "there's no cigarette like Eclipse" as "the toxicity of [Eclipse's] smoke is dramatically reduced compared to other cigarettes."[26] Vector Tobacco has marketed Omni as: "Reduced carcinogens. Premium taste."[27]

U.S. Smokeless Tobacco Company (UST), the nation's leading manufacturer of smokeless tobacco, has stated that based on extensive research, its product "involves significantly less risk of adverse health effects than cigarette smoking."[28] It even applied

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[22]Brown & Williamson, *What Are the Obstacles/Enemies of a Swing to Low "Tar" and What Action Should We Take?* Minnesota Trial Exhibit 26, 185 (1982), as cited in National Cancer Institute, *supra* note 4, at 218–19.

[23]*See, e.g.*, description of Dr. Gio Gori, National Cancer Institute, in Richard Kluger, *supra* note 1, at 428–34.

[24]Brown & Williamson, *Brown & Williamson Tobacco Tests New Advance Lights Cigarette, New Technologies Reduce the Levels of Many Toxins while Delivering Smooth Taste* (Nov. 5, 2001) (online at www.brownandwilliamson.com).

[25]*Softly Lit or Blunt, "Less Toxic" Cigarette Ads Hint at Health*, Advertising Age (Nov. 12, 2001).

[26] Eclipse Cigarettes, *The Eclipse Concept — The Eclipse Difference* (online at www.eclipse.rjrt.com/ECL/eclipse_difference.jsp).

[27]*Softly Lit or Blunt, "Less Toxic" Cigarette Ads Hint at Health, supra* note 25.

[28]Letter from Daniel C. Schwartz to the Honorable Donald S. Clark, Secretary, Federal Trade Commission (Feb. 5, 2002).

to the Federal Trade Commission for permission to make that statement in its advertising.[29]

Moreover, the companies again appear to be seeking the endorsement of the public health community for "reduced risk" products. For example, according to internal company documents, Brown & Williamson's parent company British-American Tobacco (BAT) has developed a public relations campaign aimed at developing support among public health leaders. This strategy involves "engagement and partnerships with key scientific and public health authorities [to] demonstrate that we are working effectively to develop lower risk products." BAT apparently allocated 545,000 British pounds to work on this effort.[30]

B. Deceiving Consumers

1. "Light" and "Low Tar" Cigarettes

By the late 1960s, major tobacco companies believed that the machine-based method of testing cigarettes for nicotine and tar did not measure actual intake by smokers.[31] Nonetheless, tobacco companies specifically designed cigarettes that scored low on machine-based testing without delivering substantially reduced amounts of tar and nicotine to smokers. Product features that permitted this deception included ventilation holes that diluted air on the machines but were blocked by smokers' fingers in actual use.[32]

Companies were also aware that smokers would "compensate" while smoking "light" and "low tar" brands by breathing more deeply, taking more puffs, or blocking the ventilation holes in cigarette filters.[33] In 1974, Brown & Williamson researchers had evidence indicating that "whatever the characteristics of cigarettes as determined by smoking machines, the smoker adjusts his pattern to deliver his own nicotine

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[29]*Id.*

[30]British-American Tobacco, *Cora Plan* (2001).

[31]On May 24, 1968, research directors of major tobacco companies concluded, "We expect to be able to show that FTC Tar and Nicotine are of limited or questionable value as a measure of potential exposure to the smoker." *Minutes of the Meeting of Research Directors at the Liggett & Myers Operations Center in Durham, North Carolina on Friday, May 24, 1968*, Bates Numbers 0001609623-9624 (available online a: http://www.pmdocs.com).

[32]L. Kozlowski and R. O'Connor, *Cigarette Filter Ventilation Is a Defective Design Because of Misleading Taste, Bigger Puffs, and Blocked Vents*, Tobacco Control, I40–50, (Mar. 2002).

[33]National Cancer Institute, *supra* note 4, at 13–38.

requirements."[34] In 1975, Philip Morris even tested Malboro smokers and found that they "did not achieve any reduction in smoke intake by smoking a cigarette (Malboro Lights) normally considered lower in delivery."[35]

Despite this knowledge, all of the major tobacco companies persisted in marketing "light" and "low tar" cigarettes on the basis of machine-based testing. In one telling incident, Philip Morris employees in Holland published an advertisement pointing out that the tar measurements of a BAT brand dramatically misrepresented how much tar smokers actually received. The Chairman of BAT immediately sent a telex to the head of Philip Morris, stating: "I find it incomprehensible that Philip Morris would weigh so heavily the short-term commercial advantage from deprecating a competitor's brand while weighing so lightly the long-term adverse impact from an ongoing anti-smoking programme."[36] The next month, a top Philip Morris executive spoke with his counterpart at BAT, with notes of the conversation stating: "Essential Industry hang together. Holland activity was not PM company policy. They must try to prevent this happening in the future."[37]

The fact that "light" and "low-tar" cigarettes do not offer health benefits is now well understood. A comprehensive review by the National Cancer Institute found that while "[c]igarettes have changed dramatically over the last 50 years . . . the disease risks associated with smoking have not."[38] In March 2003, an Illinois judge found that Philip Morris's actions with respect to "light" and "low tar" brands were "immoral, unethical, oppressive and unscrupulous."[39]

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[34]*Notes on the Group Research & Development Conference at Duck Key, Florida (Jan. 28, 1974)*, Bates Numbers 680048892-8897 at 680048893 (available online at http://legacy.library.ucsf.edu).

[35]Memorandum from B. Goodman to L.F. Meyer, *Marlboro-Marlboro Lights Study Delivery Data* (Sept. 17, 1975), as cited in National Cancer Institute, *supra* note 4, at 71.

[36]E. Bruell, *Letter to All No 1s of Operating Companies* (Sept. 20, 1983), as cited in Jeffrey E. Harris, *Supplemental Expert Report, Iron Workers Local Union No. 17 Insurance Fund and Its Trustees, et al. v. Philip Morris Incorporated, et al.* (Nov. 6, 1998) (available at: http://www.pmdocs.com).

[37]*Telephone Conversation between H. Culman [sic] and E.A.A.B,* (Oct. 28, 1983), as cited in Jeffrey E. Harris, *Supplemental Expert Report, Iron Workers Local Union No. 17 Insurance Fund and Its Trustees, et al. v. Philip Morris Incorporated, et al.* (Nov. 6, 1998) (available online at http://www.pmdocs.com).

[38] National Cancer Institute, *supra* note 4, at 1.

[39]Judgment, *Price v. Philip Morris,* Cause No. 00-L-112 (Cir. Ct., Madison County, Ill. Mar. 21, 2003) (applying Illinois statute with element requiring that practice be immoral, unethical, oppressive, or unscrupulous).

2. "Reduced Risk" Products

Although the "reduced risk" products are in their infancy, there are warning signs that consumers are being deceived about their benefits. In November 2001, Brown & Williamson launched "Advance Lights," a new cigarette with a "Trionic" filter and tobacco cured by a process developed by Star Scientific. In the press release heralding the product's introduction, Brown & Williamson stated that the brand "has significantly less of many toxins than the leading Lights brand styles."[40] According to Star Scientific, the key advantage of "StarCured" tobacco is fewer nitrosamines:

> Scientific research has established that TSNAs are among the most powerful carcinogens in tobacco leaf and smoke. The curing process that Star has scaled up over the last several years results in significantly reduced TSNA levels.[41]

Despite Brown & Williamson's and Star's assertions that Advance Lights offer a significant advantage over conventional products, internal employee documents reveal that a senior scientist at the Brown & Williamson parent company BAT has raised serious doubts. In April 2000, the BBC radio show "Costing the Earth" looked at the issue of Star's reduced-risk tobacco.[42] After the show, BAT Senior Research Scientist Derek Irwin e-mailed managers in Research and Development:

> I disagree with just about every point made by every speaker, including our own.
>
> Our main problem appears to be the notion that "the technology exists to make cigarettes which are appreciably less lethal and that many tobacco companies appear to be looking for any excuse not to use it."
>
> The technology does not exist . . . It will not exist. . . Internal overstatement is one thing, externally it is even less in the Company's interests.
>
> We should tone down future expectations. Firstly, it is not ethical and secondly we shall be asked to explain our failures at some point in the future.[43]

None of these concerns are made available to consumers by the companies.

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[40]Brown & Williamson, *supra* note 24.

[41]Star Scientific, *What is StarCured?™* (Sept. 2002).

[42]*Tobacco Death Toll "Needlessly High,"* BBC News (Apr. 27, 2000) (online at http://news.bbc.co.uk/1/hi/sci/tech/727103.stm.)

[43]E-mail from Derek Irwin to Graham Read (May 2, 2000) (emphasis added).

Similar questions of consumer deception have been raised by the marketing of the "reduced risk" product Eclipse by R.J. Reynolds. Although R.J. Reynolds claims that Eclipse, which acts by heating tobacco, has lower toxicity compared to combusted cigarettes, these claims have been specifically refuted by a study commissioned by the Massachusetts Department of Public Health and performed by Labstat, a cigarette testing company. R.J. Reynolds's website had claimed a reduction of 80% in carcinogens in the smoke, but the Massachusetts study found that in all measurable categories of carcinogens tested, Eclipse frequently had similar or even higher levels than two other brands of cigarettes.[44]

In communications with the public, R.J. Reynolds claims to have based its assertions about the reduced risk of Eclipse on a "four-step scientific methodology" including "[c]hemical testing and analysis," "[b]iological and toxicological testing," "[h]uman testing," and "[i]ndependent scientific verification."[45] However, the Department of Justice has determined that this characterization greatly overstates the level of analysis that R.J. Reynolds undertook:

> R.J. Reynolds has represented to the public that the four step methodology was a well thought out, peer-reviewed-in-advance protocol established to overcome an "obstacle" and to fill a void created by government, scientific, medical and public health communities' failure to establish a standard for assessing potential risk reduction. On the contrary, the evidence reveals that all R.J. Reynolds did was look at all of the work it already had done to evaluate Eclipse to date, categorize it, and retroactively dub it a "four step methodology."[46]

The Department has also determined that no trained epidemiologist worked on any part of the "four step" analysis, despite R.J. Reynolds's conclusion that "[e]pidemiology is the only way ...of estimating relative risk."[47]

The fourth prong of R.J. Reynolds's four-step methodology is "independent scientific evaluation and verification." But in this area, too, the Department of Justice has raised serious questions. As late as October 2000, the expert scientific panel for Eclipse was chaired by Dr. Bernard Wagner of New York University. According to the Department of Justice, Dr. Wagner has been affiliated with R.J. Reynolds since the

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[44]Letter from Howard Koh, Commissioner, Massachusetts Department of Public Health, to the Honorable Robert Pitofsky, Chairman, Federal Trade Commission (Oct. 3, 2000).

[45]R.J. Reynolds Tobacco Company, *Eclipse and Premier* (online at http://www.rjrt.com/TI/TIpremier_eclipse.asp.)

[46]U.S. Department of Justice, *United States' Preliminary Proposed Findings of Fact, U.S. v. Philip Morris*, No. 99-CV-2496, 947 (D.D.C. filed Jan. 29, 2003).

[47]*Id.* at 951 (ellipsis in Department of Justice filing).

1980s. He served on R.J. Reynolds's Scientific Advisory Board beginning in 1985, developed R.J. Reynolds's scientific research on Premier (Eclipse's predecessor), and acted as a paid consultant to R.J. Reynolds from 1991 to 1997.[48] From 1992 to 1994 alone Wagner received over $1.5 million in fees and reimbursements from R.J. Reynolds; a minimum of $810,000 in fees was for consulting on the development of Eclipse.[49] When he left the consultant position in 1997, Wagner commented that "Eclipse represents the future and needs to be defended in the market place."[50]

C. Marketing To Deter (or Reverse) Quitting

1. "Light" and "Low Tar" Cigarettes

To sell "light" and "low tar" cigarettes, tobacco companies targeted health conscious smokers who might otherwise have quit. As the National Cancer Institute found, "these brands were targeted at those smokers who were thinking of quitting in an effort to intercept the smokers and keep them smoking cigarettes."[51] "To smoke or not to smoke," declared a Vantage ad for R.J. Reynolds in 1974:

> That is the question.
>
> With all the slings and arrows that have been aimed at smoking, you may well be wondering why you smoke at all.
>
> * * *
>
> The cigarettes of the past provided a lot of smoking pleasure but they also delivered a lot of the 'tar' and nicotine the critics have aimed at.
>
> * * *
>
> But now Vantage has entered the scene.
>
> Vantage is the cigarette that succeeds in cutting down 'tar' and nicotine without compromising flavor.
>
> * * *
>
> If you smoke, try a pack of Vantage. And if you don't, why not show this ad to someone who does.
>
> It might settle the question.[52]

Similarly, Lorillard's brand True was advertised with the slogan, "Considering all I'd heard, I decided to either quit or smoke True. I smoke True."[53]

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[48] *Id.* at 949.

[49] *Id.* at 950.

[50] *Id.* at 949.

[51] National Cancer Institute, *supra* note 4, at 5.

[52] *Id.*, 1974 advertisement reproduced at 229.

[53] *Id.*, 1976 advertisement reproduced at 222.

Many internal industry documents show the explicit understanding of tobacco companies that "light" and "low tar" products deterred quitting. BAT noted that "[i]t is useful to consider lights more as a third alternative to quitting and cutting down — a branded hybrid of smokers' unsuccessful attempts to modify their habit on their own."[54] A study prepared for Philip Morris found, "In point of fact, smoking an ultra low tar cigarette seems to relieve some of the guilt of smoking and provide an excuse not to quit."[55]

2. "Reduced Risk" Products

There are indications that tobacco companies are again marketing new "reduced risk" products to deter quitting. Philip Morris has ostensibly sold Accord since 1998 for committed smokers.[56] But in fact, the company may also be targeting both smokers who want to quit and former smokers. According to the Department of Justice:

> [T]o the extent that Philip Morris has sought to market Accord, despite the company's statements that it will not get in the way of anyone who wants to quit smoking, there is evidence showing that it had its advertising agency assist in marketing Accord to those who want to quit or who have quit and are rejoining the cigarette market.[57]

Philip Morris may also be hinting to investors that it intends to use "reduced risk" products to increase its market share. In April 2002, financial firm Salomon Smith Barney initiated coverage of Philip Morris, a process that typically involves extensive interaction with the covered company.[58] An "Industry Note" from Salomon Smith Barney notes a 1% to 2% reduction in the "secular demand trend" for cigarettes over the preceding decade, but then suggests several reasons why this trend might not persist:

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[54]British American Tobacco, *Research & Development/Marketing Conference* (c. 1985), as cited in National Cancer Institute, *supra* note 4, at 221.

[55]Goldstein/Krall Marketing Resources, Inc., *A Qualitative Exploration of Smoker Potential for a New Entry in the Ultra Low Tar Market Category* (Jan. 1979), Bates Numbers 2040066742-6766 at 2040066754.

[56]*See* Philip Morris, *Philip Morris U.S.A. Begins Limited Retail Sales Test in Richmond on New Cigarette Smoking System* (Aug. 17, 1998) (online at http://www.philipmorrisusa.com/pressroom/content/press_release/articles/pr_August_17_1998_PMUBLRST.asp.)

[57]U.S. Department of Justice, *supra* note 46, at 1112 (emphasis added).

[58]Salomon Smith Barney Industry Note, *Tobacco: Initiating Coverage of the Tobacco Industry* (Apr. 29, 2002).

> Because most of the so-called news is already priced in, we do not expect a major shift in the secular demand trend for cigarette consumption. If anything, we might see the secular demand trend increase, as technology will play an increasingly important role for this industry in the future. Often it is fun to speculate about what this industry will look like in five years. If Philip Morris or the other manufacturers [are] successful in developing, marketing, and selling a reduced-risk cigarette, we may start to see consumption closer to flat and maybe even increase slightly. Keep in mind that for the approximate 50 million adult smokers in the United States, we believe smoking is something that, for the most part, they truly enjoy. Therefore, if there is an opportunity to develop a reduced-risk cigarette that, of course, burns, and tastes very similar to conventional cigarettes, this could possibly prevent people from quitting and may encourage some people to start smoking . . . . As the leader in so many things, Philip Morris has been working on a reduced-risk product and may be ready to introduce something this year or next year.[59]

Other companies explicitly market their products as an alternative to quitting. For example, R. J. Reynolds's advertising for Eclipse declares: "the best choice for smokers who worry about their health is to quit. The next best choice is Eclipse."[60]

Although UST says publicly that it wants to promote smokeless tobacco as a safer alternative to cigarettes, internal documents suggest that it is actually pursuing a "dual use" strategy. In 2000, UST President Murray S. Kessler presented the company's "Strategic Plan." The first slide states: "Solid Fundamentals . . . Smoking Restrictions Fuel Category Growth." The second slide elaborates: "Solid Fundamentals . . . Promoting Dual Consumption." The slide indicates that "dual usage" rose from 27% in 1998 to 33% in 1999.[61]

UST's support for "dual usage" became explicit in August 2001 with the launch of Revel, a small pouch containing smokeless tobacco. UST markets Revel as "a fresh new way to enjoy tobacco when you can't smoke." One advertisement states, "If you are a smoker, here are two words that will transform the way you enjoy tobacco: Anytime. Anywhere." In describing the campaign, UST President Kessler has said, "Whether restricted on an airplane, in a meeting, on the factory floor, or in a shopping mall, we believe that Revel is the answer adult smokers have been seeking."[62]

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[59] *Id.* at 2 (emphasis added).

[60] R.J. Reynolds Tobacco Company, *Making the Switch* (online at http://www.R.J. Reynoldst.com/TI/TIpremier_eclipse.asp).

[61] Murray S. Kessler, *United States Tobacco Co. Strategic Plan* (2000) (emphasis added).

[62] *Smoke Screens: Alternatives to Traditional Cigarettes May Have Retailers Reassessing Their Display Priorities*, Tobacco Retailer (Dec. 2001) (online at http://www.retailmerchandising.net/tobacco/2001/0112/0112smk.asp).

The public health implications of encouraging dual use are profound. Dual use can offer smokers a way to sustain addiction to nicotine, diminishing the incentive to quit. A recent study of smokeless tobacco use among teenage boys in Sweden found that 71% of smokeless tobacco users also smoke cigarettes, and dual users smoke more than those who smoke cigarettes alone.[63]

Star Tobacco's smokeless product Ariva is also marketed for "when you can't smoke."[64]

D. Exploiting the Absence of Effective Regulation

Health officials did not recognize the dangers posed by "light" and "low tar" cigarettes before it was too late. Without full access to information, some government officials even believed that substantial disease reductions were likely among "light" and "low tar" smokers.[65] For decades, cigarette manufacturers used numbers from the FTC's machine-based testing method in advertisements, with Brown & Williamson promoting Carlton's numbers on the basis of the "Latest U.S. Gov't Laboratory test."[66]

The absence of effective regulation means that even now, after scientific consensus has been reached that "light" and "low tar" cigarettes are a fraud, these brands still dominate the market for cigarettes. While several countries have moved to ban the use of these misleading descriptors,[67] not a single tobacco company has voluntarily dropped the "light" or "low tar" label to communicate honestly with consumers. To the contrary, Philip Morris and other companies have fought public health efforts to bar these descriptors on the grounds of trademark rights.[68]

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[63]M. Rosaria Galanti, Seppo Wickholm, and Hans Gilljam, *Between Harm and Dangers: Oral Snuff Use, Cigarette Smoking and Problem Behaviours in a Survey of Swedish Male Adolescents,* European Journal of Public Health, 340–45 (2001).

[64]"When You Can't Smoke" is featured prominently on Ariva packages.

[65]*See* Judgment, *Price v. Philip Morris*, *supra* note 39.

[66]National Cancer Institute, *supra* note 4, 1985 advertisement reproduced at 224.

[67]*See, e.g., Canada to Ban "Light" Labels on Cigarettes,* Boston Globe (Aug. 14, 2001).

[68]For example, Philip Morris has recently argued that Canada's attempt to ban such descriptors as "light" and "mild" violates its trademark rights under the North American Free Trade Agreement and World Trade Organization Technical Barriers to Trade Agreement. Robert Weissman, *Philip Morris' Trade Card*, Multinational Monitor (Apr. 1, 2002).

Today, the lack of effective regulation has resulted in the proliferation of bold and sometimes contradictory claims for "reduced risk" products. Some companies, such as Brown & Williamson, insist that modified tobacco can be made into cigarettes that offer significant reductions in exposure and likely risk. Other companies, including UST, say that all combusted products pose an unacceptable risk, but oral products (like smokeless tobacco) do not. No agency has the authority to assess the claims made by the companies before they are made, routinely review company research and documents, or set standards for what might justifiably pose a reduced risk to consumers. Absent effective regulation, it may be impossible to determine whether the new products have helped or harmed public health for decades.

IV. CONCLUSION

The disastrous history of "light" and "low tar" cigarettes may be repeating itself in a new generation of "reduced risk" products. As in the past, tobacco companies are making claims about the health benefits of their products; there is evidence of deceptive practices by the companies; and there is reason to believe that companies are marketing their products to quitters and former smokers.

Absent effective regulation, it will be difficult if not impossible for consumers to sort through a blizzard of health claims. As a result, unregulated marketing of "reduced risk" tobacco products could undermine smoking cessation (which is proven to save lives), cause former smokers to resume their addiction, and even attract young people to tobacco products.

June 3, 2003

The Honorable W.J. (Billy) Tauzin
Chairman
Committee on Energy and Commerce
U.S. House of Representatives
2125 Rayburn House Office Building
Washington, DC 20515

Dear Mr. Chairman:

You may have recently received a copy of a May 23, 2003, letter from U.S. Smokeless Tobacco Company (UST) in connection with today's hearings on "reduced risk" tobacco products. As you consider this letter, you should know that it is deceptive on important issues.

The UST letter was written in response to a "Dear Colleague" letter that I wrote on April 28, 2003. My Dear Colleague made two major points: (1) that public health authorities have concluded that "reduced risk" claims for tobacco products should be made only in the context of strict regulatory oversight and (2) that the need for regulatory oversight of such claims is underscored by UST's history of untrustworthy marketing. The Dear Colleague attached two fact sheets from the Campaign for Tobacco Free Kids. The fact sheets detailed UST's use of a "graduation strategy" to hook young users on low-nicotine products and then "graduate" them to higher-nicotine products. They also described the company's strategy of appealing to children through the use of cherry flavoring in its "starter" products.

In its May 23 response, UST dismisses the allegation that the company "has engaged in strategies to hook kids" as "inaccurate or misleading." UST claims that it does not and has never used a "graduation strategy," certainly not one related to marketing to youth. UST also rejects as "baseless" the suggestion that its cherry-flavored products were designed to appeal to children.

Since receiving UST's May 23 letter, I have obtained copies of internal company documents that validate the points made in my Dear Colleague and conflict with the assertions in UST's letter. These documents show that the company planned a "graduation strategy" starting with "young" consumers, that the company has long known that flavoring in smokeless tobacco products appeals to young smokeless tobacco users, and that UST deliberately adds flavoring to "starter products." The documents also indicate that UST marketed its products to children as

young as 13 or 14. Copies of these previously undisclosed documents are enclosed with this letter.

These documents and UST's response are relevant to the Committee's consideration of UST's request for permission to market smokeless tobacco as safer than cigarettes. While UST may say that it would never abuse authority to make "reduced risk" claims, the company's past practices — and its recent correspondence denying these practices — call the company's veracity seriously into question.

UST's Graduation Strategy

UST states that it never employed a "graduation strategy" in marketing its tobacco products and that any documents from officials at the company discussing the strategy merely reflected a "hypothesis," "did not relate to marketing to youth," and "did not drive the Company's marketing strategies."

This claim is difficult to believe in light of the documents that I have obtained. The documents show definitively that a graduation strategy aimed at youth was in fact the company's goal and that implementing this strategy was the objective of the highest-ranking officials in the company. In particular, a 1980 memo from the Senior Vice President for Marketing and Sales to the Chairman of the Board and President of UST sets forth two of the company's marketing "objectives" as follows:

- *Introduce an easy-to-use, "starter" product*
- *Provide new users with an easy graduation process.*[1]

That this graduation process is aimed at young customers is expressly stated later in the document. A chart labeled "Marketing Action/Staging," which includes specific dates for implementation of each action as early as two months from the date of the memo, reads as follows:

BRAND/SEGMENT	*OBJECTIVE*
Ball'n Chew	*Introduce easy to use, "starter" product*
Wintergreen	*to increase consumer base,*
Plastic Can	*especially among the young.*

[1] Memo from Barry J. Nova, Sr., Vice President Marketing and Sales, to Louis P. Bantle, Chairman of the Board and President, UST, Re: 'Moist' Development, 1 (Jan. 4, 1980).

* * * *

Skoal Straight Plastic Can	*Introduce line extension to support "natural vertical" graduation process.*[2]

This document also contains a chart, entitled "Product Development and Positioning," that depicts "young, newer" "light" users at the bottom of a continuum that ends in "older, confirmed" "heavy" users. Marching up this continuum are the company's smokeless products, with the lightest products at the bottom and the strongest products at the top.

Use of Flavored Products to Appeal to Youth

UST claims that cherry flavoring is common in adult products like Maalox and Tums and therefore that there is no basis to believe that the company used sweet flavors to appeal to children. But the company had clear understanding that flavors appeal to young users and not to adults. In the document quoted above, the Senior Vice President for Marketing and Sales states the following "assumptions":

ASSUMPTIONS:

- *Younger and lighter users prefer a flavor, not a natural*
- *Older and heavier users prefer real tobacco taste and strength*

* * * *

- *Happy Days [a lighter product] can be a better brand and better "graduator" with a change in flavor.*[3]

UST's Marketing to Children

Another document indicates that the UST's sales force marketed to children as young as 13 or 14. A memo from a regional sales manager to UST's National Sales Manager describes the effect of a competing product on sales of UST products. The memo states that retailers report that Hawken, a product from a UST competitor:

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[2] *Id.* at 6.

[3] *Id.* at 5.

> *is being used by young kids and young adults. The age of the kids is from 9 years old and up. I believe this to be true because outlets located close to schools (all grades) are definitely the heavier Hawken outlets we visited. . . . Also, the people who knew about mouth tobaccos felt the sweet taste was a definite factor with the kids.*[4]

This memo goes on to say that Hawken "has reached kids four or five years earlier than we have contacted them in the past."[5] Because the memo is describing a product being used by 9-year-olds, the clear indication is that UST was marketing to kids of 13 or 14 years.

Conclusion

As we consider UST's desire to market its products as safer than cigarettes, we must keep in mind both the company's marketing history and its continuing deceptions. Essentially, UST is asking Congress to trust that the company will make responsible claims about its products. But it is hard to see how such trust is warranted given the company's track record. Certainly, the company should not be permitted to make "reduced risk" claims about its products without strict regulatory oversight.

Sincerely,

Henry A. Waxman
Ranking Minority Member

Enclosures (2)

cc: Members of the Committee on Energy and Commerce

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[4] Memo from A.H. Cameron, Regional Sales Manager, UST, to R.R. Marconi, National Sales Manager, 2 (Jan. 21, 1980).

[5] *Id.*

cc: RLR, TBO, ML, AEM, BK, BG, PS, TS

U·S·TOBACCO

INTRA-COMPANY CORRESPONDENCE

FROM: Barry J. Nova, Sr. Vice President Marketing and Sales
TO: Louis F. Bantle, Chairman of the Board and President

January 4, 1980

Subject: "Moist" Development

U. S. Tobacco has "made" the market in moist smokeless tobacco; a segment that remains in the early stages of growth on a product life cycle graph. We must continue to "lead" the category in order to:

- Enlarge our consumer base
- Preempt probable competition
- Maintain corporate growth and profit

A recent document from Peter directed itself to "product leadership"; to the methods of ascertaining the right products in the right positions to meet potential user needs. While some of the choices and recommendations might be questioned, it is not the intent of the writer to mark down a good beginning. Rather, in conjunction with those carboned above it is the purpose of this memorandum to further define marketing action needed to meet the following objectives:

- Introduce an easy-to-use, "starter" product
- Provide new users with an easy graduation process
- Develop better packaging
- Maintain a simplicity in the product line

Easy Graduation Process

There are two "leaders" extant in today's marketplace: Skoal, with a wintergreen flavor; and Copenhagen, with a more natural tobacco taste. While Skoal is the biggest seller, reasonable percentage growth is still apparent in the Copenhagen brand; and both continue to outpace Happy Days (mint) - where about 20% of current poundage is samples - on a poundage growth basis.

In addition, two other "natural"-brands continue to show strength with very limited promotional support - W B Cut and Key.

Simply, then, we should concentrate on the two proven areas of acceptability - Wintergreen and Natural; and build vertically in these two flavors, permitting the consumer to "move-up" or strengthen his pleasure in a taste that he is used to and comfortable with. Even our new loose leaf chew would fit comfortably in the pattern.

And while we do feel that mint/spearmint is an acceptable American flavoring in food and gums, it has not yet been completely proven as a tobacco additive; and a triple flavor track rather than a vertical duality would be too complex now.

Simplified Product Line

We cannot, and should not, attempt to be "all things to all people" now. After all, it must be remembered that we are just beginning to tap the market's potential, and that the brands we sell, in most cases, seem to meet a need or a want. To proliferate many new products/line extensions might very well cause:

- Confusion among potential new users as to where to begin and with what.
- Confusion among current users regarding what to move to; possibly creating no new business, just a transfer of business intra-line.
- Problems in media promotion: difficulty in creating strong, separate positioning statements; lack of frequency to explain all various elements.
- Trade dismay and lack of support. Moist has been "welcomed" by the trade, but for the next four to five years we will not be at the point where we can demand two to three times the warehouse or retail shelf space that we now enjoy. To try to put out a myriad of products is to run the severe risk of alienating a carefully built trade rapport based on good sales from consumer demand, as well as inviting an ever-increasing damaged goods problem.

"Easy-To-Use"/Starter Product Development and Intro

This must be our priority niche at present, for the obvious reasons:

- Expansion demands a continually enlarging new user base.
- "Floating" and saliva build-up are still negatives to the "beginner".
- Most readily available entry segment for competition on both a product development basis and ratio of pay-back to investment. (And who is to say that a so-called "starter" product cannot carve-out, in part, its own on-going user base.)

Happy Days, because of some difficulty in use and apparent ill-defined flavor, may not be the best effort we can make for "starters". It can be improved, and then perhaps, could be positioned as part of the "regular" line.

Good Luck, a technological advance in packaging rather than a break through in taste, is selling reasonably well in most test areas; but requires better flavor and a final, true evaluation before capital is expended on additional machinery.

Our new, shag cut, "balling" smokeless brand (whether it is truly "balled" or just flattened between the fingers) is the one that "gut" feelings tell us can be the most successful entry. It is easy to use. Saliva build-up is minimal. It takes flavoring well. Raw materials are available. Production methods have been proven. A machine to pack both it and W B Cut could be ready by the fourth quarter of '80. However, only thorough testing of the concept will prove its validity.

Better Packaging

The general view is that the plastic can would be a positive packaging step:

- Lower manufacturing costs
- Decreases freight costs
- Easier to open
- Stands-up better in the wearing
- Adaptable to holding lesser amounts of tobacco
- May keep product fresher, longer

A small amount of research done in our overseas market, coupled with some results from Hawken testing in Jonesboro indicate good consumer acceptance for the plastic container. And it is understood that both Happy Days and Skoal can be packed this way now, without any loss in product quality.

However, we can visualize the possibility of some problems that might occur:

- Consumer perception that change in package means a change in formula and flavor. Panel testing can prove or disprove this.

- Keeping the product fresher, longer could negate the "built-in obsolesence" in the present container, thereby lessening poundage. Still, good users might just use more because it is fresher. The answer might be gotten through focus groups.

Finally, one important facet of plastic packaging - its adaptability - needs further commentary regarding how important it could become in creating new users and meeting competitive pressure:

Supposition	Strategy
New users "pinch" less often and will use less tobacco per "dip".	Build up bottom of plastic can - without changing height and circumference - in order to pack a "full" lower weight in a "starter" product; i.e. .6 ounces.
Pricing can be a determinant to trial; and may well be used as a competitive advantage.	Lower price on "starter" brands to increase trial, lower sampling costs, and preempt competitive, "low ball" pricing. For example:

	UST	Jobber	Retail
present can price	42¢	52¢	65¢
(Packing half as much tobacco may save 20% or more while maintaining margins)			
"reduced" can price	33¢	41¢	50¢

Possible result: More new users, happy with a "fair" entry price, unconcerned with lesser amounts of product, who can be graduated to one of our "regular" products at a "regular" price (and may want to "move" there faster since 1.2 ounces at 65¢ is a better "deal") .... and competitors who probably will have to cut their own margins to find a price point entry meaningfully below ours.

The foregoing discussions point the way to the recommendations included on the Product Development and Positioning Chart that follows; after which a Marketing Action Staging form indicates the R & D, research and market testing required to prove their viability.

Page 5

PRODUCT DEVELOPMENT AND POSITIONING

VERTICAL DUALITY

ASSUMPITONS:

- Younger and lighter users prefer a flavor, not a "natural"
- Older and heavier users prefer real tobacco taste and strength
- Skoal is our largest selling and fastest growing product (and best known); all "starter" products should acquaint people with its taste.
- Copenhagen is our second largest selling product and its growth could improve with a lead-in from a "natural" line extension, whose name and blend have proven themselves.
- Happy Days can be a better brand and a better "graduator" with a change in flavor.
- The "top of the line" - W B - may yet be our fastest growing product and deserves a place in both "verticals".

user	usage	WINTERGREEN FLAVOR	NATURAL FLAVOR
older confirmed	heavy	W B Cut (2) (P)	W B Cut (1) (P)
			Copenhagen (1) (CT)
		Skoal (1) (CT)	Skoal Straight (3) (PC)
		Happy Days (2) (PC) wintermint	
		Ball'n Chew (4) (PC)	
young never	light	Good Luck (2) (PC) wintermint	
		Stetson (4) (P) (loose leaf)	Stetson (4) (P) (loose leaf)

(1) Manufactured at present; requires no change
(2) Manufactured at present; requires indicated flavor additive
(3) Manufactured at present; requires new labeling
(4) Manufacturing to finalize development
Packaging: (P)-Pouch; (PC)-Plastic Can; (CT)-Cardboard and Tin

3730217

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MARKETING ACTION

STAGING

BRAND/SEGMENT	OBJECTIVE	MANUFACTURE/DEVELOP PERIOD	RESEARCH/PERIOD	TEST MARKET/PERIOD	ROLL-OUT/PERIOD
Ball'n Chew Wintergreen/ Plastic Can	Introduce easy-to-use, "starter" product, to increase consumer base especially among the young.	Blend and flavor-2/80 Hand pack for research -3/80 Hand pack for test markets - 8-12/80 Develop machine packing by 1/81 Name and label development-3/80	Taste test with new Happy Days user panel, vs. Good Luck and Hawken. In addition, test in potential user focus groups vs. Good Luck, Hawken and Happy Days 4/80 thru 8/80	4 Markets: 2 control w/media 2 reduced price and weight w/media 9/80 thru 12/80	By region, with promotional support, during 1981.
Good Luck Wintermint/ Plastic Can	Change to a new taste. Evaluate "bag" concept in terms of future sales potential and machine needs.	Blend and flavor-3/80 Full production-6/80 Prototype machinery -9/80	Taste test with user panel -new vs. present product also gather user profile and concept acceptance data -3/80-6/80. Audit selected outlets in current areas to determine future national volume.	Current areas utilizing present production capacity fully.	By region as machinery becomes available.
Skoal Straight Plastic Can	Introduce line extension to support "natural vertical" graduation process	Utilize existing Key blend, and change label-3/80	Audit in test markets at retail and wholesale to ascertain new sales growth vs. "pull down" from existing brands. 4/80 thru 9/80	4 Markets: 2 Copenhagen areas, one with local adv. 2 Skoal Areas one with local adv. 4/80 thru 9/80	National, supported by "...Skoal, and new Skoal Straight." network TV spot.
Happy Days Wintermint/ Plastic CAn	Change to a new taste and evaluate with current users.	Blend and flavor-3/80 Full production-7/80	Taste test-existing vs. new-with large Happy Days user panel. 5/80-7/80	None	National distribution - 8/80
W B Cut Wintergreen/ Pouch	Introduce line extension to create a "top-of-the line" duality	Blend and flavor-5/80 Packing machinery developed and full production by 1/81.	Taste test in panel of W B Cut users. 6/80-10/80	None	Region by region distribution only after further acceptance of natural brand is accomplished. 1/81 thru 12/81

MARKETING ACTION

STAGING

BRAND/SEGMENT	OBJECTIVE	MANUFACTURE/DEVELOP PERIOD	RESEARCH/PERIOD	TEST MARKET/PERIOD	ROLL-OUT/PERIOD
Plastic Packaging	Evaluate consumer acceptance of plastic can concept	Label development-4/80 Possible new can colorations-4/80	Full, large panel test for Happy Days with Happy Days users-5/80-9/80. Full, large panel test for Skoal with Skoal users-5/80-9/80. Results should be at least 95% positive.	None	National distribution beginning -1/81
Stetson Natural/ Wintergreen -Pouch	Introduce a loose leaf chewing entry point toward capture of 10% of market in three years	Per T. Cornell: Blend and flavor-2/80 Samples production-3/80- Production for test markets-7/80-1/81 Full production 2/81	Full, loose leaf user panel tests-Stetson vs. Levi Garrett, Red Man, Beechnut 4/80-7/80; Name and package design perception testing in 2 focus groups, 4/80-7/80 Audit at wholesale and retail to determine movement and and growth vs. competition.	8 test markets conducted in strong loose leaf areas: 2 Stetson natural lower media 2 Stetson natural -higher media 2Stetson wintergreen -lower media 2 Stetson wintergreen -higher media 8/20-2/81	National distribution 3/81-6/81; supported by national media effort

A more complete and fine-lined consumer research and workset test program will be prepared as approvals are given for "staging".

*NOTE: Panel taste test will measure various intensities of flavor

3730219

BJN LJG AEM PJG PFL RJZ HJ PJS

U·S·TOBACCO

INTRA-COMPANY CORRESPONDENCE

FROM: A. E. Cameron, Regional Sales Manager
TO: Mr. R. R. Marconi, National Sales Manager

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January 21, 1980

RE: HAWKEN REVIEW

Tuesday and Wednesday was spent in the tri-city area (Briston, Tennessee; Bristol, Virginia; and Johnson City, Tennessee) in an attempt to further evaluate Conwood's new item "Hawken". I spent this time working with Mr. C. E. Jordan, division manager. Factual information was hard to come by in some of the areas; however, I will attempt to cover what we found from consumers, retailers, and distributors.

Consumers

We were only able to actually discuss Hawken with two consumers who have used the brand for any length of time. One of these was a convenience store manager (male about 55 years old). This man was supplied with samples on a regular basis for at least four to five weeks. By this time he had developed a taste for Hawken and now believes the flavor and taste last longer than SKOAL, the brand he used before Hawken. The second consumer was a 12 year old male and his mother. He stated, and it was confirmed by his mother, that all other brands of mouth tobacco he had tried to use would make him sick. This included SKOAL, HAPPY DAYS MINT, and several brands of scrap. He felt the cause with SKOAL and HAPPY DAYS MINT was the brands were too hard to use, he could never keep them together. Scrap produced too much juice and he swallowed too much. He also felt Hawken's flavor lasted longer. A very interesting observation - his mother was delighted he had finally found a mouth tobacco he could use. During my questioning of this lady, it was clearly evident that she believes mouth tobacco is the least harmful of many habits her son could develop; therefore, she openly encourages him to chew. The price made no difference to these two consumers.

Retailers

While contacting most of the retailers we have had on the "Tracking Program", we could only find two who definitely believe Hawken is still increasing in sales. All others state the brand has peaked and most report a decline in sales. Every retailer stated that SKOAL definitely was hurt the worst; however, they all state that SKOAL is coming back and is either at, or close to its previous sales level. They all report consumers of all ages are buying

Hawken. Also, all type of consumers are using Hawken. These retailers all agree that the majority of Hawken is being used by young kids and young adults. The age of the kids is from 9 years old and up. I believe this to be true because outlets located close to schools (all grades) are definitely the heavier Hawken outlets we visited. Several retailers indicated that price was a factor with the young kids. Also, the people who knew about mouth tobaccos felt the sweet taste was a definite factor with the kids. No retailer expressed any problem with the lower price of Hawken. They all state their mark-up is the same percentage as on SKOAL and other tobaccos.

Distributors

Distributors all state that they did no more on Hawken than any other new item. They all report that the brand has peaked and they are seeing declines. No distributor indicated any promotional activity was planned for Hawken.

As you can see, all levels are pointing the same way on Hawken. I believe the brand has hurt SKOAL and HAPPY DAYS MINT as much as it is going to. Figures prove Hawken killed our increase on SKOAL (30 percent); and at this point, we are showing about 9 percent decrease in sales where Hawken is available. At one point, our loss was well over 20 percent. This has turned around and I believe SKOAL will be back to a break-even point within the next few weeks. I feel by the end of the next three-month tracking period, our increase will be back to normal. I am not at all sure our increase won't be greater than ever. It definitely is a fact that Hawken has brought a lot of new consumers into the mouth tobacco market. I think this brand has reached kids four or five years earlier than we have contacted them in the past. Indications are that some of these new users are moving up to a stronger brand. Also, indications are that some older consumers are moving from Hawken back to the brands they were using before, and some consumers have begun mixing Hawken with SKOAL and Levi Scrap. If these trends continue, Hawken may prove to be a very good starter product for SKOAL.

I am convinced we must continue our tracking of Hawken for at least another three months before our questions can be answered. However, all figures indicate Hawken, when introduced in a new market, will kill our increase on SKOAL and, in fact, cause a 10 to 20 percent loss for the first three months.

Our field personnel will continue to supply all information possible on Hawken.

Sincerely,

A. H. Cameron

ABC:dc

Mr. P. J. GHILONI
Rec'd
Date Ans'd

2038619

Dr Roger Bate
2600 Pennsylvania Avenue NW, 7A
Washington DC 20037
USA
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May 30, 2003

The Honorable Cliff Stearns
House Commerce, Trade and Consumer Protection Subcommittee
2125 Rayburn House Office Building
Washington, DC 20515

Dear Chairman Stearns:

Please accept this letter and the attached materials as official submissions for the June 3rd Committee hearing entitled, "Reduced Exposure/Reduced Risk Tobacco Products: An Examination of the Potential Public Health Impact and Regulatory Challenges."

Earlier this month I participated in a conference in London entitled "Panic Attack – Interrogating Our Obsession With Risk." The conference, sponsored by *spiked* and Tech Central Station Europe, questioned the use of the precautionary principle in public policy and pointed to ways in which our obsession with risk could be challenged.

More relevant to the business before this committee today was the panel on tobacco harm reduction, "Smoke Without Fire," that I had the honour to moderate. Specifically, the panelists and I looked at the current European Union (EU) ban on smokeless tobacco products and how the absence of this type of product in Europe has denied an effective harm reduction approach for public health officials to utilize within the EU countries. Panelists for this session included people who have dedicated much of their work to this particular issue. Those individuals included:

- Dr. Robert Nilsson recently retired from his position as senior toxicologist at the Swedish National Chemicals Inspectorate. He is a Professor of Toxicology at Stockholm University.

- Dr. Michael Kunze is head of the Institute for Social Medicine at the University of Vienna in Austria.

- Todd Seavey edits HealthFactsAndFears.com, the webzine of the American Council on Science and Health, New York.

While harm reduction is a controversial strategy with regard to tobacco use, these panelists effectively laid out the scientific and the moral reasons for putting in place an effective tobacco harm reduction strategy that utilizes smokeless tobacco. I believe that many of the points made during this panel discussion can be of help and value to this Committee. Attached you will find the transcribed remarks of the panelists.

I also would like to share with you an opinion editorial that I wrote for the Wall Street Journal Europe on April 3rd. This piece was written while I was conducting research on the issue in the month preceding the conference.

Thank you for the opportunity to share these materials with you. I urge the Members of this Committee to push the other arms of the federal government – including the Federal Trade Commission and the Department of Health and Human Services – to take a closer look at the specifics of this issue in formal proceedings before formulating and enacting public policy related to tobacco harm reduction.

Yours faithfully,

Dr Roger Bate

THE WALL STREET JOURNAL EUROPE.

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Chewing Over Tobacco

New York this week banned smoking in all work places after raising tobacco taxes by over 1000% earlier in the year. This draconian approach is spreading. The World Health Organization last month agreed on a new Framework Convention on Tobacco Control which the EU's Consumer Protection Commissioner David Byrne welcomed as major advance "in the battle to empower our citizens to live healthy lives, free from the scourge of tobacco."

The Convention might help reduce smoking around the world. It may also have a more dubious impact by restricting commercial free speech, through tobacco advertising bans, which is why Germany may not sign on. The U.S. may be wary as well of a Kyoto-type accord for cigarettes.

But a better option exists. Mr. Byrne would help the over-taxed and shunned smokers of Europe far more by removing the Europe-wide ban on smokeless tobacco.

This may seem an odd request, even odder when it is supported by anti-tobacco activists in Britain and Sweden, but it's actually very rational. Of all the types of tobacco, smokeless sucked or chewed tobacco, or wet snuff, causes the least cancer. The evidence is overwhelming, says Professor Robert Nilsson, a toxicologist at Stockholm University, and formerly with the EPA-like Swedish Chemicals Inspectorate, that "snus is the least dangerous form of tobacco."

Snus is the Swedish name for sucked snuff and Sweden is the only country in Europe where it can be said. When Sweden joined the Union it demanded the right to continue to sell the product domestically, but accepted it could not export it.

European politicians generally argued that because there is limited knowledge of how smokeless tobacco would be used or about its health effects the EU should invoke the 'precautionary principle' and keep it banned until more evidence emerges. And that has been the situation for over a decade—a ban based on precaution.

But in 1998, with the publication of Professor Nilsson's review of the evidence in the Journal of Regulatory Toxicology and Pharmacology (along with other experts' analysis), it became obvious that Sweden has the lowest male rates of relevant smoking diseases across Europe. Many health experts thought that oral cancers would be higher in those chewing and sucking tobacco, but according to Professor Nilsson "it has not been possible to detect any significant increase in the incidence of cancer of the oral cavity or pharynx—the prevalence of which by international standards remains low in Sweden."

According to a study by the eminent British epidemiologist, Dr. Richard Peto, Swedish lung cancer rates are half the EU average. And the explanation for this is that only 18% of the male population smokes, compared with an EU average of nearly 30%. Over a third of the tobacco consumed in Sweden is snus.

Some of this evidence has been around for a while, but no action was taken. As the data accumulated, though,

Dip: Illegal in the EU

the status quo changed when Swedish Match, the main producer of snus, lobbied to change EU legislation (Article 3 of directive 2001/37/EC). Swedish Match said the EU ban is unreasonable, unjustified and disproportionate.

Most unexpectedly, well-respected anti-tobacco activists indirectly supported their action. Clive Bates of Britain's Action on Smoking and Health, and Professor Martin Jarvis, a cancer researcher at the University of London, as well as continental experts from Sweden and Austria, said in a recent joint statement: "We believe that the partial ban applied to *some* forms of smokeless tobacco in the European Union should be replaced by regulation of the toxicity of *all* smokeless tobacco."

These anti-smoking experts are most concerned that the highly toxic chewing tobaccos available in India are permitted in the EU at present, whereas much less dangerous products, like snus, are not. "The current regulation is absurd. A rational regulatory approach would reverse this situation, and effectively ban the most toxic smokeless tobacco products," they said.

Ironically, these independently-funded academics and activists, much like Swedish Match, also want to amend or replace the EU directive with a "new regulatory framework," saying it is "ethically wrong to actively deny users the option to reduce their risk" from smoking tobacco. They added "it is important to consider where the EU draws its moral (and legal) authority to make such "life-or-death" choices on behalf of its citizens—especially as, on the basis of the Swedish evidence, it appears to be making the wrong choices."

I have always had a sneaking suspicion that the anti-tobacco activists were more interested in stopping people from enjoying themselves than in saving lives, but these recent statements are making me re-think. There is little doubt that banning the safest form of tobacco from European nicotine fiends is stupid, bordering on homicidal, and it is to their credit that the activists are using their credibility to push a repeal of the ban.

The devil is in the detail as always, but here the detail is even more convincing. Not only is chewing tobacco safer, it actually leads people away from smoking. Far more people switch from smoking to chewing than the other way around. The anti-tobacco activists would prefer people to quit entirely but if smokers switch, their health is likely to improve significantly, and this is a superior second-best outcome than for the smoker to continue as before.

Furthermore, the anti-smoking experts have even had the temerity to attack the use of the precautionary principle as a reason for maintaining the ban. "The [precautionary principle] usually challenges those defending the status quo with uncertainties about the impact of change. The situation with smokeless tobacco is completely different," the anti-smoking experts say in their joint statement. Its application is inappropriate because all the available evidence shows that the more precautionary approach would be to allow smokeless tobacco to be sold—to invoke change.

Now it appears that British politicians are jumping on the bandwagon. Thirty-four MPs, led by Paul Flynn, wrote an open letter in February stating that they supported a repeal of the ban.

The evidence is overwhelming: the smokeless tobacco industry, European politicians and the strongest opponents of smoking in Europe consider the status quo absurd. So how about it, Mr. Byrne, will you do what makes sense for Europe's smokers and repeal the ban on smokeless tobacco?

Mr. Bate is a fellow of the International Policy Network.

Smoke Without Fire - Smoking causes cancer - so why, some experts ask, does the EU continue to ban a safer alternative, smokeless tobacco? At a time when health warnings on cigarette packs are getting bigger and bigger, and when smoking is increasingly frowned upon in polite society, does it make sense to keep alternatives like Snus off the shop shelves?

- Roger Bate is an adjunct fellow at Competitive Enterprise Institute. He founded the Environment Unit at the Institute of Economic Affairs in 1993 and co-founded the European Science and Environment Forum in 1994. He is a board member of the South African nongovernmental organization Africa fighting Malaria.

- Dr. Robert Nilsson is a senior toxicologist at the Swedish National Chemicals Inspectorate and a professor of toxicology at Stockholm University.

- Dr. Michael Kunze is head of the Institute for Social Medicine at the University of Vienna in Austria.

- Todd Seavey edits HealthFactsAndFears.com, the webzine of the American Council on Science and Health, which is dedicated to promoting sound science and debunking unfounded health scares. He is a Phillips Foundation Journalism Fellow and has written for People, the New York Post, the National Review, Reason, the New York Press and TechCentralStation. He has worked in advertising and was an associate producer for ABC News correspondent John Stossel.

Roger Bate: There are risks that are obviously real and risks which are virtually hypothetical. Mick Hume mentioned the probable overreaction by the World Health Organization over SARS. And Michael Fitzpatrick may have just been discussing this, and I have no idea – he may have talked at length.

But I just wanted to point out a fundamental difference between the kind of virtual hypothetical risks often we see between the pesticide risk used in food, for example, as opposed to a disease which is killing 5% to 10% of those people who suffer from it. And when you're dealing with a government like China, where suppression of information may be significant, it's at least somewhat more acceptable to have an overreaction against a disease like SARS than it may be against . . . in terms of some of the regulation we have elsewhere.

And the reason I mention is that because tobacco falls very much into that kind of category. The debate over smoking at least has generated both heat and light over the last 30 or 40 years. Initially, I think it was a highpoint for the field of epidemiology in the '50s and '60s. It was one of the first major pieces of epidemiology called research by the association between lung cancer and smoking. I think a lot of that early work was exceptionally valuable. I think

somewhere towards the end of the '80s early '90s epidemiology's reputation started to get tarred somewhat – pardon the pun related to tobacco. But if you look at the discussions over passive smoke, for example, regardless of the veracity of the information on ETS. The way that epidemiology is used has become far more politicized and you find that the polarized opinions between industry and health advocates were probably at their worst or their heightened.

I think it's important to mention that and, therefore, we must see the difference between a real risk, which smoking of tobacco is. A probable risk, which passive smoking is. And, perhaps a much lower risk, which is that of tobacco when used in different ways. And I hadn't really thought about tobacco in any other way than smoking. And it seems to be that combustion is one of the main problems for tobacco. And I think that's what we're going to find out today, that chewed or sucked or a variety of different types of uses of other forms of tobacco have lower levels of harm.

We have three speakers. What I planned for this session was to introduce all three of them now and then just let all three of them speak and deal with questions at the end. Because I think that way we will get through the session and people will be able to think through all the questions. And maybe one of the latest speakers will answer a question that will come into their mind. So, we'll do that and then, as I say, take questions. If you want to ask a question in the middle of a speech or at the end of speech, only do so if want a point of clarification that you think will help the audience - not to start any kind of debate.

Our first speaker is Robert Nilsson. I've known Robert for just about six and a half years. I first came across his work when he was doing what I think became the seminal paper on passive smoking. He is an expert toxicologist, a professor at Stockholm University and was until recently a Senior Scientist at Chemi [phonetic], which is the Swedish Chemical Inspector. It's a bit like the U.S. EPA. Our next speaker will be Professor Michael Kunze, who is the head of the Institute for Social Medicine at the University of Vienna. He's an advisor to lots of governments and the World Health Organization and Director of the Nicotine Institute, which deals primarily with helping people to cease or to lower their smoking habit.

And finally we'll have Todd Seavey who I first met back in 1992 when he was just about to work for Reason magazine and then he went off to work as a producer for ABC News in New York. He is currently the Director of Publications at the American Council of Science and Health, editor of Health Facts and Fears. And also of a paper called Libertarian Smoking and Insanity, how ideology affects ideas about freedom. I would like you to all welcome our three speakers. [applause]

Robert Nilsson: Thank you, Roger. I'd like to express my gratitude for the organizers who gave us this opportunity to speak in this prestigious and historic place and also to come back to London. I used to work not far from here 35 years ago at the Chesapeake [phonetic] Institute on Fullum [phonetic] Road. I wonder if the queen's home is still there? [laughter] I might have a look. About a decade ago the European Commission in Brussels appointed an expert committee that was given the task of proposing measures to reduce the use of tobacco in the Member States of the Community.

The EU Directive from 1989 had advised that all tobacco products should carry the rather mild warning "Tobacco seriously damages health", and pressures had been exerted on the Commission to undertake more radical action. The appointed experts all agreed, of course, that

smoking is really a serious health problem within the community, but when practical measures were to be proposed, there was little agreement on what should be undertaken in practice.

The interests of the tobacco farmers in Greece and Italy had to be protected, of course, and to prohibit advertisement for cigarettes at that time was out of the question. One has to do something clearly. According to one spokesman, one English representative got a bright idea: "What about snuff, you know that kind of tobacco that some Swedish and American blokes put in their mouth. It's a disgusting habit - it turns the girls off who want to kiss you". Now the UK and Ireland had already banned snuff. And since there seemed to be hardly any consumption of snuff in the countries that were members of the EU at that time, the expert committee unanimously suggested that the Commission ban snuff for oral use for the whole of the community because Sweden was not yet a member then.

In order not to destroy a good anecdote, I have made no attempt to verify the details of this amusing anecdote. Nevertheless, that the committee emphatically recommended the banning of snuff is true, and the EU Council Directive 92/41/EEC of May 15 1992 seemed to have specifically selected "tobacco for oral use" among several types of "smokeless tobacco" as its main target. The Directive not only specified that all unit packages containing smokeless tobacco – but not cigarettes – must carry the warning "Causes cancer", but also that all Member states must prohibit the marketing of snuff.

The Directive, on the other hand, does not mention chewing tobacco or nasal snuff, which were still permitted although the health hazards from these products are almost identically the same as from snuff. If you read this directive you almost get the impression that oral snuff was more of a real threat to public health in the EU than cigarettes.

Before I go into whatever rational reasons that the Commission might have had at that time for its decision I will give a brief historical background with special reference to the widespread use of snuff in Sweden.

You may, of course, first want to know what is so special about the Swedish snuff, which is known even in the United States by its Swedish name "snus". Up-to-date, Sweden seems to be the only country in the world to have reached the World Health Organization goal of bringing the incidence of smokers in the population down below 20% by the year of 2000. Part of the explanation for this development can no doubt be ascribed to the fact that, while smoking has decreased, the use of snuff as a nicotine delivering substitute has increased to almost 20% of the grown-up male population. And as a result, the risk of dying from smoking-related diseases is less in Sweden than in any of the European countries.

About one-third of all Swedish snuff users are ex-smokers. A survey in 1989 revealed that smoking among Swedish medical doctors decreased from 46% in 1969 to 6% in 1996, but that snuff use among the male doctors meanwhile had increased to almost 10%. Now, what about the females?

Well, actually 3% of the females in the medical profession admitted using snuff, but the frequency among the female surgeons was almost like the average for the mail. You can't blow smoke, you know, if you're conducting surgery. Historically, the use of snuff reached its peak in England during the reign of Queen Anne. And George III and his wife Charlotte, nicknamed "Snuffy Charlotte", Lord Nelson, the Duke of Wellington, Frederick the Great of Preussen [phonetic], Marie Antoinette, Napoleon, Disraeli and many others were avid snuff users. The type of snuff used during the 17th and 18th centuries was inhaled through the nose, and was of the dry type different from the moist brands commonly used in Scandinavia and North America today.

Interestingly, the Bantus of Southern Africa still use a dry nasal snuff made from locally grown tobacco. Around 1800 the manner of how snuff was used gradually changed in Sweden in as much as a 'quid' of tobacco was placed in the mouth, usually under the upper lip as is still the custom in this country. As oral snuff become more common, there was a change from the finely powdered type to a more coarsely, moist snuff. At the end of the 1800s, 103 different brands of snuff were sold in 360 different type of packages, and in 1919 two million adult Swedes consumed about 7,000 tons of snuff, about 3.5 kg per person a year. That created a nice profit for the government tobacco monopoly that was founded in 1915 and lasted as such until 1961.

Today, Sweden has the highest consumption of snuff worldwide with a yearly average adult per capita consumption of about almost 1 kg. In North America the use of oral snuff is common in certain parts. And it was probably introduced during the 19th century by lumberjacks, who had emigrated from Scandinavia and spread from Minnesota down to Virginia and parts of the southeastern United States. Oral snuff is also consumed in Norway, Finland, Canada, but also in North Africa, Iraq, Afghanistan and the central Asian Republics or the Soviet Union.

The oral snuff that are commonly consumed in India are usually mixed with slaked lime and, in addition, are often mixed with ground areca nuts and wrapped with in betel leaves. Because of the presence of additional toxic and carcinogen compounds derived from the areca nut, these types of Indian snuffs are considerably more hazardous than the corresponding products used in Western societies.

It should be strongly emphasized that snuff constitutes a very heterogeneous class of tobacco products, where the manner of production is the main factor that determines the degree of health hazard associated with its use. In most countries this important fact has obviously escaped the decision makers who treat all kinds of snuffs in the same manner. I should talk a little about how snuff is produced. During the 19th century, Swedish snuff was usually produced from imported fire-cured Dark Virginia or Dark Kentucky tobacco that was aged for more than one year and then fermented for several weeks. During the final process the tobacco was ground, watered, salted, and sodium carbonate was added and aromatic agents.

And the tobacco was then often subjected to a second fermentation at elevated temperatures. With some variations, this traditional production method is still being used by some producers in North America. However, in Sweden, the sole producer of snuff, formerly the Government's Swedish Tobacco Co., which is now Swedish Match, abandoned fermentation processing after World War II in favor of a carefully controlled heating process in a closed system. This process results in a practical sterile product. And in the stores the snuff packages are usually kept in refrigerators to keep the quality and that, of course, improves the quality and decreases the health hazards from these products.

Now, this is very important, as I shall later talk about in reducing the health risk. Another improvement by the Swedish manufacturer was the introduction in 1973 of portion packed snuff. [cross-talking] Higher plants have no means of excreting solid waste products coming from their metabolism, and they instead developed complicated synthetic pathways to incorporate these products to form large organic molecules and sometimes the toxic substance is called alkaloids.

Tobacco used for the manufacture of smokeless tobacco comes from two species of the genus Nicoteana -- both from the potato family or the Solanacae family. But that includes useful plants like the potato, tomato, chilies, and aubergines, and also a number of toxic plants such as the Nightshade and Jimson Weed.

Here are the main alkaloids present in tobacco [cross-talking – chart is being referred to] obviously nicotine is the most important of these alkaloids. And they are often called tobacco specific alkaloids, but this is actually a misnomer because nicotine, for instance, occurs in a number of plants from this family, as you can see here.

It occurs in tomatoes, French fries, eggplants, and bell peppers but in small quantities. You see as a comparison the delivery from one cigarette (1,000 micrograms). The presence in tea is puzzling, but that's probably due to the fact that nicotine is still used as an insecticide in some countries. The tobacco alkaloid myosmine is even more widely distributed and is found in a number of staple foods.

Nicotine, as you probably all know, has a very high acute toxicity, and the ingestion of about 60 milligrams in a grownup person will lead to death within a couple of hours of respiratory paralysis. Nicotine is a highly toxic substance, and ingestion of about 60 mg by a grown-up person is usually promptly lethal as a result of respiratory paralysis. In lower does nicotine elevates the blood pressure and causes constriction of the peripheral blood vessels and has a stimulatory reaction on the central nervous system that provides a basis for addictive properties.

The possible hazardous long term effects of nicotine have been very much debated, but in smokers it has often been difficult to distinguish the action of nicotine from those caused by the thousands of other components present in tobacco smoke. I want you to also remember that nicotine has some decidedly positive pharmacological effects. Although the mechanism is still unknown, it has now been found beyond doubt that this alkaloid (and also smoking) reduces the risk of ulcerous colitis, and nicotine has also showed some promise in the treatment of Parkinson's as well as Alzheimer's disease. There are two main hazards that have been associated with the use of smokeless tobacco --that's cardiovascular disease and cancer. Also at the site where the quid is regularly placed, gingival recessions may also develop.

Active smoking is associated with an increased risk of cardiovascular disease, and one often cited Swedish investigator, Gunilla Bolinder, has also claimed snuff to be a moderate risk factor for this type of adverse effects. But in two other large Swedish studies of snuff users, no increased risk for cardiovascular disease was found.

Also, whereas smoking adversely affects blood coagulation, no such effects have been found in snuff users. The association between vascular disease and use of snuff found by Bolinder could be accidental, caused by the lack of control in cases and controls of confounding factors like dietary habits, blood pressure, blood lipid pattern, or a family history of cardiovascular disease.

When the European Commission decided to ban snuff it was the risk for oral cancer that was a major concern, and this body heavily relied on an assessment made in 1984 by the WHO International Agency for Research on Cancer (IARC) in Lyon that classified snuff as a human carcinogen.

The IARC expert group based their conclusions mainly on two circumstances; snuff contains potent carcinogens called *nitrosamines*. And secondly, it was based on epidemiological evidence from the United States that linked cancers of the oral cavity and pharynx to the use of snuff. In this context – and I will mention this in one of the other sessions – the fact that IARC classifies as carcinogenic, it doesn't say anything about the potency and the risk for cancer. Wood dust is classified as a human carcinogen but we don't have to worry when we go in the workshop or cut wood. And coffee drinking is classified as a possibly present carcinogenic to the ordinary bladder.

Still, of course, I don't criticize IARC; they are doing a good job, it's just that their classification is only part of the story because it doesn't say anything about the level of risk. Like spinach, salad and many other plants, tobacco leaves contain appreciable quantities of nitrate. During the fermentation of tobacco, nitrate is reduced to nitrite by micro organisms, which in turn reacts with the alkaloids in tobacco to form nitrosamines, some of which are potent carcinogens. Thus, when nicotine and nornicotine react with nitrate, the nitrosamines NNK and NNN are generated by an interaction known as nitrosation and there's also some additional formation in the mouth because in saliva there is nitrite as well.

In experimental animals NNN and NNK are powerful mutagens and carcinogens producing tumors at different sites. But our daily food and drink is full of mutagens and carcinogens, most of them of natural origin, and the fact that, for instance, peanuts and cashew nuts contain the most powerful carcinogen ever known to science – aflatoxin. It doesn't prevent us from eating these nuts in the bar. It is the matter of dose obviously.

Carcinogens like NNN and NNK or other carcinogens form naturally in our organism, initiate cancer by causing damages to the DNA in somatic cells. Fortunately, nature has endowed us with extremely efficient systems for repairing the innumerable DNA damages that harbors in our body each day. At sufficiently low levels, exposure to most carcinogens in our external environment will not increase our cancer risk to any significant degree. What should one say about the nitrosamine content in snuff?

Well, three things will be noted from this table. If you look at the last one, the snuff from Sudan the levels are obviously particularly high. You can see it that the norms are out of this world. Secondly, that the products sold in Sweden and the US, the levels of nitrosamine have been doing down with time. And thirdly, since 1983, when the measurement of these nitrosamines first started, the Swedish snuff has always had lower levels than products produced elsewhere.

Nevertheless, if I look at the animal data and at these levels, as a toxicologist, I would be concerned about the presence of nitrosamines in snuff, even if the concentrations have gone down appreciably – if these were the only hard data available, if the human epidemiological evidence is obviously crucial. In southeastern United States as well as in Scandinavia, physicians and dentists had noted that many patients with cancers in the oral cavity were snuff users. However, when IARC in 1984 evaluated the effects of oral snuff, few adequately performed investigations had been carried out.

Also, smoking, particularly in combination with alcohol, can also cause oral cancers. There was actually only one well-conducted case-control study by Winn and co-workers from 1981 that included 255 elderly women from a poor area of North Carolina with cancers of the oral cavity and pharynx. In spite of some notable drawbacks, there was little doubt that that this study did demonstrate the strong association between snuff dipping and oral cancer.

The fact that so many cases were found among women from this region can be explained by the fact that snuff dipping was formerly both acceptable and condoned for women, but cigarette smoking was considered highly improper in these parts. According to the traditional local custom, women dipped a wooden stick, wetted it with saliva in a box of dry snuff and rubbed the tobacco-covered stick around the mouth and into the interstices of the teeth. From there comes the commonly used American term "snuff dipping".

What about evidence from other parts of the world, like Sweden, where it is estimated that out of a total population of 8.5 million, about 700,000 people regularly use snuff. The creation

of a central cancer registry, covering the whole of the Swedish population, offers a unique opportunity to conduct large-scale epidemiological surveys.

Two recent, very large Swedish case of withdrawal studies, covering the whole of the country, failed to find any association between use of oral stuff and cancers of the oral cavity and pharynx constitute relatively rare tumors, and a significant. The third large cohort study has given the same results. In spite of the fact that approximately 20% of all grown-up Swedish males use snuff, the prevalence of cancers in the oral cavity remains low.

During '62 to '71, there were only 33 cases of oral cancers from all of Sweden that would be definitely associated with snuff. During the same time, there was 30,000 cases of lung cancer -- 90% of which can be related to smoking. Another extensive population-based study of the risk of gastric cancer, no increased risk could be detected.

What could be the explanation? Why are these data so different from the American data? One has to consider what type of snuff that those elderly American women have been using. In North Carolina during that time, those women have used the dry snuff, and I am sure it was made locally and we don't know anything about the quality.

When this investigation was conducted in 1980, the average age of the cases was 65 for women with gum and buccal mucosal cancer and 69 for cancer in the other parts of the mouth. One-third of these women started using snuff at the age of 10.

The induction period for cancer in this cohort includes long-term exposures to tobacco products made between the two World Wars in North Carolina traditional fashion. And that kind of tobacco was probably more similar to Sudan Toombak containing very high levels of nitrosamines. And in Sudan we know, of course, that high proportions of maple [indiscernible] of oral cancers are very common. The manner of snuffing is also important. There is evidence that the portion-bags used instead of loose snuff would markedly reduce pathological changes in the oral cavity.

Also another thing is the presence of protective agents of snuff. All plants contain protective agents, especially in the process where you don't use fermentation. Some of these [indiscernible]. This is, of course, something that would have to be investigated further. Since many individuals resort to a smokeless tobacco in order quit the habit of smoking, it is of interest to calculate the gain in terms of the number of cancer cases that can be avoided in a population of 100,000 active smokers who turn snuff dippers.

How many cancer cases can be prevented a year? In smokers you can calculate – if you calculate in Sweden with an increase of risk in the oral cavity [indiscernible] of the lung cancer by a factor of 10. I have used an incidence of about 60 cases per 100,000. And to this comes additional cases in the oral cavity, pharynx, larynx, and urinary tract.

So you guess about per year 70 cases among the smokers. These smokers will stop smoking and move over to snuff. The risk for lung cancer will go down, but it will never move down to the same as in the non-smokers. It remains about double the control value, so you will still have another six additional cases from the ex-smokers. And then you have whatever risk there is from the oral snuff.

These Swedish studies didn't show zero risk. What they did show was that the risk cannot be higher than about two cases per 100,000, so there we have another two cases. That means we can prevent about 62 cancer cases. Not to be translated into the European perspective where we have 100 million smokers turn snuff users. When using these kinds of calculations it's like a higher risk factor associated with smoking.

You can expect per year 62,000 cancer cases, which among those are 50,000 deaths because lung cancer is the most lethal. Then we have to add 50% of all deaths from chronic obstructive disease from smoking, and 20% of all deaths in cardiovascular disease. That adds another 150,000 deaths avoided per year. The numbers clearly tell us that we can avoid something like 200,000 deaths.

The quality of the recent Swedish studies were, in many respects, superior to that of the old study from North Carolina in 1981. The only adequate epidemiological study that has ever demonstrated snuff to be a cancer risk. But representatives from the anti-tobacco lobby have, nevertheless, declared that they refuse to believe in the Swedish data.

I'm glad that at least the Swedish Ministry of Health doesn't believe in these data. An argument that has also been advanced -- that snuff should be banned based on the precautionary principle is a blatant misuse of this principle. In as much as it is then only applied to uncertainty with respect to potential hazards of snuff per se, but not to the certain negative consequences for smokers who are denied an effective and much less dangerous substitute.

A UN expert group that convened in 1998 to discuss the reduction of smoking listed Swedish snuff as one feasible alternative. And in a recent statement from prominent members of the anti-smoking lobby, including Clive Bates from the Action on Smoking and Health in London, have given their support to this alternative. According to my opinion, a view that is shared by the Swedish Government, the EU directive permitting the sale of Swedish snuff without a cancer warning to Swedes. But banning this product within all other member states -- represents an unfair, unjustified, disproportionate, discriminatory, and arbitrary regulatory action that should be overturned by the European Court of Justice in the two cases that are now pending judgment.

Thank you. [applause]

Roger Bate: As part of the anti-smoking lobby, Professor Kunze will respond to that. I'll just mention it briefly and you can comment on it. There is a letter I have here that was written by Paul Flynn of the UK government along with 34 colleagues. I believe it has argued in favor of the lifting of the ban. As Robert mentions, a group of very prominent members of the – let's call them the anti-tobacco crowd, as they normally would be, including Clive Bates but also including Professor Kunze here. They came out and stated in favor of evidence of strict regulation, which you can pick up anywhere outside.

As one of the authors of this statement –

Dr. Kunze: You might be surprised that an author is talking about the Sweden issue, as you heard it. It's a problem with Sweden and also a problem of Europe. And I will brief you a little of how it comes that I got interested in it. Being an Austrian citizen doesn't mean that in the anti-tobacco or tobacco-controlled world we are not working on an international level. And it wasn't far from here, across the Brown's Hotel, not in the Brown's Hotel yet, when we decided to write in the '80s one of the first few ICC guidelines from how to treat dependent smokers.

So, the question I bring forward to you is to snus or not to snus, that is the question – that there is no brand in mind and so forth. This is the subsidiary of my university institute which is in the public health – it's called Nicotine Institute. And this group of people, including myself, we are devoting our time on treating people – heavily addicted, tobacco addicted, nicotine addicted people.

And I will come up with this snus statement also, that I need it for treatment. And I don't want to run into troubles when I give that kind of stuff out, which I bring into Austria – of course we don't sell it. You have here the samples. So we need it for treatment as well. And it is unfair to deprive Austrian heavy-dependent smokers, who cannot stop smoking not to have the opportunity to have some substitute. This is only one side of the coin.

We have just recently published together with Karl Fagerstrom, you might know this name, [indiscernible] in the [indiscernible] in the [indiscernible] guide from Sweden – [indiscernible] Development Mechanisms. This is an overview that just came out if you want to look at that and visit our homepage. There you have everything about the genetics, about the receptors and all those kinds of stuff. Underneath that we have all kinds of nicotine [indiscernible] systems.

Nicotine is a very interesting substance and most probably the best, so to speak, psycho-active drug we have in society. It is, of course, not harmless but it's not the real problem. The real problem is that the delivery system in cigarettes is the real problem because it will burn tobacco then you run into problem.

Now comes the time when we have the highest carcinogen exposure in Austria [indiscernible] and people start grilling sausages. Nobody cares about that now [indiscernible] and produce carcinogens by the kilos every Sunday. So we do a lot, and I have spent a history and a life in tobacco control. Always also looking for harm reduction.

Back in '97 and earlier we always were looking how could we reduce harm and this is one chapter in the book where we were focusing on nicotine replacement. And nicotine replacement is a pharmaceutical compound, as you all know, was also invented in Sweden. And so it was in Sweden many, many times and never really listened to this news story. Yes, I heard about snus but we were absolutely focused for a long time on the medication, on nicotine replacement.

And back in '98 and earlier we had a new approach – you see, it's not so long since we talked about harm reduction. Then we set a new approach and now we ended up this way. We even developed a concept of lung cancer prevention by long term use of alternative nicotine delivery systems, which is the only way to control lung cancer by now. The only way to really control lung cancer among the highly addicted people because lung cancer most probably is a psychosomatic disease – I can go into details if you want a little later on that.

And then another paper struck us – maybe find out that many lung cancer patients die early in life in Austria than 20 years ago. This is the absolute catastrophic lung cancer control. Treatment doesn't work, prevention works a little, screening doesn't work, so we waste billions of dollars, krones, the most pounds whatever in treating lung cancer patients and the outcome – it's absolutely negligable. So what else should we do? And one way is to provide those people who cannot stop smoking with nicotine in a way that is the least harmful for them.

So we said is snus an alternative? We published it at the European Lung Cancer Conference, where we were invited to talk and this was a big bang. It went into lung cancer, it went into the media. And suddenly we were in the midst of the political debate for snus, also which we didn't want to go into but we had to look why is Sweden so different when it comes to lung cancer in Austria or Britain or Germany or Switzerland or France or whatever. It's very simple; it's simply [indiscernible].

The Austrian and Swedish data against each other show the age and gender distribution population are very similar. Both are aging populations. Lung cancer mortality are half in Sweden than in Austria and lung cancer figures in Swedish and Austria figures are similar.

And it's logic to then go into the idea what are they doing differently and needless to say vascular mortality is better in Sweden, life expectancy is better in Sweden – [unintelligible] you have Swedish genes and it's cold up there and they are blond, many, many reasons for that. And we say only is snus an alternative, question mark. We didn't know what we were entering on a political [phonetic].

Now comes the Directive 2001/37 European Community. Now comes the political aspect. I'm serving on the EU tobacco expert working group as the Austrian representative and also on the regulatory group. The regulatory committee is the European Union Committee which oversees how this directive is implemented and on the board and all this kind of stuff. And I'm serving as the Austrian delegate there and then advising to my government and all this kind of [indiscernible].

And then we decided, a couple of us, we found out that [indiscernible] as you heard [indiscernible] prohibit the [indiscernible] marketing of smokeless tobacco for oral use except the exemption granted to Sweden. And now we are in the midst of the political and the legal debate. You already saw this documented. The document which was compiled originally by Clive Bates, Fagerstrom, Jarvis, myself and McNeill, Lastroptin [phonetic]. And we handed it in and now it's under review for Tobacco Control, which is the leading journal. And there we state we should make changes on the European level.

And, please, let me make one point extremely clear – we want more regulations. We do not want a lift and unconditional lift of tobacco. It's very, very important. David Sweanor helped us to compile this data and his comments and he can comment on this discussion. This is a paper which asks change the ban or article 8 of the directive, but make it much more strict because it's ridiculous. It's India's products, which are much more dangerous. Those are so free in England and in London and everywhere because this is not European Union. It's stupid – it's surprising, not stupid. [laughter] I never said stupid, sorry.

We believe -- the authors -- we believe that the partial ban applied to some forms of smokeless tobacco use should be replaced by regulation of all smokeless tobacco. And we state again, smokeless tobacco, as you already heard, is substantially less harmful than smoking and evidence from Sweden suggests it is used as a substitute – it's helping, at least in Sweden, the way out of cigarettes and it is good for smoking cessation. Most probably and we are starting studies on that.

But I now, as a treatment person, do I run into troubles if I hand this out to the Austrian patient? Some day there comes a lawyer or someone and it puts me not really to jail but it puts me into trouble. I don't want to experience that; I want to help the patient.

It is not leading into smoking but away from it in Sweden, and Sweden has the lowest rate of tobacco-related diseases in Europe. And the ethical problem also is for smokers that are addicted to nicotine and cannot or will not stop, we need a chance, we need an alternative for them and they mustn't get it. It's like – I know the analogy is somewhat very weak – You drink Coca Cola light. Or better to speak only in Sweden – You must not drink Coca Cola light in Austria; you drink the real stuff and get fat. [laughter]

What is the difference? From a [indiscernible] point of view, you always have to make comparisons which are not very much scientific. And, again, say the authors, we believe that the European policy on smokeless tobacco should [indiscernible] to real scientific knowledge and that the European Commission should bring forward [unintelligible] or replace Article 8.

We want more regulations, new regulations. What we don't want to have I will show you in a second. Nobody said smokeless tobacco is harmless -- nobody would say that. It's not the

safest thing. Stopping smoking is the best, not drinking wine, not drinking schnaaps, not eating cholesterol, blah, blah. There are many things in life which you could avoid in order to live longer, and I don't comment on what kind of life this would be.

Smokeless tobacco used in the India subcontinents, some products, they cause oral cancer; we have heard that. And they may be brought into the European community because this is not coming out of the European Committee, so it's not very logical. And we have already heard that there is not a real link between smokeless tobacco in the form of Swedish snus – it has to be kept in the refrigerator and you heard about the process of production of all this kind of stuff and the portions.

Of course it is a very, very active delivery system and it is addictive because it gives you the substance, the psycho-active substance. Most probably the most interesting, the type of psycho-active substance which our society has – much better than alcohol for example, because there are no actual side effects.

I could have had two cigarettes or a couple of snus pouches before coming in to stand the stress of a lecture. But if I have a couple of whiskeys then I might feel better but you may recognize it. [laughter] And Sweden has the lowest man-smoking prevalence because they get their nicotine from other sources – one being snus and another one being nicotine replacement medication.

Now, our specific points, the Nicotine Institute of Vienna. We have very specific points in that debate. The first specific point is we do not want to see an unconditional lift of the ban. It's banned – now the lawyers are coming in and blah, blah. And the European Court of Justice and suddenly somebody comes in and says no ban anymore. And in [unintelligible] we get all the toxic substances in, nobody cares, no regulation. More regulation – we want to see more regulation, not less regulation.

Plus the Swedish standard might be an example, but I'm not an expert in that field. It might be something else, but they have a standard in Sweden and this could be applied for all products coming in. So for the EU, for the European Commission, for my people and my colleagues they have a need for more and more strict elaborated regulations. It's not lifting the ban without any conditions – this would be no good. And we especially, the [unintelligible] tobacco standards – we need it. It's an ethical question now for the medical community to have these kinds of products available for those who cannot or will not stop smoking.

It's the same with any other chronic disease. Many people say that smoking – tobacco addiction in a severe form is a chronic disease. It causes changes in the brain and we have to take care of it. If we have a chronic diabetic person we take care of them. If you have a chronic whatever – [unintelligible] arthritis, we cannot cure them, we take care of them and have a lot of to. And, of course, we need that for treatment or substitution and, of course, we need the nicotine replacement medication and this is our homepage if you want to have a closer look at what we are doing.

Thank you. [applause]

Todd Seavey: I'm Todd Seavey, the Director of Publications at the American Council on Science and Health and the editor of the Web site Health Facts and Fears. I'm not a scientist; I'm an editor and a writer, but I think I have some idea of how health officials for the EU and for the US must feel when they're told that they should allow or even recommend smokeless tobacco – such as chewing tobacco or snus to people. For us at the American Council on

Science and Health, too, it was weird to find ourselves saying something nice about tobacco for the first time. [laughter]

We really hadn't thought about chewing tobacco and snus until very recently. Tobacco is not good for you, but crucially, as the other speaks have pointed out, it's far better and far safer for those who are currently addicted to nicotine and can't get over it, to get it in a smokeless form than by smoking.

And that should be all that matters, I think, for purposes of deciding whether to recommend smokeless tobacco to current smokers – harm reduction. Nicotine may be addictive, but as far as we can tell, by itself as normally used, it's very unlikely to kill, whereas the tar from smoking will. If you can separate what smokers crave from the thing that kills them, that's good. And I think it's important to keep in mind . . . a big theme in the conference, of course, is that people are very bad in judging relative risks.

The natural way for the brain to operate is to sort of divide things into good and bad, without making very fine gradations in between. So it's important to keep in mind the magnitude of the risk from smoking when talking about the potential advantages of smokeless tobacco.

And at the risk of sounding like I want scaremongers and panic inducers – I would say smoking is actually something that most people aren't frightened of enough. We at the American Council on Science and Health spend a lot of our time telling people they shouldn't panic so much over fear of cancers from pesticides or fear of brain cancer from electro and magnetic field from power lines or other things like that.

But smoking really may kill you and have lots of other negative health effects. In fact, about a third – and some would estimate as many as a half of smokers die from their habit, and that's really bad. You would never accept that level of mortality in some household cleanser. If somebody realized that a third or a half of the users of some cleaning product were going to die prematurely from the use of the product it would be banned immediately.

So in some ways, even though there's been a legal crusade against tobacco, compared to all the other regulated substances, tobacco has it easy. It's gotten sort of a free ride concerning how deadly it really is. To put the relative risks into perspective, Dr. Phil Cole from the University of Alabama, an epidemiologist, pointed out in a conference last year that while about a third or a half of smokers die from their habit. Only about one half of one percent of smokeless tobacco users, it's estimated, get oral cancer. Or only about half of one percent die from it, which means that smoking is something like 60 times as dangerous as smokeless tobacco. So it seems pretty crazy to be banning one while letting the other be freely used.

Most of us at the American Council on Science and Health are libertarians, so we would say make it all legal. I'm not suggesting that cigarettes be banned, although considering all the other things that are banned and regulated, I don't think it would be that crazy frankly to make cigarettes illegal, considering all the other things that are. But I prefer that both the smokeless tobacco and the cigarettes be legal.

I say this as a resident of New York City, which has banned smoking in public bars and restaurants, so I feel a bit torn while I'm there. On one hand, I think it's much healthier for people not to be smoking. On the other hand, it is sort of a blow to liberty as though people can't decide what they're going to do.

Smoking – it's estimated kills about four million people around the world each year, which makes even wars and terrorism seem a little petty by comparison. And I think that helps explain to some extent why people are so frightened of saying anything nice about tobacco.

Also, as I was saying before, there are tendency for people to divide things up into the good and the bad, and I think that Manakenda [phonetic] tendency, that sort of dual impulse is particularly strong in regulators and people who are trying to provide treatment to addicts.

And the U.S., in particular, there's a certain puritanical streak in some of the treatment programs. You see this in the group Alcoholics Anonymous, which is fairly religious in its tone in a way. Its language has been sectoralized, but its roots are religious and the way it functions is basically by demonizing alcohol.

You come to them as an alcoholic and you're supposed to admit that you have no real control over your own life. And that if you consume as much of one drop of alcohol you've fallen off the wagon, gone back to your bad ways and the only way you can really lead a clean life is to stay off the substance all together. To convince a group like that harm reduction, where people try to moderate their consumption of something instead of eliminating it completely, it is tricky. They'd say an addict shouldn't be exposed to these sorts of things at all.

The situation with smoking is a little more complicated than alcohol though, because with alcohol, at least, we all have every day models of what moderate consumption looks like. There are safe levels of alcohol you can consume and most of us do – maybe a beer after work or a glass of wine with dinner, but most of you probably aren't drunk in multiple times a week or anything like that.

It seems like there are social structures in place for encouraging moderate alcohol use. Though if I was going to pick all of my health policy recommendations based on my aesthetic or philosophical impulses I might say, ah, I'll recommend the same sort of things in smoking – smoke in a moderate fashion. But realistically it doesn't look like that's possible. It might be that if you only smoked one cigarette a day or two cigarettes a day, you wouldn't have a substantially elevated risk of death.

You'd still have some negative health consequences even from that small amount but perhaps significant enough for us to be worrying about it and holding conferences about what to do about the smoking problem. But there is virtually no one on the planet that can limit their smoking to that amount. It can be done but very few people do. Virtually everyone who smokes that much smokes more.

So, I'm going to recommend moderation to the hopeless and the nicotine addicted, there has to be some other way. And it would be nice to be able to recommend smokeless tobacco to them as means of moderating rather than taking the puritanical route of suddenly going cold turkey on nicotine. Or, as many people do by saying it's hopeless, I can't cut down and might as well give up and not even try.

One of the bad things I think about regulating these substances is that if people are already inclined psychologically of thinking in those manichean [phonetic] terms – good substance, bad substance. And the law could reinforce that by making something either outlawed or legal or heavily regulated. So a lot of people, as a rule of thumb, are just going to avoid the things that are illegal and assume that everything that is legal is relatively safe. Whereas, I'd say, if everything were legal, and if you could advertise the fact that smokeless is at least safer than smoking, it sort of forces people to make some of their own individual choices about relative risk.

You don't do much ranking of risks if you're just watching to see which things are perking [phonetic] and which things are legal. That's the problem with public policy in general people

just sort of wait to see what things get cut off and forbidden and lump everything together. And the media hyper-nerve [phonetic] variety of risks the media news contributes to that.

Rarely when you see one story about supposed cancer-causing properties of a household cleanser compared to the previous night's story about some other health risks. It's just the new bad thing each night and panic to about the same degree over each new threat – good or bad.

As an utilitarian myself, in the tradition of England's own John Steward Mill, I think ideally every human decision, and certainly every public policy decision, ought to be made with regard to the ethical question of whether our actions will increase or decrease human suffering. That's a very moralistic position but it's different from the dualistic good or bad substance one.

Utilitarianism recognizes that there are degrees of suffering and degrees of happiness. Making one necessarily rude comment to your friend and murdering him are both bad but they aren't equally bad. One is clearly preferable and it's just as true when comparing the real but tiny risks from smokeless tobacco to the immense devastating risk from smoking. And we need to resist that manichean [phonetic] impulse [phonetic] I was talking about before. The blanket approach, throwing all bad things into one category results in people not having to make the harder calculations about how significant risks are.

In America, if we could convince smokers to switch to smokeless tobacco, deaths from tobacco use it's estimated would drop from about 400,000 a year now to only about 6,000 a year. If that's not a reduction in harm and a victory for public health, I don't know what is. Coincidentally, the night before I flew to London I was at a party on a rooftop in New York City and there were only a few people there – maybe 15.

On a nearby rooftop there was a big bustling party on a tall building, lots of people there seemed to be having a good time. And I asked someone if they knew what was going on over at that other building and it turned out it was a methodone clinic. [laughter] So probably everyone over there was on methodone at the time and really enjoying themselves and socializing. I don't know exactly what goes on in methodone parties but I'm sure just like at a healthy [phonetic] youthful party where people are [indiscernible] there are probably some people going around going, "Oh, man, I'm so wrecked on this methodone." And I remember when I myself was young – I was probably the somewhat puritanical bent [phonetic]. I wasn't really this person but I was a rationalist and strict logician and believed in self-discipline and that sort of thing. And I probably would have looked over to the rooftop and said, "You know, that's not really appropriate. Those people are drug addicts. They shouldn't be having a good time and enjoying themselves." [laughter] "They should be ashamed themselves and they shouldn't be allowed any substance that's going to alter their minds." But now I'm a little older and my thinking is a bit more nuance. And I realize it's far better for them to be using a less hard drug in a social context, where they're being encouraged to avoid irresponsible behavior than for them individually to be off in some alley somewhere shooting heroin or something else. So I applaud them for enjoying themselves and hope that the methodone is a step toward more responsible behavior. It doesn't mean I'm encouraging people who don't use drugs at all now to go use methodone.

We sometimes fear that the public can't handle the mixed messages. I admit that the public is very ignorant, but I think it's the mixed message – it's only about two seconds long. I think they can handle it. I think you can tell people it's better to use no tobacco at all, but if you're going to use tobacco, smokeless is far safer than smoking.

Similarly, in the U.S. there's a big debate over whether schools should be encouraging the condom use. Religious groups in particular said, "If you go around telling people to use condoms, you're effectively telling teenagers to go out and have sex," which seems irresponsible.

So on the one hand you have conservatives saying, "You should just tell people about abstinence." The radicals are telling people we shouldn't make judgments about whether or not teenagers should have sex. And without really planning it in advance, the practical compromise that was worked out was that the schools now are going to tell the teenagers abstain until you're an adult or if you're going to have sex at least use a condom.

That's sort of a mixed message but it seems to work. I think most people are understanding that mixed message, and I think most people are capable of understanding the message that smokeless is preferable to smoking, even if doing neither would be best of all.

Roger Bate: Thank you very much. [applause] We should be winding to a close now, but since you spoke a little late I'm going to take some questions.

Dr. Nilsson: May I make a small addition?

Roger Bate: Please do.

Dr. Nilsson: A very short one. I just was handed an article which really upset me about mixed messages. [cross-talking] and that's something you should be aware of. That he is one of the main officers in the [indiscernible], a very skillful man, no doubt. But the kind of presentation – this is the paper of Harry Mineo [phonetic].

I don't know if you have read that. And I was very upset. What you should be aware of because he will be hearing this from other sources, and that is that he doesn't deny that the Swedish investigations found no increase of cancer. But what he says is, "Both of these studies were sponsored by the research of the Swedish tobacco companies." That sort of implicates that this [indiscernible] – these people are bought by the tobacco.

Let me just tell the audience that these companies, these investigations – it's true that the Swedish Research Council did some support, but they were also supported by the Cancer Society of Stockholm, the Swedish Cancer Fund, the Research Foundation of the Department of Oncology [indiscernible]. And then when it comes to the Swedish Tobacco Research Council -- this was funded by the Swedish Ministry of Social Affairs -- when the Swedish Tobacco Company was a monopoly. We have Nobel Prize Laureates is sitting in the committees. These are completely independent. It's not at all influenced by the tobacco industry even today.

And it is an insult to the Swedish medical profession to say that research supported by this research council is bought by the tobacco industry. A major part of all investigations into tobacco research, which has clarified the negative effects of smoking, comes from this money. But now I think that the Swedish Match is thinking of actually stopping this support because there's always these snipers [phonetic] and nobody wants to take the money because as soon as you take this money you're "bought" by the tobacco industry. It's very sad.

Roger Bate: I think the audience here is more interested in the actual discussion of the topic. Next question.

Question: I'm a smoker. I don't see any reason to ban snus nor am I particularly attractive of the idea by [indiscernible]. I'm very suspicious about this whole debate because there was this discussion about relative risk. I think the smoking debate is not about is it bad for you or not. Everyone knows it's bad for you.

Today the smoking debate is about should people be able to make their own decisions. I would say yes. I think the anti-smoking lobby says no. And I just think you're allowed to say no as well. Because what you're saying, it seems to me, is [indiscernible] the discussion so you can [indiscernible]. And it's treating people really like they're victims of addiction and they shouldn't really have the willpower to not smoke cigarettes.

A part of my question is, isn't this a dangerous avenue to go down in terms of discussing not whether smoking is good for you or not because everyone knows it's bad for you. So a more kind of fundamental issue about decision making [indiscernible].

Unidentified male: Absolutely.

Roger Bate: Let's take a few more questions. (indiscernible]

Question: [inaudible – too far from mike] when I switched from cigarettes to snus I looked at the other options [indiscernible]. And I actually found that it was much cheaper, more tastier also and there is a lot of money in those substitutes for tobacco. Isn't it in the interest of the quite powerful pharmaceutical corporations to lobby for not allowing snus into the European Union? [cross-talking]

Unidentified male speaker: [indiscernible] to kind of relate this to the theme today – and I'm having problems doing that myself. What we've been looking at in earlier sessions [indiscernible] generally comes about through an interaction between public anxiety and then some scare-mongering or risk averse institutions pushing something. From what I have heard there doesn't seem to be any type of public anxiety about smokeless tobacco. It seems to be something where for one reason or another the interest [indiscernible] of the EU and made this decision [indiscernible]. But it doesn't seem to fit into the pattern [phonetic] that we're talking about. There's not a great public panic about this issue. If I've missed something here or . . .

Roger Bate: No, no, we'll take a few more questions.

Question: I'd like to [indiscernible] on that. I must admit I'm very confused. You made an extremely good case for saying one thing is considered to be less safe than the other. Aren't you pushing an open door? And if not, could we have a clear explanation of the obstacles you're facing? It's very obscure.

Dr. Kunze: I take your point first. It's a very valid one. It's freedom of choice. We, from the scientific evidence, say that many smokers are for a certain period of time the freedom of choice is gone. It's an addiction, and it has public health person [phonetic]. Then we look for solutions. But you point is, if you still have the impression it's your choice – free will – then we cannot discuss it. Then we are on different positions.

But there are many people out there – they have done lots of studies on that – who have no more free choice. They are heavily addicted, the same as you were addicted to morphine or whatever. We could discuss endlessly, but it's from different angles. And to the Swedish gentleman, of course the pharmaceutical industry has interest. Everybody wants to make money out of this.

And, of course, you are right, the pharmaceutical industry should be entrusted not to see the ban lifted, modified, or whatever. But I don't whether somebody from a pharmaceutical industry is here right now. And putting it in the perspective of the whole conference, the point is, and therefore I will step into comment, except the invitation is that we talk about risks and SARS and electromagnetic fields and don't talk about the real stuff and the real risks we face is this reduction. I guess the organizers have chosen that topic as an example of where we really can reduce the risk, nevertheless, nobody cares for it.

You're absolutely right; nobody cares for it. So the obstacle that I see is present, that my scientific evidence of risk reduction, I cannot turn into political action. It's a problem. It is completely different than SARS. In SARS you have a couple of people who die, everybody is not okay. But then you have political elections from morning to midnight. Here you can save hundreds of thousands of lives in theory and nobody cares. So the Austrian government doesn't really care for that because it's Sweden. In Sweden they are blond and they are up there and there is [indiscernible].

Mr. Seavey: One way in which I think this does fit into the rest of the conference is that the rest of the conference, in many ways, is about crying wolf and [indiscernible] would be health risk through smoking are the real wolf. Smoking, at least in the U.S., and I'm sure it's the case in a lot of other industrialized countries, is the leading preventable cause of death.

I mean something like a quarter of people who die prematurely die from smoking. And part of the negative impact of all the other crazy pseudo health scares is that it eliminates people's ability to differentiate between big and small risks. You say a lot of smokers – and I sympathize with this reaction on their part – you say to a lot of smokers, "Hey, those cigarettes could kill you. You should stop doing that, that's dangerous." They'll often say, "Well, yeah, but everything's dangerous.

Everything has a warning label these days and everything gives you cancer, so why bother differentiating?" Well, there's a big difference between miniscule or perhaps non-existent cancer risks from pesticide residues on your fruit and the one in six chance that smokers have of getting lung cancer. And to the extent that if we sort of treat all the risks equally, people use their ability to differentiate.

At the same time I do say I'd rather have it all be legal, so you still have individual freedoms to make your choice. But I think you can have freedom of choice and still make the wrong choice. For instance, if there were no lawsuits or regulations related to power lines and electromagnetic fields, I think most of the spiked [phonetic] crowd would still say it would be tragic if people were frightened into thinking power lines were dangerous for giving them cancer. And, therefore, they freely opted to moved away from them and spend money relocating their houses. Even if no law was involved and no coercion, it would still be a tragedy just because they were misinformed and expending unnecessary energy. And likewise, I might want people free to make their own decisions about smoking, but I think it's a tragic and wrong decision if they do smoke.

And furthermore, I'd say people are pretty bad risk calculators in general. How many people here really know, who are [indiscernible] with not just the fatal health effects of smoking, but all the other heavy effects on eyesight and effects on the sinuses and all the other non-fatal things? How many people really know about all that and the odds of the fatal conditions like emphysema and heart disease increase and different types of cancers, including lung cancer? And say, "I've calculated how much joy I get from smoking. I've calculated my odds of premature death, and I've decided smoking is the way to go."

I think most smokers don't have the freedom to think this way. I think most smokers are sort of in denial, trying to ignore the long-term consequences. They say things like, "I know I shouldn't do it, but I'd rather not think about that right now. I'll probably give it up someday." And I might not want to put them in jail or tax them or anything, but I'd like to discourage them from thinking in that rather foolish way.

Roger Bate: Are there any more questions? I think I'll just wrap this up by saying I think it fits in quite well, not because it's . . . in addition to some of the points that you just said. Because I think the regulations which are being pushed through on [indiscernible] in other fields, rely to a certain extent on the same kind of inertia that was actually allowed [indiscernible] the evidence to build up over a decade, without actually overturning this ban.

The fact is it doesn't matter to a certain extent what the scientific evidence shows. And if you like the reciprocal of what we've been hearing, you know that we're banning this type of product or [indiscernible] even if there's no evidence. But in a situation where you have evidence that there is a different type approach that can be taken, whether it's harm reduction or just another product out there, it is ignored because you have the same problem of the way that information is used when it comes to regulation.

So I think it actually does fit in nicely. It has a more just approach than any of the other sessions. Because I think that there's that level of inertia in [indiscernible]. It is now coming up to 20 past or a quarter past four. We start again at 4:30. Thank you all very much for coming and especially thank you for our remaining panelists.

[Applause]

[END OF TAPE]

Statement of John R. Kalmar, D.M.D., Ph.D.

in connection with the hearing on the 3rd day of June, 2003:

I am an oral and maxillofacial pathologist and an associate professor of the College of Dentistry at The Ohio State University. In my opinion, the concept of harm reduction as it relates to the use of tobacco products is one of the most important issues facing oral health care providers today. There is enormous potential for improving public health through increased awareness of the various options available to individuals who currently smoke, including the use of smokeless tobacco products. But to do this, the true benefits and risks associated with these tobacco options have to be weighed *objectively*, *dispassionately* and *openly*. I believe that this type of unbiased public discussion has been lacking in the United States and it is my hope that this written statement will help move our health care community toward that goal in the near future.

By way of professional introduction, I received my dental degree from Southern Illinois University in 1979, followed by a residency in hospital dentistry at the University of North Carolina. I received my specialty training in oral and maxillofacial pathology at Emory University and subsequently earned a Ph.D. in pathology at Emory University in 1989 to complete my formal education. After serving on the faculty at Emory until 1992, I joined the faculty at the Eastman Dental Center and the University of Rochester. In 1999, I accepted my current position at The Ohio State University.

Oral and maxillofacial pathology is the specialty of dentistry concerned with the diagnosis, treatment and scientific study of diseases that affect the face, mouth and jaws. My practice ranges from direct patient examination and clinical consultation (I have over 25 years of experience in oral examination, diagnosis and treatment) to the microscopic diagnosis of thousands of oral biopsy specimens every year. As a faculty member of the College of Dentistry, I have numerous educational responsibilities that range from clinical instruction to lectures to course development and directorship. As a teacher of dental students and dental graduate students and as program director for our graduate program in oral and maxillofacial pathology, I essentially serve as a teacher of teachers. Since I believe that teaching at this level is a very serious undertaking, I spend a great deal of time every month critically reviewing (and then teaching) the most current, scientifically accurate information regarding topics related to oral health. I am an active provider of continuing dental education to dentists and dental specialists, especially in the states of Ohio and New York. I publish articles in peer-reviewed journals and serve on the editorial board of *Oral Surgery, Oral Medicine, Oral Pathology, Oral Radiology and Endodontics*.

During my specialty training in oral pathology, my fellow residents and I were taught that tobacco was a major risk factor for the development of oral cancer. The association was clear and consistent in papers that dealt with smoked tobacco, especially cigarettes. But the association between smokeless tobacco products and oral cancer was much less certain, until a paper published in the New England Journal of Medicine in 1981 originating from the University of North Carolina

reported up to a 47-fold increased risk of oral cancer in a small subset of women from the southeastern U.S. who had used smokeless tobacco for extended periods of time. Following this report, the oral pathology community and dentistry as a whole was concerned that there would soon be hundreds, if not thousands, of cases of oral cancer related to the use of smokeless tobacco. Statistics that suggested increased use of smokeless tobacco products in the U.S. during the early 1980s only fueled this public health concern.

But nothing happened. The projected wave of oral cancers has never materialized.

While in Atlanta for 11 years, we specifically looked for oral cancer in smokeless tobacco users. In that time, I recall one case of oral cancer occurring in an elderly, non-smoking female with a history of prolonged snuff. I looked for over six years in Rochester, New York. Zero cases. In over four years of clinical referrals and examination of over 20,000 oral biopsies in Columbus, Ohio, I am not aware of a single case of oral cancer that was related to the use of smokeless tobacco products. This experience has been reinforced through conversations with other oral pathologists around the U.S. as well as oral surgeons and dentists to whom I have spoken over the past decade.

Was the literature regarding smokeless tobacco wrong?

Hopefully, the literature has just gotten better. Interestingly, in the decade following the New England Journal of Medicine article, the epidemiologic reports relating use of smokeless tobacco to oral cancer were nearly evenly split (7 papers reporting **NO** relationship, 5 papers indicating a relationship). However, in the most recent decade (using better study designs that control for confounding variables and reduce the chance of error), most of the papers (7 out of 8) found **NO** relationship between smokeless tobacco use and the development of oral cancer. This recent literature is highly consistent with my personal clinical and biopsy experience as well as the overwhelming majority of anecdotal reports from dental health care practitioners across the US. Even if one takes the most conservative public health care view, the overall literature regarding smokeless tobacco and oral cancer is, at worst, equivocal. By comparison, the strong link between smoking and an increased risk for oral cancer has been virtually unchallenged in the epidemiologic literature. Not only has smoking been consistently linked to oral cancer, but it also increases the risk for a number of serious conditions unrelated to the use of smokeless tobacco products, including lung cancer, respiratory diseases and cardiovascular disease.

Why should the health care community care about this, let alone our elected officials?

The majority of patients with whom I have talked who smoke are completely unaware of differences in the health risks between the use of cigarettes and smokeless forms of tobacco. Most are reluctant to quit smoking because they think the alternatives are too expensive, ineffective or are just as risky to their health. Furthermore, it seems that most health care practitioners, dentists and physicians alike, are profoundly biased against substituting smokeless tobacco for combustible tobacco as part of a harm reduction strategy. I count myself among those who experienced a knee-jerk, negative reaction when I first heard about this "health care initiative". Yet, when faced with the overwhelming and multifactorial evidence for reduced health risks, I gradually changed my mind. In their defense, some health care practitioners may argue that they cannot recommend something to their patients that they do not consider completely safe. They, however, are missing the point of harm reduction. While they "know" that smokeless tobacco products are inarguably less harmful than smoking, they won't share this knowledge with their patients. Within academic settings, this attitude of "information-withholding-for-their-own-good" would presumably be passed onto students, residents, interns, and fellows who would subsequently disregard their own patients' rights to full knowledge of the relative risk associated with all forms of tobacco.

I believe that we, as members of an enlightened society, should be offering our patients who smoke the most current and complete information available regarding harm reduction and alternatives to smoking. "Quit or die" is **not** the best we can do. Easily repeated sayings such as "tobacco is tobacco is tobacco" not only confuse patients, they are disingenuous. I am doing my best to provide a balanced view to my patients who use cigarettes. I teach the concept of "harm reduction" to our graduate students here at The Ohio State University and provide my opinion at professional dental study clubs and certified dental continuing education courses regarding our current understanding of the relationship between smokeless tobacco and oral cancer, backed up by my own clinical experience. These, however, are baby steps.

In February 2003, a white paper was published by a group of public health advocates and researchers from the United Kingdom, Austria and Sweden entitled *European Union policy on smokeless tobacco. A statement in favour of evidence-based regulation for public health.* In it, the authors recommend that the current European Union ban on smokeless tobacco should be replaced by a regulatory program in which smokeless tobacco could play a significant role, based upon its potential for harm reduction. It occurred to me while reviewing this document that if individuals concerned with public health issues affecting over 350 million people could call for such sweeping policy changes, then it is certainly time for the United States to seriously consider (or reconsider) harm reduction measures that include smokeless tobacco products. Inactivity on this issue will certainly place us behind

the bold, new direction proposed for the European Union. It will also suggest that one of the stated goals of our medical and dental associations, to investigate and institute any and all measures with the potential to improve, if not save, the lives of those who smoke, has qualifiers that may be based more on history and personal bias than current, evidence-based medicine and dentistry.

This is the giant step that I hope we take in the very near future.

Thank you.

Statement of Paul L. Perito
Chairman, President & Chief Operating Officer
Star Scientific, Inc.
Submitted to the House Committee on Energy and Commerce
Hearing – June 3, 2003

I appreciate the opportunity to submit this statement on behalf of Star Scientific to the Committee for its hearing on smokeless tobacco products. While I, like my company, am a relative newcomer to the tobacco industry, my earlier experience as the first Deputy Director of the White House Special Action Office on Drug Abuse Prevention (known as the "Drug Czar" office) allowed me to develop a thorough understanding of the value of harm reduction in impacting the public health. I believe the perspective I gained from that experience, that reducing the harm associated with any addiction or dependence can play a vital role in reducing chronic health problems and premature death, must be embraced by all stakeholders if we are to make real progress in reducing smoking-related disease and death.

There is no dispute that cigarette smoking causes the premature deaths of over 420,000 Americans each year. Both mainstream and environmental tobacco smoke can cause cancer, cardiovascular disease and other health problems. Smokeless tobacco, however, is not burned, and for this reason it contains far fewer toxins than combusted tobacco products. Tobacco specific nitrosamines, or TSNAs, have been identified as one of the two major cancer-causing agents in smoked tobacco, and the most significant toxin group in smokeless tobacco, and the Surgeon General and respected researchers agree. These views encouraged Star to undertake its efforts to find a way to significantly reduce the levels of TSNAs in tobacco leaf. (See the appended *Reduction of TSNAs in Smokeless Tobacco Products: A Serious and Important Public Health Goal*).

Star Scientific, Inc. is a technology-oriented tobacco company with a mission to reduce tobacco toxins. Our company's mission and business plan focuses on the reduction of the toxins that are linked with the staggering morbidity and mortality that results from decades of cigarette smoking. The company is engaged in the development and implementation of scientific technology for the curing of tobacco so as to significantly reduce the formation of carcinogenic toxins present in tobacco and tobacco smoke, primarily the TSNAs. Over several years, the company invested significant time and capital in developing a proprietary tobacco curing technology, and a contractual cultivation and curing program, that reduces major tobacco toxins: TSNAs, and particularly the highly carcinogenic NNNs and NNKs within that group. This patented, non-chemical process, which is implemented by growers who contract with the company and follow instructions for cultivating and curing the tobacco, interferes with the biochemical process in the tobacco leaf that, during curing, results in the formation of TSNAs. As a

result, there is a dramatic and consistent reduction in the TSNA levels of tobacco cured using this patented process.

The Company's first StarCured™ harvest and processing occurred in 1999 and it produced 3.5 million pounds of very low-TSNA, Virginia flue-cured tobacco. At that time it was the only very low-TSNA tobacco available for sale in the United States. Just three growing seasons later, in 2001, Star Scientific processed approximately 20 million pounds of very low-TSNA flue-cured tobacco. We believe it is of great significance that in September 2001, the Department of Agriculture announced that beginning in 2002, only tobacco with reduced TSNA levels would be eligible for full price support from USDA.

At about the same time that Star was scaling up its technology, several seminal papers, particularly those of Lewin et al. and Schildt et al., appeared in the medical literature. These papers, copies of which are appended to this statement, reported that oral cancers were not significantly elevated among users of Swedish smokeless tobacco, or "snus ". Furthermore, these papers suggested that one possible explanation for the minimal risk of oral cancer among Swedish smokeless tobacco users as compared to those using American smokeless tobacco or users in other parts of the world was the special effort made by Swedish producers to reduce the TSNA levels, and to keep them low, by heat sterilization and refrigerated storage prior to sale. It is our understanding that as of 1998, American smokeless tobacco products had total TSNA levels that were as much as 15 times higher than those in Swedish snus, which were then about 10 ppm (parts per million). By 1999, Star was producing Virginia flue-cured tobacco with TSNA levels of roughly 200 ppb (parts per billion) or less, which were substantially lower than those of Swedish snus, .

At about the time Star learned of the results of the Swedish case-control studies on oral cancer and snus use, we also became aware of the fact that cigarette smoking rates among Swedish men (17.9%) were probably among the lowest in the developed world, a dramatic reduction from the same smoking rates (36%) twenty years before. During the intervening two decades a transition in tobacco use occurred, and 20% of Swedish men were now users of snus. Further, among Swedish men, cardiovascular disease and lung cancer deaths have fallen. In contrast, snus use was not common among Swedish women: their smoking rates were higher than those of their male counterparts, and not substantially lower than women in other European countries. Their lung cancer rates continued to rise. Star reasoned that snus was not used by women because women, more than men, found the need for frequent expectoration esthetically unacceptable. It reasoned further that a product more acceptable to women might result in reduced smoking and associated reductions in smoking-related medical problems. **Star does accept the evidence that smokeless products are associated with substantially fewer health hazards than smoking.** Star set about to develop a smokeless product that would not require

expectoration. This effort led to the development of a compressed smokeless tobacco prduct brand-named Ariva™.

In 2001, Star Scientific introduced three new smokeless tobacco products, Stonewall™ moist and dry snuffs, and Ariva™ powdered compressed tobacco cigalett™ pieces. Unlike most U.S. smokeless tobacco products, the tobacco content in these products is 100% StarCured™ flue-cured tobacco. These smokeless tobacco products have TSNA levels that Star believes are lower than those found in any smokeless tobacco product sold throughout the world. This is of particular significance, for as we stated above, a number of researchers believe that TSNAs are the major group of toxins in smokeless tobacco.

Stonewall™ moist and dry snuffs are similar to smokeless tobacco products that are currently marketed widely throughout the United States. The ingredients in Ariva™ are identical to those in Stonewall™ dry snuff, and the difference between these products is solely that the dry snuff has been compressed into the Ariva™ cigalett™ bits. Ariva™ was developed to address the need of dependent adult smokers of both genders who find themselves in situations where they cannot, or choose not, to smoke – in front of children and family members, in the workplace and during travel, for example.

All of Star Scientific's smokeless tobacco products contain natural and artificial flavors and ingredients that are commonly found in other commercially marketed smokeless tobacco products. Because Star Scientific uses only non-fermented tobacco in its smokeless tobacco products, these products contain lower levels of other toxins, in addition to TSNAs, that are commonly associated with smokeless tobacco products. Also, because the StarCured™ tobacco curing process substantially prevents the formation of TSNAs at the time that the tobacco is cured, the process also retards the residual formation of TSNAs as the tobacco ages, which typically occurs in other smokeless tobacco products, particularly where product is maintained or stored at room temperature.

Star's development of non-fermented smoke-free tobacco products that also have extremely low TSNA levels represents the goal urged by the Massachusetts Department of Public Health in its 2001 report on the popular smokeless tobacco products then available in the U.S.:

> *Research on animal exposure to TSNAs shows a dose response relationship between exposure levels and the incidence of oral tumors. Human data has also found the dose response relationship between the length of oral snuff use and the risk of developing oral cancer. These data strongly suggest that the lowering of TSNA levels in oral snuff could reduce the risk to oral cancer but not eliminate it…*

> *According to the 2000 Surgeon General's Report, if new technology exists that can significantly reduce levels of known carcinogens in a tobacco product, then that technology should be used…*
>
> *There can be no excuse for this failure to remove a known toxin from an already hazardous product, when this technology exists and US manufacturers should respond immediately.*

When the American Health Foundation (recently renamed the Institute For Cancer Prevention) measured TSNA levels in a number of smokeless tobacco products for the Massachusetts Department of Public Health in 2001, Star Scientific's first smokeless tobacco product, Stonewall™ moist snuff, was not ready for production. However, within a few months, Star Scientific shipped a sample of Stonewall™ moist snuff to the American Health Foundation for testing. It is our understanding that those tests revealed the lowest TSNA levels that they had ever measured. Compared with the low levels achieved by Swedish Match in developing its low-TSNA snus (10 parts, or even 3 parts, per million), the Stonewall™ and subsequent Ariva™ samples that were tested by American Health showed that they contained TSNA levels of less than 0.2 part per million, or 200 parts per billion. A series of charts showing the comparison of TSNA levels in smokeless products with Star Scientific's Ariva™ and Stonewall™ products, and several charts showing the annual exposure to carcinogenic TSNAs through the use of various smokeless products including Stonewall™ and Ariva™, are appended.

In an article that appeared in the July 2001 edition of *Chemical Research and Technology*, Dr. Dietrich Hoffman, who is regarded as the "dean" of research on tobacco chemistry and carcinogenicity in the United States, reiterated that TSNAs are the major carcinogens in chewing tobacco and snuff and are associated with cancer of the oral cavity of snuff dippers. In the article Dr. Hoffman noted:

> *TSNAs are the major carcinogens in chewing tobacco and snuff and are associated with cancer of the oral cavity of snuff dippers….*
>
> *Star Scientific, Inc. has succeeded in reducing the formation of N-nitrosamines, and especially that of the highly carcinogenic NNK, during curing and aging of tobacco…*
>
> *On the basis of our current knowledge, a drastic reduction of TSNA levels in chewing tobacco and snuff is expected to lower the risk of oral cancer; in fact such low levels of TSNA may be below the threshold level for the induction of tumors in snuff dippers.*

However, it will be of importance to investigate the possible endogenous formation of the carcinogenic TSNA in consumers of the snuff brands that contain only traces of TSNA.

Although the StarCured™ process results in smokeless tobacco products with TSNA levels that are approximately 30 times lower than those found in Swedish snus, and despite the potential correlation between a reduction in TSNA levels and health risks noted by leading toxicologists like Dr. Hoffman, Star Scientific has consistently avoided making any health or therapeutic claims about the use of its smokeless products. The company also has been careful to communicate to adult tobacco consumers that it does not yet have sufficient scientific evidence to demonstrate that a reduction in TSNA levels can be equated with a reduction in health risks. Notwithstanding the extremely low TSNA levels in Ariva, the product packaging does not refer to or describe those levels. However, Ariva™ packaging includes the following warnings on each box:

- **There are no safe tobacco products**
- **Quitting or not starting is your best option**
- **All tobacco products, including Ariva™ contain nicotine, an addictive substance.**

None of the above health warnings are required either by federal legislation, or directives from the Surgeon General. We want to emphasize that all of Star's smokeless tobacco products prominently state that the product is for adult tobacco users only, and that underage sale is prohibited. Further, Star Scientific has assiduously avoided any marketing efforts directed at adolescents. Instead, the company has relied primarily on point of sale materials and communications to distributors and retailers concerning these products. Finally, Star Scientific is the first company to manufacture a smokeless tobacco product (Ariva™) in child resistant packaging, in light of the existing data from Poison Control Centers on the illness caused by toddlers' and young children's accidental ingestion of cigarettes and other nicotine-containing products.

We were the first tobacco company, in 1999, to publicly call for a comprehensive, rational regulatory structure to oversee the manufacture, marketing and sales of all tobacco products by the FDA. At that time, Star's Board of Directors unanimously approved a Policy Statement, which is appended, that remain the guiding principles on which Star bases its efforts. The Statement includes:

- Acceptance that conventionally cured tobacco is a major factor in disease and addiction, and that those who use tobacco should be given incentives and opportunities to quit.

- Support for having the FDA as the lead regulatory agency charged with overseeing the manufacture, sale distribution, labeling and marketing of all tobacco products.

- Support for research by both the federal government and the private sector to identify and understand the complexities of what causes tobacco related disease, to reduce and eliminate those causes, and for setting "benchmarks" for the development of reduced risk and less hazardous tobacco products.

There is abundant evidence, based not only on our own success in reducing TSNA levels, but also on the Swedish experience, that providing reduced-toxin tobacco products to adult smokers is both critical and achievable. A rational and comprehensive regulatory structure can ensure that information about these and all other tobacco products' is fair, balanced and accurate, and that all products are measured by reasoned and consistent standards. A schedule of well-documented tobacco toxins, that includes maximum permissible levels that can be present in a product, may be one effective regulatory strategy. Companies that wish to distribute a tobacco product with the claim that its toxin levels are low enough to qualify it as a "reduced exposure" product should be able to document that the product toxin levels fall below established maximum allowable limits. As one example, the Swedish Match Company, which manufactures and distributes Swedish snuses, developed what is known as the "GothiaTek Standard". This consists of the following listing of well-documented toxins and carcinogens in tobacco, together with their maximum allowable limits in a tobacco product:

Toxin	Limit
Nitrite	3.5 mg/kg
TSNA	5 mg/kg
NDMA	5 ug/kg
BaP	10 ug/kg
Cadmium	0.5 mg/kg
Lead	1.0 mg/kg
Arsenic	0.25 mg/kg
Nickel	2.25 mg/kg
Chromium	1.5 mg/kg
ug = microgram or 10^{-6}g. mg/kg ~ parts per million (ppm). ug/kg is equivalent to parts per billion (ppb). Limits based on 50% water content - double the limits for dry weight equivalents.	

Star Scientific would support the development of maximum toxin content at these levels or below.

While this hearing does not address one particular piece of legislation, we were concerned last year when we read some of the language in the legislation (S

2626) sponsored by Senators Kennedy and DeWine. That bill described the possibility of requiring companies to conduct lengthy and complex research using animal models in order to demonstrate a reduction in risk for new products. Our concern centers on the possibility that the standard required to demonstrate risk reduction among smokeless tobacco products could be set so unrealistically high that many reduced-toxin smokeless products would be prevented from entering the marketplace. The tragic consequence of this scenario would leave the adult tobacco user with much the same array of products from which to choose as before regulation, with no opportunity to reduce his or her exposure to tobacco toxins. A regulatory framework that is not based on measuring and disclosing established tobacco toxins would have no impact on the public health.

The fact that legislation still has not been passed has not stopped us, however, from moving forward in what we believe is a responsible fashion. We have believed from the beginning that there must be a level playing field on which all tobacco manufacturers must embrace standards for product manufacture that will expose adult tobacco users to the lowest relative risk possible, given available technologies. Star has listened closely to many thoughtful public health advocates. We believe we have taken a very responsible and conscientious position on our label and labeling for Ariva™. It is ironic, therefore, that these products nonetheless have been criticized by other segments of the public health community who themselves have called for the "development of products that reduce consumer health risks or serve as less harmful alternatives". We concur, and we believe that product evaluation and post-market surveillance should be pursued consistently to avoid any possible unintended consequences of product use.

However, those in the public health community who embrace a "quit or die" philosophy – that the only goal worthwhile pursuing is a tobacco-free world – on the one hand say that reduced-toxin products are important, but on the other, want these products made available without any indication that toxin levels have been reduced lest people think such products are "safe". We are baffled by this reasoning because we have followed the very recommendations of the advocates who now appear to be in favor of keeping Ariva™ and other reduced-toxin products off the market until there is a perfect regulatory structure in place. **It is our firm belief that adult consumers have the right to be given fair, honest and balanced information about all products they may choose to consume, and that companies have the obligation to act responsibly and ethically whether or not that structure is in place.** We have been very impressed with the articles on this topic authored by Professor Lynn Kozlowski at Penn State University and his colleagues, and we append to this statement a copy of a recently published article by Professor Kozlowski on this subject.

A growing segment of the European public health community already has realized and embraced the distinction among tobacco products. There currently is a ban on the sale of smokeless tobacco products among all European Union

(EU) countries, with the exception of Sweden, which made continued snus manufacture and sales within that country a condition of joining the EU. Several months ago the Royal College of Physicians issued a report criticizing this ban and explaining that the use of smokeless tobacco was "between 10 to 1000 times less hazardous than smoking" (we have appended a copy of this document). Shortly thereafter, a group of highly respected public health advocates and researchers released a jointly authored report titled, "European Union Policy on Smokeless Tobacco: A Statement in Favour of Evidence-Based Regulation for Public Health". This document makes a powerful statement about the value of offering adult dependent smokers alternatives that reduce exposure to tobacco toxins:

> *We believe that the partial ban applied to some forms of smokeless tobacco in the European Union should be replaced by regulation of the toxicity of all smokeless tobacco. We hold this view for public health reasons: smokeless tobacco is substantially less harmful than smoking and evidence from Sweden suggests it is used as a substitute for smoking and for smoking cessation. To the extent there is a 'gateway' it appears not to lead to smoking, but away from it and is an important reason why Sweden has the lowest rates of tobacco-related disease in Europe. We think it is wrong to deny other Europeans this option for risk-reduction and that the current ban violates rights of smokers to control their own risks. For smokers that are addicted to nicotine and cannot or will not stop, it is important that they can take advantage of much less hazardous forms of nicotine and tobacco – the alternative being to "quit or die"... and many die.*

Star Scientific's corporate mission is to make available to the adult tobacco user tobacco products that contain significantly reduced TSNA levels compared to products currently available in the market. The company believes that the tobacco industry has an obligation to remove those tobacco toxins that are known to cause harm to the extent it is technologically possible. In the most Surgeon General's August 2000 Report (Executive Summary), this rational concept is succinctly articulated: "...as with other consumer products, tobacco products should be no more harmful than necessary given available technology." Star Scientific, we believe, has the cutting-edge tobacco processing technology for substantially preventing the formation TSNAs levels in flue-cured tobacco, and we have expressed our willingness to license this patented technology, to which we are the exclusive licensees, to others in the industry.

Further, Star Scientific agrees with the public health advocates and physicians in Western Europe cited above that the public has the right to be fully informed about the hazards associated with tobacco consumption. Star Scientific believes that it has been a catalyst for positive change in developing a commercially viable process for consistently producing very low-TSNA tobacco. We also believe that our recently introduced smokeless tobacco products provide a

further catalyst for a change in the way that tobacco products are manufactured and marketed. Our efforts, we hope, have helped push the discussion and debate in Congress on the need for fair and effective FDA regulation of tobacco products. We are committed to continuing to take a leadership role for responsible innovation in the tobacco industry, in the hope that significant tobacco toxin reductions and reasoned regulation will have a positive impact on the public health.

The Reduction of Tobacco Specific Nitrosamines (TSNA's) in Smokeless Tobacco Products: A Serious and Important Public Health Goal

Why It Must and Can Be Done

September 2002

PREFACE

Tobacco use remains this nation's single most preventable cause of disease and death accounting for over 400,000 deaths each year. The vast majority of those deaths are caused by cigarette smoking. When tobacco is burned it produces over 4,000 chemical constituents. There are over 40 cancer-causing agents that have been identified in tobacco smoke. Many other toxins, including various gases, cause cardiovascular disease, chronic obstructive lung disease and numerous other health problems. In addition the smoke produced from cigarettes is also a cause of disease and other health problems in nonsmokers.

Smokeless tobacco products, because they are not burned, have a significant lower level of toxins. However, almost all smokeless tobacco products on the market today contain significantly high levels of tobacco specific nitrosamines (TSNAs), which are considered to be the most significant cancer causing agent in smokeless tobacco products. Smokeless products contain a number of other toxins that may also impact on public health.

As this background paper will establish, nitrosamines and tobacco specific nitrosamines have been a major public health concern as the onset of various forms of cancer. Scientific evidence has clearly established that TSNAs cause cancer in animals. To that end public health authorities have called for the reduction and/or removal of TSNAs from tobacco and tobacco products. Although TSNAs are not the only cancer-causing agents in tobacco, they are considered the leading cancer-causing agents in smokeless tobacco.

Over the last several years Star Scientific has led the way in the development of patented curing technologies designed to significantly reduce TSNAs to almost undetectable levels. Star has also worked to develop products that incorporate that technology, and it has been on the cutting edge of following the recommendation of the public health authorities to provide greater disclosure and warnings about tobacco products, as well as conducting responsible advertising.

Star believes that in addition to the need for fair and equitable regulation of all tobacco products by the Food and Drug Administration, tobacco companies should be encouraged to take responsible actions NOW. Much what we have done, and what we will continue to do, is to stimulate the rest of the industry to consider significant changes that will ultimately benefit public health, establish a level playing field for the future development and regulation of all tobacco products, and move the industry and the products it develops from those high in deadly toxins to those with significantly reduced toxins.

The purpose of this summary is to demonstrate what we know about the science related to tobacco specific nitrosamines (TSNAs), as well as what has been advocated about their reduction and removal. The references in the section are just examples of the far more extensive base of literature on the subject of TSNAs and the need to reduce their levels in tobacco products.

It is of special significance that the preparation of smokeless tobacco products, which entails, curing, fermentation, and aging, occurs under conditions favoring the formation of tobacco-specific N—nitrosamines (TSNA's) from nicotine and other tobacco alkaloids in smokeless tobacco. N-nitrosonornicotine (NNN) and 4-(methylnitrosamino)-1-(3-prydil)-Nutanone (NNK) are strong carcinogens in mice, rats, and hamsters, inducing benign and malignant tumors of the oral cavity, nasal cavity, esophagus, lung, liver, and pancreas (Hecht and Hoffman 1988; Rivenson et al., in press).....The concentration of carcinogenic nitrosamines in smokeless tobacco co exceed those in other consumer products by at least 2 orders of magnitude (US DHHS 1986b).....Carcinogenic TSNA's have been regarded as a major actor for the association of snuff dipping with oral cancer in humans (Craddock 1983). Other carcinogens identified in smokeless tobacco are volatile nitrosamines (N-nitrosodimethylamine), N-nitrosomorpholine, N-nitrosodiethylamine, formaldehyde, crotonaldhyde, and benzo(a)pyrene, as well as trace of the radioactive element polonium-210 (US DHHS 1986; Hoffman et. al. 1987; Chamberlain, Schlotzhauer,Chortyk 1988).

Reducing the Health Consequences of Smoking, 25 Years of Progress, report of the Surgeon General, 1989, page 90.

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We want consumers to be aware that oral snuff made in the United States contains alarming levels of cancer causing agents....If oral snuff manufacturers have the capability to reduce carcinogens in their product, they have the obligation to do it.

Dr. Howard Koh, Commissioner
Massachusetts Department of Public Health
Press Release (August 21,2001)
"MDPH Issues Challenges to U.S. Snuff Makers and Warns Consumers of High Cancer Risk Tied to Smokeless Tobacco"

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Research on animal exposure to TSNA's shows a dose response relationship between exposure levels and the incidence of oral tumors. Human data has also found the dose response relationship between the length of oral snuff use and the risk of developing oral cancer. These data strongly suggest that the lowering of TSNA levels in oral snuff could reduce the risks to oral cancer but not eliminate it.

According to the 2000 Surgeon General's Report, if new technology exists that can significantly reduce levels of known carcinogens in a tobacco product, then that technology should be used.

There can be no excuse for this failure to remove a known toxin from an already hazardous product, when this technology exists and US manufacturers should respond immediately.

Memorandum from Dr. Gregory N. Connolly to Massachusetts Public Health Council, "Informational Update – research on Tobacco Specific Nitrosamines (TSNAs) in Oral Snuff and a Request to Tobacco Manufacturers to Voluntarily Set Tolerance Limits for TSNAs in Oral Snuff": August 21,2001

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TSNAs are the major carcinogens in chewing tobacco and snuff and are associated with cancer of the oral cavity of snuff dippers.

Star Scientific, Inc. has succeeded in reducing the formation of N-nitrosamines, and especially that of the highly carcinogenic NNK, during curing and aging of tobacco.

On the basis of our current knowledge, a drastic reduction of TSNA levels in chewing tobacco and snuff is expected to lower the risk of oral cancer; in fact such low levels of TSNA may be below the threshold level for the induction of tumors in snuff dippers. However, it will be of importance to investigate the possible endogenous formation of the carcinogenic TSNA in consumers of the snuff brands that contain only traces of TSNA.

"The Less Harmful Cigarette: A Controversial Issue. A Tribute to Ernst L. Wynder", Hoffman, Hoffman, El-Bayoumy, **Chemical Research in Toxicology**, Vol. 14, Number 7, July 2001.

* * * *

Nitrosamines are carcinogenic in animals. What level of exposure to these carcinogens do humans have? A 1981 report from the National Academy of Sciences (NAS) estimated per capita exposure is about 1 microgram per day from foods and beverages, mainly from fired bacon and beer. Current exposure is probably closer to 0.1 microgram per day due to successful efforts over the past 20 years to reduce nitrosamine formation in foods and beverages. In contrast, the NAS report estimated an exposure of 17 micrograms per day from cigarette smoking, although use of filters as somewhat lowered smokers' exposure..... An enormous amount of indirect evidence indicates that nitrosamines are human carcinogens. For instance, tobacco-specific nitrosamines are one of the major groups of chemical carcinogens in tobacco products, and no doubt remains about the causal link between tobacco use and cancer.

Nitrosamines and Cancer, Richard A. Scanlan, Ph.D., Dean of research Emeritus and Professor of Food Science, The Linus Pauling Institute,Oregon State University (website).

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The production of tobacco has remained relatively consistent for decades, and little attention has been given to how new and developing technologies can be applied to tobacco. New technologies are already being implemented to significantly reduce the amount of tobacco specific nitrosamines (TSNAs) in tobacco leaf. TSNAs are some of the most significant among the more than 40 carcinogens in tobacco leaf. While many questions remain about the health impact of lower TSNA leaf and genetically modified tobacco, it makes sense to promote the exploration of these technologies under the guidance of agencies such as the USDA, EPA, and FDA to ensure that adequate safety and health controls are in place.....requiring disclosure of additives, ingredients, constituents, pesticides, and toxins (emphasis added) could promote the greater use of US tobacco....

Tobacco Communities at a Crossroad, Preliminary report of the President's Commission on Improving Economic Opportunity in communities Dependent on Tobacco Production While Protecting Public Health, January 26, 2001.

In addition we noted in our preliminary report that numerous technologies have had and will have impacts on the way tobacco is grown, processed and eventually manufactured. Some of these technologies remove toxins from tobacco and reduce the level of nicotine in tobacco. Others involve improving per-acre yields of tobacco and controlling for plant disease. The Commission believes that such technological developments and others may, if handled carefully, have positive economic impacts on U.S. growers and contribute to the public health goals. We agree that through education and training in new technologies, U.S. tobacco growers have an opportunity to improve their competitive position at home and abroad and contribute to public health goals.

Tobacco at a Crossroad, Final report of the President's Commission on Improving Economic Opportunities in Communities Dependent on Tobacco Production While Protecting Public Health, May 14, 2001.

* * * *

.....A major concern of health professionals is the presence of carcinogenic N-nitrosos compounds in smokeless tobacco, which has been demonstrated to cause cancer of the mouth and lip, nasal cavity, esophagus, stomach, and lungs in laboratory animals. Hemoglobin adducts to these carcinogens are measurable in the blood of smokeless tobacco users and, thus, may useful as biomarkers for measuring exposure levels among users. Urinary metabolites of TSNA's have been measured in persons using smokeless tobacco products, and higher levels were associated with oral leukoplakia, indicating greater use of products. Also, levels in snuff users were higher than those using chewing tobacco.

.....Common carcinogens found in smokeless tobacco include TSNAs, PAHs (especially benzo[a]pyrene and polonium –210. The concentration of TSNA's in snuff ranges from 5,280 to 141,000 parts per billion (ppb) which is hundreds of times higher than allowed in other consumer and food products (Connolly). TSNA's are thought to be important carcinogens in smokeless tobacco in Europe and North American. Hecht et al (1986) showed that the oral exposure to NNK and NNN in rates caused lung tumors as well as oral tumors at the site of exposure. A snuff user (10 grams per snuff per day) is exposed to 24-46 ug of TSNA's per day compared to a pack per day smoker who is exposed to, on average, 16 ug of nitrosamines. Snuff use also exposes the user to trace amounts of lead, cadmium, and selenium.

.....In Sweden, there is a very high rate of Swedish snuff use. But the use of snus in Sweden has generally not been associated with oral cavity cancer. Snus is not fermented and so has a much lower level of N-nitrosamines which might be related to the lack of increased risk.

CLEARING THE SMOKE, Assessing the Science Base for tobacco Harm Reduction, Institute of Medicine, January 2001.

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Smokeless tobacco products have been shown to cause nicotine addiction and a number of diseases including mouth cancer. The total concentration of carcinogenic tobacco-specific nitrosamines found is highest in the three leading U.S. brands of moist snuff (which represented ninety-two percent of the market in 1994), varying between 11.0 and 17.2 nanograms per gram. These levels are more than 2,000 times higher than the levels of N-nitrosamines permitted in other products such as bacon or beer.

There are a number of opportunities to make tobacco products less dangerous than they presently are. Among the possibilities that the agency (FDA) should explore, include:

- **Reducing or eliminating tobacco-specific nitrosamines from smokeless tobacco products.**

Tobacco Product Regulation: Context & Issues, Slade, Henningfield. **Food and Drug Law Journal,** Vol. 53 Supplement (1998).

* * * *

The International Agency for Research Against Cancer (IARC), in 1987, published a monograph (number 38) on cigarette smoking which drew attention to the role of nitrosamines in cancer and noted that, in particular, that 4-(methynitrosamino)-1-(3-pyridyl)-1-butamone (NNK) is carcinogenic in several animal species, producing adenocarcinoma of the lung regardless of route of administration. Another nitrosamine N-Nitrosonornicotine (NNN) is an oseophageal carcinogen in similar testing systems.....Other (references) in the early nineties published analysis showing a great diversity between cigarettes from various countries in nitrosamine yields. Nitrosamines correlate with nitrates in tobacco, the nitrates coming from fertilizer and other sources, and nitrosamines being formed during the curing and storage process.

As you can imagine, we find this material (great diversity in the levels of nitrosamines found in various brands around the world) a serious cause for anger as the global tobacco industry, which has the necessary technology to reduce the carcinogenic load of its products, has chosen not to do so, apparently never informed the Product Modification Programme of such data, which we believe they certainly have.

Memorandum by Nigel Gray, submitted to the Select Committtee on Health, House of Commons, United Kingdom, September 1999.

There are a number of opportunities to make tobacco products less dangerous than they are now. for example, an international committee of experts under the supervision of the World Health Organization (WH) could:

Set a ceiling for yields of toxic ingredients such as tobacco specific nitrosamines and specify progressive reductions.

Framework Convention For Tobacco Control, Technical Briefing Series, Paper 2, World Health Organization, 1999.

* * * *

The Massachusetts study reaches two important conclusions. First snuff tobacco manufactured and sold in the United States contains several times the level of cancer-causing nitrosamines as a snuff brand made and sold in Sweden by Swedish Match. Second, the study found that the levels of nitrosamines in the U.S. snuff increase as it ages, but the cancer-causing nitrosamines do not increase with age in the Swedish product. Consumers should be warned to check freshness dates on snuff packages and be made aware that these products become poisonous over time. Unfortunately, no package warning system exists because there is no federal law requiring such warnings.

The Massachusetts study demonstrates that the technology exists to greatly reduce levels of one of the most dangerous carcinogens in snuff tobacco, but that America's largest smokeless manufacturers continue to sell brands – like Copenhagen, Skoal, and Silver Creek – that exceed the levels in comparable products sold in Sweden by more than ten times.

As a result the Massachusetts Department of Health has asked all manufacturers of snuff sold in the state to reduce levels of

nitrosamines. If they fail to do so voluntarily, the Massachusetts Department of Health has indicated it will amend its hazardous substance regulations to require them to do so.

Study Shows American Being Exposed to Higher Levels of Nitrosamines, Press Statement, Campaign for Tobacco Free Kids, August 21, 2001.

* * * *

Proposals Concerning Product Modification:

2. Increase the number of chemical parameters measured by adding benzene, formaldehyde, cyanhydric acid, and *the two most carcinogenic nitrosamines, NNN and NNK.*

5. Decrease the level of the known carcinogenic nitrosamines NNN and NNK in tobacco smoke in all tobacco on the market.

11. Add information on the package about smoke content of formaldehyde, benzene, cyanhydric acid, and the *nitrosamines NNN and NNK.*

Proposals from the Working Group on Tobacco Risk Reduction (Paris France 2002), Society for Research on Nicotine and Tobacco (SRNT) Newsletter, Spring 2002/Volume 8, Number 2.

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Smokers receive very little information regarding chemical constituents when they purchase a tobacco product. Without information about toxic constituents in tobacco smoke, the use of such term as "light" and "ultralight" on packaging and advertising may be misleading to smokers.

As with all other consumer products, adult users of tobacco should be fully informed of the products' ingredients and additives and of any known toxicity when used as intended. Additionally, as with other consumer products, the manufactured tobacco product should be no more harmful than necessary given available technology.

Reducing Tobacco Use: A Report of the Surgeon General, Executive Summary, August 2000.

* * * *

Changes in the agricultural, curing, and manufacturing processes of cigarettes have resulted in an increase over the last several decades in the amounts of tobacco-specific nitrosamines in cigarette smoke. These changes are considered to have contributed to the increase in adenocarcinoma of the lung observed over the past several decades.

Risks Associated with Smoking Cigarettes with Low Machines Measured Yields of Tar and Nicotine, Monograph 13, National Cancer Institute, October 2001.

Legislation should grant FDA the authority to evaluate scientifically, and then through rulemaking process, to decide whether to reduce or where appropriate eliminate the harmful and addictive components of all tobacco products in order to protect the public health.

Legislation should grant FDA authority to *encourage the development of products that reduce consumer health risks or serve as less harmful alternatives and the authority to evaluate scientifically whether new products are actually "less harmful."*

Excerpts from Critical Elements of Any Legislation to Grant FDA Authority to Regulate Tobacco Products, The Campaign for Tobacco Free Kids, American Cancer Society, American Heart Association, American Lung Association, 4/9/02

* * * *

Tobacco-specific nitrosamines (TSNA) are found only in tobacco products and are highly carcinogenic. They are found in chewing tobacco, in smoking tobacco, and in snuff, and they are known to induce tumors of the lung, oral cavity, esophagus, pancreas, and liver.

Tobacco- Specific Nitrosamines: How Nicotine Becomes a Carcinogen, Physicians for a Smokefree Canada, September 1999.

* * * *

The committee believes that harm reduction is a feasible and justifiable public health policy – but only if it is implemented carefully to achieve the following objectives:

- **Manufacturers have the necessary incentives to develop and market products that reduce exposure to tobacco toxicants and that have a reasonable prospect of reducing the risk of tobacco related-related disease;**
- **Consumers are fully and accurately informed of all of the known, likely, and potential consequences of using these products:**

CLEARING THE SMOKE, Assessing the Science Base for Tobacco Harm Reduction, two of several *Principal Recommendations*, Institute of Medicine, January 2001

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Smoking Tobacco, Oral Snuff, and Alcohol in the Etiology of Squamous Cell Carcinoma of the Head and Neck

A Population-Based Case–Referent Study in Sweden

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BACKGROUND. This case-referent study was conducted to elucidate the role of selected exogenous agents in the etiology of head and neck cancer. The factors studied were tobacco smoking, alcohol intake, the use of moist oral snuff, dietary factors, occupational exposures, and oral hygiene. In this first report, the authors discuss the impact of tobacco smoking, the use of oral snuff, and alcohol consumption.

METHODS. The study base was approximately 2 million person-years at risk and consisted of Swedish males age 40–79 years living in 2 geographic regions during the years 1988–1990. A total of 605 cases were identified in the base, and 756 controls were selected by stratified random sampling from population registries covering the base.

RESULTS. Among those who were tobacco smokers at the time of the study, the relative risk of head and neck cancer was 6.5% (95% confidence interval, 4.4–9.5%). After cessation of smoking, the risk gradually declined, and no excess risk was found after 20 years. The relative risk associated with alcohol consumption of 50 grams or more per day versus less than 10 grams per day was 5.5% (95% confidence interval, 3.1–9.6%). An almost multiplicative effect was found for tobacco smoking and alcohol consumption.

CONCLUSIONS. Tobacco smoking and alcohol intake had a strong interactive effect on the risk of squamous cell carcinoma of the head and neck. Moderate alcohol intake (10–19 grams per day) had little or no effect among nonsmokers. No increased risk was found for the use of Swedish oral snuff. ***Cancer* 1998;82:1367–75.** © *1998 American Cancer Society.*

KEYWORDS: tobacco smoking, alcohol, oral snuff, squamous cell carcinoma, head and neck cancer, esophageal cancer, case–referent study, epidemiology.

There is a geographic variation in the incidence of cancer of the head and neck among different countries of the world and among different regions within a country.[1] This indicates that environmental factors may play an important role in the pathogenesis of cancer of the head and neck. In Europe, Sweden has one of the lowest incidences of these cancers. In Sweden, the majority (two-thirds) of patients with squamous cell carcinoma of the head and neck are males. It has been shown previously that tobacco smoking and alcohol intake are major risk factors.[2–4] In Asia, chewing-tobacco causes a high incidence of oral cancers,[5] and in the U.S. there have been reports of oral snuff as a risk factor in oral cancer.[6,7] About 15% of all adult males in Sweden use, or have used for part of their lives, an oral snuff produced

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mainly in Sweden. The snuff is a moist, nonfermented tobacco product originating from the species *Nicotinum tabacum*. It is placed on the gum under the upper lip and is rarely used outside the Scandinavian countries. The "Swedish" moist oral snuff is known to cause reversible white patches on the site of application.[8] The possible association of Swedish oral snuff with cancer of the head and neck has not yet been determined. However, due to potentially carcinogenic substances contained in Swedish oral snuff, a concern regarding such a possible association exists.

To identify possible factors involved in the etiology of cancer of the head and neck (oral cavity, oro- and hypopharynx, larynx, and the esophagus) among men, a population-based case–referent study was performed over 3 years in 2 defined geographic regions in Sweden. Tobacco smoking, oral snuff, alcohol, dietary factors, occupational exposures, and indicators of oral hygiene were investigated. In this first report, we discuss the impact of tobacco smoking, the use of oral snuff, and alcohol consumption.

MATERIALS AND METHODS

The study base was the person-time generated by all men born in Sweden, ages 40–79 years, living in (and included in the population registers of) the Stockholm county or the southern healthcare region of Sweden during the study period January 1988 through January 1991. Thus, the study base was approximately 2 million person-years at risk.

Cases

Efforts were made to identify all incident cases of cancer of the head and neck (squamous cell carcinoma of the oral cavity, oro- and hypopharynx, larynx, and esophagus) that occurred in the study base. Cancers occurring outside the study base were not included. The cases were identified at weekly multidisciplinary conferences at all of the six ear, nose, and throat departments (ENT) where almost all head and neck cancers in the two regions were treated. In addition, patients with esophageal cancers not diagnosed at the ENT departments were reported by all the departments of surgery in the two regions. To identify cases not presented at the conferences or reported from the departments of surgery, information was obtained every second week on the recent reports to the regional cancer registers in Stockholm and in the southern region. About 10% of the cases were identified in this way. Notification of the regional cancer registries about new cancer cases is compulsory for both clinicians and pathologists. Of all cancers of the head and neck, almost 99% are being registered in the regional cancer registries.[9] Cancers identified incidentally at autopsy were not included.

Referents

The referents were selected by stratified random sampling every 6 months during the study period from a computerized population register in each region. Stratification was by region (Stockholm and the southern region) and age (40–54, 55–64, and 65–79 years). The population registers are updated every month.

Interviews

Cases and referents were asked to participate in an interview on life-style and environment. Informed consent was obtained from each subject. The interview followed a structured questionnaire covering smoking history, the use of oral snuff, and alcohol intake as well as dietary factors (food frequencies) and indicators of oral hygiene (the number of toothbrushes used per year and the number of visits to a dentist per year) and occupational exposure. All interviews were conducted by two nurses, one in each of the two regions. The nurses were trained for health interviews and for treating cases and referents alike. Most of the cases were interviewed at the hospital. The cases were interviewed approximately 1 month after diagnosis. The delay was deliberate, to give the patients time to get used to the new medical situation. Referents were usually interviewed in their homes.

Smoking

Lifetime smoking histories included information on the time when a subject began or stopped smoking and the average number of cigarettes, cigarillos, cigars, and grams of pipe tobacco smoked per day during different time periods. Total consumption of smoking tobacco was calculated by adding the quantity of tobacco smoked during different time periods, considering 1 cigarette or cigarillo equivalent to 1 gram and 1 cigar equivalent to 5 grams of tobacco. The mean intensity of smoking was calculated by dividing the subject's total consumption by the duration of smoking. "Ever-smokers" were men who had ever regularly smoked at least 7 grams of tobacco per week. To avoid the possibility that cases would be classified as ex-smokers because they had stopped smoking due to insidious cancer symptoms, subjects were considered current smokers if they smoked 1 year prior to the time of the interview.

Oral Snuff

Oral snuff usage was recorded in a similar way as smoking history, considering men who had ever regularly used 1 package (50 grams) per week as ever-users

TABLE 1
Total Number of Cases Identified, Referents Selected, Numbers Interviewed and Lost, and Reasons for Nonparticipation in the Interviews

	No. (%) of cases	No. (%) of referents
Identified/selected	605 (100%)	756 (100%)
Lost (not interviewed)	60 (10%)	115 (15%)
Refused	17	80
Disabled	9	8
Dead	30	6
Not located	—	21
Other reasons	4	—
Interviewed	545 (90%)	641 (85%)

and men who used oral snuff 1 year prior to the time of the interview as current users. Total consumption, duration, and mean intensity of usage were calculated in the same ways as for smoking tobacco.

Alcohol Intake

Intake of alcoholic beverages 5 years prior to the time of the interview was assessed using a questionnaire slightly modified from Gerhardsson de Verdier et al.[10] It provided information on the intake of beer, wine, and hard liquor, using seven categories of consumption frequency, and the average amount consumed on each occasion. This information was translated into grams of alcohol per day using a data base at the Swedish National Food Administration.[11]

Data Analysis

The referents were selected to provide information on exposure frequencies in the person-time that generated the cases. The relative risk (RR, incidence rate ratio) was calculated by logistic regression analysis.[12] Adjustments were made according to study design for age (three categories) and region (two categories). In some analyses, adjustments were also made for tobacco smoking (current smokers, ex-smokers, and those who never smoked) or alcohol intake (<10, 10–19, 20–49, and ≥50 grams per day), or both. As a check of residual confounding, adjustments were also made for age in 5-year categories, duration of smoking, oral hygiene, and certain dietary factors. The EGRET (1988) computer program from the Statistics and Epidemiology Research Corporation was used to process the data.

RESULTS

A total of 605 cases were identified, and 756 referents were selected. Ninety percent of the cases and 85% of the referents participated in the interviews. Reasons for not participating are shown in Table 1.

The effect of smoking was similar when men who smoked cigarettes only (RR = 3.7, 95% confidence interval [CI] = 2.5–5.5) were compared with those who smoked cigarillos, cigars, or a pipe (RR = 4.1, 95% CI = 2.3–7.4) and those who mixed use of different smoking tobacco (RR = 4.1, 95% CI = 2.8–6.1). Due to there being only two pure cigar smokers in the material, it was not possible to perform the RR analysis for this subgroup. All smoking tobacco was considered together in Table 2, showing the RRs associated with different aspects of smoking. The risk was considerably lower for ex-smokers than for current smokers and was related to time since smoking cessation. No increased risk was found for men who had stopped smoking more than 20 years previously. There was also some association between risk and the mean intensity of smoking. Cessation of smoking was, however, more common among men who smoked only a few cigarettes or grams of tobacco per day than among men with a high daily consumption. To evaluate the impact of the mean intensity of smoking aside from smoking cessation, it was investigated in current smokers: RR = 6.1 (95% CI = 4.0–9.5) for men smoking <15 grams per day, RR = 6.1 (95% CI = 4.0–9.3) for men smoking 15–24 grams per day, and RR = 6.6 (95% CI = 3.4–12.7) for men smoking ≥25 grams per day. This suggested that aside from the effect of smoking cessation, there was little or no impact of mean smoking intensity. If so, the impact of total consumption would essentially reflect an effect of duration of smoking, because total consumption equalled mean intensity multiplied by duration of smoking. As shown in Table 3, smoking cessation and the duration of smoking each had a decisive impact on risk.

The cancer subsites in the interviewed cases were: the oral cavity in 128 cases, the pharynx in 138 cases (75 oropharynx and 63 hypopharynx), the larynx (mainly glottic) in 157 cases, and the esophagus in 123 cases. Analysis by cancer subsite showed similar results, although the relative effect of smoking was more pronounced for cancers of the pharynx and larynx than for cancers of the other subsites. For current smokers, the RRs (with 95% CIs) were as follows: for cancer of the pharynx, RR = 8.5 (4.0–18.2); larynx, RR = 7.5 (3.9–14.2); esophagus, RR = 5.2 (2.6–10.3); and oral cavity, RR = 4.9 (2.6–9.2). For men who had smoked 45 years or longer: pharynx, RR = 10.1 (4.6–22.1); larynx, RR = 7.6 (3.9–14.7); esophagus, RR = 5.4 (2.7–11.0); and oral cavity, RR = 6.3 (3.2–12.4).

Overall, the use of oral snuff had little or no effect on risk, as shown in Table 4. In an analysis performed with the reference category "never-tobacco-users," precision was very low, as there were only 9 cases and 10 referents who had ever used snuff but had never smoked

TABLE 2
Smoking[a] and Relative Risk of Head and Neck Cancer[b] in Swedish Men Ages 40–79 Years

Smoking	No. of cases	No. of referents	Relative risk (95% confidence interval) adjusted for: Design[c]	Relative risk (95% confidence interval) adjusted for: Design[c] + alcohol[d]
Never smoked	44	193	1.0	1.0
Ever smoked	501	448	5.0 (3.5–7.0)	4.0 (2.8–5.7)
Current smokers	385	214	8.4 (5.8–12.2)	6.5 (4.4–9.5)
Ex-smokers	116	234	2.1 (1.4–3.1)	1.9 (1.3–2.8)
Stopped smoking				
1–10 yrs ago	61	75	3.5 (2.2–5.7)	3.2 (2.0–5.2)
11–20 yrs ago	32	76	1.8 (1.1–3.1)	1.7 (1.0–2.9)
≥21 yrs ago	23	83	1.1 (0.6–2.0)	0.9 (0.5–1.7)
Age at start				
<15 yrs	110	77	6.5 (4.2–10.1)	5.0 (3.2–7.9)
15–19 yrs	257	220	5.2 (3.6–7.6)	4.0 (2.7–5.9)
20–24 yrs	101	102	4.4 (2.8–6.7)	3.8 (2.4–5.9)
≥25 yrs	33	49	2.8 (1.6–4.9)	2.6 (1.5–4.6)
Duration of smoking				
<30 yrs	50	156	1.3 (0.8–2.0)	1.2 (0.7–1.9)
30–44 yrs	168	148	4.9 (3.3–7.3)	3.9 (2.6–5.9)
≥45 yrs	283	144	9.3 (6.3–13.8)	7.2 (4.8–10.8)
Total consumption[e]				
<125 kg tobacco	53	145	1.6 (1.0–2.5)	1.5 (1.0–2.4)
125–250 kg tobacco	181	146	5.5 (3.7–8.2)	4.3 (2.9–6.5)
>250 kg tobacco	267	157	7.5 (5.1–11.0)	5.9 (4.0–8.8)
Intensity of smoking[f]				
<15 g tobacco/day	202	211	4.1 (2.8–6.0)	3.4 (2.3–5.1)
15–24 g tobacco/day	230	189	5.5 (3.8–8.1)	4.4 (2.9–6.5)
≥25 g tobacco/day	69	48	6.5 (4.0–10.7)	4.8 (2.9–8.1)
Deep inhalers[g]				
Yes	341	176	8.9 (6.1–13.0)	6.7 (4.5–10.0)
No	41	33	5.3 (3.0–9.3)	3.9 (2.1–7.0)

[a] Cigarettes, cigarillos, cigars, pipe.
[b] Squamous cell carcinoma of the oral cavity, oro- and hypopharynx, larynx, and esophagus.
[c] Age (40–54, 55–64, 65–79 yrs) and region (Stockholm and the South Sweden healthcare area).
[d] Four categories (<10, 10–19, 20–49, ≥50 g alcohol/day).
[e] One cigarette or cigarillo = 1 g, 1 cigar = 5 g.
[f] Total consumption divided by duration of smoking (g per day).
[g] Among current smokers. Data missing for 3 cases and 5 referents.

tobacco. The RR (95% CI) for ever-users of snuff was RR = 4.7 (1.6–13.8). For current users, RR = 3.3 (95% CI = 0.8–12.0), and for ex-users, RR = 10.5 (95% CI = 1.4–117.8), further illustrating the low precision. When former smokers were the reference category, the precision was higher, with 24 cases and 46 referents who had ever used snuff. For ever-users of snuff with this reference category, RR = 1.1 (95% CI = 0.6–1.9). For current users of snuff, RR = 1.4 (95% CI = 0.7–2.8), and for ex-users RR = 0.8 (95% CI = 0.4–1.8). With current smokers as a reference category, the RRs (95% CIs) were as follows: RR = 0.8 (0.5–1.2) for ever-users of snuff, RR = 0.6 (0.3–1.1) for current snuff users, and RR = 1.0 (0.5–2.0) for ex-users.

In an analysis by anatomic subsite, precision was again low. The RRs by subsites are shown in Table 5.

The effect of alcohol intake is illustrated in Table 6. The results suggest a gradual increase in the risk of cancer of the head and neck with increasing alcohol intake. However, moderate alcohol intake (10–19 grams per day) had little or no impact on the risk of cancer in ex-smokers and in men who never smoked (Table 7). Moderate alcohol consumption was found to increase the risk only among current smokers. The joint effect of a high alcohol intake (≥20 grams per day), with an RR of 4.2 and current smoking RR = 6.3, was nearly multiplicative: RR = 22.1.

TABLE 3
Duration of Smoking for Current Smokers and Ex-Smokers and Relative Risk of Head and Neck Cancer in Swedish Men Ages 40–79 Years

	Relative risk (95% confidence interval) No. of exposed cases/exposed referents	
Duration of smoking	Current smokers	Ex-smokers
≥45 yrs	7.3 (4.8–11.0)	4.4 (2.4–8.0)
	247/113	36/31
30–44 yrs	6.1 (3.8–9.8)	2.4 (1.5–4.0)
	120/74	48/74
<30 yrs	2.4 (1.1–5.3)	1.0 (0.6–1.7)
	18/27	32/129

Unexposed (never smokers): 44 cases/193 referents.
Relative risks are adjusted for age (40–54, 55–64, 65–79 yrs), region (Stockholm and the South Sweden healthcare area), and alcohol intake (<10, 10–19, 20–49, ≥50 g alcohol/day).

Analysis by subsite showed the strongest relative effect of alcohol for cancer of the esophagus (RR = 8.6, 95% CI = 3.8–19.2) and pharynx (RR = 8.5, 95% CI = 4.0–18.1) at an alcohol intake of ≥50 grams per day. For the other subsites, the corresponding effects were as follows: oral cavity, RR = 5.7 (95% CI = 2.8–11.9) and larynx, RR = 2.0 (95% CI = 0.9–4.7). The RRs were adjusted for design and smoking, as shown in Table 5.

To check for residual confounding, RRs for smoking, oral snuff, and alcohol (Tables 2, 4, and 5) were adjusted for age in 5-year categories, and RRs for snuff and alcohol (Tables 4 and 5) were also adjusted for duration of smoking. This, however, left the results virtually unchanged. In addition, adjustments for dietary intake of calories, protein, fat, carbohydrates, fibers, and vitamins and for indicators of oral hygiene had little or no impact on these results.

DISCUSSION

The possibility of bias due to identification of cases and selection of referents is important in any case–referent study. To avoid such bias in the current study, we made efforts to identify all incident cases of head and neck cancer that occurred during the study period in a population defined by age, gender, and residence. This was facilitated by close cooperation with the clinicians involved and by the availability of population-based cancer registries. In addition, the referents were selected from continuously updated registers of the base population for the purpose of obtaining a representative sample of the person-time that generated the cases.

The interviews were completed by 90% of the cases identified and by 85% of the referents selected. Thus, even a substantial difference in exposure between those interviewed and those not interviewed would only have changed our results modestly. To avoid differential misclassification, the interviewers were trained to ask the questions in such a way that any impact of the disease on the answers would be minimized. However, for medical reasons, there were differences in the interviews. The cases were mostly interviewed at the hospital and the referents were usually interviewed in their homes. The cases were interviewed about 1 month after diagnosis but had experienced symptoms for some time prior to diagnosis. Some cases could have reduced (or increased) their tobacco or alcohol consumption due to such symptoms. To avoid this source of bias, exposure information for cases and referents did not include smoking and oral snuff usage during the last year prior to the interview, and information was obtained on alcohol intake 5 years prior to the interview. However, smokers who have reduced their smoking tend to underreport their past smoking.[13] Thus, if our cases had reduced their smoking due to symptoms of disease, smoking cases could have underestimated the number of cigarettes they smoked per day in the past. This would result in some underestimation of the effect of mean intensity of smoking in the current study. Underreporting of alcohol intake is another possibility. Patients with a serious disease (our cases) could be less likely to underreport their alcohol intake than healthy subjects (our referents). If exposed referents were classified as unexposed, the effect of alcohol intake would be overestimated. If highly exposed referents were classified as moderately exposed, the effect of a high alcohol intake would also be overestimated, but the effect of moderate alcohol intake would be underestimated.

Tobacco smoking has previously been shown to increase the risk of several cancers, including squamous cell carcinoma of the head and neck. We found a fourfold increased risk for ever-users of smoking tobacco (RR = 4.0, 95% CI = 2.8–5.7) for all sites. This was well in accordance with the results of other studies.[14–17] Mean intensity of smoking had little or no impact, but the risk increased with the duration of smoking. Similarly, Rothman et al. found only a minor difference in risk according to mean intensity, whereas Brugere et al. found a strong correlation between intensity and risk.[17,18] However, whether the intensity indicated is the mean intensity or current intensity is unclear. In results similar to those of our study, Blot et al. found a smaller difference in risk regarding intensity of smoking as compared with duration of the habit. Their risk estimates were generally lower than ours.[14,18] Bundgaard et al. found that the risk of oral

TABLE 4
Oral Snuff Usage and Relative Risk of Head and Neck Cancer in Swedish Men Ages 40–79 Years

			Relative risk (95% confidence interval) adjusted for	
Oral snuff usage	No. of cases	No. of referents	Design[a]	Design[a] + alcohol[b] and smoking[c]
Never used	462	550	1.0	1.0
Ever used	83	91	1.1 (0.8–1.5)	1.1 (0.7–1.5)
Current users	43	50	1.0 (0.7–1.6)	1.0 (0.6–1.6)
Ex-users	40	41	1.2 (0.8–1.9)	1.2 (0.7–1.9)
Age at start				
<25 yrs	39	43	1.1 (0.7–1.7)	1.0 (0.6–1.6)
≥25 yrs	44	48	1.1 (0.7–1.7)	1.1 (0.7–1.8)
Duration of usage				
<30 yrs	52	59	1.1 (0.8–1.7)	1.0 (0.7–1.6)
≥30 yrs	31	32	1.1 (0.7–1.9)	1.1 (0.6–2.0)
Total consumption				
<125 kg	57	63	1.1 (0.8–1.7)	1.0 (0.7–1.6)
≥125 kg	26	28	1.1 (0.6–1.9)	1.1 (0.6–2.0)
Intensity of usage[d]				
≤50 g/week	45	57	1.0 (0.6–1.4)	0.8 (0.5–1.3)
>50 g/week	38	34	1.4 (0.9–2.3)	1.6 (0.9–2.6)

[a] Age (40–54, 55–64, 65–79 yrs) and region (Stockholm and the South Sweden healthcare area).
[b] Four categories (<10, 10–19, 20–49, ≥50 g alcohol/day).
[c] Three categories (never smokers, ex-smokers, current smokers).
[d] Total consumption divided by duration of usage (g per week).

TABLE 5
Oral Snuff Usage and Relative Risk of Head and Neck Cancer in Swedish Men Ages 40–79 Years by Site

	Oral cavity		Larynx		Esophagus		Pharynx	
Oral snuff usage	Cases/referents	RR[a]	Cases/referents	RR[a]	Cases/referents	RR[a]	Cases/referents	RR[a]
Never used	103/550	1.0	133/550	1.0	103/550	1.0	123/550	1.0
Ever used	25/91	1.4 (0.8–2.4)	24/91	0.9 (0.5–1.5)	19/91	1.2 (0.7–2.2)	15/91	0.7 (0.4–1.3)
Current users	10/50	1.0 (0.5–2.2)	15/50	1.0 (0.5–1.9)	10/50	1.1 (0.5–2.4)	8/50	0.7 (0.3–1.5)
Ex-users	15/41	1.8 (0.9–3.7)	9/41	0.8 (0.4–1.7)	9/41	1.3 (0.6–3.1)	7/41	0.8 (0.3–1.9)

[a] Relative risk (RR) (95% confidence intervals) are adjusted for age (40–54, 55–64, 65–79 yrs), region (Stockholm and the South Sweden healthcare area), smoking (never smokers, ex-smokers, current smokers), and alcohol intake (<10, 10–19, 20–49, ≥50 g alcohol/day).

cancer increased with current daily consumption of smoking tobacco, but also with lifetime consumption.[15] Tuyns et al., however, found that the risk increased with mean intensity.[19] For supraglottic cancer they found a RR of 2.8 (95% CI = 1.2–6.8) for a mean consumption of 1–7 cigarettes per day and a RR of 24.0 (95% CI = 11.8–48.7) for a mean consumption of more than 26 cigarettes per day. We found a tendency towards a higher RR for deep inhaling of tobacco smoke. This was also reported by Tuyns et al., but only for glottic cancer.[19] It is known that the risk of developing cancer of the head and neck decreases after smoking cessation. Blot et al. and Tuyns et al. found no excess risk after 10 years,[14,19] whereas Spitz et al. found no excess risk later than 15 years after cessation of smoking.[20] We found a gradual decrease in risk up to 20 years after smoking cessation in our study. Some differences were found in the magnitude of the effect for different subsites. This was also in accordance with previous results.[18,19] However, the number of cases in each subsite was small, and the results should therefore be interpreted with caution.

Alcohol intake may increase the risk of head and neck cancer, according to previous studies.[2–4,21–24] Even though alcohol per se is not mutagenic, possible mechanisms for alcohol-related carcinogenesis have

TABLE 6
Alcohol Intake and Relative Risk of Head and Neck Cancer in Swedish Men Ages 40–79 Years

Alcohol intake	No. of cases	No. of referents	Relative risk (95% confidence interval) adjusted for: Design[a]	Relative risk (95% confidence interval) adjusted for: Design[a] + smoking[b]
<10 g/day	385	363	1.0	1.0
10–19 g/day	117	156	1.6 (1.2–2.1)	1.3 (1.0–1.8)
20–49 g/day	171	101	3.8 (2.8–5.2)	2.7 (1.9–3.8)
≥50 g/day	72	21	8.4 (4.9–14.3)	5.5 (3.1–9.6)

[a] Age (40–54, 55–64, 65–79 yrs) and region (Stockholm and the South Sweden healthcare area).
[b] Three categories (never smokers, ex-smokers, current smokers).

TABLE 7
Smoking, Alcohol Intake, and Relative Risk of Head and Neck Cancer in Swedish Men Ages 40–79 Years

Smoking	Relative risk (95% confidence interval) No. of cases/no. of referents Alcohol intake: ≥20 g/day	10–19 g/day	<10 g/day
Current smokers	22.1 (13.0–37.8) 196/62	10.4 (5.9–18.3) 84/51	6.3 (3.7–10.5) 105/101
Ex-smokers	5.4 (2.8–10.2) 34/40	2.2 (1.2–4.1) 26/68	2.4 (1.4–4.1) 56/126
Never smoked	4.2 (1.8–9.7) 13/20	1.2 (0.5–3.1) 7/37	1.0 24/136

Relative risks are adjusted for age (40–54, 55–64, 65–79 yrs) and region (Stockholm and the South Sweden healthcare area).

been discussed by Kato and Nomura.[25] In our study, RR = 5.5 (95% CI = 3.1–9.6) for consumption of more than 50 grams per day, compared with less than 10 grams per day, after adjustment for smoking. A dose-dependent increased risk was found for tumors in the oral cavity, pharynx, and esophagus. These results seemed to be in accordance with other studies.[2,3,26–28] Even though not completely comparable, the magnitude of RRs in our study regarding alcohol consumption were similar to those of other studies. We found different RRs for different subsites of the head and neck. This is also known from others. No significant increased risk was found for tumors in the larynx, even at the highest dose level, suggesting a local effect of alcohol on the mucosa of the upper digestive tract. In this study, supraglottic cancer was not analyzed separately, as the patients in Sweden with supraglottic cancer represent only about 20% of all patients with laryngeal cancer. Others have found an increased risk for supraglottic tumors of the larynx from alcohol consumption.[3,29] Modest consumption of alcohol only had a minor impact on the risk of head and neck cancer. Franchesi et al. got the same result in their study.[2] Hedberg et al. found a significant increase of laryngeal carcinoma among alcoholics as measured by the Michigan alcoholism screening test, even after adjustment for cigarette smoking.[29] We did not classify our patients as alcoholics or nonalcoholics.

Notable is the almost multiplicative effect of combined high exposure to both tobacco smoking and alcohol, with an RR of 22.1 (95% CI = 12.9–37.8). This result has also been found by others.[3,14,15,30,31] Maier et al., for example, found that heavy smoking and drinking together increased the risk 146 times, and Bundegaard et al. found a multiplicative effect (with RR = 80) for more than 20 grams tobacco smoked and more than 5 drinks per day.[3,15] The mechanism behind the pathogenesis is largely unknown. However, there is circumstantial evidence for a genetic link to DNA repair. An increase in numeric and structural chromosomal rearrangements in the normal mucosa of smokers compared with nonsmokers has been recorded.[32] A defect in DNA repair might explain the impact of alcohol on cancer induced by tobacco smoking. On the molecular level, it has been shown that the frequency of p53 mutations among patients with squamous cell carcinoma of the head and neck are higher in smokers than in nonsmokers and even higher in smokers who also drink alcohol.[33] The magnitude of the RR associated with tobacco smoking and alcohol consumption varies among different studies. This may partly be due to differences in the consumption patterns in different parts of the world. We did not investigate the impact of different kinds of smoking tobacco, as the vast majority of smokers in Sweden smoke blond tobacco (dark tobacco is used by less than 1%

of the smoking population). We also did not categorize exposure according to different types of alcoholic beverages, as there is as yet no convincing evidence that nonethanolic ingredients in alcoholic beverages are of any importance in the etiology of head and neck cancer.[24]

Of special interest to the Nordic countries is "Swedish" oral snuff. It is a moist, nonfermented tobacco, mainly produced from dark Virginia tobacco mixed with Kentucky tobacco. It is a special Scandinavian product used mainly in Sweden and to a lesser extent in the other Nordic countries. Outside this geographic area this snuff is virtually not used at all. It is sometimes said that 15% of all males in Sweden use or have used Swedish oral snuff. In our material, 14% of the referents and 15% of the cases had used or were current users of Swedish oral snuff. The consumption is highest among males and the habit is most common in the North of Sweden. This geographic area is a low incidence area for head and neck cancers. In the areas with the highest incidence of cancer of the head and neck (the urban areas of Stockholm, Gothenburg, and Malmö), the consumption of oral snuff is lower. In comparison with countries where oral snuff is seldom used, Sweden has a much lower incidence of head and neck cancer, especially cancer of the buccal mucosa and gingiva.[1] Within the European Union, a discussion is taking place over the role of oral snuff in the etiology of cancer with special concern for cancer of the head and neck. The concern is especially important, as this type of oral snuff is believed to be widely used among male teenagers and it is often being regarded as an alternative to cigarette smoking. Oral snuff contains *N*-nitrosamines with carcinogenic potential. Reports from the U.S. have indicated an increased risk of oral cancer associated with the use of oral snuff,[6,7] and the International Agency of Research on Cancer has concluded that nonsmoking tobacco is hazardous.[34] The prohibition of oral snuff by the European Union member nations has been urged. Sweden has so far been an exception to this prohibition. In our study, relative risks were usually close to RR = 1. Age at start, total number of years of use, and total amount used in a lifetime had little or no impact on RR. A high intensity of usage (>50 grams/week) was associated with moderately, but not significantly, elevated risks: RR = 1.7 (95% CI = 0.8–3.9) for cancer of the oral cavity and RR = 1.9 (95% CI = 0.8–3.9) for cancer of the esophagus. The snuff is known to produce ulceration at the place of application on the gum under the upper lip. Also, white lesions often appear at the place of application. There is no clinical evidence that these lesions transform into malignancies, and the mucous tissue normalizes after cessation of snuff dipping.[8] On the contrary, as mentioned before, cancers of the gingiva or buccal mucosa are very rare, with only 14 cases a year on average in the Stockholm area (1990–1993). Of these, none were located inside the upper lip. The difference in results between the studies by Winn et al. and ours might be related to differences in study techniques.[6,7] The studies by Winn et al. involved referents selected from among patients admitted to hospital for reasons other than cancer. These patients do not necessarily represent the true use of oral snuff in the study base. Also, no consideration of chronic iron deficiency anemia was taken, although it is known that chronic anemia among women can produce squamous cell carcinoma of the upper gastrointestinal tract. The fact that different types of oral snuff contain different amounts of carcinogenic agents, due to both the ingredients used and the production process,[34] is also a plausible explanation for the different results. It is noteworthy that the RR (47.5) for the use of oral snuff found by Winn et al. was based on small numbers of individuals. Before forming public health recommendations or regulations, the RR for squamous cell carcinoma of the head and neck associated with Swedish oral snuff compared with tobacco smoking, as well as the possibility of other yet unknown health risks, has to be considered.

In conclusion, we confirm others' findings of a dose-dependent excess risk of cancer of the head and neck from tobacco smoking and alcohol consumption among Swedish males. Moderate alcohol intake had little or no effect among nonsmokers. No significantly increased RR was found for the use of Swedish oral snuff.

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ORAL SNUFF, SMOKING HABITS AND ALCOHOL CONSUMPTION IN RELATION TO ORAL CANCER IN A SWEDISH CASE-CONTROL STUDY

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The use of oral snuff is a widespread habit in Sweden. We investigated whether the use of Swedish moist snuff leads to an increasing risk of oral cancer. Other risk factors such as smoking tobacco and alcoholic beverages were also investigated. Our study comprised 410 patients with oral cancer, from the period 1980–1989, and 410 matched controls. All subjects received a mailed questionnaire. The response rates were 96% and 91% for cases and controls, respectively. In the study, a total of 20% of all subjects, cases and controls, were active or ex-snuff users. The univariate analysis did not show any increased risk [odds ratio (OR) 0.7, 95% confidence interval (CI) 0.4–1.1] for active snuff users. We found an increased risk (OR 1.8, CI 1.1–2.7) for oral cancer among active smokers. Alcohol consumption showed the strongest risk for oral cancer. Among consumers of beer, an increased risk of 1.9 (CI 0.9–3.9) was found. Corresponding ORs for wine and liquor were 1.3 (CI 0.9–1.8) and 1.6 (CI 1.1–2.3), respectively. A dose-response effect was observed. Although not statistically significant, a multivariate analysis similarly suggested that the most important risk factors were beer and liquor consumption, followed by smoking. *Int. J. Cancer* 77:341–346, 1998.
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Oral cancer is a disease with an increasing incidence and a rising mortality in most West European countries. In males, it is most common in France and India. High rates are also reported from countries in Central Europe, including Switzerland, Slovakia, Slovenia and Hungary. Consistently low rates are reported from Japan, China and countries of Northern Europe. For women, high rates are found in India, countries of Southeast Asia and the United States (Boyle *et al.*, 1995).

During the 1950s, 1960s and 1970s, epidemiological reports noted continuing decreases in the incidence of intraoral cancer, *e.g.*, in the United States, Australia and countries of Western, Central and Eastern Europe (Boyle *et al.*, 1995). Data for more recent time periods, however, suggest that oral cancer is now increasing. A low rate is still reported from Scandinavia, but slowly increasing incidence rates among men even in Sweden and Norway have been reported (Hakulinen *et al.*, 1986). In Sweden, intraoral cancer accounted in 1993 for 1.5% and 0.8% of all malignant tumors among Swedish men and women, respectively (National Board of Health and Welfare, 1992). In Denmark, there has been a steep rise in incidence during the past decades (Hakulinen *et al.*, 1986; Bundgaard *et al.*, 1995). On the other hand, no increase in the incidence for oral cancer has been reported in Finland (Hakulinen *et al.*, 1986).

The relationship between tobacco smoking and alcoholic beverages and oral cancer has been described repeatedly (Bundgaard *et al.*, 1995; Blot *et al.*, 1988; Mashberg *et al.*, 1993; Franceschi *et al.*, 1992). These factors are the 2 strongest individual risk indicators for oral cancer known at present. Regarding some types of smokeless tobacco, *e.g.*, moist snuff, no relation with oral cancer has been established.

Ahlbom (1937) has observed that Swedish patients with buccal, gingival or "mandibular" cancer reported the use of snuff or chewing tobacco more frequently than patients with other types of cancer. Case reports of oral cancer among users of snuff or chewing tobacco also appeared in the United States (Wynder *et al.*, 1957*a*). The first modern epidemiological study concerning smokeless tobacco was conducted by Wynder *et al.* (1957*b*) and indicated an increased risk of buccal and gum cancer in snuff users. Concurrently with the investigation presented here, another Swedish epidemiological study has been performed by Lewin *et al.* (1998), who investigated the role of Swedish snuff for cancer of the oral cavity, pharynx, larynx and esophagus. The results could not confirm any association between cancer and the use of oral snuff.

There are 2 main types of snuff: moist and dry. Moist snuff is mainly used in Scandinavia and the United States, and it is usually kept in the gingival-buccal area. The Swedish moist snuff is a non-fermented variety. The ground tobacco, after addition of salt and water, undergoes a heath treatment which renders it practically free from microorganisms, lowering the risk of nitrate formation and subsequent formation of nitrosamines.

In United States, the moist snuff is a fermented product. The fermentation is a spontaneously occurring biochemical process in the moistened tobacco which causes chemical changes (IARC, 1985).

In Sweden, the use of oral snuff has been a traditional and well-established habit for several decades. Due to concerns about health hazards, it has been vigorously debated within Sweden, especially during the last few years.

The most common snuff type in Sweden is loose moist snuff used as a 1–2 g quid, which is formed by the fingers and generally placed under the upper lip. A portion-bag-packed snuff is now often used, which consists of a 0.5 or 1 g portion of moist snuff. By far, Sweden has the highest *per capita* sales figures in the world for moist snuff. In 1989, 4,850 tons were sold, *i.e.*, 0.6 kg *per capita* (Andersson, 1991), and in 1995 the sale had increased to 5,400 tons.

In our study, the risk for oral cancer was evaluated in relation to exposure to moist snuff, smoking and alcohol. In another report, based on the same material, we shall present the risk for oral cancer according to other factors, *e.g.*, oral infections, dental status, anemias, occupations and occupational exposures.

MATERIAL AND METHODS

Our population-based case-control study included all histopathologically verified squamous cell oral cancer cases (ICD-7 codes 140, 141, 143–145) diagnosed in the 4 most northern counties in Sweden—Norrbotten, Västerbotten, Jämtland and Västernorrland—during 1980–1989 and reported to the Cancer Registry.

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Cases

Of 419 identified patients, 1 was excluded because of wrong diagnosis coding and 8 deceased cases due to lack of relatives. Thus, our study comprised in total 410 cases, distributed as described in Table I. The mean age was 72.3 years for women and 69.6 years for men.

Controls

For each of the 175 living cases, 1 living control was drawn from the National Population Registry. The person closest in age, *i.e.*, with the closest personal identification number, with the same sex and living in the same county, was used. For each of the 235 deceased cases 1 deceased control was selected from the National Registry for Causes of Death. The same matching criteria were used (age, sex, county) and furthermore, deceased controls were matched on year of death.

Assessment of exposure

All of the 350 living subjects received a mailed questionnaire. To obtain information concerning deceased persons, the questionnaire was sent to the next-of-kin defined in the order of husband or wife, child, parent, sibling or other. The specific nature of the investigation was not disclosed, and there was no reference to the disease under study. Instead, the general information given was that different factors of potential importance for health were studied. The questions concerned different exposure factors of possible importance for oral cancer. This report deals with exposure to tobacco and alcoholic beverages, and the following factors were taken into account.

Tobacco exposure. Use of moist snuff, cigarettes, cheroots, cigars and pipe tobacco was covered. The questionnaire mapped both the daily consumption and the time period of smoking. In the analysis, lifetime consumption (kg tobacco) was assessed. All tobacco exposure was expressed in grams of tobacco/day. One cigarette is equivalent to 1 g of tobacco, 1 cheroot to 3 g and 1 cigar to 5 g. One pack of pipe tobacco is equivalent to 50 g of tobacco and 1 pack of moist snuff to 50 g. One quid of moist snuff is estimated to contain 1 g of tobacco. The brand of snuff was also recorded.

An ex-smoker or ex-snuff user was defined as a person who had quit the habit at least 1 year before the diagnosis; for controls, the corresponding year was the year of diagnosis for the respective case. Subjects who had stopped smoking or stopped using moist snuff within the year before diagnosis were coded as current users of tobacco and with a daily consumption corresponding to the actual consumption by the time they quit.

Alcohol exposure. These questions covered the use of light beer (alcohol content less than 4.5 volume %), beer (alcohol content minimum 4.5 volume %), wine and liquor. The questionnaire asked for weekly consumption and if there was any substantial change over the years.

The subjects were asked to estimate the light beer consumption according to 4 alternatives: (1) no light beer at all; (2) 1–9 light beer bottles (33 cl)/week; (3) 10–19 bottles/week; (4) at least 20 bottles/week. Beer consumption was surveyed in a corresponding way with the following 4 alternatives: (1) no beer at all; (2) 1–4 beer bottles/week; (3) 5–9 bottles/week; (4) at least 10 bottles/week.

Estimation of wine and liquor exposure was made with regard both to how often the subjects drank and to the average amount each time. Regarding the frequency of wine drinking, the subjects had to choose between 5 alternatives: (1) never; (2) seldom; (3) about once a month; (4) about once a week; (5) daily. As for the approximate quantity on each occasion, there were 3 alternatives: (1) not more than 1 glass; (2) about 2 glasses; (3) 1 bottle or more. The results of these answers were transformed into a score taking amount and frequency into account. The different categories are described in the Results.

For liquor consumption, the same frequency alternatives were used as for wine, but regarding the quantity per occasion 4 alternatives were given: (1) not more than 1 glass; (2) about 2 glasses; (3) about 37 cl; (4) more than 37 cl. The answers regarding liquor consumption were also transformed into an exposure score.

If the questionnaire was incomplete or a question was obviously misunderstood, the subject was contacted by telephone by a specially trained interviewer who did not know whether the person under investigation was a case or a control, and the data were supplemented according to written instructions. Five persons were unable or unwilling to answer the questionnaire, but accepted a full telephone interview.

After the questionnaire had been completed by the interviewer, the front page including name, personal identification number and address was removed, thus enabling a blind coding of the answers.

Statistical methods

In the univariate and the multivariate analyses, conditional logistic regression was used with 708 subjects and 354 numbers of matched pairs. The calculations were performed using the EGRET program (Epidemiological Graphics Estimation and Testing package, SERC, Seattle, WA). The variables were expressed in categorical forms and the results are presented as the odds ratio (OR) and 95% confidence interval (CI) in the particular category compared with the reference category.

TABLE I – NUMBER OF THE INTERVIEWED FEMALES AND MALES, CASES AND CONTROLS, BEFORE AND AFTER EXCLUDING OF INCOMPLETE PAIRS

	Initially included	Females	Males	Refusers	Remaining after exclusion	Females	Males
Cases	410	134	276	18	354	117	237
Alive	175	53	122	11	143	43	100
Deceased	235	81	154	7	211	74	137
Controls	410	134	276	38	354	117	237
Alive	175	53	122	21	143	43	100
Deceased	235	81	154	17	211	74	137

RESULTS

Of 410 cases, 11 living subjects and 7 next-of-kins to deceased persons refused to participate. Corresponding numbers of refusers for controls were 21 alive subjects and 17 next-of-kins to deceased persons. This gave a response rate of 96% and 91% for cases and controls, respectively. Since we used a matched study design, the 56 refusers and their counterparts were excluded from further analysis, which thus deals with the remaining 708 subjects or 354 matched pairs distributed as described in Table I.

Univariate analyses

Snuff. Of the 708 subjects in this study, 20% were active or ex-snuff users, 67 cases and 72 controls. Only 1 woman reported use of moist snuff. The univariate analysis yielded for active snuff users OR 0.7 (CI 0.4–1.1) and for ex-users of snuff OR 1.5 (CI 0.8–2.9) (Table II). When analyzing only the alive snuff users, the OR for active use decreased to 0.5 (CI 0.2–1.2) and increased for ex-use to 3.0 (CI 0.9–9.4).

When snuff users, active and ex-users, were analyzed according to whether they had smoked or not, increased risks were observed for ex-snuff users regardless of smoking habits, but only significantly increased if the subjects also were active smokers (OR 3.1, CI 1.4–6.8) (Table III). On the other hand, active snuff users did not experience any significantly increased risk regardless of smoking habits (Table III).

To investigate whether a dose-response effect pertained, we divided the snuff users into 2 groups according to lifetime consumption if we were able to assess duration of use. The median value among the controls in kg was calculated to 156.0 kg, which corresponds to about 2 packages (100 g) of snuff per day during

TABLE II - ORs AND 95% CIs FOR THE DIFFERENT VARIABLES CONCERNING TOBACCO AND ALCOHOL CONSUMPTION, UNIVARIATE ANALYSIS

Exposure factors	Ca/Co[1]	OR	95% CI
Oral snuff			
Never snuff user	287/282	1.0	—
Active	39/54	0.7	0.4–1.1
Ex-user	28/18	1.5	0.8–2.9
Ever user	67/72	0.9	0.6–1.4
Smoking			
Never smoker	152/171	1.0	—
Active	122/88	1.8	1.1–2.7
Ex-smoker	80/95	1.0	0.6–1.6
Ever smoker	202/183	1.3	0.9–1.9
Chewing tobacco	5/8	0.6	0.2–2.0
Light beer	148/120	1.4	1.0–2.0
Beer	27/16	1.9	0.9–3.9
Wine	188/168	1.3	0.9–1.8
Liquor	234/202	1.6	1.1–2.3

[1]Ca/Co = cases/controls.

TABLE III - ORs FOR NON-USERS, EX-USERS AND ACTIVE USERS OF SNUFF IN RELATION TO SMOKING HABIT

Snuff use	Smoking	Ca/Co[1]	OR	95% CI
Never snuff user	Never smoker	124/144	1.0	
	Ex-smoker	54/67	0.9	0.6–1.4
	Active smoker	109/71	1.7	1.1–2.6
Ex-user of snuff	Never smoker	9/4	1.8	0.9–3.5
	Ex-smoker	16/13	1.6	0.8–3.4
	Active smoker	3/1	3.1	1.4–6.8
Active snuff user	Never smoker	19/23	0.7	0.4–1.2
	Ex-smoker	15/10	0.6	0.3–1.3
	Active smoker	10/16	1.2	0.6–2.4

[1]Ca/Co = cases/controls.

roughly 30 years. Life consumption over 156.0 kg yielded OR 1.1 (CI 0.5–2.0); less than that, OR 0.8 (CI 0.4–1.5).

The most common tumor site in this material was the lip. When analyzed separately, an increased risk was found for lip cancer (OR 1.8, CI 0.9–3.7) among ex-snuff users. The risk was close to unity for current users. For all other sites combined, a decreased risk was found for active users of snuff with OR 0.4 (CI 0.1–0.9).

No difference in risk was found among the different snuff brands used.

Smoking. Of the subjects in the study, 30% were active smokers and 25% were ex-smokers. Among the cases, 34% were active smokers and 23% ex-smokers. Corresponding numbers among controls were 25% and 27%, respectively. In the group of active or ex-smokers, 76% used cigarettes, 55% used pipe and only 5% used cigars or cheroots.

The univariate analysis showed a statistically significant increased risk for developing oral cancer among active smokers (OR 1.8, CI 1.1–2.7), whereas no increased risk was found for ex-smokers (Table II). A division of ex-smokers into 2 groups according to whether they had stopped smoking for more or less than 10 years, did not yield any increased risk either (data not shown). When analyzing only the alive smokers, the OR for active smoking decreased to 1.7 (CI 0.8–3.3). For ex-smoking, the result did not change.

To investigate whether there was a dose-response effect in the group who could state their extent of consumption, we divided tobacco smokers into 2 groups according to lifetime consumption. The median value among the controls was calculated to 124.8 kg, which corresponds to about 1 package of cigarettes per day during 17 years. Current smokers with >124.8 kg lifetime consumption of tobacco had a significantly increased risk for oral cancer (OR 1.8, CI 1.2–2.8). Lower consumption produced a risk around unity.

When dividing the material according to localization, an increased risk was found among smokers for cancer in the floor of the mouth (OR 8.0, CI 1.0–64.0).

Pipe smokers were also analyzed separately, first regardless of localization, then divided into two groups; lip and other sites. The analysis for all localizations together showed a non-significant OR of 1.2 (CI 0.7–1.9) among ever pipe smokers. The group of pipe smokers was also divided into current and ex-smokers. Among current pipe smokers, significantly increased ORs were produced for all localizations together (OR 2.0, CI 1.1–3.4) and all localizations combined excluding lip (OR 3.1, CI 1.3–7.5), whereas no significantly increased risk was found for lip cancer (OR 1.5, CI 0.7–3.1).

Chewing tobacco. Only 13 individuals (5 cases and 8 controls) were, or had regularly been, users of chewing tobacco (OR 0.6, CI 0.2–2.0) (Table II).

Alcohol. Except for active smoking, some types of alcohol showed the strongest association with oral cancer in this study, as shown in Table II.

Light beer: Our results showed an increased risk for oral cancer among consumers of light beer (OR 1.4, CI 1.0–2.0) (Table II). This risk was particularly strong among those who consumed 10–19 bottles/week (OR 9.7, CI 2.2–43) based on 18 cases and 3 controls. A consumption of ≥20 bottles/week gave a possibly less pronounced increased risk of 4.8 (CI 1.0–23) based on 9 cases and 2 controls.

Beer: An increased risk for oral cancer was found among consumers of beer (OR 1.9, CI 0.9–3.9) (Table II). The individuals who reported beer drinking were divided into 2 groups: one group (22 cases and 13 controls) consumed 1 4 bottles/week and the other group (5 cases and 3 controls) consumed at least 5 bottles/week. In both groups, an increased risk for oral cancer was calculated, with an OR of 1.8 (CI 0.4–7.7) in the high group and an OR of 1.9 (CI 0.8–3.9) in the low group.

Wine: Of the 708 subjects in the study, 356 reported wine drinking. Wine consumption in general did not show a statistically significant increased risk for oral cancer (OR 1.3, CI 0.9–1.8) (Table II). Using a score system taking amount and frequency into account, high consumption gave an OR of 8.6 (CI 1.0–70) (Table IV).

Liquor: Liquor consumption showed an increased risk for oral cancer (OR 1.6, CI 1.1–2.3) (Table II). Among the responders, more than 50% belonged to the group of low consumers. Using the same score system as for wine, significantly increased risks for oral cancer were found among medium and high consumers of liquor (Table IV). The individuals in the medium group showed an OR of 1.6 (CI 1.0–2.7) and those with the highest consumption yielded an OR of 3.6 (CI 1.8–7.2). When analyzing only alive individuals reporting liquor consumption, the OR decreased to 1.1 (CI 0.6–1.8).

The score system described for wine and liquor does not correspond exactly to the amount of beverages consumed. Thus, persons who have consumed relatively small amounts daily tend to accumulate larger amounts during lifetime than those who drink much and seldom. It is unclear whether the frequency of drinking or the total amount consumed is of greatest importance in carcinogenesis. We have also analyzed the total volume consumed without considering the frequency of consumption. In this analysis, we found a similar dose-response effect as in the score analyses (Table IV).

Multivariate analyses

The multivariate analysis is based on ever habits according to snuff use, smoking and alcohol. The most important risk factors

TABLE IV – WINE AND LIQUOR SCORES BASED ON DRINKING HABITS[1]

Amount of wine	Amount of liquor	Rarely	Approx. once a month	Approx. once a week	Daily
≤1 glass	≤1 glass (6 cl)	1	2	3	4
Approx. 2 glasses	Approx. 2 glasses	2	4	6	8
Approx. 75 cl	Approx. 37 cl	3	6	9	12
>75 cl	>37 cl	4	8	12	16
			Ca/Co[2]	OR	95% CI
Wine group	1 = score 1–3		150/132	1.3	0.9–1.8
Wine group	2 = score 4–8		25/32	0.9	0.5–1.8
Wine group	3 = score 9–16		8/1	8.6	1.0–70
Liquor group	1 = score 1–3		125/125	1.3	0.9–2.0
Liquor group	2 = score 4–8		60/53	1.6	1.0–2.7
Liquor group	3 = score 9–16		42/18	3.6	1.8–7.2
Wine group	1 = <75 cl		166/149	1.3	0.9–1.8
Wine group	2 = 75–300 cl		12/14	1.0	0.4–2.4
Wine group	3 = >300 cl		5/2	2.7	0.5–15
Liquor group	1 = <37 cl		152/152	1.4	0.9–2.0
Liquor group	2 = 37–148 cl		47/35	2.0	1.1–3.5
Liquor group	3 = >148 cl		28/9	5.5	2.1–14

[1]The score for amount consumed on each occasion (1–4) was multiplied with frequency scores (1–4) to produce the total score values. ORs were calculated for total score values as well as for total consumption volume per month.–[2]Ca/Co = cases/controls.

TABLE V – ORs FOR ALL EXPOSURE FACTORS, UNIVARIATE AND MULTIVARIATE ANALYSES[1]

Exposure factor	Univariate analysis		Multivariate analysis	
	OR	95% CI	OR	95% CI
Snuff	0.9	0.6–1.4	0.8	0.5–1.3
Smoking	1.2	0.8–1.8	1.1	0.7–1.6
Light beer	1.4	1.0–2.0	1.2	0.7–1.7
Beer	1.9	0.9–3.9	1.5	0.7–3.2
Wine	1.3	0.9–1.8	1.0	0.6–1.5
Liquor	1.6	1.1–2.3	1.5	0.9–2.3

[1]Only subjects with data available for all factors are included.

were beer and liquor consumption followed by smoking (Table V). However, no OR was statistically significant.

To further evaluate if there existed any important interaction between the 3 factors—smoking, oral snuff and alcohol consumption—pairwise analyses were done and results are presented in Tables VI and VII. Smoking tobacco appeared to be a risk factor independent of oral snuff use. For oral snuff use and liquor consumption, the risk decreased with the dose of oral snuff in the group high consumption of alcohol, a tendency not seen in the other alcohol consumption groups (Table VI). Smoking tobacco and liquor appeared to interact with the highest risk in the highest consumption group of both exposures.

DISCUSSION

Our primary aim was to investigate the role of moist snuff in the etiology of oral cancer. The use of this form of tobacco is a widespread and increasing habit in Sweden (Andersson, 1991; Pershagen, 1996), and has been much discussed in recent years.

We also considered it important to investigate the role of the established risk factors of smoking and alcohol, since the incidence of oral cancer is increasing in Sweden, traditionally a low incidence area (Boyle *et al.*, 1995). This trend is especially notable in light of a decrease in smoking habits among men, parallel to the increase in snuff use (Anonymous, 1986; Ramström, 1989).

Thanks to population registries and the national cancer registration in Sweden, this country is particularly suitable for population-based case-control studies. The cases were recruited from the Regional Cancer Registry of Northern Sweden. The Swedish compulsory reporting system for malignant diseases makes it most likely that practically all incident cases in the study base were included.

In Sweden, complete population registries cover the whole population, which permits the use of a control group from the general population, thereby avoiding selection bias. Efficacy in the analyses was increased by using a matched study design controlling for age, sex, county and vital status. The reason for using dead controls is the matter of comparability in data collection between cases and controls, *i.e.*, to obtain similar recall conditions.

In case-control studies, there is always a possibility of recall bias, *e.g.*, a tendency for the cases to remember or express more hazardous exposures than controls. To further reduce this risk, the aim of the study was concealed. Thus, no allusion to the disease under study was made in information given to the subjects. Furthermore, the questionnaire asked for information on many different occupational and other exposure factors, not only tobacco and alcohol habits. Results of other factors of interest will be analyzed and published later.

Oral snuff was not found to be a risk factor for oral cancer in our study. Former snuff users showed a tendency to increased risk, compared with current snuff users who rather had a decreased risk. The reason for this paradoxical finding, also noted by Lewin *et al.* (1998), is unclear but one possibility could be that persons with mucosal problems and perhaps premalignant changes experienced inconvenience while using snuff, and therefore stopped this habit, and thereby constituted a group with a potentially increased risk for oral cancer. The suggested hypothesis that ex-snuff users tend to be current smokers was considered. However, in the presented material, only 1 person had begun smoking after having quit using snuff.

Our finding of a slight but not significantly increased risk for cancer of the lip in users of oral snuff might be in accordance with other findings describing a local mucosal reaction caused by the use of snuff. Studies on the histopathology of mucosal reaction have been carried out in the United States (Smith *et al.*, 1970), Denmark (Roed-Peterson and Pindborg, 1973) and Sweden (Andersson *et al.*, 1989; Axell *et al.*, 1976) whereby epithelial changes have been described, but in most cases, such changes were seen in the outermost layers of the mucosa only. Axell *et al.* (1976), in the material of 114 biopsies from current snuff dippers in Sweden, found no cellular atypia or epithelial dysplasia. Andersson *et al.* (1989) did not find any epithelial dysplasia in biopsies from 252 current Swedish snuff users either.

The manufacturing processes for Swedish and American snuff differ and result in different concentrations of tobacco-specific N-nitrosamines (TSNA). When analyzing nitrosamines in both types of snuff, much higher concentrations were found in American snuff (up to 18-fold higher) compared with Swedish snuff (IARC,

TABLE VI – ORs FOR ORAL CANCER DEPENDENT ON LIFE CONSUMPTION OF ORAL SNUFF, SMOKING TOBACCO AND LIQUOR USE

	Liquor[1]											
	Never liquor			Low consumption			Medium consumption			High consumption		
	Ca/Co[2]	OR	95% CI	Ca/Co	OR	95% CI	Ca/Co	OR	95% CI	Ca/Co	OR	95% CI
Oral snuff[3]												
Never snuff	99/125	1.0		88/92	1.4	0.9–2.1	44/34	2.1	1.1–3.8	33/8	7.4	2.8–20
Low consumption	5/9	1.2	0.3–4.2	6/11	0.7	0.2–2.1	6/4	2.8	0.7–11	5/3	2.7	0.5–13
High consumption	2/2	1.8	0.2–16	17/11	2.6	1.0–6.4	6/9	1.1	0.3–3.7	1/4	0.4	0.0–3.5
Smoking tobacco[4]												
Never smokers	80/100	1.0		50/45	1.2	0.8–1.9	7/11	1.4	0.8–2.6	4/2	4.2	1.8–9.4
Low consumption	15/22	1.0	0.6–1.6	26/31	1.2	0.6–2.1	19/17	1.4	0.7–2.7	4/4	4.0	1.6–9.8
High consumption	8/9	1.4	0.8–2.3	30/31	1.6	0.9–2.9	27/21	2.0	1.0–3.6	30/7	5.7	2.4–14

[1]Liquor consumption. Low: score 1–3; medium: score 4–8; high: score 9–16.–[2]Ca/Co = cases/controls.–[3]Life consumption of oral snuff. Low: life consumption ≤156.0 kg; high: life consumption >156.0 kg.–[4]Life consumption of smoking tobacco. Low: life consumption ≤124.8 kg; high: life consumption >124.8 kg.

TABLE VII – ORs FOR ORAL CANCER DEPENDENT ON LIFE CONSUMPTION OF SMOKING TOBACCO AND ORAL SNUFF

Smoking tobacco[1]	Oral snuff[2]								
	Never snuff			Low consumption			High consumption		
	Ca/Co[3]	OR	95% CI	Ca/Co	OR	95% CI	Ca/Co	OR	95% CI
Never smokers	117/133	1.0		4/8	0.8	0.4–1.6	13/12	1.3	0.6–2.6
Low consumption	48/52	1.2	0.7–1.9	6/7	1.0	0.4–2.1	7/7	1.5	0.6–3.5
High consumption	79/58	1.8	1.1–2.9	10/8	1.5	0.6–3.3	3/2	2.3	0.9–5.6

[1]Life consumption of smoking tobacco. Low: life consumption ≤124.8 kg; high: life consumption >124.8 kg.–[2]Life consumption of oral snuff. Low: life consumption ≤156.0 kg; high: life consumption >156.0 kg.–[3]Ca/Co = cases/controls.

1985). This difference, as well as the 1.5–2-fold higher concentrations of nicotine in American snuff (Djordjevic *et al.*, 1993), may be one explanation why our results differ from American ones on the cancer risk from oral snuff use.

Other forms of locally adapted tobacco have been associated with an increased risk of oral cancer. Thus, in India the chewing of the betel quid, with or without tobacco, is a very widespread habit. The basic betel quid consists of betel leaf, areca nut and lime. Chewing these quids is associated with oral cancer (IARC, 1985). However, these quids differ considerably from Swedish moist snuff, and conclusions drawn from one may not be at all valid for the other.

Our results confirm the earlier findings of smoking and alcohol as risk factors for oral cancer. However, the rather low risk from smoking, as well as the lack of any risk in ex-smokers, are not in accordance with some other studies from Europe. The proportion of current smokers among the cases and controls is, indeed, consistent with Swedish smoking statistics (National Board of Health and Welfare, 1986; Pellmer and Wramner, 1997). Studies from, *e.g.*, Italy, generally show much higher ORs compared with our results (Franceschi *et al.*, 1992). One could speculate that the difference lies in different drinking and smoking habits, different types of cigarettes and perhaps even genetic differences.

The majority of subjects in our study had deceased and the exposure information from relatives could potentially have been inaccurate. Furthermore, the use of deceased controls is a theoretical problem when studying factors such as tobacco and alcohol drinking, which are related to earlier death. For these reasons, we also analyzed the main potential risk factors separately for alive subjects only, *i.e.*, when exposure information was given by the living subjects themselves. This did not lead to significantly different ORs for tobacco exposure, compared to the overall results, but lower ORs were found for alive subjects admitting liquor consumption, indicating recall bias for this group.

In this study, there was no increased risk for ex-smokers for this type of malignancy. This result is in contrast with the findings of a study from Florida, where elevated risks also for ex-smokers were noted (Stockwell and Lyman, 1986). In that study, alcohol data were not known, however, and the data must be interpreted with caution, since alcohol might be an important confounder. In other studies, however, no significantly increased risks among ex-smokers were found (Blot *et al.*, 1988; Mashberg *et al.*, 1993).

Tumors located in the floor of the mouth showed the strongest correlation with smoking in our study. This confirms results from previous studies (*e.g.*, Stockwell and Lyman, 1986).

In our study, cigarette smoking totally dominated the types of smoking habits followed by pipe smoking. The use of cigars and cheroots was too infrequent to permit an evaluation of any association with oral cancer.

Alcoholic beverages turned out to be the strongest risk factor for oral cancer in our study. As in some other studies, (Bundgaard *et al.*, 1995; Blot *et al.*, 1988; Mashberg *et al.*, 1993), the increased risk was confined to beer and liquor, whereas wine drinking only appeared to constitute a risk factor for high consumers as in Italy (Franceschi *et al.*, 1992). The dose-response effect regarding liquor strongly supports this finding.

Tobacco and alcohol may be expected to occur together among many consumers. To investigate the relative importance of each factor a multivariate analysis was performed. Liquor turned out to be the strongest associated factor, followed by beer and light beer, although the ORs did not differ significantly. The differences in the detection of statistically significant differences among the ORs between the multivariate and univariate analyses may be attributable to sample size and intercorrelations between variables.

In conclusion, our results do not support any association between the use of oral snuff and oral cancer. Current smoking was correlated with this disease, but to a lesser extent than in some other studies, mainly from countries with a higher incidence of the disease. For alcohol, our results support earlier findings on beer and liquor as being rather strong risk factors for oral cancer.

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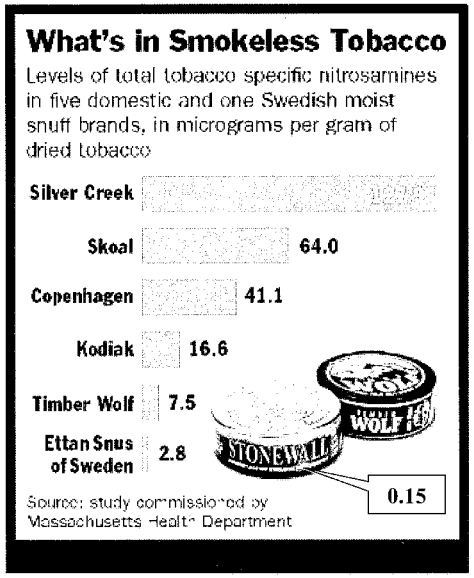
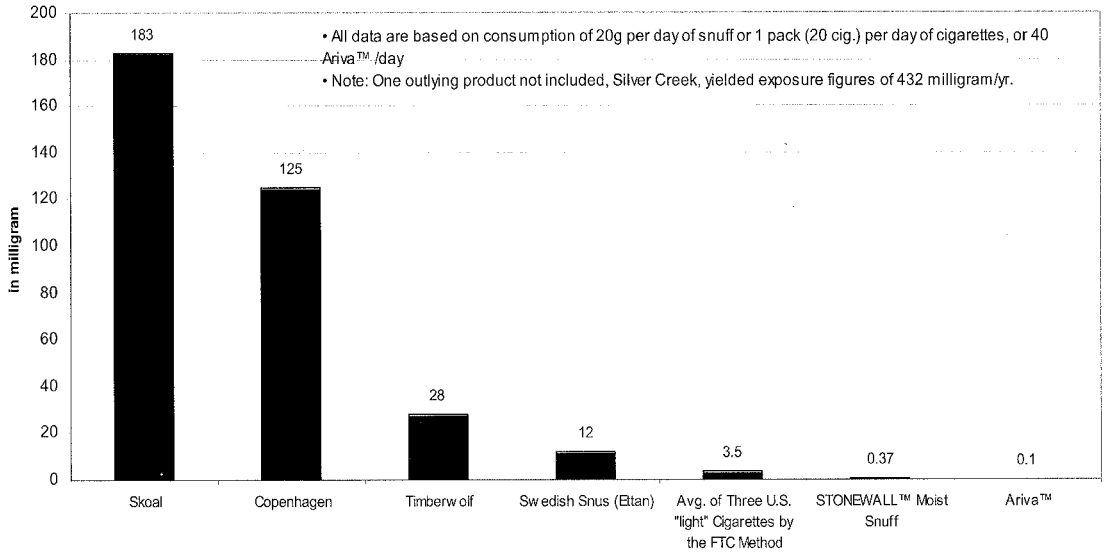
American Health Foundation Test Results



We have added the "0.15" TSNA level. This is based on independent test results reported by the American Health Foundation after this graph appeared in the August 2001 Wall Street Journal story on the MDPH study

Annual Exposure to Carcinogenic TSNAs (NNN + NNK) in Tobacco Products



Sources: Brunnemann, K., Hoffmann, D. Crit. Rev. Toxicol., v. 14, n.7 2001, p.780; Brunnemann, K., Hoffmann, D. "Aging of Oral Moist Snuff and Yields of TSNA", 2001; for Mass. Dept. of Health, August 2001; H. Burton, University of Kentucky; Star Scientific Independent Lab Data

Comparison of Six Smokeless Products
Selected Constituents

	% Oven Volatiles	Nicotine (mg/g)	pH	NNN (ug/g)	NAT (ug/g)	NAB (ug/g)	NNK (ug/g)	Total TSNA (ug/g)
Copenhagen	54.8	33.4	7.6	5.4	6.0	0.29	1.4	13.1
Kodiak	54.4	24.2	8.1	6.3	5.3	0.26	0.8	12.6
Skoal	55.4	32.4	7.6	4.9	5.2	0.25	1.2	11.8
Stonewall Moist	**37.4**	**16.7**	**7.4**	**0.04**	**0.05**	**0.02**	**0.04**	**0.15**
Ariva (per cigalett)	**4.3**	**6.0**	**7.4**	**0.02**	**0.01**	**BDL**	**BDL**	**0.03**
Exalt (data in per pouch	6.3	7.7	6.3	0.47	0.21	0.03	0.12	0.73

University of Kentucky, (January 22, 2002)

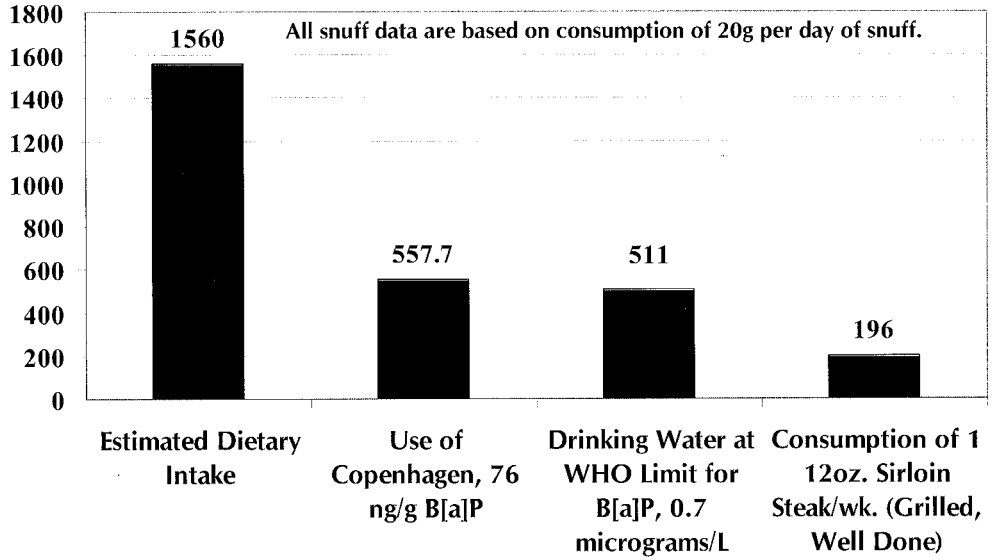
Some Other Toxins in Snuff

Benzo[a]Pyrene [PAHs]

Po^{210}

Formaldehyde

Annual Exposure to Benzo[a]pyrene From Various Sources



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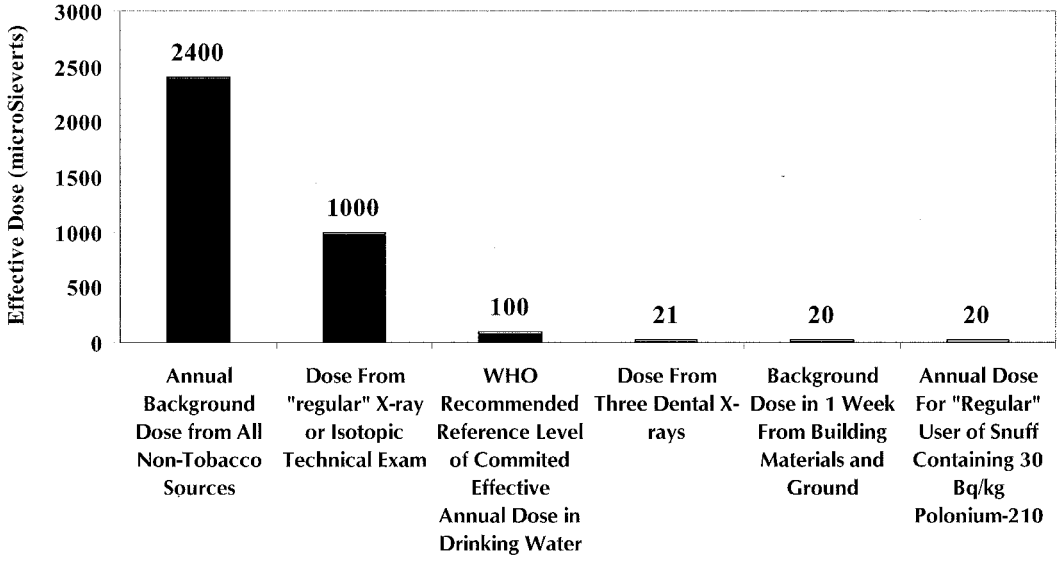
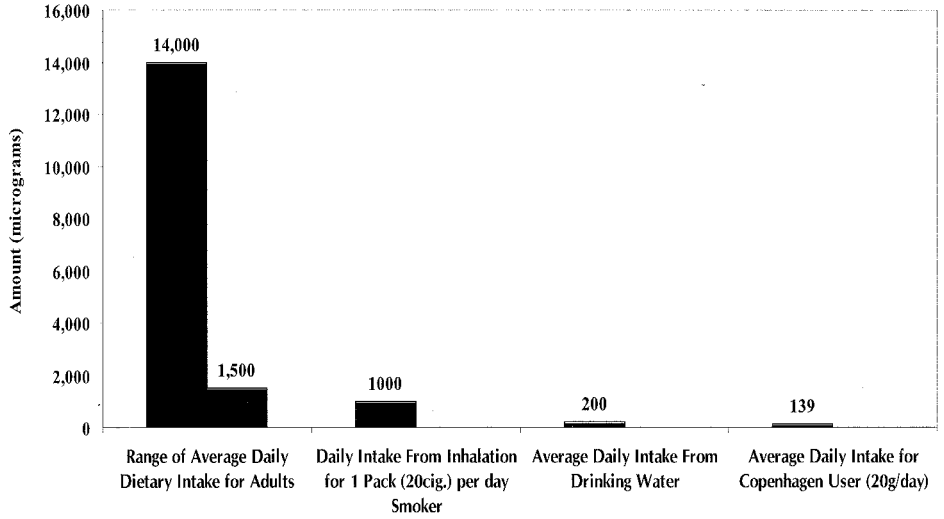
Exposure to Radiation From Various Sources



Sources: Guidelines for drinking-water quality, 2nd ed. Vol. 1. Recommendations. Geneva, World Health Organization, 1993. pp. 114-121; Guidelines for drinking-water quality, 2nd ed. Vol. 2. Health criteria and other supporting information. Geneva, World Health Organization, 1996. pp. 908-915; IARC Monograph, v. 78, 2001;Samuelsson, C. "Medical Consequences of Polonium in Snuff", *The Swedish Medical Journal*, v. 85, Is. 24, 1989.

Exposure to Formaldehyde From Various Sources



Sources: WHO Health and Safety Guide n. 57, Formaldehye, 1991; NCI Monograph on Smoking and Tobacco Control n.2, Smokeless Tobacco or Health,p. 99.

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Perspective

The Less Harmful Cigarette: A Controversial Issue. A Tribute to Ernst L. Wynder

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The dose−response relationship between number of cigarettes smoked and risk for lung cancer was established in 1950 by epidemiological studies. Laboratory assays with tobacco tar on mouse skin and smoke inhalation experiments with hamsters provided further evidence for this relationship. In cigarette smoke, among 4800 identified compounds, 69 are carcinogens, and several are tumor promoters or cocarcinogens. The major toxic agents are nicotine, carbon monoxide, hydrogen cyanide, nitrogen oxides, some volatile aldehydes, some alkenes, and some aromatic hydrocarbons. Public health information and education have led to a reduction of cigarette smokers among U.S. adults from 40 to 25%. However, in high school students, smoking increased to 35% and in adults with less than a high school education it remains high at 33.3%. Intervention studies were augmented with attempts of risk reduction by changing the tobacco composition and makeup of cigarettes. This led to cigarettes that, according to the FTC, reduced the tar and nicotine yields from an average of 37 and 2.7 mg to 12 and 0.85 mg. The anticipated reduction of mortality rates from chronic diseases among cigarette smokers did not occur, primarily, because of a major adjustment in smoking intensity and depth of inhalation by the habitual smokers. It is, therefore, imperative that smoking control efforts are intensified and that, short of banning cigarette sales, cigarettes delivering smoke with the lowest potential for toxicity, addiction, and carcinogenicity are declared a matter of public health policy.

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I. Introduction

In developed countries, lung cancer is the major cause of mortality from cancer in men and women. Despite curative surgery and with the best therapeutic approaches, less than 14% of all lung cancer patients survive 5 years (*1*−*3*). In the United States, smoking contributes to more than 90% of all deaths from lung cancer in men and to about 80% of all deaths from lung cancer in women (*2*, *4*). Cigarette smoking is also causally associated with cancer of the larynx, oral cavity, esophagus, pancreas, renal pelvis, and urinary bladder, and it is linked to cancer of the cervix (*2*−*5*). In the United States in 1991, more than 30% of 514 000 cancer deaths were attributed to cigarette smoking (*5*, *6*). The Surgeon General's report for the year 1989 concluded that cigarette smoking accounted also for 81.8% of all deaths from chronic obstructive pulmonary disease (COPD),[1] for 21.5% of deaths from coronary heart disease (CHD), and for 18% of deaths from stroke (*2*). In 1990, smoking in 44 developed countries, as a whole, was responsible for 24% of all male deaths and 7% of all female deaths. These rates increased to over 40% in men in some East European countries and 17% in women in the U.S. (*7*).

The most promising avenue for the reduction of early death from cancer, COPD, CHD, and stroke among cigarette smokers is the vigorous implementation of comprehensive preventive strategies (*8*). These encompass increased taxation for all tobacco products, severe restriction or, better yet, elimination of advertisements, preventing minors to gain access to any tobacco product, banning of smoking at work sites, in public buildings, and public conveyances. Moreover, such measures would include a mandate for providing young people from kindergarten classes throughout high school with curricula about the harmful effects of smoking and use of other addictive substances. Whereas, scientists and physicians have only indirectly influenced the enactment of antismoking regulations, they should fully participate in interventions aimed at treating tobacco dependence for those who cannot stop smoking on their own.

Clinical smoking cessation programs should include instruction about the specific hazards of smoking and chewing of tobacco. Such instructions are to be conducted by trained psychologists and, where indicated, be accompanied by hypnosis, acupuncture, or treatment with drugs, including nicotine (*8*). In recent years, the development of chemopreventive agents for smoking-related diseases has advanced (*9*, *10*). Such agents could be especially helpful toward reducing the risk for neoplastic disease among ex-smokers. This is an important goal in view of the fact that there are 45 million ex-smokers in the U.S. alone who will face an increased risk for smoking-related cancers compared to the risk of life-long nonsmokers and who never reach the low risk of a nonsmoker (*7*, *8*).

In 1950, there were 55 million cigarette smokers in a U.S. population of 151.3 million and, in 1990, 50.1 million cigarette smokers among 248.8 million U.S. residents. The annual consumption of cigarettes rose from 511.2 billion in 1964, the year of the Surgeon General's first report, to a high of 640 billion in 1981. Since then, annual consumption has declined to 465 billion in 1998 (*11*, *12*). In 1972, consumption of cigarettes per adult (≥18 years) amounted to 3700 in the US, to 3280 in the U.K., and to 3900 in Canada. By 1990−1992, these figures declined to 2670, 2210, and 2540, respectively, and they continue to fall (*1*, *13*). A similar decline of cigarette consumption has occurred in most West European countries (*7*). While this is encouraging, the figures unfortunately also reflect the limited success of smoking cessation efforts. Contrary to the trend of lower cigarette consumption among adults, there has been, since 1990, a significant increase in cigarette use among teenagers and adolescents in the U.S. In 1999, 9.2% of all middle school students and 34.8% of all high school students had smoked cigarettes in the month prior to being surveyed; overall, smoking and/or smokeless tobacco consumption was reported by 12.8 and 38.8% of the students, respectively (*14*).

The concept of "the less harmful cigarette" has been, and continues to be, an alternate approach toward reducing the morbidity and early deaths caused by cigarette smoking. However, "the less harmful cigarette" can, at best, be considered a compromise (*15*). Nevertheless, it is a necessary compromise for smokers who remain addicted to nicotine or will not give up their habit. The tobacco industry appears now to have decided to work toward a modified cigarette. Research on a "less harmful cigarette" actually began about 50 years ago by E. L. Wynder and his associates but it was always fully realized that there can be no "safe cigarette" (*16*).

This article discusses the controversy that has developed ever since the concept of "the less harmful cigarette" has emerged; with emphasis on the chemistry of tobacco smoke. Public health officials and some physicians and scientists were not and are not willing to accept this concept as a compromise. In fact, some scientists strongly opposed efforts toward the development of "the less harmful cigarette". This is evident from the enforced closing of the Tobacco Working Group of the National Cancer Institute (*17*). The major reasons for opposition to the concept of "the less harmful cigarette" lie in the assumption that any cigarette considered to be "less harmful" would inhibit a smoker's incentive to quit and that more of such cigarettes would be smoked. Moreover, the very term "less hazardous cigarette" may entice even more young people to start the addictive cigarette smoking habit. The counter-argument remains that men and women who continue to smoke should find on the market nothing but products with the least toxicity and the lowest carcinogenic activity that can be achieved with advanced science and technology. Those who view "the less harmful cigarette" as a compromise may agree, at least in part, with the sentiment of a 1989 editorial in a leading U.S. newspaper which reads, "Obviously, not smoking is better than smoking, but the best should not be the enemy of the good. There is a strong social case

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[1] Abbreviations: AC, adenocarcinoma; BaA, benz(*a*)anthracene; BaP, benzo(*a*)pyrene; CHD, coronary heart disease; COHb, carboxyhemoglobin; COPD, chronic obstructive pulmonary disease; cpi, cuts per inch; CPS, cancer prevention study; CORESTA, Centre de Coopération pour les Recherches Scientifiques Relatives au Tabac; DMNA, *N*-nitrosodimethylamine; EHC, electrically heated cigarette; ET, expanded tobacco; DMBA, 7,12-dimethylbenz(*a*)anthracene; FDA, Federal Drug Administration; FTC, Federal Trade Commission; GRAS, generally regarded as safe; IARC, International Agency for Research on Cancer; MS, mainstream smoke; NAB, *N*-nitrosoanabasine; NAT, *N*-nitrosoanatabine; NNAL, 4-(methylnitrosamino)-1-(3-pyridyl)-1-butanol; NNK, 4-(methylnitrosamino)-1-(3-pyridyl)-1-butanone; NNN, *N*-nitrosonornicotine; PAH, polycyclic aromatic hydrocarbons; PG, 1,2-propylene glycol; RT, reconstituted tobacco; SCC, squamus cell carcinoma; TSG, tobacco study group; TSNA, tobacco-specific *N*-nitrosamines; TWG, tobacco working group; VNA, volatile *N*-nitrosamines.

for encouraging manufacturers to develop safer cigarettes that will sell" (*18*).

As scientists who have studied "the less harmful cigarette" for many years, we have proposed various ideas toward this concept. Working with the late E. L. Wynder, our group was the first to publish a reproducible bioassay method for estimating the carcinogenic potential of the particulate matter of cigarette smoke. We were the first to isolate from cigarette smoke, in crystalline form, a major carcinogen, benzo(*a*)pyrene (B*a*P). Our group was also the first to report that nicotine gives rise to highly carcinogenic nitrosamines that induce cancer of the lung, upper aerodigestive tract, and pancreas (*1*, *2*). These findings were initially challenged by the industry. Scientists outside the industry also demonstrated, for the first time, that charcoal filter tips have the capacity for selective removal of ciliatoxic smoke constituents and that cellulose acetate filter tips selectivity reduce volatile phenols, which are tumor promoting agents. We reported that during tobacco processing and during smoking a portion of the sucker growth inhibitor maleic hydrazide diethanolamine (MH-30) turns into a strong carcinogen, *N*-nitrosodiethanolamine and that in the course of smoking, as also reported by others, the human carcinogen ethylene oxide is formed from the humectant ethylene glycol. These are only a few findings that have contributed significantly to a better understanding of the chemistry, toxicity, and carcinogenicity of cigarette smoke (*1*, *2*).

In Section II, we summarize our present knowledge of the chemical composition of cigarette smoke, list the known carcinogens in cigarette smoke, and discuss those agents that are likely contributors to the disorders induced by cigarette smoking. Section III presents, in some detail, the changes that have occurred since 1950 in the makeup and the chemical composition of the U.S. cigarette and discusses concurrent changes in the smoke.

II. Chemical Composition and Toxic and Carcinogenic Agents in Cigarette Smoke

In 1950, two large-scale case control studies demonstrated that cigarette smoking is associated with cancer of the lung (*19*, *20*). This finding was supported by the induction of skin tumors in mice treated with cigarette "tar" (*21*, *22*).[2] Moreover, in 1973, the formation of benign and malignant tumors in the larynx of hamsters exposed to whole cigarette smoke confirmed the link (*23*). These reports led to intensive research on the chemical composition of cigarette smoke and to the identification of toxic and carcinogenic agents in the smoke. The high interest in the physicochemical nature of tobacco smoke and in its toxicology and carcinogenicity is reflected in the progressive identification of smoke constituents. In 1959, Johnstone and Plimmer reported that about 600 compounds had been found in cigarette smoke (*24*). In 1968, Stedman listed 1000 smoke compounds (*25*). In 1980, Ishiguro and Sugawara claimed 1889 compounds and in 1988, Roberts listed 3794 cigarette smoke constituents (*26*, *27*). In 1996, Green and Rodgman reported that 4800 compounds had been identified in tobacco smoke (*28*). Roberts listed the identified smoke components according to their functional groups; a slightly modified version of this list is presented in Table 1.

[2] The term "tar" has been chosen as a descriptive noun only. It does not reflect the freshly generated particulate matter in cigarette smoke, but is arbitrarily defined as the portion of the smoke trapped on a Cambridge glass fiber filter CM-20 with water and nicotine deducted.

Table 1. Compounds Identified in Tobacco and Smoke[a,b]

functional groups	no. in tobacco	no. in smoke	no. in tobacco and smoke
carboxylic acids	450	69	140
amino acids	95	18	16
lactones	129	135	39
esters	529	456	314
amides and imides	205	227	32
anhydrides	10	10	4
aldehydes	111	106	48
carbohydrates	138	30	12
nitriles	4	101	4
ketones	348	461	122
alcohols	334	157	69
phenols	58	188	40
amines	65	150	37
N-nitrosamines	23	18	19
sulfur compounds	3	37	2
N-heterocyclics			
pyridines	63	324	46
pyrroles and indoles	9	88	3
pyrazines	21	55	18
non-aromatics	13	43	7
polycyclic aromatic	1	36	0
others	4	50	2
ethers	53	88	15
hydrocarbons			
saturated aliphatics	58	113	44
unsaturated aliphatics	38	178	10
monocyclic aromatics	33	138	25
polycyclic aromatics	55	317	35
pesticides	28	25	25
miscellaneous	112	110	19
inorganics and metals	105	111	69

[a] D. L. Roberts (*27*). [b] Two additional groups have been added, *N*-nitrosamines and pesticides.

Cigarette smoke is composed of a vapor phase and the particulate phase. The vapor phase is arbitrarily defined as that portion of the smoke aerosol which passes through a Cambridge glass fiber filter. The particulate phase is that portion which is trapped on the glass fiber filter. Its particle sizes range from 0.1 to <1.0 μm in diameter. This definition does not fully reflect the conditions prevailing in freshly generated cigarette smoke. Some semivolatile agents, such as phenol for example, appear to some extent in the vapor phase. Some of the substituted phenols, the semi-volatile *N*-nitrosamines, and volatile compounds, such as hydrogen cyanide and low-boiling aldehydes are partially trapped as aerosol inclusions in the particulate matter. The vapor phase accounts for 90–96% of the weight of the mainstream smoke of a nonfilter cigarette with the following compounds as major constituents: nitrogen ~60%, oxygen ~13%, carbon dioxide 13%, carbon monoxide 3.5%, water 2%, argon 1%, hydrogen 0.1–0.2%, acetone ~1%, nitrogen oxides (NO, NO_2, N_2O) < 0.1%, and volatile sulfur compounds likewise < 0.1% (Table 2). Major components of the particulate phase include nicotine (0.2–0.6% of the weight of the total smoke); the remaining Nicotiana alkaloids amount to ~0.02%, and compounds specific to solanaceae, namely *n*-hentriacontane ($C_{31}H_{64}$) and solanesol (0.1–0.2%). In addition, the particulate phase contains catechols (~1%), 3- and 4-ring noncarcinogenic aromatic hydrocarbons (~0.0003–0.007% = 3–7 ppm) and the carcinogenic PAH 0.00002–0.00007% (0.3–0.7 ppm) (Table 3). These relative proportions of smoke components are approximate figures.

Table 2. Major Constituents of the Vapor Phase of the Mainstream Smoke of Nonfilter Cigarettes

compd	concentration/cigarette (% of total effluent)
nitrogen	280–320 mg (56–64%)
oxygen	50–70 mg (11–14%)
carbon dioxide	45–65 mg (9–13%)
carbon monoxide	14–23 mg (2.8–4.6%)
water	7–12 mg (1.4–2.4%)
argon	5 mg (1.0%)
hydrogen	0.5–1.0 mg
ammonia	10–130 μg
nitrogen oxides (NO_x)	100–600 μg
hydrogen cyanide	400–500 μg
hydrogen sulfide	20–90 μg
methane	1.0–2.0 mg
other volatile alkanes (20)[a]	1.0–1.6 mg[b]
volatile alkenes (16)	0.4–0.5 mg
isoprene	0.2–0.4 mg
butadiene	25–40 μg
acetylene	20–35 μg
benzene	6–70 μg
toluene	5–90 μg
styrene	10 μg
other volatile aromatic hydrocarbons (29)	15–30 μg
formic acid	200–600 μg
acetic acid	300–1700 μg
propionic acid	100–300 μg
methyl formate	20–30 μg
other volatile acids (6)	5–10 μg[b]
formaldehyde	20–100 μg
acetaldehyde	400–1400 μg
acrolein	60–240 μg
other volatile ketones (3)	80140 μg
methanol	100–650 μg
other volatile ketones (3)	50–100 μg
methanol	80–180 μg
other volatile alcohols (7)	10–30 μg
acetonitrile	100–150 μg
other volatile nitriles (10)	50–80 μg[b]
furan	20–40 μg
other volatile furans (4)	45–125 μg[b]
pyridine	20–200 μg
picolines (3)	15–80 μg
3-vinylpyridine	7–30 μg
other volatile pyridines (25)	20–50 μg[b]
pyrrole	0.1–10 μg
pyrrolidine	10–18 μg
N-methylpyrrolidine	2.0–3.0 μg
volatile pyrazines (18)	3.0–8.0 μg
methylamine	4–10 μg
other aliphatic amines (23)	3–10 μg

[a] Parentheses show the number of individual compounds identified in a given group. [b] Estimate.

In 1954, Cooper, Lindsey, and Waller identified the polycyclic aromatic hydrocarbon (PAH) BaP as the first carcinogen in cigarette smoke (*29*). Advances in chemical analytical techniques and increased knowledge of genotoxic environmental agents brought the number of carcinogens identified in tobacco smoke to 69 by the year 2000. These include, in addition to BaP, another nine PAH, and four aromatic amines, among them two known human bladder carcinogens; they also include nitrosamines, aldehydes, and several other organic and inorganic compounds (Table 4). The carcinogenic potential of these compounds has been assessed according to the classification of carcinogens by IARC, the International Agency for Research on Cancer (*30*). Accordingly, there are among the identified smoke constituents 69 animal carcinogens; 48 of these are possibly also carcinogenic to humans, 8 are probably carcinogenic to humans, and 11 are proven human carcinogens. Two of these compounds

Table 3. Major Constituents of the Particulate Matter of the Mainstream Smoke of Nonfilter Cigarettes

compd	μg/cigarette
nicotine	100–3000
nornicotine	5–150
anatabine	5–15
anabasine	3–12
other tobacco alkaloids (1.7)[a]	n.a.[d]
bipyridyls (4)	10–30
n-hentriacontaine (n-$C_{31}H_{64}$)	100
total nonvolatile hydrocarbons (45)[b]	300–400[b]
naphthalene	2–4
naphthalenes (23)	3–6[b]
phenanthrenes (7)	0.2–0.4[b]
anthracenes (5)	0.05–0.1[b]
fluorenes (7)	0.3–0.5[b]
pyrenes (6)	0.3–0.45[b]
fluoranthrenes (5)	0.1–0.25
carcinogenic polynuclear aromatic hydrocarbons (11)[c]	80–160
phenol	60–180[b]
other phenols (45)[b]	200–400
catechol	100–200[b]
other catechols (4)	200–400[b]
other dihydroxybenzenes (10)	15–30
scopoletin	n.a.
other polyphenols (8)[b]	40–70[b]
cyclotenes (10)[b]	0.5
quinones (7)	600–1000
solanesol	200–350
neophytadienes 94)	30–60
limonene	n.a.
other terpenes (200–500)[b]	100–150
palmitic acid	50–75
oleic acid	40–110
linoleic acid	150–250
linolenic acid	150–250
lactic acid	60–80
indole	10–15
skatole	12–16
other indoles (13)	n.a.
quinolines (7)	2–4
other aza-arenes (55)	n.a.
benzofurans (4)	200–300

[a] Parentheses show the number of individual compounds identified in a given group. [b] Estimate; n.a., not available.

have not yet been evaluated for their carcinogenicity by the IARC (*15*, *30*).

Of the 69 carcinogens listed in Table 4, all but 1,2-propylene oxide have been identified independently by at least two research teams. Scientists in the industry have confirmed the presence in tobacco smoke of at least 50 of the 69 carcinogens even though they published their findings in many cases several years after the first reports on the identification of such carcinogens in the literature. For example, vinyl chloride, first reported as a tobacco smoke constituent at the 28th Tobacco Chemists' Research Conference in 1975 and published in 1976, was not acknowledged by industry scientists until the 51st Tobacco Chemists' Research Conference in 1997 (*31*, *32*).

However, the turn of events and changing policies of the industry are reflected in the fact that, in 1999, scientists from the Research Laboratories of the R. J. Reynolds Company listed all but 2 of the 69 cigarette smoke carcinogens in their publications. The exceptions were polonium-210 and 1,2-propylene oxide (PO) (*33*–*36*). Levels of ^{210}Po in the lungs of cigarette smokers were found to be generally three times higher than those in the lungs of nonsmokers (*37*). The U.S. National Council on Radiation Protection and Measurement ascribed about 1% of the risk for lung cancer after 50 years of cigarette

Table 4. Carcinogens in Cigarette Smoke[a]

agent	concentration in smoke of nonfilter cigarette	IARC evaluation of carcinogenicity		group[a]
		in lab animals	in humans	
PAH				
benz(*a*)anthracene	20−70 ng	sufficient		2A
benzo(*b*)fluoranthene	4−22 ng	sufficient		2B
benzo(*j*)fluoranthene	6−21 ng	sufficient		2B
benzo(*k*)fluoranthene	6−12 ng	sufficient		2B
benzo(*a*)pyrene	20−40 ng	sufficient	probable	2A
dibenz(*a,h*)anthracene	4 ng	sufficient		2A
dibenzo(*a,h*)pyrene	1.7−3.2 ng	sufficient		2B
dibenzo(*a,e*)pyrene	present	sufficient		2B
indeno(1,2,3-*cd*)pyrene	4−20 ng	sufficient		2B
5-methylchrysene	0.6 ng	sufficient		2B
heterocyclic hydrocarbons				
furan	18−37 μg	sufficient		2B
quinoline[b]	1−2 μg			
dibenz(*a,h*)acridine	0.1 ng	sufficient		2B
dibenz(*a,j*)acridine	3−10 ng	sufficient		2B
dibenzo(*c,g*)carbazole	0.7 ng	sufficient		2B
benzo(*b*)furan	present	sufficient		2B
***N*-nitrosamines**				
N-nitrosodimethylamine	2−1000 ng	sufficient		2A
N-nitrosoethylmethylamine	3−13 ng	sufficient		2B
N-nitrosodiethylamine	ND−2.8 ng	sufficient		2A
N-nitrosodi-*n*-propylamine	ND−1.0 ng	sufficient		2B
N-nitroso-di-*n*-butylamine	ND−30 ng	sufficient		2B
N-nitrosopyrrolidine	3−110 ng	sufficient		2B
N-nitrosopiperidine	ND−9 ng	sufficient		2B
N-nitrosodiethanolamine	ND−68 ng	sufficient		2B
N-nitrosonornicotine	120−3700 ng	sufficient		2B
4-(methylnitrosamino)-1-(3-pyridyl)−1-butanone	80−770 ng	sufficient		2B
aromatic amines				
2-toluidine	30−337 ng	sufficient		2B
2,6-dimethylaniline	4−50 ng	sufficient		2B
2-naphthylamine	1−334 ng	sufficient	sufficient	1
4-aminobiphenyl	2−5.6 ng	sufficient	sufficient	1
N-heterocylic amines				
AaC	25−260 ng	sufficient		2B
MeAαC	2−37 ng	sufficient		2B
IQ	0.3 ng	sufficient		2A
Trp-P-1	0.3−0.5 ng	sufficient		2B
Trp-P-2	0.8−1.1 ng	sufficient		2B
Glu-P-1	0.37−0.89 ng	sufficient		2B
Glu-P-2	0.25−0.88 ng	sufficient		2B
PhIP	11−23 ng	sufficient	possible	2B
aldehydes				
formaldehyde	70−100 μg	sufficient	limited	2A
acetaldehyde	500−1400 μg	sufficient	insufficient	2B
phenolic compounds				
catechol	90−2000 μg	sufficient		2B
caffeic acid	<3 μg	sufficient		2B
methyleugenol[b]	20 ng			
volatile hydrocarbons				
1,3-butadiene	20−75 μg	sufficient	insufficient	2B
isoprene	450−1000 μg	sufficient		2B
benzene	20−70 μg	sufficient	sufficient	1
styrene	10 μg	limited		2B
nitrohydrocarbons				
nitromethane	0.5−0.6 μg	sufficient		2B
2-nitropropane	0.7−1.2 μg	sufficient		2B
nitrobenzene	25 μg	sufficient		2B
misc. organic compounds[c]				
acetamide	38−56 μg	sufficient		2B
acrylamide	present	sufficient		2B
acrylonitrile	3−15 μg	sufficient	limited	2A
vinyl chloride	11−15 ng	sufficient	sufficient	1
DDT	800−1200 μg	sufficient	probable	2B
DDE	200−370 μg	sufficient		2B
1,1-dimethylhydrazine	present	sufficient		2B
ethyl carbamate	20−38 μg	sufficient		2B
ethylene oxide	7 μg	sufficient	sufficient	1
propylene oxide	0−100 ng	sufficient		2B

Table 4. (Continued)

agent	concentration in smoke of nonfilter cigarette	IARC evaluation of carcinogenicity in lab animals	IARC evaluation of carcinogenicity in humans	group[a]
inorganic compounds				
hydrazine	24–43 ng	sufficient	inadequate	2B
arsenic	40–120 μg	inadequate	sufficient	1
beryllium	0.5 ng	sufficient	sufficient	1
nickel	ND–600 ng	sufficient	sufficient	1
chromium (only hexavalent)	4–70 ng	sufficient	sufficient	1
cadmium	7–350 ng	sufficient	sufficient	1
cobalt	0.13–0.2 ng	sufficient	inadequate	2B
lead	34–85 ng	sufficient	inadequate	2B
polonium-210	0.03–1.0 pCi	sufficient	sufficient	1

[a] IARC Monographs on the Evaluation of Carcinogenic Risks. Vol. 1–77 and Suplements 1–8, 1972–2000. (1) Human carcinogens; (2A) probably carcinogenic in humans; (2B) possibly carcinogenic to humans; (3) not classifiable as to their carcinogenicity to humans. [b] Unassigned line in column IARC Evaluation Carcinogenicity in lab animals; so far not reviewed. [c] In 1982, IARC assigned di(2-ethylhexyl)phthalate as sufficient to Group 2B. However, more recently, its carcinogenicity was reevaluated and it was classified as not carcinogenic (IARC, 1982; 2000). [d] Abbreviations: ND, not detected; PAH, polynuclear aromatic hydrocarbons; AaC, 2-amino-9H-pyrido[2,3-*b*]indole; MeAaC, 2-amino-3-methyl-9H-pyrido[2,3-*b*]indole; IQ, 2-amino-3-methylimidazo[4,5-*b*]quinoline; Trp-P-1, 3-amino-1,4-dimethyl-5H-pyrido[4,3-*b*]indole; Trp-2, 3-amino-1-methyl-5H-pyrido[4,3-*b*]indole; Glu-P-1, 2-amino-6-methyl[1,2-*a*:3′,2″-*d*]imidazole; Glu-P-2, 2-aminodipyrido[1,2-*a*:3′,2″-*d*]imidazole; PhIP, 2-amino-1-methyl-6-phenylimidazo[4,5-*b*]pyridine.

Table 5. Probable Causative Agents for Cigarette Smoke-Related Disorders[a]

disorder	contributing agents	possible enhancing or associated agents
tobacco dependence	major: nicotine minor: secondary *Nicotiana* alkaloids, flavor components	acetaldehyde
cardiovascular disease	major: carbon monoxide, nitrogen oxides, hydrogen cyanide, tar minor: cadmium, zinc, carbon monoxide, tar	nicotine, alkylating species
chronic obstructive lung disease	hydrogen cyanide, volatile aldehydes, nitrogen oxides, carbon monoxide, tar	
lung and larynx cancer	major: PAH, NNK minor: ^{210}polonium, formaldehyde, acetaldehyde, butadiene, metals (Cr, Cd, Ni)	catechol, tumor promoters acetaldehydes, diet, alkylating species
oral cavity cancer	major: NNN, NNK minor: PAH	*herpes simplex*, irritation ethanol, diet
esophageal cancer	NNN	ethanol, diet
urinary bladder	4-aminobiphenyl, 2-naphthylamine, other aromatic amines	
pancreas cancer	NNK, NNAL	diet

[a] Abbreviations: PAH, polynuclear aromatic hydrocarbons; NNK, 4-(methylnitrosamine)-1-(3-pyridyl)-1-butanone; NNN, *N*-nitrosonornicotine; NNAL, 4-(methylnitrosamino)-1-(3-pyridyl)-1-butanol.

smoking to ^{210}Po inhaled as a smoke constituent (*38*). Propylene oxide was identified in cigarette smoke in 1999. It is derived, in large part, from 1,2-propylene glycol which is present in cigarette tobacco at a level of ~1%. However, the 1,2-propylene glycol used as a tobacco humectant already contains traces of PO (*36*).

Table 5 presents a list of disorders induced in cigarette smokers, the major and minor contributing agents, and the possible enhancing agents. This table serves as a guide for studies on "the less harmful cigarette"; it makes no claims for completeness (*39*).

III. The Changing Cigarette

Epidemiological studies in the 1950s reported an association of cigarette smoking with cancer of the lung. Mounting epidemiological evidence in the following 3 decades revealed that cigarette smoking was not only causally related to lung cancer but that it was also causally associated with cancer of the larynx, oral cavity, esophagus, pancreas, kidney, and urinary bladder; moreover, it showed an association with cancer of the cervix (*3*). Shopland et al. estimated that out of 514 200 deaths from cancer at all sites, a total of 157 200 (~ 31%) were attributable to cigarette smoking. There were 123 100 (~ 24%) cases of lung cancer among the 514 200 deaths (*5*). Thus, studies on tobacco carcinogenesis have focused primarily on lung cancer (*39*).

Factors regarded to be of major importance in the identification of key lung carcinogens include (1) the unambiguous identification of lung carcinogens in biologically significant amounts, (2) the uptake of significant doses of the suspected lung carcinogen as deduced from reliable biomarkers of exposure in physiologic fluids, (3) the induction of AC or SCC of the lung by the suspected carcinogen in 2 animal species, and (4) in vivo adduct formation of metabolite(s) of the suspected carcinogen with DNA in the lungs of mice and/or rats or at least in vitro DNA adduct formation in human lung cell culture.

On the basis of these criteria, the carcinogenic PAH in cigarette smoke as well as certain TSNA, typified by NNK and NDMA, can be viewed as important and highly relevant lung carcinogens for cigarette smokers.

In addition, consideration needs to be given to several elements that play a role as lung carcinogens in occupational environments. These are arsenic, beryllium,

nickel, chromium, cadmium, cobalt, and polonium-210, albeit most of these are present in tobacco and in cigarette smoke at low concentrations (Table 4). Another group of smoke carcinogens with a likely role as contributors to lung cancer risk in humans are free radicals that induce oxidative DNA damage.

In the 1950s, studies in the U.K. and the U.S.A. reported on the identification of the carcinogen BaP in cigarette smoke. These reports were challenged as merely representing BaP-like UV absorption spectra (*40*). Subsequent tedious analytical work finally led to the isolation and chemical identification of crystalline BaP from the smoke of several thousand cigarettes (*41*). Chemical-analytical studies led to the isolation and identification of the nicotine-derived nitrosamines NNN and NNK that proved to be highly carcinogenic in bioassays (*42*). For more than 10 years, the tobacco industry challenged the evidence for nicotine-derived carcinogens while research data emanating from groups outside the industry clearly pointed to organ-specific carcinogenicity and routes of metabolic activation of the tobacco-specific *N*-nitrosamines NNN, NNK, and five other alkaloid-derived nitrosamines. NNK induces primarily adenoma and adenocarcinoma of the lung in mice, rats, hamsters and mink independent of its route of application, i.e., regardless of whether it is injected intraperitoneally, intravenously, intravesically, or given by gavage, swabbed onto oral surfaces, or administered in the drinking water. NNK also induced tumors in the nasal cavity of rats and hamsters and in the pancreas of rats (*43, 44*).

While the industry now has acknowledged the existence of TSNA (*45*) and even endeavors to prevent or at least reduce TSNA formation in smoke, it suggests that any possible carcinogenic action of TSNA is counteracted by inhibitors, including nicotine, nornicotine, and other smoke constituents. This contention is based on significant reduction of mutagenic activity of NNK and NDMA, but not NNN, by nicotine, nornicotine, or cotinine in in vitro assays. Similarly, SEC induction in mammalian cells by NNK was also markedly reduced by co-application of nicotine or cotinine (*46*). The concurrent application of NNK with nicotine or NNK with cotinine to perfused rat liver resulted in significant inhibition of NNK clearance, and in decreased metabolic activation by α-hydroxylation; it also caused a significant increase in *N*-oxidation of NNK and in the formation of NNAL-glucuronides (*47*).

In contrast, neither the NNK clearance from perfused rat lung nor its pattern of metabolites were substantially affected by the co-administration of nicotine or cotinine (*47*). Isolated rat lungs perfused with NNK revealed only small differences in pulmonary clearance and pattern of NNK metabolites between fed and starved animals (*47*). Rats on a high-fat diet who were given NNK in their drinking water developed lung adenoma and adenocarcinomas sooner but the overall incidence of lung tumors was similar to that in rats given NNK and a low-fat diet. However, the role of induction of carcinoma of the pancreas by NNK was significantly higher in the group of rats on the high-fat diet than in those on a low-fat diet (*48*). As to underlying mechanisms in NNK lung carcinogenesis, it is thought that 11β-hydroxysteroid dehydrogenase reduces the carbonyl group of NNK to yield NNAL whose secondary alcohol group is subject to glucuronidation so that it gets excreted as a urinary constituent. Inhibition of 11β-hydroxysteroid dehydrogenase raises the rate of α-hydroxylation of NNK, thus, increasing its carcinogenicity. On the other hand, activation of the 11β-hydroxysteroid dehydrogenase decreases α-hydroxylation of NNK, thus diminishing its carcinogenic potential (*49*). When rats were treated with a low dose of NNK and given drinking water that contained 0.002% nicotine, the alkaloid did not diminish DNA methylation (*50*). Additional well-designed bioassays are needed to clarify how nicotine and other smoke constituents affect the carcinogenicity of NNK.

The impetus for changing the makeup of cigarettes can be traced back to the landmark articles by Ernst L. Wynder and Evarts A. Graham in the United States and by Richard Doll and A. Bradford Hill in the United Kingdom in 1950 (*19, 20*). Both studies revealed a dose–response relationship between the number of cigarettes smoked and the risk for developing lung cancer. In 1953 and 1957, these findings were supported by bioassays showing a dose–response between the amount of tar applied to mouse skin and the induction of skin tumors (*21, 22*). In 1973, inhalation studies with hamsters at the Research Institute of the West German Cigarette Industry demonstrated a dose–response between the amount of cigarette smoke inhaled and the induction of tumors in the upper respiratory tract (*23*). On the basis of the epidemiological data and the bioassays with mice and hamsters, initial emphasis was placed on reducing the smoke yields of tar and nicotine as a measure that should lead to a less harmful cigarette. Because tar as a whole is the major carcinogen, and nicotine is the major toxic and addictive agent in tobacco smoke, measures of tar and nicotine were chosen as analytical parameters for each marketed brand.

The Federal Trade Commission (FTC) adopted, with some modifications, the standard machine smoking conditions for cigarettes developed by Bradford et al. in 1936 (*51, 52*). These prescribe taking one puff per minute with a 35 mL volume over 2 s. The butt lengths for nonfilter cigarettes were set at 23 mm and those for filter cigarettes at the length of the filter, plus overwrap, plus 3 mm. CORESTA, the International Organization for Research on Tobacco, developed a standard machine-smoking method in 1968 that is widely used in most of the developed countries (*53*). The CORESTA method differs from that of the FTC only in respect to the butt length to which filter cigarettes are smoked (CORESTA, length of filter, plus 8 mm). The standard machine-smoking conditions are otherwise identical to those of the FTC (*52, 53*). The data presented here are based on the FTC standard smoking conditions, except when otherwise specified.

A. Filter Tips

Figure 1 displays the sales-weighted average smoke yields for tar and nicotine of U.S. cigarettes for 1953–1996. The tar yields decreased from 38 to 12 mg and the nicotine yields from 2.7 to 0.85 mg (*39*). Figure 1 also approximately marks the year for the introduction of specific changes in the makeup of commercial U.S. cigarettes. Filter cigarette sales increased from 0.5% of all cigarettes on the U.S. market in 1950 to more than 97% as of 1997 (*11, 12, 54, 55*). Similar consumer acceptance of filter cigarettes has been recorded in other developed countries with the exception of France, where it had been delayed. In 1975, only about 70% of all French

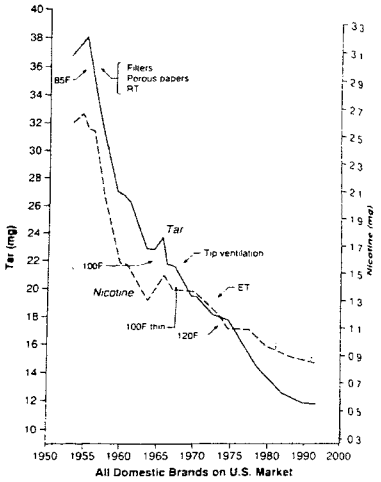

Figure 1. Sales-weighted average tar and nicotine deliveries, 1953–1993, U.S.

cigarettes had filter tips (*56*). There are basically three types of filter tips for cigarettes.[3] These are filters made from paper, from cellulose acetate (*57*) and filter tips that contain charcoal. The latter consist either of two or three sections, cellulose and granulates of activated charcoal, or cellulose acetate, activated charcoal and cellulose acetate. In addition, instead of granulates of charcoal in one section of the filter tip, charcoal has been dusted onto the cellulose acetate of the inner section.

In 1959, Haag et al. reported that charcoal filter tips selectively remove certain volatile agents from the smoke (*58*). Some of these are strong ciliatoxic agents, such as hydrogen cyanide, formaldehyde, and acrolein (*59–62*). In vitro studies have demonstrated that the smoke from cigarettes with charcoal filter tips is less ciliatoxic than smoke from other types of filter cigarettes and smoke from plain cigarettes. Thus, the movement of the cilia in the bronchi and trachea is significantly less impaired by the smoke of charcoal filter cigarettes than by the smoke of the other types of cigarettes (*59–62*). In the United States, and in most other countries, cigarettes with charcoal filters amount to less than 1–2% of total sales. However, of all the cigarettes on the market in Japan and Venezuela, 95% have charcoal filter tips, and so have 90% in South Korea and Hungary (*63, 64*).

Cigarettes with cellulose filters account for less than 1% of all cigarettes sold in the developed countries, whereas cigarettes with cellulose acetate filter tips, primarily made from secondary cellulose acetate, amount to more than 90% of all cigarettes (with the exception of Japan, Venezuela, South Korea, and Hungary) (*12*). Cellulose acetate filters retain up to 80% of semivolatile phenols. The retention of phenols was desirable because these compounds are active as tumor promoters in the experimental setting (*65–67*). Cigarette smoke contains the parent phenol and about 20 additional volatile phenols. Their total amount in the smoke of an 85-mm nonfilter cigarette amounts to about 300 μg. The individual, semi-volatile phenols range from 80 to 200 μg from phenol itself to less than 1 μg of *o*-chlorophenol (*26*). Boutwell and Bosch bioassayed some volatile phenols for their tumor-promoting activity on mouse skin initiated with 7,12-dimethylbenz[*a*]anthracene. The highest tumor-promoting activity was found for the following semivolatile phenols that had been identified in cigarette smoke: phenol, *o*-, *m*-, and *p*-cresol; 2,4-, 2,6-, 3,4-, and 3,5-dimethylphenol (*68, 69*); *o*-chlorophenol, 2-ethylphenol, and 2-*n*-propylphenol had lower tumor-promoting activities (*68, 69*). When bioassayed and compared for effects on a gram-to-gram basis, the tars from cellulose acetate filter-tipped cigarettes were slightly more toxic but less carcinogenic than tars collected from the smoke of plain cigarettes or from cigarettes with charcoal filter tips (*69*). Cellulose acetate filter tips also remove from the smoke up to 75% of the carcinogenic, volatile *N*-nitrosamines (VNA) (*70*). Twice daily exposure of Syrian golden hamsters for over 60 weeks to the air-diluted total MS from cellulose filter cigarettes induced a significantly lower incidence of tumors of the larynx than did exposure to the air-diluted total MS from nonfilter cigarettes. In contrast, whole smoke from cigarettes with charcoal filter tips induced carcinoma of the larynx to a similar extent as the whole smoke from nonfilter cigarettes (*23*).

Around 1965, perforation of the filter tips of cigarettes was introduced as a measure toward reducing toxins in the smoke. The smoke of cigarettes with filter perforation is indicated to be consumer acceptable up to about 50% air dilution. The velocity of the air flow through the burning cone of these filter cigarettes slows down as part of the negative pressure generated by the puff drawing. These changes result in more complete combustion of the tobacco (*71–73*). In 1999, more than 65% of all U.S. cigarettes had filter tips with various degrees of perforation. In the 70s, the analysis of the smoke of the experimental cigarette was completed for the Tobacco Working Group of the National Cancer Institute by M. R. Guerin, R. A. Jenkins et al. from the National Laboratory in Oak Ridge, TN (*69, 74–76*) (a) with cellulose acetate filter tips, (b) with perforated cellulose acetate filter tips, (c) with porous paper and with a perforated cellulose acetate filter tip, and (d) a nonfilter cigarette. The same tobacco blend was used as a filler for all four cigarettes. Table 6 shows that the smoke of filter cigarettes with perforation delivers the lowest yields of CO, hydrogen cyanide, nitrogen oxides (NO_x), acetaldehyde, and acrolein of all types of cigarettes. However, the yields of carcinogenic PAH in the smoke of the cigarettes with perforated filter tips were comparable with those from cigarettes without filter tips. Thus, the perforation of the filter tip results in a selective reduction of volatile, toxic agents but no major changes in the yields in particulate components (*77, 78*).

B. Cigarette Paper

Since about 1960, higher cigarette paper porosity and treatment of paper with citrate has significantly contributed to the reduction of the yields of several smoke

[3] In the People's Republic of China the leading material for the filter tip is polypropylene; there is little use in other countries for this polymer as filter material for cigarettes.

Table 6. Comparison of Experimental Cigarettes (yields/cigarette)[a,b,c]

smoke components	nonfilter cigarette (72–75)	cellulose acetate filter cigarette (91)	cellulose acetate filter 2/perforation (89)	cellulose acetate filter w/perforation and highly porous paper (96)
carbon monoxide (mg)	16.2	19.2	8.52	6.66
hydrogen cyanide (μg)	338	296	201	109
nitrogen oxides-NO_x (μg)	439	438	364	224
formaldehyde (μg)	36.0	20.9	31.7	21.4
acetaldehyde (μg)	1170	1290	608	550
acrolein (μg)	109	104	58.6	48.6
tar (mg)	27.2	14.7	19.2	19.5
nicotine (mg)	1.8	0.94	1.31	1.50
phenol (μg)	170	61.7	122	129
benz(*a*)anthracene (ng)	40.6 (1.40)	35.3 (2.25)	38.5 (1.88)	40.1 (1.91)
benzo(*a*)pyrene (ng)	29.9 (1.09)	19.6 (1.25)	29.2 (1.13)	23.9 (1.14)

[a] U.S. National Cancer Institute (*69*). [b] The composition of the cigarette tobacco is identical in all four experimental cigarettes. [c] Numbers in parentheses (*μg of benz*[*a*]anthracene or benzo[*a*]pyrene in 1 g dry tar).

components. During and between puff drawing, porous paper enhances the outward diffusion through the paper of hydrogen, NO, CO, CO_2, methane, ethane, and ethylene. On the other hand, it accelerates the diffusion of O_2 and N_2 from the air into the tobacco column; this, in turn, causes more rapid smoldering during puff intervals (*15, 77*). Table 6 compares smoke data from cigarettes with perforated filter tips but regular cigarette paper vs cigarettes with perforated filter tips and highly porous paper, with the tobacco blends in both cigarettes being identical (*69*). Whereas porous cigarette paper causes a significant decrease of volatile toxic agents, it hardly changes the smoke yields of tar, nicotine, BaA, and BaP. Importantly, the significant reduction of nitrogen oxides in the smoke of these cigarettes reduces the formation and, thus, significantly lowers the yields of VNA and TSNA (*77–79*).

In several countries, the use of hand-rolled cigarettes has risen significantly (*80, 81*). Making hand-rolled cigarettes requires sturdy cigarette paper. Such papers have low porosity. Rickert et al. compared the smoke yields of hand-rolled cigarettes with those of manufactured cigarettes, some of these two types of cigarettes contained the same tobacco; all cigarettes were machine-smoked under the same conditions. The handmade cigarettes, weighing 26% more, delivered mainstream smoke yields that were 100, 85, and 86% higher in tar, nicotine, and carbon monoxide, respectively, than those of manufactured cigarettes (*80*).

C. Cigarette Construction

Smoke yields also depend on physical parameters, such as length and circumference of the cigarette, and the width of the cut (number of cuts per inch; cpi) of the tobacco filler. Extending the cigarette length from 50 to 130 mm produces an increase in the level of oxygen in the mainstream smoke, while the levels of hydrogen, CO, CO_2, methane, ethane, and ethylene decrease. The major reason for this occurrence lies in the diffusion of oxygen through the paper into the smoke stream (*82*). This phenomenon is also reflected in increased CO delivery with ascending number of puffs, while the available surface area of the paper diminishes. With an increase in the length of the cigarette, the overall yields of tar, nicotine, PAH, and other particulate components also rise (*83, 84*). Circumference of cigarettes below the regular 24.8–25.5 mm (e.g., 23 mm or less) translates not only into less tobacco being burned but also into greater volume of oxygen available during combustion (*83, 84*). Thus, the smoke yields of tar, nicotine, and other particulate components are lowered (*15, 83, 84*). Cigarettes with small circumference also have a lower ignition propensity toward inflammable materials than cigarettes that have the ~25 mm circumference (*79*). It has been estimated that in 1980 of the almost 5200 U.S. residents who died from fires, about 1200 of these deaths occurred in fires started by cigarettes (*85*).

The number of cpi applied to the filler tobacco of cigarettes has no major impact on the carcinogenicity of the tars. The first investigation on the importance of tobacco cuts per inch, with regard to smoke yields and tumorigenicity of the resulting tars, was published in 1965. It compared the smoke yields of tar and BaP when 8, 30, 50, or 60 cpi of leaf were applied. Tar yields per cigarette decreased from 29.1 to 23.0 mg and BaP from 37 to 21 ng. In a large-scale study of cigarettes filled with an identical blend, and cuts at 20 and 60 cpi, respectively, the smoke yields per cigarette of tar, nicotine, volatile aldehydes, BaA, and BaP were significantly reduced for the fine-cut (60 cpi), however, hydrogen cyanide was insignificantly increased. Gram-to-gram comparison of tumorigenicities of the two tars on mouse skin revealed statistically insignificant differences (*74*).

D. Tobacco Types

The botanical genus *Nicotiana* has two major subgenera: *N. rustica* and *N. tabacum*. *N. rustica* is primarily grown in Russia, the Ukraine, and other East European countries, as well as in South America, and, to a limited extent, in India. In the rest of the world, *N. tabacum* is grown as the major tobacco crop; it comes as *flue-cured type* (often called bright, blond, or Virginia tobacco), *air-cured type* (often called burley tobacco), light air-cured tobacco (grown in Kentucky), and dark air-cured tobacco (grown in parts of Tennessee and Kentucky, South America, Italy, and France), as well as *sun-cured* (often called oriental or Turkish) tobacco (primarily grown in Greece and Turkey). In addition, there are special classes of air-cured tobaccos for cigars, chewing tobacco, and snuff (*86*).

Until the recent 2 decades, only flue-cured tobaccos were used for cigarettes in the U.K. and in Finland, and they were the predominate type used in Canada, Japan, China, and Australia. Air-cured tobaccos were preferred for cigarettes in France, southern Italy, some parts of Switzerland and Germany, and South America; cigarettes

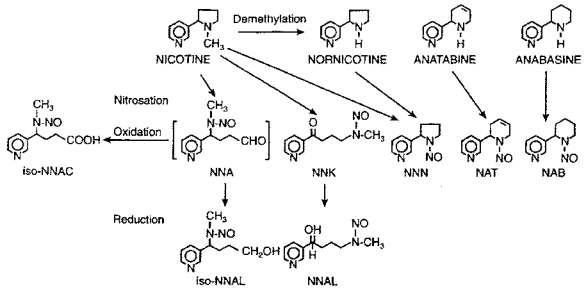

Figure 2. Formation of tobacco-specific *N*-nitrosamines (TSNA), 1994 (*43*).

made exclusively from sun-cured tobaccos are popular in Greece and Turkey. In the rest of Western Europe and in the U.S., cigarettes contain blends of flue-cured and air-cured tobaccos as major components. Today, in many countries, including the U.K, France, and other developed nations, the U.S. blended type of cigarette is gaining market shares. In the U.S., the composition of the cigarette blend has undergone gradual changes. In the sixties and early seventies, 45–50% of the cigarette blends were flue-cured (Virginia) tobaccos, 35% air-cured (burley) tobaccos, and a few percent were Maryland air-cured and oriental tobaccos. By 1980, blends averaged 38% flue-cured, 33% air-cured, and a few percent each of Maryland and oriental tobaccos and up to 30% reconstituted and expanded tobacco. In the early nineties, these proportions were 35%, 30%, and, again, a few percent of Maryland and oriental tobaccos. The blended cigarette is preferred in many countries, in part, because each of the three major *N. tabacum* types lends a specific aroma to the smoke.

In regard to the toxicity and carcinogenicity of tobacco and tobacco smoke, the difference in the nitrate content of the tobaccos is of primary significance. Flue-cured tobacco can contain up to 0.9% of nitrate; yet, as it is used for regular cigarettes, it contains <0.5% of NO_3. In oriental tobaccos one finds up to 0.6% NO_3, in air-cured tobaccos between 0.9 and 5.0%, but generally below 3% in commercial cigarettes. The highest concentration of nitrate is present in the ribs, the lowest concentration is in laminae, especially in laminae harvested from the top stalk positions of the tobacco plant (*87, 88*). With the utilization of a greater proportion of air-cured tobacco in the blended U.S. cigarette, the average nitrate content of the blended U.S. cigarette tobacco has risen from below 0.5% in the fifties to 1.2–1.5% in the late eighties (*15, 89, 90*).

The concentrations of nitrogen oxides (NO_x) and methyl nitrite in smoke depend primarily on the nitrate concentrations of the tobacco; although a portion of the nitrogen oxides is formed during smoking from amino acids and certain proteins (*87, 91–94*). Cigarettes made entirely with flue-cured tobaccos deliver up to 200 μg of NO_x and 20 μg of methyl nitrite in the smoke. Smoking U.S. blended cigarettes produces up to 350 μg of NO_x and 160 μg of methyl nitrite, and the smoke of air-cured tobacco cigarettes contains up to 700 μg of NO_x and 470 μg methyl nitrite. The stems of air-cured tobaccos are especially rich

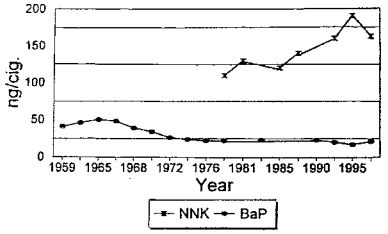

Figure 3. BaP and NNK in mainstream smoke of a leading U.S. nonfilter cigarette, 1959–1997.

in nitrate (≤6.8%). Consequently, stems, as components of expanded and reconstituted tobaccos in a cigarette blend, contribute in a major way to NO_x in the smoke (*95*).

Freshly generated smoke, as it leaves the mouthpiece of a cigarette, contains NO_x virtually only in the form of nitric oxide (NO), and only minor amounts of nitrogen dioxide (NO_2) and of nitrous oxide (N_2O) (*92, 93*). However, nitrogen dioxide is quickly formed upon aging of the smoke. It has been calculated that, within 500 s half of the NO in undiluted smoke is oxidized to NO_2 (*94*). Nitrogen dioxide can cause inflammation of the lungs which may lead to edema. Of major importance is the high reactivity of NO_x upon its formation in the burning cone and in the hot zones of a cigarette. The thermically activated nitrogen oxides serve as scavengers of C,H-radicals, whereby they inhibit the pyrosynthesis of carcinogenic PAH (*94, 96, 97*).

The freshly generated nitrogen oxides also react with secondary and tertiary amines resulting in the formation of volatile *N*-nitrosamines (VNA) and of several *N*-nitrosamines from amino acids, as well as from some additives. Furthermore, NO_x also form tobacco-specific *N*-nitrosamines (TSNA) by *N*-nitrosation of nicotine and of the minor tobacco alkaloids (Figure 2) (*44, 98*). Figure 3 depicts data on the decline of BaP and the increase of NNK in the smoke of a leading U.S. nonfilter cigarette between 1974 and 1997. Both trends are correlated with the use of tobacco blends with higher nitrate content. Increasing concentrations of nitrate in tobacco have also led to an increase in cigarette smoke of nitroalkanes,

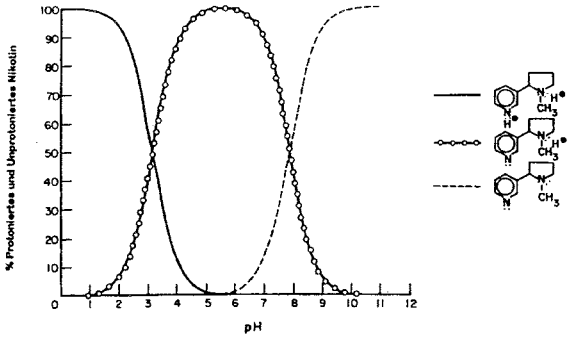

Figure 4. pH of total mainstream smoke of various tobacco products, Brunnemann and Hoffmann, 1974 (*101*).

Table 7. Smoke Yields and Tumorigenicity of the Tars from the Four Major *N. Tabacum* Varieties[a]

factors	flue-cured tobacco	sun-cured tobacco	air-cured tobacco Kentucky[b]	air-cured tobacco Maryland
(A) yields/cigarette				
tar (mg)	33.4	31.5	25.6	21.2
nicotine (mg)	2.4	1.9	1.2	1.1
phenol (μg)	95	120	60	43
benzo(*a*)pyrene[c] (ng)	53 (1.6)	44 (1.4)	24 (0.94)	18 (0.85)
(B) tumorigenicity[d]				
% of mice with skin tumors[e]	34	36	22	18

[a] Wynder and Hoffmann (*96*). [b] Low nicotine, air-cured tobacco (Kentucky). [c] Number in parentheses (μg of BaP/1 g of tar). [d] Bioassayed on a gram-to-gram basis of tar. [e] Fifty mice in each group.

including the carcinogenic nitromethane, 2-nitropropane, and nitrobenzene, and of aromatic amines, including the human bladder carcinogens 2-naphthylamine and 4-aminobiphenyl (*15, 97, 99, 100*).

Another important aspect relative to the toxicology of cigarette smoke is the correlation between the nitrate content of tobacco and the pH of cigarette smoke. Even though the different processes used to flue-cure and air-cure tobaccos significantly influence the smoke composition of the major types of tobacco, the amount of nitrate present is also of major importance in determining the pH of the smoke. Whereas flue-cured tobacco and U.S. cigarette tobacco blends deliver weakly acidic smoke (pH 5.8−6.3), cigarettes made from air-cured tobacco deliver neutral to weakly alkaline smoke (pH 6.5−7.5). The major reason for the range of pH values encountered in the smoke of the two major tobacco types is the concentration of ammonia in the smoke, which is primarily tied to the concentration of nitrate in the tobacco. When pH levels of the smoke rise >6.0, the percentage of free, unprotonated nicotine increases to about 30% at pH 7.4 and to about 50% at pH 7.8 (*101*). Protonated nicotine is relatively slowly absorbed in the oral cavity; yet, unprotonated nicotine, some of which is present in the vapor phase of the smoke, is quickly absorbed through the mucosal membranes of the oral surfaces (*102*). This is a distinguishing factor in cigar smoking. The pH of cigar smoke rises with increasing puff numbers from pH 6.5 to 8.5; therefore, the rapid oral absorption of the free nicotine in the vapor phase gives the primary cigar smokers instant nicotine stimulation so that there is no need to inhale the smoke (Figure 4). Similarly, the primary smoker of black, air-cured cigarettes tends not to inhale the smoke or to do so minimally (*13, 102, 103*).

In 1963, the first comparative study of the tumorigenicity on mouse skin of the tars from the four major types of *Nicotiana tabacum* revealed the highest activity for tars obtained from flue-cured and sun-cured tobaccos and the lowest for tars from two types of air-cured tobacco (Table 7). The concentration of BaP, a surrogate measure for the carcinogenic PAH, was correlated with the tumor initiation potential of the tars (*96*). Upon topical application to mouse skin and bronchial epithelia, carcinogenic PAH induce papilloma and carcinoma. In inhalation studies with Syrian golden hamsters, the smoke of a cigarette, made with a U.S. tobacco blend, was significantly more active in inducing carcinoma of the larynx than was the smoke of a cigarette with air-cured (black) tobacco (*23*).

To support the concept that the reduction of carcinogenic PAH in the smoke by means of high levels of nitrate in tobacco leads to diminished mouse skin tumorigenicity of the tar, sodium nitrate (8.3%) was added to the standard tobacco blend. On a gram-to-gram basis, the tar from the cigarette with added nitrate (0.6 μg of BaP/g of tar) induced skin tumors in only 2 out of 50 mice, whereas the tar from the control cigarette (without the addition of nitrate; 1.05 μg of BaP/g of tar) induced skin tumors in 25 of 100 mice (*104*). In inhalation experiments with Syrian golden hamsters, smoke from the experimental cigarette, made with 8.0% of sodium nitrate, induced laryngeal carcinomas in only 25 of 160 animals compared to this type of neoplasm in 60 of 200 animals in assays

with the control cigarette (*23*). Thus, mouse skin bioassays with tar and smoke inhalation studies with hamsters support the concept that increased nitrate content of the tobacco inhibits the pyrosynthesis of the carcinogenic PAH and that the tars of these cigarettes, and their smoke as a whole, have a reduced potential for inducing tumors in epithelial tissues of the skin and of the upper aerodigestive tract compared to the tar or whole smoke of cigarettes with low-nitrate tobacco.

E. Reconstituted Tobacco and Expanded Tobacco

In the early 1940s, the technology of making reconstituted tobacco (RT) was developed. It was first applied to the manufacture of cigar wrappers. The RT technology enables the utilization of tobacco fines, ribs, and stems in cigarette tobacco blends (*105*). Prior to this technology, tobacco fines and stems had been wasted. The utilization of RT as part of the tobacco blend requires less of the top quality tobaccos for cigarette manufacture. Beginning in 1965, laboratory studies have shown that cigarettes made entirely of RT deliver a smoke with significantly reduced levels of tar, nicotine, volatile phenols, and carcinogenic PAHs. The two major technologies for making RT for cigarettes are the slurry process and the paper process; both lead to RT with low density. It permits a high degree of aeration of the tobacco which enhances combustion. Most of the tested tars from cigarettes made with these reconstituted tobaccos had significantly reduced carcinogenic activity on mouse skin (*74, 106*). In inhalation assays with Syrian golden hamsters, diluted smoke from cigarettes made of reconstituted tobacco induced significantly fewer carcinoma in the larynx (19/160) than the diluted smoke from control cigarettes (60/200). The cigarette with RT, tested in the smoke inhalation assay, gave per cigarette only 7 puffs and yielded 20.8 mg of tar and 16 ng of BaP compared to 10 puffs, 33.7 mg of tar, and 35.4 ng of BaP for the control cigarette (*23*). Burton, Dye, and Bush analyzed in detail the distribution of nitrite, nitrate, alkaloids, and TSNA in segments of an air-cured, dark tobacco leaf. They reported the highest concentrations of the alkaloids in the tips and the lowest in the base of the leaf, whereas, nitrite and TSNA were present in the highest concentrations in the base of the leaf and decreasing concentrations toward the tip of the leaf. These data indicate a better relationship between nitrite and TSNA than between the alkaloids and TSNA (*107*). Tobacco ribs and stems, the major components of RT, contain more nitrate and nitrite (and this applies especially to the ribs and stems of air-cured tobaccos) than the laminae of tobacco (*95, 107, 108*). Therefore, in general, the nitrate content of today's blended U.S. cigarette, which may contain 20–30% RT, is at a level of 1.2–1.5%—significantly higher than the nitrate level in cigarettes during the fifties and sixties when it was ≤0.5% (*89, 109*). Commercial cigarettes with RT emit in their smoke significantly more TSNA than cigarettes of the past. These TSNA include the NNK which induces AC in rodents. NNK is metabolically activated to carcinogenic species in target tissues such as the lung (*43*). One major U.S. cigarette manufacturer has been granted a patent in December of 1978, presenting a process that reduces more than 90% of the nitrate content of the RT made from ribs and stems (*110, 111*).

There are at least three methods for expanding tobacco by freeze-drying (*75*). As a result of freeze-drying, the expanded tobacco has greater filling power than natural tobacco; thus, less tobacco is needed to fill a cigarette. An 85-mm filter cigarette, filled entirely with expanded tobacco, required 363 mg of tobacco, while a regular filter-tipped cigarette of the same dimensions required 667 mg of tobacco. The tar yields in the smoke of these two types of cigarettes were 12.4 and 22.1 mg, respectively (*75, 76*). In 1982, incorporation of all possible modifications in the makeup of the cigarette required only 785 mg of leaf tobacco; in contrast, in 1950, making the blended U.S. cigarette required 1230 mg of leaf tobacco (*109*). Levels of most components measured in the smoke of cigarettes with puffed tobacco, expanded tobacco, or freeze-dried tobacco, were significantly reduced, by comparison to the control cigarette (*75, 76*).

F. Additives

1. Humectants. Humectants serve to retain moisture and plasticity in cigarette and smoking tobaccos. They delay or prevent the drying of tobacco. Dry tobacco (<8% moisture) gives a harsh tasting smoke. Humectants also preserve those compounds that impart flavor to the smoke. Today, the principal humectants in cigarette tobacco are glycerol (propane-1,2,3-triol) and propylene glycol (PG; propane-1,2-diol); of lesser importance are diethylene glycol (2,2′-di[hydroxyethyl]ether) and sorbitol (*112*). In the past, ethylene glycol (ethane-1,2-diol) has been used as a humectant for cigarette tobacco. During smoking, this compound leads to the formation of ethylene oxide. Workers exposed to this volatile agent face an increased risk for lymphatic leukemia and non-Hodgkin's lymphoma (*113*). For this reason, ethylene glycol is no longer used as a humectant for tobacco. In 1972, Binder and Lindner reported the presence of 7 μg of ethylene oxide in the smoke of a cigarette brand filled with tobacco that had not been treated with ethylene glycol (*114*). The significance of the possible endogenous oxidation of the inhaled ethylene (150–300 μg/cigarette) has not been evaluated (*115*).

Humectants may comprise up to 5% of the weight of cigarette tobacco. In a 1964 study, 18 U.S. cigarette tobacco blends contained between 1.7 and 3.15% of glycerol. To some extent, glycerol decomposes to the ciliatoxic acrolein; U.S. cigarette tobacco contains also between 0.46 and 2.24% of PG (*116*). Four American cigarettes contained between 0.34 and 0.96 mg/cigarette of PG (*117*); during smoking, PG gives rise to the carcinogenic propylene oxide (*118*). Recently, levels of 12–100 ng of propylene oxide have been determined in the smoke of U.S. cigarettes. Several samples of PG that were intended as humectants for cigarette tobacco already contained traces of propylene oxide (*36*).

2. Flavor Additives. Natural tobacco contains a wide spectrum of components that, upon heating, release flavorants. These include tobacco-specific terpenoids, pyrroles and pyrazines among others (*119–122*). The effective reduction of smoke yields by filter tips and by the incorporation of reconstituted tobacco also brought about a reduction of flavor components. In 1993 and 1994, the industry convened an expert panel of toxicologists to screen agents that were in use, or considered for use, as tobacco additives. The panel then released a list of 599 agents that were generally regarded as safe (GRAS), whereby the term "safety" applied only to the additives as such without considering the fate and reactivity of

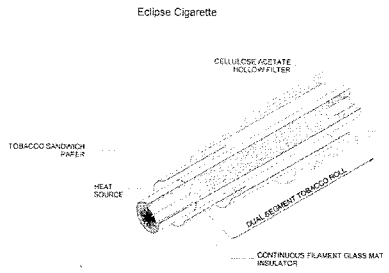

Figure 5. A new type of cigarette: Eclipse, Bombick et al. (*130*).

these agents during combustion (*123*). In inhalation assays, the mainstream smoke (MS) of cigarettes with and without flavor additives induced essentially the same responses in the respiratory tracts of rats; specifically hyperplasia and metaplasia in the nose and larynx (*124*). As this study involved maximally 65 h of exposure, one cannot deduce with certainty that the addition of these flavoring agents to tobacco blends has no additional impact on the development of tumors by cigarette smoke.

G. New Types of Cigarettes

The industry has initiated research toward developing new types of cigarettes, During smoking, such cigarettes were to generate an aerosol with nicotine in the range present in the smoke of conventional filter cigarettes, but low to very low emissions of tar and of toxic and carcinogenic agents. In 1988, the first new type of cigarettes appearing on the test market was called "Premier", a cigarette that "heats rather than burns tobacco" (*125*–*129*). This 80-mm cigarette is comprised of three sections. The first 40-mm section is made with compressed, activated charcoal that is linked to an inner aluminum tube containing tobacco, flavor additives, and glycerol. This tube is embedded in tobacco. Section 2 (~10 mm) is a cellulose acetate filter, dusted with charcoal powder. The third section (~30 mm) is a cellulose acetate filter tip. Under standardized smoking conditions (*52*), Premier delivered a MS with low levels of most of the toxic and genotoxic agents compared to concentrations of these agents in the MS of the University of Kentucky reference filter cigarette. Short-term bioassays indicated that the MS of Premier most likely exhibits reduced toxic and genotoxic activities (*125*–*129*). In 1988, Premier was placed on a test market; however, it was not accepted by the consumers.

Undergoing significant changes, the Premier re-emerged as "Eclipse". This product consists of four sections. Section 1, the heat source, is a specially prepared charcoal; section 2 consists of tobacco plus glycerol; section 3 contains finely shredded tobacco; and section 4 is a filter tip (Figure 5). Upon ignition, the special charcoal heats the air stream during puff drawing. The heated air stream enters the tobacco sections and aerosolizes volatile and semivolatile tobacco constituents including nicotine, as well as portions of glycerol. Eclipse is produced in four prototypes; their MS were thoroughly analyzed. Under FTC smoking conditions, the standard Eclipse delivers 8 mg of CO (low-yield filter cigarette, 6–12 mg), 150 μg of acetaldehyde (700 μg), 30 μg of NO_x (200–300 μg) and 180 μg of hydrogen cyanide (300–400 μg), 5.1 mg of tar (11–12 mg) and 0.2–0.4 mg of nicotine (0.7–1.0 mg). The tar consists of 33% water, 47% glycerol, and 17% of various other compounds. The emissions of the major smoke carcinogens, such as BaP, 2-naphthylamine, 4-aminobiphenyl, and the TSNA, are lowered by 85–95% (*126*–*129*). The particulate matter of the aerosol generated by smoking Eclipse, according to the FTC standard method, contains as major a constituent about 47% glycerol (in the low-yielding Eclipse this means 2.4 mg glycerol in 5.1 mg smoke particulates) (*129*).

A number of short-term tests were completed with whole smoke, the vapor phase, the tar and/or fractions of the tars of one or several prototypes of Eclipse; the University of Kentucky reference filter cigarette 1R4F and, in some cases, also 1R5F, served as a positive controls. The tars of the two reference cigarettes were cytotoxic, while the tars of two types of Eclipse were not (*130*). Whole smoke of four prototypes of Eclipse had minor cytotoxic activity. However, the activities were significantly less than those of the whole smoke of the Kentucky reference cigarettes (*131*). The tars of the four Eclipse prototypes were not, or at best weakly, mutagenic (with or without activation by the S9 enzyme fraction from rat liver homogenate), but in each case, they were significantly less active than the tars of the reference cigarette (*130*). In the sister chromatid exchange test, the tars of the Eclipse induced only a slightly positive response or no response; the tars from the Kentucky reference cigarettes were significantly more mutagenic (*130*).

The exposure of rats and random-bred Syrian golden hamsters to diluted whole smoke for 5 days a week for 13 weeks led only to moderate changes in the upper respiratory tract of these animals. In each case, the recorded histopathological changes in the short-term assay were less pronounced than the changes observed in the upper respiratory tract of the animals exposed to the diluted smoke of the Kentucky reference cigarette (*132*). The tars of the reference filter cigarette 1R4F and four types of Eclipse were bioassayed at three doses (10, 20, and 40 mg/application) for their tumor promoting activity on the skin of Sencar mice, initiated with DMBA. With one exception, the tumor promoting activities of the tars from the Eclipse cigarettes were reduced by at least two-thirds compared with the tumor promoting activity of the tar from the reference tobacco cigarette (*132*). Using the ^{32}P-postlabeling technique in mice exposed dermally to the tars of four prototypes of Eclipse, resulted in significantly lower DNA-adduct formations in the skin, heart, or lung than DNA adducts in the three organs with the tar from the 1R4F reference cigarette (*133*).

Regular cigarette smokers were asked to switch for 2 weeks from their regular brand to Eclipse and the smoking parameters for these types of cigarettes were determined. There were four study groups, composed of 26–30 volunteers each, for a total of 109 smokers. On the basis of the main values for the four groups, the smoking of Eclipse resulted in about a 30% larger volume per puff, about 50% more puffs per Eclipse adding up to a total puff volume that was more than twice that of the total volume drawn from the control cigarettes (*134*). These data indicate that the Eclipse was very intensely

smoked. This is also reflected in the uptake of nicotine (*135*). The mutagenic activities of the urine of smokers of the four types of Eclipse, assayed on two bacterial strains were reduced by 72% to 100% compared with the mutagenic activities of the urine of the same persons, after smoking their usual cigarette brand (*136*). On request of the Food & Drug Administration, the Institute of Medicine of the National Academy of Sciences assembled an Expert Committee to assess the scientific basis for a possible reduction of the "harm" of the changing cigarette, including Eclipse. The Committee published the evaluation of the Eclipse independent of the entire report on "harm" reduction of tobacco smoke that is to be released in the summer of 2001. The Eclipse evaluation is summarized as follows: "'Eclipse' offers the committed smoker an option that is not currently available." Eclipse does not add to the inherent biological activity of smoke for the range of cigarettes currently on the market. The elevated COHb levels should be regarded as a potential risk factor for cardiovascular diseases. The magnitude of the risk remains to be determined (*132*).

The high concentration of glycerol in the aerosol generated by the Eclipse cigarette motivated scientists to bioassay glycerol in "nose only" inhalation studies with Sprague–Dawley rats. These 2-week (1.0, 1.93, and 3.91 mg/L) and 13-week (0.033, 0.167, and 0.662 mg/L) assays tested for toxicity and especially for irritating effects. The investigators detected metaplasia of the lining of the epiglottis (*132*). The 13-week inhalation studies with rats and hamsters had also resulted in some early histopathological changes in the upper respiratory tract in both types of laboratory animals. These findings, the exposure to the smoke of Eclipse, and to glycerol aerosol, should lead to lifetime inhalation assays with the smoke of Eclipse in rats, preferably Fisher 344 rats, or better yet, in Syrian golden hamsters possibly with an inbred strain of hamsters susceptible to carcinogens in the respiratory tract (*137*). Pauly et al. from the Roswell Park Cancer Institute, Buffalo, NY, caution that harmful glass fibers have been found to migrate into the filter tip of the Eclipse and may be inhaled during puffing (*138*).

The Massachusetts Department of Health and the Society for Research on Nicotine and Tobacco challenged the claim made for Eclipse as the consumer's "next best choice". They request that the FTC and the FDA formulate regulatory procedures. Such procedures should ensure that insufficiently documented health claims for tobacco products such as Eclipse, or for tobaccos with reduced TSNA-levels ("safer tobacco") cannot be used in advertising (*139, 140*).

In 1998, a second U.S. tobacco company manufactured another new type of cigarette; in this case, an electrically heated cigarette (EHC). The EHC releases an aerosol which, on the basis of chemical analyses and short-term bioassays, induces significantly lower toxicity and mutagenicity than the smoke of the Kentucky reference filter cigarette, 1R4F. The prototype, containing a tobacco filler wrapped in a tobacco mat, is kept in constant contact with eight electrical heater blades in a microprocessor-controlled lighter (Figure 6) (*141*). This cigarette contains about half the amount of tobacco of a conventional cigarette. Under FTC-standardized smoking conditions, the cigarette delivered within an average of 8 puffs about 1 mg of nicotine, whereas all other analyzed smoke constituents were significantly lower than those in the smoke of the University of Kentucky reference cigarette, 1R4F. The carcinogenic PAH were below the detection level (*141*). However, formaldehyde yields were significantly higher in the smoke of the EHC and emissions of glycerol and 2-nitropropane were comparable to those recorded in the smoke of the 1R4F cigarette. Per gram tar, the smoke of the EHC had significantly lower mutagenic activity than the smoke of the 1R4F reference cigarette in TA98, TA100, and TA 1537 tester strains with and without the S9 fraction of rat liver homogenate (*141*).

View of EHC Cigarette with Electrical Lighter

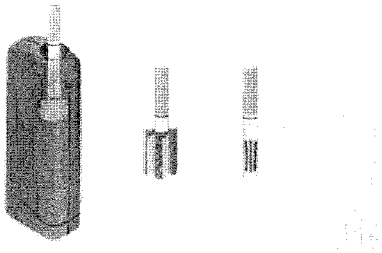

Figure 6. A new type of cigarette: EHC. Terpstra et al. (*141*).

H. Summary of the Changing Cigarette

Table 8 summarizes the changes in the composition of cigarette smoke that resulted from alterations in the makeup and in the composition of the tobacco filler of cigarettes since 1950. In examining these modifications, we gained important, new knowledge about the physicochemical nature of tobacco smoke, the toxic and carcinogenic agents in this aerosol, and their precursors in tobacco. We are now aware of methods that will selectively reduce or even remove specific carcinogenic agents from cigarette smoke. With regard to major carcinogenic agents in cigarette smoke, it has been documented that the gradual increase of the nitrate content of the tobacco blend caused lower smoke yields of the PAH, as shown with B*a*P as a surrogate; however, the smoke yield of the lung carcinogen NNK (and of other TSNA) has increased (Figure 3) (*15*). Around 1990, the nitrate content of U.S. cigarette tobacco amounted to 0.6−1.5% and that of the Canadian cigarette, composed only of bright varieties was ≤0.3%. At that time, the leading U.S. cigarette gave smoke yields of 1.04 ± 0.3 μg of B*a*P/g of tar, while the smoke of the leading Canadian cigarette contained 1.47 ± 0.36 μg of B*a*P/g of tar; the average smoke yields per cigarette of the leading U.S. cigarette amounted to 150 ng of NNN and 100 ng of NNK; and those of the leading Canadian cigarette were 35 ng of NNN and 75 ng of NNK (*142, 143*).

All analytical data presented in Section III, the "Changing Cigarette", were based on the standard machine smoking method of the FTC (*52*). However, smokers create their own patterns of puff drawing and inhaling smoke primarily for satisfying their acquired need for nicotine. When smoking a low-nicotine cigarette, long-term habitual smokers (≥1 year) tend to smoke more

Table 8. Reduction of Smoke Components[a]

smoke component	charcoal filter	cellulose acetate filter	perforated filter	cigarette paper	reconstituted tobacco	expanded tobacco	flue-cured tobacco[b]	air-cured tobacco[b]
tar	↓	↓↓	↓↓	↓	↓	↓	±	↓
nicotine	↓	↓↓	↓	↓	↓	↓	±	±
CO	↓	±	↓	↓	↓	↓	±	±
HCN	↓	±	↓	↓	±	↓	±	±
acetaldehyde	↓	±	↓	±	±	±	±	±
acrolein	↓	±	↓	±	±	±	±	±
VNA	±	↓↓	↓	↓	±	↓	↓	↑↑
volatile phenols	±	↓↓	↓	±	±	±	↑	↓
BaP	±	±	±	±	↓	↓	↑	↓
TSNA	±	±	±	±	±	↓	↓	↑↑
carcinogenicity of tar	±	±	±	±	↓	↓	↑	↓

[a] (±) Insignificant change; (↑) significant increase (≥20%); (↓) significant reduction; (↓↓) highly significant decrease (>30%); (↑↑) highly significant increase (>30%). [b] For air-cured and flue-cured tobaccos, values are measured against those in the U.S. blended cigarette.

intensely and to inhale the smoke deeper into their lungs. Doing so, they may partially block the perforations of the filter tip or even completely close them (*144*–*148*). These observations were supported by studies in which the smokers used cigarettes that varied from each other in the yields of nicotine but not in other major smoke components. The smokers of the low-nicotine cigarettes compensated for the low dose delivery (low according to smoking by the FTC method) by inhaling a greater volume of smoke than the smokers of (FTC) high-yield cigarettes (*149*, *150*). In the 1980s, the actual puffing parameters of American smokers recorded for the high- and low-nicotine cigarettes substantiated the concept that the smoker of the low-nicotine cigarette takes larger puffs than the smoker of nonfilter cigarettes (*149*–*152*).

In summary, the sales-weighted average nicotine yield in the mainstream smoke of U.S. cigarettes changed from 2.7 mg/cigarette in 1953 to 0.85 mg since 1991 (Figure 1) as determined with the Federal Trade Commission standard machine-smoking method (*52*). Today, reconstituted and expanded tobacco make up 25–30% of the cigarette filler; in addition, the proportion of burley tobacco in the blended U.S. cigarette has increased. Therefore, the nitrate content of the U.S. cigarette has risen, in general, from ≤0.5% to between 1.2 and 1.5%. Other changes pertain to the increased consumption of filter-tipped cigarettes as it rose from 0.5% in 1950 to more than 97% of all U.S. cigarettes since 1997. About two-thirds of all U.S. cigarettes have perforated filter tips that cause air dilution of the smoke to vary between 20 and 45%. In addition, the porosity of the wrapping paper has significantly increased for all manufactured cigarettes.

An important outcome of these changes in the commercial cigarette is the increase in the smoke of the carcinogenic volatile nitrosamines, nitrosamino acids, tobacco-specific *N*-nitrosamines, aromatic amines, and nitroalkanes (*43*, *98*–*100*).

IV. Observations on Cigarette Smokers

A. Comparison of the Smoke of High- and Low-Yield Cigarettes, 1950–1975

On the basis of the laboratory data generated with the FTC standard machine smoking method for cigarettes, it was assumed that the lung cancer risk among cigarette smokers would decrease. Three cohort studies and four case-control studies published between 1968 and 1981 had reported that the long-term smoker of low-yield cigarettes had a 20–50% lower risk for lung cancer than the smoker of the conventional high-yield nonfilter cigarettes (*1*, *153*–*159*). In a longitudinal study that began in 1959, Hammond et al., from the American Cancer Society, followed 1 million men and women over 12 years. Few of the smokers who shifted from high-tar and nicotine to low-tar and nicotine cigarettes increased their daily cigarette consumption. Adjusted for numbers of cigarettes smoked per day, the smokers of low-yield cigarettes showed somewhat reduced total death rates and death rates from coronary heart disease and from lung cancer (*155*). Wynder and Stellman reported in 1979 that long-term smokers of filter cigarettes had reduced risks for cancer of the lung as well as for cancer of the larynx (*158*).

Auerbach et al. examined the bronchial tubes of 211 men (including 154 smokers) from autopsy specimens collected in the years 1955–1960 and bronchial tubes from 234 men (187 smokers) from autopsy material obtained in 1970–1977. Auerbach compared the loss of cilia, and the occurrence of bronchial metaplasia and atypical nuclei. The earlier samples presented significantly more pronounced changes in the bronchial tubes than the samples collected in 1970–1977 (*160*).

A U.S. Surgeon General's Committee on the changing cigarette stated in 1981 that low-tar, low-nicotine cigarettes produce lower rates of lung cancer than the higher tar and higher nicotine predecessors (*78*). In 1986, an IARC expert panel on the epidemiology of smoking-associated cancers, on tobacco toxicology, and on tobacco carcinogenesis concluded that epidemiological studies suggest that "prolonged use of nonfilter, high-tar cigarettes is associated with a greater risk for lung cancer than the prolonged use of filter and low-tar cigarettes" (*1*).

B. Comparison of the Smoke from High- and Low-Yield Cigarettes, 1976–1999

These tentative conclusions about the lower toxicity and carcinogenicity of low-yield cigarettes manufactured during the 1970s and early 1980s were questioned as to their applicability to cigarettes produced in the 1980s and

thereafter. Study groups in the U.K., in the U.S., and elsewhere observed that the machine-smoking schedule chosen by the FTC, CORESTA, and other agencies, did not reflect the smoking patterns observed among most of the cigarette smokers in developed countries during the preceding 2−3 decades (*144*−*149*, *161*, *162*).

In 1978, the tobacco industry was well aware of the fact that the standard machine-smoking schedule did not reflect the smoking habits of most of the cigarette smokers. Schultz and Seehofer, determining nicotine in the butts of cigarettes smoked by men and women, found significantly higher levels of it in these butts than in those from identical cigarettes that were machine-smoked, whereby the butt lengths were not different from those left by the smokers (*163*).

In 1970, Ashton and Watson, and Benowitz et al., had already observed that smokers of low-yield cigarettes took more puffs than smokers of high-nicotine cigarettes (*149*, *164*). This observation was confirmed by Haley et al. in 1985 (*150*). Kozlowski et al. were the first to report that smokers of low-nicotine cigarettes with perforated filter tips tend to occlude the holes in the filter tip with their lips and/or fingers, thereby increasing the smoke yields of tar, nicotine, and carbon monoxide (*148*, *165*, *166*). This was also confirmed by studies in other laboratories (*167*, *168*). Using the ninhydrin color reaction of the saliva-derived residual protein and amino acids on the perforated filter tips, it was determined in a study examining 1229 cigarette butts that 5.2% of the holes were completely or partially closed and 18.9% were partially closed during smoking (*169*). In a second report, 15% of 300 butts gave evidence of the holes being covered with saliva (*170*).

Assays on nicotine uptake by smokers demonstrated that there is no significant relationship between plasma cotinine, a major nicotine metabolite, and the nicotine yield of cigarettes smoked according to the FTC method (*171*). Benowitz et al. reported that the cotinine level in plasma was virtually the same for all cigarettes smoked and inhaled, except for ultra-low-yield cigarettes (*172*). Gori and Lynch found no correlation between expired carbon monoxide from cigarette smokers and the FTC yields of carbon monoxide (*173*).

The development of a tobacco smoke inhalation testing system (TSITS) in the late 1980s enabled assays of the smoking intensities of smokers of cigarettes with different nicotine yields (*174*, *175*). This system was utilized for the determination of smoking profiles of long-term smokers (≥1 year) of a specific brand of cigarettes that had FTC nicotine yields of 0.6−0.8 mg/cigarette (56 volunteers) and of 0.9−1.2 mg of nicotine/cigarette (76 volunteers). The observed average values were puff volumes of 48.6 and 44.1 mL (FTC, 35 mL), puff duration of 1.5 s (FTC, 2.0 s), and a total puff volume per cigarette between 615 and 523 mL (FTC, 280−350 mL). The average smoke yields for nicotine were 1.74 mg (FTC, 0.7) and 2.39 mg (1.11), for tar 22.3 mg (8.5) and 29 mg (15.4), and for carbon monoxide 17.3 mg (9.7) and 22.5 mg (14.6), respectively. This study revealed also that, compared with FTC data, smokers of cigarettes with low or medium smoke yields actually not only inhaled significantly higher quantities of tar, nicotine and carbon monoxide but also of the major lung carcinogens, PAH (B*a*P = 1.6−1.8 times higher) and of the TSNA (NNK = 1.7 times higher) (*176*).

Unfortunately, the public generally assumes that the smoke yields published by the FTC are reflecting the degree of exposure to harmful smoke constituents inherent in smoking a given brand of cigarette. Thus, it is believed that smoking low-yield and ultra-low-yield brands carries less of a risk than smoking high-yield nonfilter cigarettes. However, the suggestion that there is a meaningful quantitative relationship between FTC-measured smoke yields and actual uptake of smoke carcinogens by the cigarette smoker is misleading (*171*). It has, therefore, been stated that "the time has come for (requiring) meaningful information on the smoke yields of cigarettes" (*177*, *178*). While the tobacco industry has not taken a stand on this issue, the FTC principally agrees that a better and more comprehensive test program for cigarettes is needed (*179*).

C. Epidemiological Studies

As cited in subsection V. A., seven independent epidemiological studies published between 1969 and 1981 in the U.K. and in the U.S. reported a 20−50% lower risk of lung cancer for long-term smokers of filter cigarettes than for smokers of nonfilter cigarettes (*1*, *153*−*159*). One may assume, on the basis of previous reports, that during the years 1950−1975, when filter cigarettes gave relatively high yields of nicotine (in 1962, sales weighted average = 2.0 mg), smokers had not significantly increased their smoking intensities, in the way smokers did in later years. Therefore, they may have benefited from the reduction of tar in the smoke of filter cigarettes between 1950 and 1975 as is reflected in a somewhat reduced risk for lung cancer.

The sales-weighted average FTC nicotine yields of the U.S. cigarette decreased since 1980 from 1.0 mg to 0.85 mg and that of filter cigarettes declined from 0.9 mg to 0.80 mg/cigarette (*180*). Because smokers compensate for nicotine uptake (*175*, *176*), the consumers of low-nicotine cigarettes are likely to smoke these cigarettes more intensely and inhale the smoke more deeply into the lung than do smokers of nonfilter cigarettes.

Since 1983, at least 10 epidemiological studies have reported that the lung cancer risk of smokers of low-tar, low-nicotine cigarettes is comparable to, or only slightly lower than that of smokers of nonfilter cigarettes (*181*−*189*). The large prospective study, CPS I (Cancer Prevention Study I), by the American Cancer Society, involving more than one million men and women, compares lung cancer mortality and morbidity rates, CHO, COPD, and stroke during the period 1959−1965 with corresponding data from the CPS II study for the years 1982−1988 (*187*, *190*). The smokers in the CPS II group had a significantly higher lung cancer risk than the smokers of filter cigarettes in the CPS I group, and only a slightly lower risk than the smokers of nonfilter cigarettes in the CPS II study (*191*). These epidemiological data are supported by laboratory data from smokers of low- and high-yield cigarettes (*144*−*152*, *161*−*176*). Over the years, the changing cigarette led to a decline in sales-weighted average FTC-nicotine yields for the U.S. cigarette. In 1970, it was 1.31 mg; since 1990, it declined further from 0.94 to 0.85 mg of nicotine (*180*). Since 1990, more than 60% of all U.S. cigarettes delivered ≤1.2 mg of nicotine under the FTC machine-smoking conditions. During the past 2 decades, most of the cigarette-smoking men and women in the United States smoked their cigarettes

rather intensely. There are many indications, though no actual measurements have been reported that smokers of cigarettes yielding ≤1.2 mg of nicotine/cigarette do, in fact, inhale the smoke more deeply than smokers of cigarettes with higher yields.

One indication for differences in depth of smoke inhalation between smokers in earlier and recent decades is the apparent shift in the prevalence of adenocarcinoma in the peripheral lung in both men and women who smoked cigarettes. In the first large-scale epidemiological study on cigarette smoking and lung cancer, the tumors were classified as bronchiogenic carcinoma and adenocarcinoma (AC). Bronchiogenic carcinoma included squamous cell carcinoma (SCC) and small cell carcinoma. Of the 605 men with lung cancer, 566 had bronchiogenic carcinoma and only 39 had AC, i.e., there was a ratio of 15:1. Among the 592 male cigarette smokers with lung tumors in this study, there were 561 cases of bronchiogenic carcinoma and 31 AC (16:1) (*19*). These assessments were completed before the WHO's acceptance of the classification system by Kreyberg in 1967 (*193*). Thus, caution is necessary in comparisons of the SCC to AC ratios of the studies conducted in the 1950s and in later years. Nonetheless, there has clearly been a gradual change in that the prevalence of lung tumors leaned more and more toward AC in the peripheral lung while there initially was a preponderance of SCC in the major bronchi. The SCC:AC ratios for lung cancer cases changed from 3.1:1.0 in men and 1.0:1.64 in women in the years 1964 to 1971 to 1.4:1.0 in men and 1.0:1.8 in women in 1984−1986 (*185, 194−200*). The prevalence of centrally originating bronchiocarcinoma declined from 69.3% in specimens examined before 1978 to 57.3% in specimens collected between 1986 and 1989 (*201*).

In Section III,D, we discussed that the average nitrate content of the U.S. blended cigarette tobacco increased gradually from less than 0.5% in the 1950s to between 1.2 and 1.5%; since the 1980s. Increased nitrate content is a major factor for the increased formation of TSNA during tobacco processing and during smoking (*43, 107*). NNK, a TSNA, formed by the nitrosation of nicotine, is an organ-specific carcinogen that induces lung adenocarcinoma in mice, rats, and hamsters (*43*). Literature data support the potential contribution of NNK in the development of human lung cancer in smokers (*200*). Carbonyl reduction of NNK is the major metabolic pathway. α-Hydroxylation leads to the formation of intermediates that can damage lung DNA (*43, 202*). These data support the concept that smoking low-yield cigarettes enhances the formation of adenocarcinoma of the lung. It appears that efforts to render cigarettes less harmful have had an impact on changes in the type of lung tumors caused by cigarette smoking but have not led to a reduction of the overall lung cancer risk for smokers.

V. Future Directions

The Surgeon General's report on Smoking and Health for the year 2000, entitled "Reducing Tobacco Use", reviews past achievements and outlines the most promising methods for the treatment of nicotine addiction (*203*). It is encouraging that the prevalence of cigarette smoking among adults has decreased from 40% in the 1960s to about 25% in the late 1990s. However, the decline of smoking prevalence progressed only at the rate of 0.5%/year. It is of great concern that, during the last 10 years, cigarette smoking among junior high school students has increased to 9.2% and among high school students to 34.8%. In addition, snuff dipping prevalence in these groups of students increased to 3.6 and 10.0%, respectively (*14, 203*). It is also of great concern that in certain subgroups in our society the percentage of smokers is now significantly higher than in the rest of the U.S. population. In 1997, among men and women with less than 12 years of education, 35.4% smoked cigarettes compared to 11.6% among college graduates. Among those in the lower income strata (income below the poverty level), cigarette smoking prevalence is 33.3% (*196*).

The most promising approaches toward reducing tobacco smoking are four types of intervention: (1) education (school curricula and by mass media), (2) clinical approaches (prescription of drugs, including nicotine, and other treatment for behavioral changes); (3) regulatory intervention (product controls, restriction of product sales to minors, smoking bans at the workplace), and (4) economic measures (taxation) (*203*).

The Surgeon General's report for the year 2000 neither discusses nor mentions the concept of "the less harmful cigarette". As discussed earlier, from a public health standpoint, the only harmless cigarette is the one that is not smoked. Adherence to this view may have been reinforced by the lack of significant progress over the past three decades toward "the less harmful cigarette". However, several scientists outside the industry see it as a mandate that cigarettes with significantly reduced overall toxicity, carcinogenicity and with less addictive potential are made available. After all, smoking control and prevention has not reached the many millions of cigarette smokers who remain dependent on nicotine and are, therefore, at high risk for tobacco-related diseases. These smokers include the large segment of economically disadvantaged, healthcare-underserved men and women in our society.

There are a number of possibilities for changing tobacco products toward overall reduction of toxicity, carcinogenicity and their addictive nature. It needs to be strongly emphasized that there will never be a safe cigarette (*16, 203*). However, "the less harmful cigarette" is a necessary compromise for those smokers who cannot overcome their nicotine addiction. It is suggested that the first step toward such renewed efforts will be the inception of a Tobacco Study Group (TSG) composed of individual experts in the tobacco-related sciences and disease research areas. This TSG will not be a revival of the Tobacco Working Group (TWG) that was active at the National Cancer Institute between 1968 and 1979. The first step for the proposed TSG will be the establishment and adoption of the conditions that will ensure its credibility. The group will be composed of scientists from academia, tobacco control agencies of state and federal governments, and industry. It will be the primary goal of the TSG to study and to establish the conditions for research strategies that, on the basis of current scientific knowledge, would represent the most promising approaches toward the "less harmful cigarette". In the second step, the smoke of the research cigarettes will be analyzed for tar, nicotine, CO, and those smoke parameters and components that contribute to the toxicity, carcinogenicity, and addictive nature of cigarette smoke. The cigarettes will be smoked under conditions that reflect the average smoking habits of long-term cigarette

smokers. The smoke of these experimental cigarettes will be bioassayed in short-term in vitro and in vivo tests for their mutagenicity and carcinogenic potential and for their cilia toxicity. These tests would be followed by long-term smoke inhalation assays with Syrian golden hamsters for the indication of tumors in the upper aerodigestive tract. Tars will also be assayed on the skin of strain A mice for their potential for induction of skin tumors and lung adenomas. Those experimental cigarettes that deliver smoke with lower potentials for toxicity, carcinogenicity, and nicotine addiction than current U.S. cigarettes with comparable tar and nicotine yields will be smoked by voluntary long-term cigarette smokers who volunteer to participate in this assay. The serum of these smokers will be analyzed for nicotine, cotinine, thiocyanate, NNAL, 1-hydroxypyrene, and for COHb. The urine will be analyzed for the same metabolites determined in serum and, in addition, for *N*-nitrosoproline and total NNAL after hydrolysis, and for muconic acid.

A. Some Thoughts on Cigarettes with Low Nicotine Delivery

To achieve low nicotine delivery, the cigarette tobaccos will consist of a low-nicotine blend and will have efficient filter tips. These filter tips will be constructed in a manner that precludes smokers' compensation and manipulation of the perforation, thus allowing nicotine delivery in the smoke to be no greater than that deemed the lowest appropriate dose per cigarette according to the TSG. Initial aims will be for a nicotine delivery of no more than 0.7−0.8 mg of nicotine/cigarette. This dose may be gradually reduced to between 0.5 and 0.6 mg/ cigarette.

A survey by the American Cancer Society reported that between 1992 and 1998 among 1.2 million men and women in the United States, 7.8% of all male smokers and 13.9% of female smokers, consumed cigarettes that deliver ≤6 mg FTC tar. Of the cigarettes delivering 6 mg of tar (57 cigarette brands), five brands delivered 0.6 mg, 42 brands 0.5 mg, and 10 brands 0.4 mg of nicotine (*180, 204*).

Benowitz and Henningfield estimated 0.4−0.5 mg of nicotine content in the tobacco of one cigarette to be the upper limit for effective prevention of nicotine addiction in young people (*205*). It is unlikely that a cigarette with such a low nicotine delivery would be accepted by the consumers. The smoker will rather seek products with higher nicotine yield so that any concept of "a less harmful cigarette" would be self-limiting. However, ultimately, the lowest acceptable level of nicotine emission per cigarette has to be part of "the less harmful cigarette".

B. Major Reduction of TSNA

At a 1962 meeting on *N*-nitrosamines in Hamburg, Germany, sponsored by the West German Cigarette Research Council, H. Druckrey and R. Preussman discussed the possibility that nornicotine and possibly nicotine may give rise during smoking to the suspected carcinogen *N*-nitrosonornicotine (NNN) (*206*). In 1975, Klus and Kuhn, from the Austrian Tobacco Company, determined in the smoke of a cigarette filled with tobacco rich in nornicotine 40 ng of NNN (*207*). On the basis of the absence of publications in the open literature, it appears that the tobacco industry had only limited interest in the analytical and chemical aspects of the TSNA and their carcinogenic activities until the early 1990s (*208−210*). Following a large-scale bioassay for the carcinogenic activity of NNN in the 1970s, the tobacco industry did not publish data on the carcinogenicity of any of the seven TSNA identified in tobacco products (*201*).

TSNA are the major carcinogens in chewing tobacco and snuff and are associated with cancer of the oral cavity of snuff dippers (*43, 211, 212*). The nicotine-derived NNK is an organ-specific carcinogen that induces adenocarcinoma in the peripheral lung of mice, rats, and hamsters. In addition, NNK and its enzymatic reduction product NNAL are the only environmental agents known to induce cancer of the exocrine pancreas in laboratory animals (*48, 202*). NNK and NNN are specifically formed by *N*-nitrosation of nicotine. NNN is also formed from nornicotine (*43*). The *N*-nitrosation of nicotine and nornicotine occurs during curing, fermentation, and aging of tobacco and involves reduction of nitrate, primarily by bacteria, leading to the formation of nitrite which is a *N*-nitrosating agent (*86, 213, 214*).

Star Scientific, Inc. has succeeded in reducing the formation of *N*-nitrosamines, and especially that of the highly carcinogenic NNK, during curing and aging of tobacco (*215*). However, about 30−50% of the TSNA in cigarette smoke result from pyrosynthesis in the burning cone and the hot zones of the cigarettes and are emitted into mainstream smoke together with the preformed TSNAs that are aerosolized into the smoke stream (*216, 217*).

On the basis of our current knowledge, a drastic reduction of TSNA levels in chewing tobacco and snuff is expected to lower the risk for oral cancer; in fact, such low levels of TSNA may be below the threshold level for the induction of tumors in snuff dippers. However, it will also be of importance to investigate the possible endogenous formation of the carcinogenic TSNA in consumers of the snuff brands that contain only traces of TSNA (*43, 218−222*).

Inhibition of NNN and NNK formation in the hot zones of burning cigarettes may also be achieved by trapping the nitrogen oxide radicals. The trapping by free radicals will at the same time, at least partially, remove these freshly generated, highly reactive and, therefore, undesirable agents from tobacco smoke.

C. Nicotine Analogues

Nicotine is regarded as the major addictive agent in smokeless tobacco and in tobacco smoke. Nicotine is also the primary substrate for the two highly carcinogenic, tobacco-specific *N*-nitrosamines, NNK, and NNN (*43, 202, 223*). Thus, a possible approach toward "the less harmful cigarette" would be the replacement of nicotine with an analogue that has reduced receptor binding but also a low potential for the formation of NNN- and NNK-analogues and that these *N*-nitrosamines are also only weakly carcinogenic or noncarcinogenic. Preliminary data by several investigators supports this approach (*224−227*).

VI. Epilogue

The first large-scale epidemiological studies on smoking and disease in 1950 revealed a dose−response

relationship between the number of cigarettes smoked and the risk for lung cancer. These findings were supported by bioassays resulting in a dose–response between the amount of tar applied to mouse skin and the induction of skin tumors. They were further strengthened by inhalation studies with hamsters documenting a dose–response between the amount of cigarette smoke inhaled and the occurrence of tumors in the upper respiratory tract. On the basis of these observations, the initial research toward the less toxic cigarette emphasized the reduction of smoke yields for tar and nicotine and utilized the standard machine smoking method of the FTC to measure such reduction. The emission of tar and nicotine from the U.S. sales-weighted average cigarette was gradually lowered from 38 mg of tar and 2.7 mg of nicotine in 1953 to 18 and 1.2 mg in 1975, and since 1996, to 12 and 0.85 mg, respectively. The tar and nicotine reductions were achieved by using filter tips primarily made from cellulose acetate. The prevalence of filter tipped cigarettes increased from 0.5% of all U.S. cigarettes in 1950 to more than 97% since 1990. Reductions were also achieved by incorporating into the cigarette blend reconstituted and expanded tobacco, by increasing the porosity of the cigarette paper, by changing the tobacco blend, including increasing the portion of air-cured tobacco, and by developing perforated filter tips. It was always recognized that it is highly unlikely that there will ever be a nontoxic cigarette and that there is only one certain way to prevent, respectively to reduce, smoking-related diseases, namely, by not starting the smoking habit or, for smokers, to stop the habit. "The less harmful cigarette" was, and is, only regarded as a compromise for those who cannot or will not give up smoking cigarettes. The group of men and women who continue to smoke includes a large segment of the economically disadvantaged, healthcare-underserved people who also, in general, lack the opportunity to be treated for nicotine addiction.

Between 1969 and 1981, epidemiological studies indicated that the long-term smoker of filter cigarettes has a 20–50% reduced risk for smoking-related diseases compared with the risk of the smoker of nonfilter cigarettes. However, beginning with the 1980s, this difference in risks for cancer, heart disease, chronic obstructive lung disease, and stroke between smokers of low-yielding cigarettes and of smokers of nonfilter cigarettes gradually disappeared. Primarily, three factors are considered to be associated with the disappearance of a reduction in the differences in risks for diseases among smokers of filter cigarettes and among smokers of nonfilter cigarettes. These are the increased smoking intensities and increased depth of inhalation by the smokers of filter cigarettes as a consequence of their acquired need for nicotine. The third major reason is the increased nitrate concentration in the tobacco of the U.S. blended cigarette. The nitrate increase leads to greater concentrations of nitrogen oxides in the smoke and, thereby enhancing formation of carcinogenic *N*-nitrosamines, especially of the nitrosamines formed from nicotine and nornicotine during tobacco processing and during smoking. These TSNA are organ-specific carcinogens that induce adenocarcinoma in the peripheral lung, carcinoma in the upper aerodigestive tract and carcinoma in the pancreas.

For those adults who did not succeed in refraining from smoking, "the less harmful cigarette" has to be developed as the U.S. cigarette of the future. A number of scientists in tobacco control and tobacco-health research regard "the less harmful cigarette" as a "must" for our society.

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POLICY STATEMENT FOR STAR SCIENTIFIC, INC.
Responsible Standards For Changing Certain Prevalent Views in
The Tobacco Industry

* STAR SCIENTIFIC accepts and supports effective measures at the national, state and local levels to ensure that tobacco products are not distributed, sold, or marketed to children and adolescents.

* STAR SCIENTIFIC accepts the findings and conclusions of the Surgeon General of the United States, as well as the informed public health community, that conventionally cured tobacco is a major factor in disease and addiction and that those who use tobacco products who wish to quit should be given incentives and opportunities to do so.

* STAR SCIENTIFIC acknowledges that the use of tobacco products generally poses health hazar and that no known tobacco product or process, even the process that Star has developed, while virtually eliminating nitrosamines, eliminates all health hazards associated with the smoking of tobacco.

* STAR SCIENTIFIC supports having the Food and Drug Administration (FDA) as the lead regulatory agency charged with overseeing the implementation of fair and meaningful regulations over the manufacture, sale, distribution, labeling and marketing of al l tobacco-containing products.

* STAR SCIENTIFIC supports increased biomedical and allied research by the private sector, as well as such federal agencies as the FDA, NIH, CDC, and the USDA, that will continue to identify and understand the complexities of what causes the diseases associated with tobacco use and work to find ways of reducing and/or eliminating these causes, and setting standards and "bench marks" for the development of reduced risk and less hazardous tobacco products.

* STAR SCIENTIFIC believes that it has a corporate responsibility to continue to expand research and development efforts to manufacture tobacco products that are as safe as is technologically possible to address the serious public health problems associated with tobacco use, and to respond to the needs of adult tobacco users who continue to consume tobacco products notwithstanding the broad range of health risks associated with using such products.

* STAR SCIENTIFIC believes that adults who choose to smoke and/or make an adult choice regarding the use of any tobacco products should be fully and completely informed about the dangers of the tobacco products they choose to use, including specific information regarding ingredients and constituents of tobacco and tobacco smoke and the levels of such toxic constituent elements in tobacco and tobacco smoke. This should include any scientifically established information that indicates that a product may or will reduce certain exposure to major toxic elements associated with tobacco use.

* STAR SCIENTIFIC is committed to working with the public health community, the FDA, and other federal regulatory agencies in seeking to prevent the use of tobacco products by children and adolescents and in the scientific development of products that have the potential for lessening or even eliminating the incidence of disease, death and addiction associated with tobacco use.

* STAR SCIENTIFIC believes that the time has come for health groups, researchers, scientists, policy makers, senior government officials, tobacco farmers and responsible tobacco companies to sit down and talk about the future of tobacco and the tobacco industry, including an articulation of reasonable parameters under which new products that will reduce exposure to certain toxic constituents in tobacco and tobacco smoke can be developed, evaluated and marketed.

COMMENTARY

Harm reduction, public health and human rights: Smokers have a right to be informed of significant harm reduction options

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COMMENTARY

Harm reduction, public health and human rights:
Smokers have a right to be informed of genuine harm reduction options

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Abstract

Public health policy needs to be assessed for effects on human rights as well as public health. Although promoting harm reduction products to cigarette smokers might lead to greater total public health harm, if the products become too popular, human rights issues need also to be considered. Avoiding, or objecting to, the fair presentation of information on effective harm reduction products to smokers to allow them to make an informed choice to reduce health risk can represent a violation of a human right--the right to information. The necessary conditions are not met for protecting public health by restricting information on certain risk reduction products. As examples, based on current evidence, smokers have a right to information on snus and medicinal nicotine as harm reduction options that would reduce substantially the risk of death to individuals. Smokers also have a right to truthful information about lower-tar cigarettes that have been erroneously promoted as risk reducing.

Introduction

Two recent, major publications have helped shape consideration of pharmaceutical or tobacco products for reducing harm to cigarette smokers who are unwilling to cease nicotine use completely. The first book resulted from an international workshop funded by the Robert Wood Johnson Foundation, the American Society of Addiction Medicine, and the Addiction Research Foundation (Ferrence, Slade, Room, & Pope, 2000), and the second book was the result of an expert committee convened by the prestigious Institute of Medicine of the National Academy of Sciences and partially funded by the U.S. Food and Drug Administration (Stratton, Shetty, & Bondurant, 2001). In nicotine-related public health policy, there has been a desire to avoid promotion of harm reduction products that, while reducing toxicity to individual users, might increase public health harm because of increased numbers of users.

Ferrence *et al.* (2000) noted one of the important questions is "Would there be a net benefit to society if novel products reduced risk but increased use?" (p. x). Later in the book, Henningfield and Fant (2000) indicate that, in evaluating a harm reduction product, it is important to include, "the potential immediate and long-term health effects at the population level" (p. 240). A discussant in a later chapter urges that a key question in evaluating harm reduction products is whether the product "ends up reducing harm for the population as a whole" (Reuter, 2000, p. 337). The Institute of Medicine (IOM) report (Stratton, *et al.*, 2001) assessed the science base for tobacco harm reduction. Before endorsing any product, the committee wanted to see evidence on increase in harm "to the population from encouraging initiation or continuation of smoking" (p. x). The Executive Summary has as its last conclusion: "Conclusion 6. *The public health impact of PREPs [Potential Reduced Exposure Products] is unknown. They are potentially beneficial, but the net impact on public health could, in fact, be negative*" (p. 6).

The principle of protecting the health of the public has been offered, then, as one guiding principle in the development of harm reduction products, but these major works (Ferrence *et al.*, 2000; Stratton *et al.*, 2001) offer no consideration of another established principle: the human right of individuals to receive information relevant to their health and their health choices. The right to information derives from the principle of respect for autonomy. (The principle of autonomy is also the source of the requirement for informed consent for individuals who take part in research.) If people are deprived of information relevant to their health, they will necessarily be deprived of choices that might protect their health (Freedman. 1999). In a tradition deriving from the Nuremberg Code (1949) and the United Nations Universal Declaration of Human Rights (1948), the American Public Health Association concluded: "Human rights must not be sacrificed to achieve public health goals, except in extraordinary circumstances, in accordance with internationally recognized standards" (Bird, 2001). Assessments need to be made if a public health goal justifies restrictions on human rights (Gostin & Mann, 1999).

The present commentary asserts that (a) snus and medicinal nicotine, based on present evidence, make dramatic reductions in health risks to individual smokers, (b) there is an established right to information that affects health and (c) the potential public health harm is not clear and convincing enough to justify suspension of advice about reduced risks to individuals from these products. Other possible issues involved with reluctance to promote known harm

reduction products will be discussed briefly. These include: a) concern that addicts are impaired in making free choices, b) belief that no harm reduction products of any kind are warranted, c) refusal to advise at all in the absence of strong governmental regulation, and d) preference to let the industry solely promote their own products.

Two significant harm reduction products for individuals who smoke cigarettes

This commentary is not the place for a detailed review of harm reduction products; for that, see the IOM Report (Stratton *et al.* 2001). The IOM Report avoided recommendations about harm reduction products, declared every product as a "potential" harm reduction product, and proposed an elaborate, extensive scheme for assessment (based on toxicology, epidemiology, as well as proper governmental regulation). Though desirable, the feasibility or practicability of the IOM report is far from clear. It is sufficient in this commentary to establish that a product lowers risks substantially to individuals. While further research is needed, the toxicology and epidemiology of smokeless products and medicinal nicotine are well enough understood at present to be confident that these products are substantially less dangerous than cigarettes. For purposes of this argument, it is unnecessary to establish a precise estimate of risk and unnecessary to show that the product is absolutely "safe." This commentary focuses on two types of products to illustrate, snus and medicinal nicotine.

Snus (Swedish moist snuff) reduces tobacco harm dramatically in comparison to cigarettes (Ramstrom, 2000; Henningfield & Fagerstrom, 2001). Rodu & Cole (1994, 1999) have presented evidence for substantial harm reduction from smokeless tobacco in general. Since about half of cigarette deaths arise from lung cancer and respiratory disease (English, Holman, Milne, *et al.*, 1995; Peto, Lopez, Boreham, Thun, & Heath, 1994) and since smokeless products are not otherwise more dangerous than cigarettes, smokeless tobacco products can be estimated to reduce mortality by at least half, because they do not cause lung cancer or respiratory disease. Snus is lower than other moist snuffs in known toxins (N-nitrosamines and polynuclear aromatic hydrocarbons) (see, Ramstrom, 2000). There has been concern about smokeless tobacco and oral cancer. Noting the high rate of snus use in Sweden and citing five studies, the IOM report (Stratton *et al.*, 2000) notes, ". . . the use of snus in Sweden has generally not been associated with oral cavity cancer" (p. 428). The IOM Report also reports that "In a large population-based study looking at risk factors for squamous cancer of the head and neck, Lewin et al. (1998) found no increased risk with the use of Swedish snuff" (p. 301). There are also no secondhand smoke or fire risks from snus. The findings are mixed on whether snus contributes to cardiovascular disease (Ramstrom, 2000; Henningfield & Fagerstrom, 2001; Rodu & Cole, 1999). Snus is not "safe," but, on the basis of toxicological principles (no smoke toxins from smoke exposure to the lungs) and current epidemiological knowledge, snus is *significantly less dangerous* than cigarettes to individual users.

Medicinal nicotine products (nicotine replacement therapies) such as gum, patch, nasal spray, and inhaler are also likely to be much less dangerous than cigarettes (Kozlowski , Strasser, Giovino, Erickson, & Terza, 2001). They deliver no smoke or tobacco toxins (except nicotine) to the user. Medicinal nicotine products have been judged to be so low in risk that some of the varieties are available as non-prescription pharmaceuticals in many countries around the world, including Australia, Austria, Brazil, Canada, Denmark, France, Taiwan, United States, Spain,

and Sweden (Corrao, Guindon, Sharma, & Shokoohi, 2000). On current epidemiological evidence, these products appear to reduce risk in comparison to cigarettes by close to 100% (Kozlowski, Strasser, Giovino, *et al.*, 2001). They have been demonstrated to carry little to no excess cardiovascular risk (Kimmel *et al.*, 2001; Benowitz & Gourlay, 1997), even in heart patients (Rennard, Daughton, & Windle, 1998), and no risks of oral cancer, lung cancer, or respiratory disease (Greenland et al, 1998). As much as five years use of medicinal nicotine in the Lung Health Study (Murray & Daniels, 1998) was unrelated to cardiovascular disease or other serious health effects. While greater, longer-term use of medicinal nicotine might reveal some increased to risk to health, it is not plausible to expect that such risks would ever come close to the dangers of cigarettes.

The IOM report, itself, shows guarded support for this position: "The committee also concludes that for persons addicted to nicotine, a nicotine-containing drug product is preferable to a cigarette or other tobacco-containing product as a chronic source of nicotine" (p. 227). The very next sentence in the IOM report goes on, not to encourage such use, but rather to encourage that the Food and Drug Administration look into the matter: "The FDA should therefore be prepared to consider the chronic administration of nicotine products as a reasonable exposure reduction strategy, again, if supported by valid clinical data" (p. 227).

Snus and medicinal nicotine are not safe or completely without risk. Both snus and medicinal nicotine may cause reproductive health problems and should be avoided during pregancy, but these problems should still likely be less than for cigarettes (Benowitz, 1998, Stratton et al, 2001). I would estimate that medicinal nicotine is somewhat less dangerous than snus, because medicinal nicotine lacks some of the tobacco toxins still present in snus and because medicinal nicotine gives clearer evidence of low cardiovascular risk. However, for the present argument, it is not important to compare snus with medicinal nicotine, but it is critical to establish each significantly less dangerous than cigarettes.

There are supposed harm reduction products that have been proven to not reduce harm to individuals. The lower-tar cigarette appears to not reduce toxic smoke delivered to smokers (e.g., Jarvis *et al.*, 2001; Kozlowski & O'Connor, 2000; Kozlowski, O'Connor, & Sweeney, in press; USNCI, 1996; Benowitz *et al.*, 1983) or mortality (e.g., Burns *et al.*, in press). Newer cigarette-like products (e.g., Eclipse®, Accord®) at best make smaller changes in the product (smaller than Snus or MN in comparison to cigarettes), and likely make concomitantly small changes, if any, in risk. Careful testing such as prescribed by the IOM Report (Stratton *et al.*, 2001) would be needed to establish the magnitude, if any, of risk reduction from the products.

The human right to health relevant information arises out of the principle of autonomy

Several ethical traditions (legal, medical, public health) lead to a view that there is a human right to fair information relevant to health care. All traditions depend upon the principle of individual autonomy. Beauchamp and Childress (1994) argue that both Emmanuel Kant and John Stuart Mill helped establish the philosophical basis for valuing an individual's self worth and the individual's rights to determine goals. The Nuremberg Code (1949) and the United Nations Universal Declaration of Human Rights (1948) acknowledge a basic human right of autonomy. Legal traditions have also helped shape expectations about patient autonomy and patient rights to be informed of and consent to medical treatment (Wear, 1998). McCullough

and Wear (1985) described a "new ethos of patient autonomy" that has arisen in the face of, benevolent, but paternalistic (Doctor knows best) practices. Increasing governmental regulations on formal informed consent procedures and research have influenced the modern context in which patients deal with health care (Wear, 1998).

Public health ethics overlap with biomedical ethics, but also have some distinctive emphases (e.g., Mann, 1999). Working in the public health field of family planning information, which can involve both one-on-one clinical encounters as well as diverse social sources of information, Freedman (1999) argued that censorship of information about reproductive and sexual health violates individual human rights. Freedman wrote: "Women need and want reproductive health services because they want--and have--a fundamental human right to live lives that are free from unnecessary physical and mental suffering, and that permit the exercise of fundamental freedoms" (p. 147). Similarly, censoring information on genuine risk reductions to individual smokers restricts the ability of smokers to exercise their fundamental freedoms to make choices that can have dramatic effects on individual health risks.

In public health, benefit to the many can override the rights of the individual. Public health interests should prevail when there is low cost to the individual and high benefit to society (Annas, 1999). For an individual smoker who will not give up nicotine use, the benefits of snus or medicinal nicotine could be profound to the individual (and possibly to society), while the costs to society are far from clear and convincing.

Clear and convincing evidence is needed to favor public health over individual health

In law there are three standards of evidence, in order of increasing stringency: 1) the *preponderance* of the evidence, where a conclusion is "more likely than not" to be true; 2) *clear and convincing* evidence, producing firm belief or conviction; and 3) evidence *beyond a reasonable doubt.* Clear and convincing evidence has been required in court cases involving issues like quarantine, where an individual's rights are suspended to protect the public from the risk of spreading a serious disease (Annas, 1999).

Two principles have been emphasized in determining whether public health interests should override individual health interests: proportionality and probability. The limitation of rights "must be proportional to the public health interest and its objective." (International Federation of Red Cross and Red Crescent Societies and François-Xavier Bagnoud Center for Health and Human Rights, 1999, p.48); and "The risks to the public must be probable, not merely speculative or remote." (Gostin & Mann, 1999, p. 67)

The language of the prospects for adverse public health effects is decidedly tentative with little indication of adverse public health effects being either probable or proportional. The IOM Report (Stratton et al., 2001) notes: "Both Pauly & colleagues (1995) and Hughes (1998) *raise the possibility* that the introduction of PREPs and their promotion as less harmful ways to smoke *could* lead to increased initiation." (Stratton *et al.*, 2001, p. 73); and "The major concern for public health is that tobacco users who might have otherwise quit will use PREPs instead, or others may initiate smoking, feeling that PREPs are safe. That will lead to less harm reduction for a population (as well as less risk reduction for that individual) than would occur without the

PREP, and *possibly* to an adverse effect on the population."(Stratton *et al.*, 2001, 8-4). (Emphasis added.)

When risks from a product are relatively small, the level of increased use needed to maintain a public health equilibrium (no changes in population-level problems) becomes very high (Kozlowski, Strasser, Giovino, *et al.*, 2001). The risk to individuals from medicinal nicotine seems to be so low that it is not possible for use to increase enough to cause a net public health loss: if risks from these often over-the-counter products are less than 0.1% (1 per 1,000), then use would have to increase over 1,000 times, to cause an equal public health problem (Kozlowski, Strasser, Giovino, *et al.*, 2001). For a product like snus, if the risk is even 1% that of cigarettes, use would have to increase 100 times to equal the problems from cigarettes. If the risk from Snus were as much as 5% that of cigarettes, use would still have to increase an unlikely 20 times for the public health problems to equal those from cigarettes.

Some other issues that might prevent public health advice about snus and medicinal nicotine as harm reduction products

Are addicts in a position to freely choose?

To hold that adult nicotine addicts are too impaired by their addiction to give informed choice is not in keeping with prevailing legal traditions on competency. Nearly every individual is assumed to be competent to choose, unless proven otherwise (Wear, 1998).

Are any harm reduction products warranted?

At least one distinguished public health scientist has raised doubts about whether harm reduction products are needed at all (Pierce, 2000, p. 227). He stated that prevention and cessation programs should possibly be the sole focus of controlling smoking-caused disease. This position can be seen as an extreme form of neglecting the right of smokers to make informed choices. If complete abstinence is *not* the only way for an individual smoker to significantly reduce health risks from nicotine addiction, then the rights of smokers to be informed of this is still in opposition to an exclusive emphasis on prevention and cessation.

Should we advise on harm reduction products in the absence of proper governmental regulation?

The failure of governments to establish any effective regulation of tobacco products can be seen as arguably the greatest failure of public health policy for the past 100 years. I have recently been in a meeting with several distinguished scientists and opinion leaders interested in smoking-related public policy and regulation. The majority of these individuals expressed an unwillingness to express any public opinion about would-be harm reduction products for tobacco, until such time as proper regulatory/evaluation systems were in place to unequivocally judge the degree of harm reduction afforded by the products as used by society. (This might be viewed as in keeping with the position of the IOM report.) Clearly the best of all possible research has not yet been done on snus or medicinal nicotine, but, equally clearly, it is wrong to assume that we lack practical scientific bases for estimating that there will be harm reduction to individual smokers from these products. Though it is important to attain proper regulation over tobacco and harm reduction products, this goal is logically and ethically independent of the need to provide smokers today with what information we do have about the risks of various products.

Shouldn't manufacturers do their own promotion?

I have also heard colleagues say that manufacturers of these products don't need our help to promote their products. But that should not be justification for avoiding any positive comment or support for information that might reduce for individual smokers the harm from smoking. Note that the public health community has not similarly left all advice or encouragement about products--vaccines or seat-belts or condoms (another harm reduction product)--to the manufacturers.

Public health approaches to informing smokers of harm reduction options

I am not primarily calling on the medical profession to talk with their noncompliant smoking patients about harm reduction. A broad-based model for public health interventions can be found in work on reproductive health. In the area of reproductive health and the right to information, it is argued that *comprehensive programming is needed to inform individuals* (Cohen, 1994). Such programs should include mass media advertising, message placements in TV programs, and systematic training of health professionals to discuss the needed information (Freedman, 1995).

Public health policies should be assessed for their affect of human rights

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Insert Figure 1 here

The late Jonathan Mann was a leader in calling for formal assessments of the impact of public health policies on human rights (Gostin & Mann, 1999; Mann *et al.*, 1999). Figure 1 is derived from some of his work (Mann *et al.*, 1999). The best policies are those that protect human rights as well as promote public health. Mann noted that it was a violation of human rights on the part of governments to not be providing honest information about the dangers of cigarettes (Mann et al, 1999). Low-tar cigarettes are designed to reassure smokers and keep them smoking (e.g., Kozlowski & Sweeney, 1997), but do not reduce health risks to smokers (Burns *et al.*, in press). This is both a violation of the human right to know and a counterproductive public health measure.

Cigarettes kill about half of those who smoke them (English *et al.*, 1995; Peto *et al.*, 1994; U.S. Department of Health and Human Services, 1989). It is urgent to inform smokers about options they have to reduce risk. This needs to be done in ways that inform smokers as fully as possible that never starting and complete quitting as soon as possible are the best choices to promote health, while also indicating that snus or medicinal nicotine (the latter more than the former) would be preferable to continued smoking. Also, complete substitution of these products should be encouraged over mixing them with continued smoking. The harm reduction message will be complex. There will be many ways to give it. Some will misinterpret even the most artfully framed message. Notwithstanding, public health policy in this instance lacks compelling justification to override the human rights of the individual. Individuals have the right to such health relevant information.

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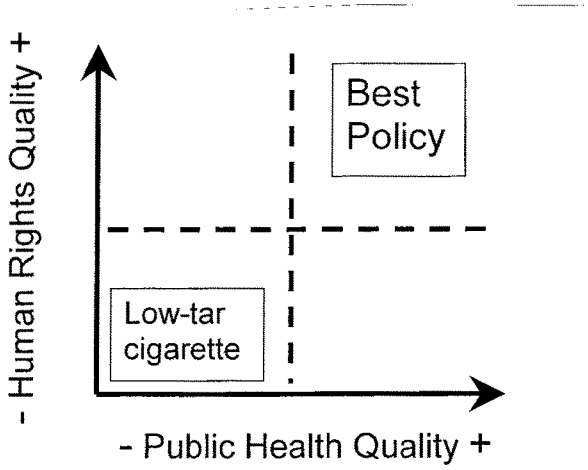
Figure Legend

Figure 1. Schematic showing the interactive relationship between public health policy and human rights. The best policies are those that are consistent with human rights. Low-tar cigarettes are both poor public health policy and in violation of human rights to information. (See text for more details.)



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ONE
Introduction

1.1 Tobacco is a uniquely dangerous consumer product, killing 120,000 people per year in the UK and 4 million worldwide when used as intended by the manufacturer. Cigarettes are highly addictive, and are the most toxic and carcinogenic means of delivering nicotine. They are also heavily promoted and widely available.

1.2 In February 2000, the Royal College of Physicians' Tobacco Advisory Group published an extensive, authoritative account of the role of nicotine in British society, *Nicotine addiction in Britain*. The final two recommendations of that report were:

> *14. Tobacco products in Britain should therefore be regulated either by the Medicines Control Agency or by a nicotine regulatory authority similar in concept to the Food Standards Agency.*
>
> *15. We recommend that an independent expert committee should be established to examine the institutional options for nicotine regulation, and to report to the Secretary of State for Health on the appropriate future regulation of nicotine products and the management and prevention of nicotine addiction in Britain.*

1.3 In June of 2000, the Commons Health Select Committee examined the issue in detail and arrived at a similar conclusion, endorsing the recommendation of the College and adding:

> *189. [...] It seems to us entirely illogical that treatments for nicotine replacement therapy are subject to stringent regulation whereas the infinitely more deadly tobacco products they are designed to supersede escape any fundamental regulation. So we believe a Tobacco Regulatory Authority should be introduced.*

1.4 The purpose of this report is to take those recommendations forward and to encourage the government to address the strategic issue of how it should regulate the tobacco industry and tobacco and other nicotine products. This report considers the regulatory challenges that lie ahead and are already evident, and examines various institutional and legal structures for regulation, based on three models. These are the Irish Office of Tobacco Control, the Medicines Control Agency (MCA) and the Food Standards Agency (FSA).

1.5 The report examines the options for regulation at European level (the stated preference of the Government) and the options available in UK law to create the necessary regulatory capacity.

TWO

The case for a tobacco and nicotine regulatory authority

2.1 This document argues that considerably more regulatory capacity for tobacco is required and justified in order to protect public health in the UK. The impact of tobacco on British society is quite unprecedented – consider eight aspects:

1 **The scale of the impacts of tobacco use.** 10 million users are addicted to nicotine, and tobacco-related disease kills 120,000 per year (one fifth of all deaths). It is responsible for one third of cancer, one seventh of cardiovascular disease and most chronic lung disease in adults. Tobacco is the single largest cause of social inequalities in health and aggravates poverty among poor smokers. There are multiple impacts on non-smokers and children exposed to tobacco smoke. There are pronounced economic impacts on the public sector (especially the NHS) and on productivity in the economy. It is the largest cause of fires with fatal injury and creates the single largest source of litter.

2 **The challenges of developments in the tobacco market.** Tobacco companies are designing products which claim reduced risk or other benefits, and smokeless tobacco producers are seeking to exploit very large reductions in risk compared to smoking. At the same time, novel nicotine products are coming to market that could greatly reduce harm, but face regulatory barriers far greater than cigarettes – the most harmful means of delivering nicotine.

3 **The complexity of the policy responses.** The policy responses require skilled programme management in order to spend money and expend resources wisely. Some may be scientifically complex, such as regulating the chemistry of smoke and tobacco products. Some policies are highly contentious, such as banning tobacco advertising, raising taxes and securing smoke-free areas. Some responses may give rise to unintended consequences, for example some youth initiatives may encourage smoking. In the area of smoking cessation, strict regulatory systems for pharmaceutical nicotine clash with the much weaker regime for tobacco, causing perverse outcomes that harm smokers.

4 **The current regulatory imbalances.** At present, nicotine replacement therapies are strictly controlled under medicines regulation, and oral tobacco is banned completely under European Union (EU) law – yet both represent much less hazardous ways of administering nicotine than cigarettes and both may be used for smoking cessation. However, cigarettes are subject only to the most cursory regulation and restrictions. This perverse regulatory imbalance favours the most deadly means of delivering nicotine.

5 **The strength of the commercial interests.** The UK industry is highly profitable, achieving profit margins of about 40% on turnover after deduction of duty. There are three FTSE 100 companies and major multinationals such as Philip Morris and Japan Tobacco International are involved at UK, EU and international level.

6 **The money involved.** Tax revenue raised from this sector is £9.3 billion per year in duties and VAT. This exceeds the monies committed in the tobacco white paper, *Smoking Kills*, by 250 times. Closer regulation of this industry in the interests of consumers is a modest return to those who pay their tobacco taxation. The whole enterprise should be funded by levies on the tobacco industry at no net cost to the public purse.

7 **Precedents from other areas of policy.** The government benefits from considerable regulatory capacity in the area of food and pharmaceuticals. Other governments are establishing reasonable regulatory capacity for tobacco.

8 **The 'pitiful' resources currently devoted to regulating tobacco.** No other area of public health policy has such large stakes in health, welfare and the economy, combined with such a complex and contentious policy environment and such large sums of money involved. Against this background, the Health Select Committee described the regulatory capacity for tobacco within government as 'pitiful' and at EU level 'utterly derisory'.

THREE

Forthcoming regulatory issues in tobacco policy

3.1 The following are examples of issues that already arise or are likely to arise in the regulation of tobacco products over the next few years.

The emergence of reduced-risk tobacco products

3.2 Manufacturers have already introduced products in the United States that they claim offer smokers reduced risks. Products include those making false, implied claims, such as 'lights'; products with certain carcinogens or other toxins selectively reduced; novel technologies such as heating rather than burning tobacco; and smokeless tobacco products to be chewed or sucked. In each case there are marketing claims made and applications suggested.

3.3 These present multiple challenges for regulators.

- What reduction in risk does the product achieve and how is this measured? The ISO tar yield measurements are of no use.
- What happens when some risks increase and others decrease?
- What claim may be made for the reduced risk, and who will give approval or regulate such claims?
- At what level of reduced risk would the authorities be negligent in not allowing consumers to be informed about products that do them less harm?
- How should claims that are true but may be misunderstood or understood disproportionately ('reduced cancer risk') be dealt with?
- How should relevant consumer information reach the consumer in a situation where advertising is prohibited?
- How should the market testing of such products be handled?
- What should government policy be in this treacherous area of public health?

The scope for reducing harm caused by mainstream cigarettes

3.4 There are technologies and techniques available that may reduce the harm caused by smoking by reducing hazardous chemicals in the smoke: what scope is there to *impose* technical performance standards on tobacco product manufacturers – what legal basis could be used? How would such standards be set and monitored?

Smokeless tobacco

3.5 As a way of using nicotine, the consumption of non-combustible tobacco is of the order of 10–1,000 times less hazardous than smoking, depending on the product. Some manufacturers want to market smokeless tobacco as a 'harm reduction' option for nicotine users, and they may find support for that in the public health community.

3.6 This raises many questions.

- Should the ban on oral tobacco (EU Directive 2001/37/EC article 8) be lifted and what kind of regulatory regime should replace it?
- Can product 'purity' standards be used to reduce the toxins in smokeless tobacco?
- What claims could be made about the relative health risk of smokeless tobacco and smoking and how should these be communicated?
- How can the use of smokeless products as a 'starter' product for young smokers be minimised?
- How can the risk of unintended consequences (eg reduced cessation) be minimised?
- How would the government and EU respond to a successful legal challenge to the EU ban on oral tobacco?
- How should 'smokers' rights' to have access to products that do them much less harm be reconciled with possible negative consequences at the population level?
- What options are there to 'promote' smokeless tobacco as a much safer alternative to smoking, without promoting tobacco use per se?

Pharmaceutical regulation of nicotine products: the level playing field

3.7 There may be 'harm reduction' indications for pharmaceutical nicotine, which involve long-term use or use during temporary abstinence from smoking. There are pharmaceutical products in the pipeline that may be branded more like tobacco products with a view to appealing to smokers. How is it possible to avoid letting the far more onerous pharmaceutical regulation keep such products from the market, while the almost non-existent regulation of tobacco allows cigarettes to be widely available with minimal safety restrictions or warnings?

Use of pure nicotine as a consumer alternative to smoking

3.8 There may be a generation of nicotine products that are offered outside the conventional pharmaceutical and medical framework as consumer products. One company has placed nicotine water on the market and another wished to offer a nicotine gum packaged and branded as an alterative to smoking. Such developments offer the potential for competition with cigarettes with much lower health impacts, but may also create new population risks.

Legal challenges

3.9 The tobacco industry has shown that it will challenge any meaningful public health measure on tobacco. Even if the measure cannot be overturned, the effect is to delay implementation, to tie up official time and to 'chill' the government's determination to regulate in this area. All of which means that legislation must be as robust as possible, offer a proper public health benefit and be robustly defended. The legal challenges to tobacco product regulation threaten a precipitous destruction of the government's policy on consumer protection for tobacco products.

3.10 This raises several questions:

- Why was legislation which in places is at variance with best available scientific knowledge written in the first place? For example, the Royal College of Physicians' February 2000 report, *Nicotine Addiction in Britain*, illustrated how tar-yield reductions offer little benefit to contemporary smokers.
- What scientific and public health capacity is available to work with lawyers to defend against legal challenges brought by the tobacco industry?
- How can UK regulation be made consistent with EU law and international trade agreements, while still achieving its aim of protecting public health, and who will gather the evidence?
- Are the trade-related treaties – World Trade Organisation (WTO) agreements, Trade-Related Aspects of International Property Rights (TRIPS) and the EU single market – adequately framed to protect health? Should the UK press for a public health article in the EU treaty?

Warnings on packaging

3.11 The UK will have to decide if it wants to include pictorial warnings on packs following the Commission's specification of how such warnings might be used. A regulatory committee will be established with the power to modify the warnings specified in EU Directive 2001/37/EC, but what are the appropriate warnings for the UK and how would these be determined?

Additives and design features

3.12 The regulation of additives is wholly inadequate in the UK and EU. How can a proper public health assessment be made of the impact of individual tobacco additives and what sort of approval process would be needed? What more could be done to force the introduction of fire-safe cigarettes?

Successor directive

3.13 EU Directive 2001/37/EC contains provisions for a review to be completed by 2004, with new proposals to follow if necessary. How will the UK government address the many areas that will be covered by the review and provide good scientific advice to the Commission?

Research agenda

3.14 Tobacco companies clearly know a great deal more about tobacco products than their regulators. What funds can be justified for research into tobacco products and how should these be spent?

Other areas of tobacco policy

3.15 The items listed above reflect just one aspect of tobacco policy – the regulation of the product and its packaging. There is also government regulatory involvement in a number of other areas of the tobacco market.[1]

- **Advertising, sponsorship and promotion – monitoring, enforcement, and legislative development.** The Tobacco Advertising and Promotion Bill allows for modification of the legislation in response to changes in technology and marketing practices.
- **Smoking in the workplace and public places.** The Health and Safety at Work Act places obligations on employers to protect the health, safety and welfare of employees. How should the scientific evidence on passive smoking be reconciled with the requirements on employers to do what is reasonably practicable to offer protection to workers?
- **NHS treatment of tobacco dependence.** There are several areas in which the Government defines policy and regulation of smoking cessation.
- **Taxation and economic effects.** There is a strong case to gather and analyse much greater data on the impact of tax policy both in shifting patterns of consumption and any unintended consequences.

Knowledge and experience

3.16 In addition to regulation and enforcement, there is a need for authoritative scientific, economic and public health advice and research to inform policy and regulation. Programmes with substantial funding, such as the national tobacco education campaign, also need to draw on best available knowledge of what works and programme experience from elsewhere.

1. See Action on Smoking and Health (ASH), 'Tobacco legislation, regulations and voluntary agreements', http://www.ash.org.uk/html/policy/legislation.html<8 November 2002 (Last accessed 13 November 2002)>

FOUR

Views of Parliament and Government responses

4.1 After an extensive review of the history of tobacco regulation in the UK and the role played by the tobacco industry, the Commons Health Select Committee made the following observations and recommendations:

> *189. The final conclusion of the RCP in its Report* Nicotine Addiction in Britain *was that 'an independent expert committee should be established to examine the institutional options for nicotine regulation, and to report to the Secretary of State for Health on the appropriate future regulation of nicotine products and the management and prevention of nicotine addiction in Britain'. We concur. It seems to us entirely illogical that treatments for nicotine replacement therapy are subject to stringent regulation whereas the infinitely more deadly tobacco products they are designed to supersede escape any fundamental regulation. So we believe a Tobacco Regulatory Authority should be introduced.*
>
> *190. We have, throughout our report, indicated areas for which we think a Tobacco Regulatory Authority (TRA) could take responsibility. It could look at all aspects of the marketing of tobacco, the product itself and the nature of its health risks and developments in respect of 'safer' cigarettes. [...]*
>
> *191. Consequently we would envisage the creation of a TRA with its own scientists, completely independent of the tobacco companies. When considering its function we should like to stress that we do not believe that the TRA could, for example, seek the elimination of nicotine from cigarettes. Its policies would have to recognize the realities of a global market for tobacco products, where any attempt to exclude nicotine – which would in our view be tantamount to prohibition of cigarettes, in that nicotine is, in the words of the RCP, the 'unique selling point' of cigarettes – would be likely to be counter-productive. The proposed TRA could, however, examine nicotine:tar ratios to determine how these could be optimised to minimise exposure to toxins.*
>
> *192. The TRA would, as we have stated, be the ideal objective judge of which additives and flavourings should or should not be permitted to be added to tobacco products, having as its test the overall impact on public health. The TRA could consider the marketing of tobacco products, looking at areas of promotion going beyond advertising into issues such as point of sale displays.*
>
> *194. In a research capacity, the TRA could examine, and offer definitive statements, on the current scientific consensus as to the dangers of smoking, and could examine the most effective ways of persuading people to quit or never to start.*
>
> *195. Assuming there is a will on the part of Government to tackle nicotine addiction in the very fundamental way that we propose, the question remains where should a TRA be located? One possibility would be for the UK to have its own TRA, in a way analogous to the Food Standards Agency or Medicines Control Agency; another would be for a TRA to be located in Europe, the source of much of what currently passes for tobacco regulation. [...]*
>
> *198. Turning to the question of how the TRA should operate we think it vital that such a body should be very well resourced to deal with the huge scientific and legal resources of the tobacco*

companies. We think that a proportion of tobacco duty should be hypothecated to finance the regulatory authority. In oral evidence the DoH told us that, to analyse and understand the technical composition of cigarettes, it relied on a scientific adviser, Professor Frank Fairweather, who worked one day a week, another scientific advisor working two days a week, and Mr Tim Baxter who worked full time. Mr Baxter explained that, as head of the Tobacco Research Unit, he had access to a technical advisory group via the Scientific Committee on Tobacco and Health. Finally the DoH provided over £500,000 a year to the Laboratory of the Government Chemist to test tar and nicotine ratings. Mr Baxter recognized there were many calls on the Department's resources, but he admitted that it would be 'very nice' to have more resources since his team were 'highly stretched'. When we put our concerns on this matter to the Secretary of State he agreed that the tobacco team in the Department was 'quite small', but he contended that its work was supplemented by, for example, the professionals working in Health Action Zones and the Scientific Committee on Tobacco and Health. This latter body he described as 'a very useful organisation'.

199. We would have more faith in the Secretary of State's assessment of the added benefit of SCOTH had that organization not been in abeyance for almost two years. We regard the current staff resources devoted to tobacco control, especially in the area of scientific knowledge and advice, to be pitifully weak. Irrespective of whether the Secretary of State accepts our recommendation that root and branch reform is needed in terms of a TRA, we would expect to see a major increase in resources, met out of the enormous income the tobacco companies pay in duties to the Treasury.

200. If UK staff resources are pitiful, those in the EU are utterly derisory. As the Secretary of State informed us, and as we saw for ourselves in Brussels, in Europe 'there is just one official dealing with tobacco', Mr John Ryan. In fact the situation is graver still, in that tobacco forms only one half of Mr Ryan's portfolio. We met Mr Ryan on our visit to Brussels and were extremely impressed by his knowledge and commitment. But we do not see how the Health Commissioner can deliver his objective of reducing tobacco consumption with such scant resources. We recommend that the Secretary of State makes immediate and urgent representations in Brussels to create a far more substantial unit to combat the enormous resources of the tobacco industry. We believe that European policy is already hugely compromised by the CAP subsidy, and that unless appropriate resources go into tobacco control European action in this sphere will lack credibility. [2]

4.2 The government's response dealt with these recommendations in a cursory manner:

The Government agrees with the Select Committee that tobacco products need to be regulated more effectively than at present. We believe that much of this regulation will be most effective if it is done at the European level, which is why we continue to argue strongly for tighter regulation and greater openness in negotiations with our European partners. The Draft European Directive on the manufacture, presentation and sale of tobacco products requires much greater openness, something which the UK has argued for strongly in Europe. Once adopted, we will be implementing the Directive.[3]

4.3 However, there is little sign of effective regulation at the European level, and indeed such regulation may not even be possible without a change to the EU Treaties. At present the treaties

2. House of Commons Select Committee on Health. *The tobacco industry and the health risks of smoking. Second report, session 1999/2000.* London: The Stationery Office, 2000.

3. Department of Health. *Government response to the second report of the Health Committee: the tobacco industry and the health risks of smoking.* London: DH, 2000.

emphasise the operation of the single market and do not allow regulation by qualified majority for health protection. In our view, it would be unduly constraining to require regulation of tobacco to fit within the single market provisions of the treaty – see the discussion in Appendix 2.

4.4 Evidently dissatisfied, the Health Select Committee raised the matter again in its report on public health:

> *248. We would welcome a clear statement of principle by the Government on the desirability of a Tobacco Regulatory Authority. We feel that our report was one of the most comprehensive analyses of the tobacco industry ever undertaken in the UK, had access to documentation that had hitherto been concealed, and got very much to the heart of the behaviour of the tobacco companies. We would like the Government unequivocally to support our recommendation and – when parliamentary time permits – introduce appropriate legislation to support it.*[4]

4.5 In its response, the Government offered a more open-minded view than its previous response to the Committee's report:

> *The Government agrees that there is a need for tighter regulation of tobacco products, and more information about the additives used in them and their effect upon health.*
>
> *It also agrees that there is a need for greater control of the contents of tobacco products and more information about the effects on health of the various ingredients. However, the Government is not convinced that all existing legislative powers have been fully applied and is considering how these might be used to regulate tobacco products more effectively. Wide-ranging powers exist under the Consumer Protection Act 1987 to ensure the safety of consumer goods, and the Government will not hesitate to use these, if necessary, to ensure that changes are made to tobacco products so as to reduce the harm these cause. That said, it is not in principle opposed to the idea of a Tobacco Regulatory Authority, should existing mechanisms prove inadequate, and will keep this whole area under review.*
>
> *The Government continues to believe that work in this area will be most effective at a European level and good progress is being made. The Directive of the European Parliament and Council on the manufacture, presentation and sale of tobacco products (2001/37/EC) came into force on 18 July 2001. This Directive will require Member States to collect thorough details of the contents of tobacco products on the market and to submit these to the European Commission, which in turn will be required to draw up a report on its application. The Directive requires that the Commission will be assisted by the necessary scientific and technical expertise.*[5]

4. House of Commons Select Committee on Health. *Second report, session 2000/1*. London: The Stationery Office, 2001.

5. Department of Health. *Government response to the House of Commons Select Committee on Health's second report on public health*. London: DH, 2001.

FIVE

Resources for tobacco: Department of Health 'regulatory' staff

5.1 A key criticism made by the Health Select Committee was that government resources devoted to regulating tobacco were 'pitiful' at UK level and 'utterly derisory' at EU level. However, since the publication of the Committee's report, the position has not improved and may actually have deteriorated. There has also been a rapid turnover of key staff, leading to loss of continuity and experience.

- At the Department of Health branch head level (civil service grade 5), there have been four senior officials in the last five years.
- At the team leader level (grade 6 or 7) there have been three complete changes of staff in five years. In the most recent change, the team leader has assumed wider responsibilities.
- The science and medical capacity was regarded as inadequate at the time of the Health Committee report in 2000, and has since been reduced. An experienced full-time medical officer has been replaced by a part-timer new to the field.
- The Department was previously able to draw on a pool of experience and expertise at the Health Education Authority – there was a team of ten professionals in 1999, but there are now only two part-time staff devoted to tobacco at its successor, the Health Development Agency. Though there have been some compensating increases in resources in the Department's communications and policy units, the government has lost a substantial body of expertise.
- The Scientific Committee on Tobacco and Health relies on voluntary and unpaid participation by established scientists in the field. After its 1998 report, it was in abeyance for more than two years. The Committee was reformed in late 2000 and has since met approximately quarterly. The Committee itself has registered concerns about its own level of resources, time commitment and expertise in relation to the scale of scientific challenges which lead to problems in its effective functioning.
- The Health Committee spoke highly of the experienced Commission official, Mr John Ryan. Mr Ryan has since been moved. The European Commission does have a slightly larger team now, but comprised of less experienced officials. It also has greater demands on its time due to legal actions by tobacco companies.

5.2 This is not intended to be a criticism of civil service career structures. However, it does suggest that the government needs an institutional solution to the problem of regulating tobacco that may be in some way separate from the Department of Health's Cancer and CVD Prevention branch. This would be similar to the approach taken towards regulating drugs and food, whereby external agencies exercise statutory powers and advise the Secretary of State on the use of his powers.

The Royal College of Physicians' view

5.3 The Royal College of Physicians urges the government to act on its commitment to tighter regulation and at least to follow the recommendation of the College's 2000 report *Nicotine addiction in Britain*:

> *We recommend that an independent expert committee should be established to examine the institutional options for nicotine regulation, and to report to the Secretary of State for Health on the appropriate future regulation of nicotine products and the management and prevention of nicotine addiction in Britain.*[6]

5.4 The College maintains that the regulation of tobacco and conduct of tobacco policy needs to be addressed at an institutional level – and that this means creating a permanently staffed agency with adequate responsibility and authority to create a proper regulatory environment for tobacco.

6. Royal College of Physicians. *Nicotine addiction in Britain*. London: RCP, 2000.

SIX

Regulating tobacco at the European level

6.1 The Government has argued that tobacco should be regulated at the European level and that any regulatory agency needs to be established at the EU level. There are a number of reasons why this is an insufficient response to the challenge.

- The institutions do not exist at EU level and the government has done little to press for them to be established. The tobacco product directive 2001/37/EC establishes a regulatory committee to deal with three narrow areas of regulation and requires that the Commission takes appropriate scientific advice in reviewing the effect of the directive. However, this does not amount to a proper regulatory authority.
- The government is ultimately responsible to the British electorate for positions adopted in the EU, and needs to place British interests to the fore while EU regulation and legislation is made. Where the regulatory capacity is weak at EU level and in other member states, the UK should not find itself agreeing with weak or inappropriate measures (as happened with 2001/37/EC) simply because it has, as stated by the Health Select Committee, 'pitiful' resources devoted to the issue.
- The competence of the EU to regulate for public health is at best ambiguous and the EU regulations in place governing tobacco are primarily to ensure the operation of the single market and compliance with trade agreements. The government therefore has the scope (and obligation) to introduce tobacco regulation for public health and consumer protection purposes as UK legislation or regulation – this has been the case for the advertising legislation. This will remain the case as long as the EU treaties (eg article 152) do not allow negotiation of binding directives or regulations at EU level for public health reasons.
- Enforcement and operation of EU laws are the responsibility of member states and there are many issues that arise at national level in the practical implementation of EU regulation.
- In the case of food and pharmaceuticals, the regulatory agencies are at both national and EU level, with very substantial agencies (the FSA and MCA respectively) in the UK. A similar structure should apply to tobacco.
- Regulation of tobacco at EU level has not been a conspicuous success so far (see Appendix 2 for a discussion of the limitations of tobacco regulation at EU level). This is mainly because tobacco legislation in this arena has been formulated under *single market* articles of the EU Treaties rather than as *health* legislation. Any regulatory body would also be formulated in the same way. Thus its dominant pre-occupation would be operation of the single market rather than public health.

SEVEN

Comparison: The Office of Tobacco Control, Ireland

7.1 In Ireland, new tobacco control legislation completed its passage on 27 March 2002. Part of the bill was to establish the Office of Tobacco Control (OTC). The legislation gives the following functions to the Office at section 10:

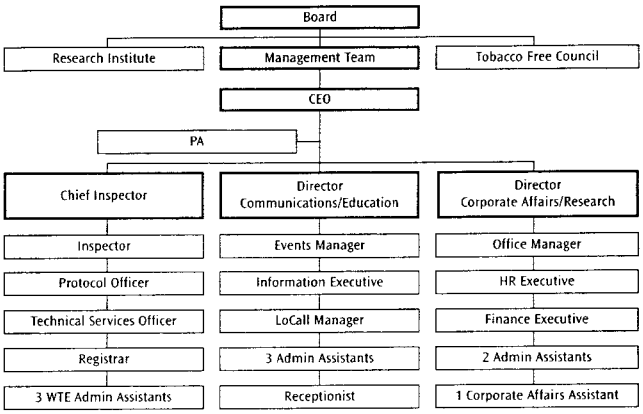
> *10.–(1) The general functions of the Office shall be to –*
>
> *(a) advise the Minister in relation to the formulation, and assist him or her in the implementation, of policies and objectives of the Government concerning the control and regulation of the manufacturing, sale, marketing and smoking of tobacco products,*
>
> *(b) consult with such national or international bodies or agencies having a knowledge or expertise in the field of smoking prevention for the purpose of identifying measures designed to eliminate, reduce the incidence of, or discourage smoking,*
>
> *(c) make such recommendations to the Minister as it deems appropriate in relation to measures that the Office considers should be taken in order to reduce or eliminate smoking or its effects in the State,*
>
> *(d) undertake, sponsor or commission, or provide financial or other assistance for, research aimed at identifying measures that when adopted are likely to reduce the incidence of smoking or its effects,*
>
> *(e) prepare and publish, in such manner as it thinks fit, reports on any research undertaken, sponsored or commissioned, or for which financial or other assistance was given, under paragraph (d),*
>
> *(f) furnish advice to the Minister, whenever he or she so requests, on matters relating to the control and regulation of the manufacture, importation, sale or supply of tobacco products and on measures to reduce, eliminate or discourage smoking,*
>
> *(g) provide, and where appropriate exchange with the Garda Siochana and the Revenue Commissioners, information relating to the control and regulation of the manufacture, sale, supply, importation and distribution of tobacco products,*
>
> *(h) prepare and implement a plan for the coordination nationally of the activities of the Office and of health boards in relation to this Act and the cooperation of the Office and the health boards in the performance of their functions under this Act,*
>
> *(i) furnish advice to the Minister, whenever he or she so requests, on matters relating to –*
>
> > *(i) strategies employed by manufacturers, importers, distributors or retailers of tobacco products in the marketing, sale or promotion of such products,*
> >
> > *(ii) technology used in the manufacture, production or marketing of tobacco products,*
> >
> > *(iii) any innovations on the part of manufacturers, importers, distributors or retailers of tobacco products relating to the manufacture, production or marketing of those products,*

(j) coordinate and implement a programme for the inspection of all premises in which tobacco products are manufactured, stored, subjected to any process or sold by retail, and all premises to which the public have access, either as of right or with the permission of the occupier or person in charge of the premises concerned, for the purposes of ensuring that there is compliance with the provisions of this Act,

(k) collect or disseminate such information as may reasonably be necessary for the effective performance of its functions,

(l) furnish, whenever the Office considers it appropriate or is so requested by the Minister, advice or information to a Minister of the Government (including the Minister) in relation to any matter connected with its functions.[7]

***Fig. 1* Organisation chart of the Office of Tobacco Control, Ireland.**



7.2 The role of the Board is described in section 12 of the Act:

12.–(1) The Office shall consist of the following members, that is to say, a chairperson and 11 ordinary members.

(2) The members of the Office shall be appointed by the Minister.

(3) The chairperson of the Office shall hold office for a period of 5 years from the date of his or her appointment.

(4) An ordinary member of the Office shall hold office for such period not exceeding 5 years as the Minister may determine when appointing him or her.

(5) A member of the Office whose term of office expires by the effluxion of time shall be eligible for reappointment to the Office.

7. Government of the Republic of Ireland. Public Health (Tobacco) Bill 2001. March 2002.

7.3 The role of the Tobacco Free Council is described in section 22 of the Act:

> *22.–(1) The Office shall establish a body to be known as the Tobacco Free Council (hereafter in this section referred to as the 'Council').*
>
> *(2) The Council shall make themselves available to be consulted by the Office in relation to the performance by the Office of functions (of such a class as may be determined by the Office, with the consent of the Minister) and may give advice or an opinion to the Office regarding any matter (of such a class as may, with the consent of the Minister, be determined by the Office) falling to be decided by the Office or the performance by it of such functions.*

Budget

7.4 The OTC is part of a comprehensive programme outlined for Ireland, *Towards a Tobacco-Free Society.*[8] The programme was budgeted at IR£20 million per year (UK£15.6 million) of which IR£600,000 was allocated to the OTC and IR£100,000 to the Tobacco Free Council. The final budget has yet to be settled (in July 2002).

7.5 The population of Ireland is 3.8 million, compared to 56 million for the UK. There are about 7,000 tobacco-related deaths per year in Ireland, compared to 120,000 for the UK. If Britain spent equivalent in per capita terms to Ireland's OTC and Tobacco Free Council, the budget would be £8.8 million.

8. Tobacco-Free Policy Review Group. *Towards a tobacco free society.* Dublin: DoH, 2000.

EIGHT

Comparison: The Food Standards Agency

8.1 The Food Standards Agency is an independent food safety watchdog set up by the Food Standards Act 1999 to protect the public's health and consumer interests in relation to food. The Act sets out the Agency's main objective of protecting public health in relation to food and the functions that it will assume in pursuit of that aim, and gives the Agency the powers necessary to enable it to act in the consumer's interest at any stage in the food production and supply chain. The Act provides for the Agency's main organisational and accountability arrangements. In addition, it provides powers to establish a scheme for the notification of the results of tests for foodborne diseases.

What are the FSA's aims?

8.2 Between 2001 and 2006, the Agency's aims as stated on its web site are to:

- reduce foodborne illness by 20% by improving food safety right through the food chain (it is estimated by the FSA that there could be up to 4.5 million cases of food poisoning every year in the UK);
- help people to eat more healthily;
- promote honest and informative labelling to help consumers;
- promote best practice within the food industry;
- improve the enforcement of food law;
- earn people's trust by what it does and how it does it.

How is the FSA structured?

8.3 The Agency is led by a board that has been appointed to act in the public interest and not to represent particular sectors. Board members have a wide range of relevant skills and experience. The UK headquarters are in London, but the Agency also has national offices in Scotland, Wales and Northern Ireland. The Meat Hygiene Service is an executive agency of the FSA. The FSA is accountable to Parliament through health ministers, and to the devolved administrations in Scotland, Wales and Northern Ireland for its activities within their areas.

The FSA's responsibilities

8.4 The work of the FSA involves food safety across the whole of the food chain, including:

- food contaminants (defining tolerable levels, risk management and policy);
- food additives, contact materials, and novel foods (including safety assessment and surveillance);

- microbiological safety and food hygiene (including providing advice on the management of food borne outbreaks and prevention of food borne illness);
- inspection and enforcement action to protect consumers;
- local authority enforcement (developing policy, and auditing and improving enforcement);
- pesticides, veterinary medicines and animal feed (assessing food safety implications);
- food labelling and standards (developing policy, improving consumer choice and representing the UK in the EU);
- nutrition (providing advice and guidance on the nutritional composition of food, and providing information on a healthy, balanced diet, so as to promote and protect public health).

The FSA's powers and accountability

8.5 Although the FSA is a Government agency, it works at 'arm's length' from Government because it does not report to a specific minister and is free to publish any advice it issues. The FSA is accountable to Parliament through health ministers, and to the devolved administrations in Scotland, Wales and Northern Ireland for its activities within their areas.

8.6 The powers and function of the FSA are defined in the Food Standards Act 1999:

- **The Food Standards Agency (sections 1–5)**, concerns the establishment of the FSA, its main objective and its main organisational arrangements including the establishment of advisory committees (more detailed provisions are contained in Schedules 1 and 2).
- **General functions in relation to food (sections 6–8)**, confers on the FSA responsibility for developing food policy and advising Ministers and other public authorities, for advising consumers and other interested parties and for keeping abreast of developments relevant to its remit.
- **General functions in relation to animal feedingstuffs (section 9)**, supplements the FSA's functions in relation to animal feed.
- **Observations with a view to acquiring information (sections 10–11)**, gives the FSA functions in relation to surveillance and provides powers to enable it to carry them out.
- **Monitoring of enforcement action (sections 12–16)**, gives the FSA a function of monitoring food and feedingstuffs law enforcement and provides powers to enable it to carry it out.
- **Other functions of the Agency (sections 17–21)**, describes the Secretary of State and the devolved authorities' powers to delegate the making of emergency orders to the FSA, and the FSA's power to publish its advice.

- **General provisions relating to the functions of the Agency** (sections 22–25), concerns certain considerations which the FSA must observe in carrying out its functions, provides for directions by ministers and the devolved authorities should the FSA fail to perform its duties, and allows for modification of enactments to allow disclosure of information to the FSA and publication by it.
- **Miscellaneous provisions** (sections 26–35), sets out the functions no longer to be exercised by the Minister of Agriculture, Fisheries and Food, and the Department of Agriculture for Northern Ireland, and makes various provisions for consultation with other parts of Government or the devolved administrations on aspects of food safety.
- **Final provisions** (sections 36–43).

European dimension

8.7 There is considerable EU regulation in the area of food and food safety, currently managed by the European Commission and several scientific and regulatory committees.[9,10,11] The mission of the Directorate General for Health and Consumer Protection (known as the 'DG Sanco') is to implement the responsibilities entrusted to it by the treaty and derived legislation so as to ensure that a high level of human health and consumer protection is attained throughout the EU. DG Sanco also has prime regulatory responsibility for tobacco.

8.8 In January 2002, the EU agreed to establish the European Food Safety Authority (EFSA).[12] The measures introduced will reinforce existing consumer protection and should help re-establish consumer confidence in the food chain in Europe. The EFSA is an intrinsic part of a more strategic approach to food safety issues across the EU.

Budget

8.9 The net cost of the Westminster funded FSA (ie excluding Wales, Northern Ireland and Scotland) in 2000/1 was £83.7 million. The FSA also raises substantial funds (£48 million) through charges for the meat hygiene service. General food hygiene inspection is outside the remit of the FSA and is undertaken by the local authority's environmental health officers.

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9. DG Sanco, 'Food safety: from the farm to the fork', http://europa.eu.int/comm/food/index_en.html <Last accessed 13 November 2002>

10. DG Sanco, 'Scientific committees', http://europa.eu.int/comm/food/index_en.html <Last accessed 13 November 2002>

11. DG Sanco, 'Regulatory committees', http://europa.eu.int/comm/food/ls/rc/index_en.html <Last accessed 13 November 2002>

12. Regulation 2002/178/EC of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety.

13. Food Standards Agency. *Food Standards Agency annual report and accounts*. London: The Stationery Office, 2002.

8.10 The FSA divides up its expenditure according to the aims set by Government and Parliament.[13]

Table 1. FSA expenditure and income divided by aim.

Aim	Expense (thousands of pounds)	Income (thousands of pounds)	Net (thousands of pounds)
Aim 1: Measurably improve public confindence in the national food safety and standards arrangements	23,434	(397)	23,037
Aim 2: Reduce foodborne illness by 20% over the next 5 years including reducing salmonella in UK produced chickens on retail sale by at least 50% by the end of 2004/2005	38,910	(2,305)	36,605
Aim 3: To protect consumers through improved food safety and standards	69,447	(45,346)	24,101
Total	**131,791**	**(48,048)**	**83,743**

NINE

Comparison: The Medicines Control Agency

9.1 The MCA's primary objective is to safeguard public health by ensuring that all medicines on the UK market meet appropriate standards of safety, quality and efficacy. Safety aspects cover potential or actual harmful effects; quality relates to development and manufacture; and efficacy is a measure of the beneficial effect of the medicine on patients. The MCA achieves its objectives through:

- a system of licensing before the marketing of medicines;
- monitoring medicines and acting on safety concerns after they have been placed on the market;
- checking standards of pharmaceutical manufacture and wholesaling;
- enforcement of requirements;
- responsibility for medicines control policy;
- representing UK pharmaceutical regulatory interests internationally;
- publishing quality standards for drug substances through the *British Pharmacopoeia.*

History

9.2 The MCA was established in April 1989, taking over the duties of the Medicines Division of the Department of Health. It became an executive agency of the Department in July 1991 and was established as a trading fund on 1st April 1993 by the Medicines Control Agency Trading Fund Order 1993.

9.3 Effectively, a function previously managed within the Department of Health was moved out to become a separate and separately accountable body with autonomous funding. This could be a useful model for a tobacco and nicotine regulatory authority.

Advisory committees

9.4 There are several advisory committees that interact with the MCA. These are established under the Medicines Act 1968 or related regulations and many have functions that could find parallels in the regulation of tobacco.

- **Medicines Commission.** Twenty three members meet five times per year, to advise the Secretary of State on the application of the Medicines Act 1968. The Medicines Commission also advises on setting up other committees under the Act.

- **Committee on the Safety of Medicines (CSM).** This body provides advice on licensing of medicines to the Licensing Authority in conjunction with the MCA. The CSM is comprised of 34 members who are appointed by the UK's health ministers. Members include pharmacists, pharmacologists, toxicologists and physicians from a wide range of disciplines working in general practice, hospitals and universities across the UK. It also includes two lay members. The Committee meets fortnightly (except in August) and its secretariat is provided by the staff of the MCA.
- **The Advisory Board on the Registration of Homoeopathic Products (ABRHP)** gives advice with respect to safety and quality in relation to any homoeopathic medicinal product for human use.
- **Independent review Panel for Advertising.** The Medicines (Advertising and Monitoring of Advertising) Amendment Regulations 1999 came into force on 5 April of that year and complete the implementation of EU Directive 92/28/EEC. Regulation 13 and the Schedule contain a procedure for a review of the Health Minister's preliminary decision on whether an advertisement complies with the Medicines (Advertising) Regulations 1994, as amended ('the Regulations').
- **Veterinary Products Committee (VPC).** The VPC was established in 1970 under Section 4 of the Medicines Act 1968. Its terms of reference are to give advice with respect to safety, quality and efficacy in relation to the veterinary use of any substance.

European dimension

9.5 The control of medicines in the UK is primarily through the system of licensing and conditional exemptions from licensing laid down in EC legislation, the Medicines Act 1968 and in relevant subordinate legislation. Controls on medicines under the Medicines Act matched or in some cases exceeded those of existing European Directives and the UK played a major part in the development and revision of the EEC Directives in this area. European Community (EC) legislation now takes precedence over the Medicines Act, its Instruments and Orders, which are amended from time to time to align with new EC requirements.

9.6 The MCA plays an active role in negotiations and discussions in Europe and continues to represent the UK at key European meetings, such as Heads of National Regulatory Agencies, the Pharmaceutical Committee and the Committee for Proprietary Medicinal Products (CPMP). In addition, towards the end of 2000 the draft EU directive on good clinical practice and clinical trials reached a critical stage in its progress through the European legislative procedure.

9.7 The MCA continues to contribute to issues on which wider Department of Health and other government departments are in the lead. This has notably included the review of the General Product Safety Directive (that is the responsibility of the Department of Trade and Industry).

9.8 There is also a body operating at EU level; the European Agency for the Evaluation of Medicinal Products (EMEA), which is based in London. This body supervises the operation of the 'mutual recognition procedure' for authorisation of medicines, co-ordinates research, directly authorises biotechnology products and operates a pharmacovigilance network

throughout Europe. EMEA cooperates closely with the MCA – the current Chairman is Dr Keith Jones, who is also Chief Executive of the MCA. The MCA is one of the 'competent authorities' recognised by EMEA.

Budget

9.9 The budget for the MCA for 2000/1 was £38.4 million and it employed 436 people. The MCA raises its funds by charging for licensing and inspections (£18.3 million) and services (£12.4 million).

9.10 The budget for EMEA is EUR 65.9 million for 2001 (£40 million), and roughly equivalent to the budget for the UK regulator.

TEN
Options for a Tobacco and Nicotine Regulatory Authority

Objective

10.1 A tobacco and nicotine regulatory authority should have a clear objective:

> *... to reduce the overall burden of tobacco-related disease by contributing to a reduction in smoking prevalence and by regulating to reduce the harm caused to continuing nicotine users.*

Organisational form

10.2 There are several potential models that could be used:

- **Move existing functions to a new agency.** This approach was used with the formation of the Medicines Control Agency which advises the Secretary of State on the exercise of powers that were defined in earlier legislation.
- **Introduce new enabling legislation and powers to create a new agency.** This was how the Food Standards Agency was formed. The FSA has an independent role and powers conferred by its own legislation, the Food Standards Act, 1999. Tobacco could conceivably be included within the definition of food used in the Act (see Appendix 1).
- **Add tobacco regulation to the mandate of an existing body, amending its enabling legislation if necessary.** This could be the FSA or the MCA – or possibly a split between both.
- **Re-examination of existing legislation to create specific powers to regulate tobacco.** For example, the Consumer Protection Act 1987 or the newly adopted General Product Safety Regulations could be used to create a framework for tobacco regulation. The new agency could be created to advise the competent authorities defined in that legislation on the exercise of the relevant powers. The use of consumer protection legislation is discussed in question and answer form in Appendix 1.

Funding

10.3 Funding should, as far as possible, be raised from charges to the regulated industry – tobacco manufacturers, wholesalers, importers and exporters as appropriate. The MCA is entirely funded from external income, the FSA receives about 36% of its total funds from inspections and the Environment Agency earns 38% of its income from fees and levies.[14]

14. Environment Agency, 'Our income', http://www.environment-agency.gov.uk/aboutus/275155/234158/?version=1&lang=_e <Last accessed 13 November 2002>

Mandate for a tobacco and nicotine regulatory authority

10.4 The mandate of a tobacco and nicotine regulatory agency could be as follows:

Product regulation and consumer protection

- enforcing legislation in place – in concert with local enforcement agencies;
- establishing standards for novel tobacco or nicotine products;
- taking test cases on behalf of the Secretary of State where there is ambiguity or contention;
- managing disclosure of additives and publishing of public data;
- managing testing and disclosure of toxicity data for smoke and ingredients;
- formulating proposals for regulation of constituents of tobacco products and smoke;
- representing ministers on EU regulatory committees;
- conducting market surveillance;
- advising on warnings and consumer protection information required on packs;
- advising Secretary of State on risk communication to the public;
- challenging misleading risk communication;
- evaluating, approving or challenging health claims, whether explicit or implicit;

Non-tobacco nicotine products

- to advise the medicines 'licensing authority' (ie ministers) on the public health consequences of licensing particular non-tobacco nicotine products for sale in the UK. The authority would strike a 'concordat' with the MCA over their respective responsibilities.

Research and evidence clearing house

10.5 There is a clear need to have some continuity and experience with the science, law, economics and other policy aspects of tobacco. The authority could 'own' and develop expertise in this field on behalf of the government. For example, it could take responsibility for the following:

- Secretariat for Scientific Committee on Tobacco and Health;
- research and monitoring of wider tobacco control policies;
- gathering data on trends in tobacco use
  - prevalence and consumption
  - brand data
  - tobacco related disease trends
  - use of smuggled or budget cigarettes and switching to hand-rolling tobacco

- impact of new products
- impact of policy measures, including primary and secondary prevention intervention
- passive smoking exposure and indicators of responses.

10.6 Other functions that could be included in the mandate of a nicotine and tobacco regulatory authority are:

Marketing activity

- control and supervision of marketing activities of tobacco companies;
- enforcement of advertising legislation;
- developing regulations in response to technology developments;
- acting as a source of pressure for voluntary restraints on use of tobacco in films, magazines etc;
- contracting effective mass-media advertising campaigns and organising an education campaign;

Counter-marketing

- collating evidence and advise on campaign strategy;
- possibly 'owning' the campaign;
- commissioning evaluation;

Smoking cessation

- developing, disseminating, promoting and auditing implementation of best practice;
- offering support infrastructure;
- developing economic analysis and monitoring economic impacts;
- commissioning evaluation;

Passive smoking

- implementing the Approved Code of Practice on passive smoking at work;
- monitoring impact of voluntary agreements; and
- proposing legislation where necessary.

Economic and trade regulation

10.7 The UK tobacco industry is a duopoly and its two main companies earn super-normal profits. A large share of the UK cigarette market is also lost to contraband and counterfeit, and measures such as fiscal markings have been introduced to tackle these. There are a number of

economic and trade-related issues that could be managed by a tobacco regulator, including:

- smuggling;
- under-age sales;
- illegal sales;
- vending machines; and
- budget brands and price ranges in the marketplace.

ELEVEN
Conclusion

11.1 Having considered the issues discussed in this report, the College draws the following conclusions.

1. There are numerous and formidable regulatory challenges in the field of tobacco and nicotine. The approach taken to these challenges will be an important factor in determining the burden of disease caused by tobacco and nicotine use in the future.
2. The current almost-entirely unregulated position enjoyed by tobacco products and tobacco manufacturers should not be allowed to continue. Detailed consideration by Parliament concluded that some regulatory authority was essential to control and contain the tobacco industry and the harm caused by tobacco. The College has already argued the case for a Tobacco and Nicotine Regulatory Authority.
3. The Government has not strengthened its regulatory capacity since the Health Select Committee's report. The scientific capacity has actually been reduced. The practice of leaving tobacco policy and programme implementation to career civil servants who will often stay in post for less than two years will not be adequate to match the regulatory challenges posed by the evolving tobacco market.
4. The harm done by tobacco and nicotine use is to some extent controllable by influencing the design, blending and ingredients of tobacco products. Tobacco manufacturers will introduce new products with the aim of capturing a niche market for smokers concerned about health. Some smokeless tobacco products and pharmaceutical nicotine may offer substantial reductions in harm compared to smoking. Regulators cannot afford to ignore such developments – which are both public health threats and opportunities.
5. The regulatory arrangements for nicotine products apply the toughest controls to the least hazardous forms of delivery and apply minimal controls to cigarettes, the most hazardous form. A new authority should reconfigure this system so as to give the best outcome for public health.
6. We believe that the Government should act on the recommendations of the Health Select Committee and earlier advice of the College and establish a regulatory function for tobacco and nicotine outside the Department of Health. The function of a 'tobacco and nicotine regulatory authority' would be to advise the Secretary of State on how to exercise his regulatory powers, and to assume any responsibilities allocated to it in legislation.
7. Institutional precedents – notably the FSA – already exist. The FSA receives very substantial funding (£83 million p.a.) as well as fee income, yet the impact of food safety on public health is considerably less than the impact of tobacco.

8. Existing consumer protection legislation is available to give an authority the powers to act on behalf of ministers. Food and medicine regulation could also be applied to tobacco. However, the over-riding importance of tobacco in public health means that the Government should develop whatever legislation proves necessary at a later stage.

9. The body should be entirely funded by fees levied on the regulated industry – as is the case with the MCA and to some extent the FSA and Environment Agency. The authority should be established at national level without delay, with a European agency developed later. This is the approach adopted with food: the UK's Food Standards Agency has preceded the emerging European Food Safety Agency.

Appendix 1
Legal Q&A on a Tobacco and Nicotine Regulatory Authority

Given the existing and planned legislation, and experience of consumer protection measures, in the UK, what more could be done to regulate tobacco products, and how could an entity with the functions of the Tobacco and Nicotine Regulatory Authority be created?

Whilst it might be possible to apply the Medicines Act 1968 and Food Safety Act 1990 to tobacco, the Consumer Protection Act 1987 seems a more obvious and less contentious route to regulation. So long as the matter governs safety, that Act has fairly broad regulation-making powers, which should be broad enough to fulfil most European obligations. However, it might seem strange for a tobacco and nicotine regulatory authority to have to use the Consumer Protection Act (CPA) 1987 for tobacco when most of its uses are in relation to consumer products regulated by the Department of Trade and Industry, rather than public health matters. Specific tobacco legislation would be a more desirable basis for developing regulation in this area and would remove any doubt.

What new legislation would we need to achieve the aim of having a tobacco and nicotine regulatory authority with the mandate set out in the Commons Health Select Committee report and by the Royal College of Physicians?

There would need to be primary legislation establishing a tobacco and nicotine regulatory authority. Existing powers of secondary legislation might be able to be invoked by this authority recommending action to the relevant ministries, but equally it might be more desirable to create a new enabling power. The authority's role may well be simply one of supervising enforcement authorities. Such powers could be outlined in the legislation establishing the authority. If it were thought desirable for the authority to have enforcement powers itself these would have to be specified.

What obligations do the CPA 1987, and General Product Safety Regulations 1994 place on tobacco and nicotine manufacturers or vendors? Is there any existing body responsible for enforcing such obligations?

Obligations on manufacturers and vendors

The CPA 1987 Part II, s. 10, makes it an offence for a person to supply or undertake steps preparatory to the supply of defective consumer goods. Unfortunately the definition of consumer goods excluded tobacco from its scope (s. 10(7)(f)). Tobacco was defined as including any tobacco product within the meaning of the Tobacco Products Duty Act 1979 and any article or substance containing tobacco and intended for oral or nasal use.

In 1992 the EC adopted Directive 92/59/EC on general product safety, which also included a general safety requirement. This was implemented by the General Product Safety Regulations

S.I. 1994/2328, which, whilst not formally repealing s.10, disapplied it in most contexts. The important point for this discussion is that the definition of 'product' under these regulations is broader than the definition of consumer goods under the CPA 1987. Of most significance is the fact that tobacco is no longer excluded. The definition covers 'any product intended for consumers or likely to be used by consumers' (reg. 2(1)) and tobacco products seem to fall squarely within this definition. Thus there would seem to be no need to pass any measure to bring tobacco within the CPA's general safety requirement since this has effectively been done by the 1994 regulations.

Product safety

The main obligation is placed on producers only to place on the market products that are safe (reg.7). A safe product is,

> *any product, which under normal or reasonably foreseeable conditions of use, including duration, does not present any risk or only the minimum risks compatible with the product's use, considered as acceptable and consistent with a high level of protection for the safety and health of persons, taking into account in particular –*
>
> *a) the characteristics of the product, including its composition, packaging, instructions for assembly and maintenance;*
>
> *b) the effect on other products, where it is reasonably foreseeable that it will be used with other products.*

Whilst this would not seem to provide the means to condemn tobacco products as a class, given that the risk only has to be the minimum compatible with the product's use, nevertheless the risk must be an acceptable one consistent with a high level of protection. The wording of the definition seems rather strict: 'does not present any risk or only minimum risks compatible with product's use'.

The question of what constitutes minimum risk is a thorny one. There have been recent product innovations that may reduce risk, but it is extremely difficult to measure with confidence. There is also the problem that it may be possible to make genuinely 'safer' products but such products may differ so much from the existing product line that consumers would not find them acceptable.

Warnings

As packaging can be taken into account it might be possible to argue that inadequate warnings render a product unsafe, but this is unlikely, especially given the statutory prescriptions on warnings. Although one might find a court reluctant to condemn a product which complies with regulations this is not an automatic defence. Reg. 10(1) merely provides that where a product conforms to specific rules of UK law laying down health and safety requirements there shall be a presumption that the product is safe, until the contrary is proved. However, reg. 10(2) states assessment of conformity with the general safety requirement will take into account (in what is not expressly stated to be a hierarchy, but probably should be treated as such):

(i) UK voluntary standards giving effect to a European standard;

(ii) Community technical specifications and then if none of them exist;

(iii) UK standards, codes of good practice or the state of art and technology and finally;

(iv) the safety which consumers may reasonably expect.

The general safety requirement found in reg. 7 is fleshed out for producers in reg. 8. These may be of some use in connection with tobacco. Reg. 8(1)(a) concerns risks which are not immediately obvious without adequate warnings. Consumers must be provided with relevant information to enable them to assess inherent risks and to take precautions against them. Thus this would seem to require tobacco manufacturers to have clean hands as regards disclosing potential dangers. Of course it may not always be possible to take precautions against inherent risks, save by not using the product, but disclosure of risks would seem to be adequate.

Research into risks

Reg. 8(b) is also of interest because it requires producers to adopt measures commensurate with the characteristics of their products to enable them to be informed of the risks the products might present. This is normally seen as requiring a strategy to be in place to learn about problems presented by the product in the market place. However, this can also be read as requiring the industry to have a research strategy adequate to learn more about the risks posed by its products. One problem with reg. 8 is that there is no specific offence for breaching it, the offence is for breach of reg. 7, the general safety requirement. It might of course be possible to argue that failure to undertake the activities required by reg. 8 would make the product less safe than it otherwise might be and therefore constitute evidence of a breach of the general safety requirement, but this is by no means self-evident, especially where the problem is lack of a strategy to be informed of risks.

Under reg. 9 distributors are under an obligation to act with due care to ensure compliance with the general safety requirement. In particular reg. 9(a) requires that they shall not supply products they know or should have presumed to be dangerous. Reg. 9(b) requires that within the limit of their activities they participate in the monitoring of products, particularly by passing on information and co-operating in action taken to avoid those risks. Breach of reg. 9(a) is an offence.

Enforcement powers

The 1994 Regulations share the same enforcement powers as the CPA 1987 (reg. 11). Some of these are granted to the Secretary of State and are exercised by the Consumer Safety Unit of the Department of Trade and Industry. In practice these powers are used very sparingly. Prohibition notices can be served on individuals by the Secretary of State to prevent them from supplying the goods specified in the notice (s. 13(1)(a)). They are used for rogue products and only a handful of such notices have been issued. A notice to warn issued by the Secretary of State can require a person to publish a warning about goods considered to be unsafe (s. 13(1)(b)). This power has never been used and is unlikely to be used as the procedures are very cumbersome.

The majority of enforcement action is taken by trading standards officers at the local level. Their main weapon is the suspension notice (s. 14) which can prohibit a person from taking a variety of measures related to the sale of the product for a period of up to six months. They can also apply to the magistrates' court for a forfeiture order (s. 16). A major impediment to the effective use of these powers is the requirement that authorities pay compensation if it turns out their suspicions were not well founded (s. 14(7)).

What are the powers to regulate tobacco and nicotine available in the CPA 1987 and General Product Safety Regulations 1994?

The CPA 1987 provides specific enabling powers to permit the enactment of safety regulations. These powers are broader than that act's general safety requirement, for it applies to all goods rather than just consumer goods, and whilst some products are excluded these do not include tobacco. One of the exclusions does relate to controlled drugs and licensed medicinal products (s. 11(7)(d)) and so if tobacco or nicotine was deemed to fall under the medicinal products regime the regulation making powers in the CPA 1987 would not be available.

The regulation making power in s. 11(1) of CPA 1987 is very broad and covers securing that the goods are safe, preventing products from falling into the hands of persons for whom they would be unsafe, and making sure that appropriate information is, and inappropriate information is not, provided. The section is thus very wide-ranging and would seem to be broad enough to do many of the things one might wish to do, ie ban constituents/toxins/additives or demand reductions in them, set upper limits to emissions, demand product modifications, demand that cigarettes meet common performance standard on constituents or by-products, demand changes to cigarette paper/filter etc. To this extent the advice of the Government solicitor seems correct. S. 11(1) is developed in s. 11(2) where certain specific provisions that safety regulations may contain are listed. It should be borne in mind that this list is expressly stated to be without prejudice to subsection (1), but that the overall objective listed in s.11(1) must guide the content of the regulations, ie safety must be to the fore. One might imagine some debate as to whether, for example, passive smoking was a safety or a discomfort issue.

There does not seem to be any express power which would require the licensing of manufacturers and importers. The rules on approvals seem to relate to the goods rather than the person controlling them. Indeed the overarching power in s. 11(1) seems to be related to the goods, and so controls on who can deal in the goods might well be deemed to fall outside its scope.

The safety regulations themselves cannot provide that any contravention of them will be an offence (s. 11(4)), but s. 12 provides for various offences against safety regulations.

What are the implications of the exemption of tobacco from the consumer safety part of the CPA 1987 at s. 10(7)(f) – and, by extension, what would be the implications and feasibility of amending the Act to remove this?

The exemption of tobacco in s. 10(7)(f) of the CPA 1987 would seem to be of little relevance now. It had the effect of not making the general safety requirement in s. 10 applicable to

tobacco, but this has now been superseded by general safety requirements in the General Product Safety Regulations, which do not exclude tobacco. The other powers in the CPA 1987 relating to safety refer to 'goods', which has a broader meaning than 'consumer goods' and would include tobacco, unless tobacco was deemed to be a licensed medicinal product.

What are the implications of the section 3(c) (application and revocation) of the 1994 regulations? Given that tobacco is to be regulated under the new tobacco product directive (and previously under 90/239/EEC on tar yields, and 89/622/EEC and 43/92/EC on labelling) would the directive mean these regulations did not apply to tobacco?

The relationship between the general safety requirement and specific sectoral directives is problematic. The best approach from a consumer protection point would be to have both sectoral rules and the general safety requirement apply. This is clearly not the approach of the General Product Safety Directive. At the other extreme one might wish the general safety rules to be disapplied whenever there were any sectoral safety rules in directives that were intended to be total harmonisation directives dealing with all safety aspects. Slightly less extreme would be to argue that if sectoral rules covered safety then the general product safety directive only applied as regards its post-marketing notification obligations. In fact the United Kingdom seems to have adopted the sensible approach of retaining the controls afforded by the general safety requirement whenever the specialist legislation does not cover a specific aspect of safety. This seems to be the effect of the Regulations, for although reg. 3(c) excludes any product for which there are specific community rules, this exclusion only applies where the specific provisions govern all safety aspects of the product. Furthermore reg. 4 makes it clear that the regulations do apply where the product is subject to Community law provisions in so far as those provisions do not make specific provision governing an aspect of the safety of the product. However, the matter is not entirely free of ambiguity. There may still be some situations where producers may try to argue that all safety aspects are covered by the Community law and the authorities are then forced to show that some novel or distinct aspect has not been included in the specific EC law, even if it had been intended to be a total harmonisation directive.

It should be noted that the General Product Safety Directive is in the process of being revised. There has not been time to make a detailed study of the proposed changes, but of interest is the fact that one issue to be reformed is the relationship between sectoral legislation and the general safety requirement. The procedure for assessing conformity is also to be reworked with it being likely that a greater role will be given to standards implementing European standards.

Going beyond the issue of exclusion from the general safety requirement where sectoral directives exist, it should be noted that there is a more general issue concerning the relationship between EC internal market law and domestic law. As confirmed by the tobacco advertising decision internal market law is an area of exclusive Community competence. This means that, at least once the Community has enacted laws in this area, member states cannot regulate, except as provided for by EC laws. This is an important issue, which may prevent national activity in areas such as tobacco products that have been regulated at the EC level and needs exploring in more detail. In particular art. 13(2) of the Tobacco Products Directive needs consideration because it does seem to permit member states to keep or introduce more

stringent rules, but only in so far as they do not prejudice the rules laid down in the Directive. The scope this gives member states to derogate from the directive needs to be assessed.

What are the powers to regulate tobacco and nicotine available in the Medicines Act 1968?

If tobacco (or nicotine) fall within the definition of a 'medicinal product' then they would be subjected to the licensing regime of the Medicines Act 1968. To fall within this definition they would have to fulfil a 'medicinal purpose' and the most relevant test would seem to be that found in s. 130(2)(e) of 'otherwise preventing or interfering with the normal operation of a physiological function, whether permanently or temporarily, and whether by way of terminating, reducing or postponing, or increasing or accelerating, the operation of that function or in any other way'.

There does not seem to be any express exclusion for tobacco. In deciding whether tobacco products fall within this definition some assistance might be gleaned from the US Supreme Court case of *Food and Drug Administration v Brown & Williamson* where the Food and Drug Administration (FDA) was denied authority. Some aspects of this case turn upon particular US issues. Under the US legislation 'drugs' are defined to include 'articles (other than food) intended to affect the structure or any function of the body' and a 'device' is 'an instrument, apparatus, implement, machine, contrivance ... or other similar or related article... intended to affect the structure or any function of the body'. The FDA considered nicotine a drug, and cigarettes and smokeless tobacco products 'drug delivery devices'. The issue of intent does not seem to be a factor in the UK. Moreover the majority in Supreme Court were clearly influenced by the FDA having previously denied authority and Congress having created a special regime to regulate tobacco products. However, what is perhaps of most interest is the view of the majority that because of the need for any approved drug device to have a 'reasonable assurance of safety and effectiveness' the result would have to be a ban and that it could not have been intended to give a regulatory agency the power to ban a product which is so central to American society. The FDA and the minority argued that they would have power to take less drastic steps than banning the product, particularly as they could take into account the harm caused from the sudden withdrawal of the product.

The wording of the UK Medicines Act 1968 would appear to be more favourable to tobacco regulation. The concepts of 'safety', 'quality' and 'efficacy' that underpin the regulation of medicine are not easily applied to tobacco, and these are stated to be the three factors the licensing authority shall take into consideration. However, they are simply that – factors to be taken into consideration. It seems quite striking that in the US there was little dispute that nicotine and tobacco products fell within the literal interpretation of drug or device. Thus it would seem to be feasible to argue that tobacco products should be regulated under the medicines regime. Indeed the irony has been noted that whilst tobacco is not regulated in such a manner, many of the products (nicotine replacement treatment) used to treat the effects of nicotine addiction do have to go through the medicine licensing process. However, one suspects there will also be a deal of popular resistance to tobacco being equated with a drug and it must also be recognised that tobacco would then fall outside the regulation-making powers of the CPA 1987 (s. 11(7)(d)). Furthermore one might wonder whether a licensing regime was an adequate means of implementing Community obligations. This matter would have to be looked into further if this avenue was to be seriously explored.

What are the powers to regulate tobacco and nicotine under the Food Safety Act 1990?

The Food Safety Act 1990 might cover tobacco products. There is certainly no express exclusion for tobacco (again there is an exclusion for licensed medicinal products, unless excepted by Ministerial order). Food is said to include 'articles and substances of no nutritional value which are used for human consumption' (s. 1(1)(b)). It would seem that tobacco products fall within the definition of articles or substances (s. 53(1)). The only debate might be whether they are consumed. If this was seen as being a crucial point then more research could be undertaken.

There are wide ranging regulation-making powers under s. 16 and schedule 1 of the 1990 Act. These include regulation on composition, governing processes and treatment in the preparation of food, regulating the labelling, marking, presentation and advertising. There is also a general power for regulations to secure that food complies with food safety requirements, the interests of public health or to protect or promote the interests of consumers. S. 25 also allows the minister to require persons to furnish specified information about the food.

Could the new tobacco product directive be introduced as regulations under the CPA s. 11?

The tar yield (90/239/EEC) and labelling (89/622/EEC etc) directives are implemented in regulations under the CPA, and the new directive 2001/37/EC is a consolidation of these directives with a few new but related provisions. It will be obvious from the above that there would seem to be a sufficient basis in s. 11 of CPA 1987 to use this to implement most safety measures relating to tobacco. However a future project might take the directive and assess whether every provision can be validly adopted on this basis. The preference would clearly be for specific enabling powers geared to tobacco and supervised by a tobacco and nicotine regulatory authority.

For products other than tobacco, what kind of institutional arrangements have been used to enforce the CPA 1987 and GPS Regulations 1994?

As outlined above the main enforcement authorities are the local government trading standards departments. Central government, through the Consumer Safety Unit of the Department of Trade and Industry, does have some enforcement powers but uses these infrequently and tends to act more as a supervisory body, handling data collection and the development of any regulations or standards.

Appendix 2
Review of European Union tobacco regulation

Product regulation and consumer protection

Though the 1989 labelling directive (89/622/EEC) was welcomed at the time, it normalised warning labels that are too small, with weak messages using contrasting colours that can be almost impossible to read. Although a member state can impose more substantial warnings on its domestic manufacturers, it cannot block the import of products conforming to this directive.

The 1992 update to labelling directive (92/41/EC) provided new warnings and banned oral tobacco outside Sweden. This form of tobacco is substantially lower risk than cigarettes and is one reason why there is a lower cancer rate in Sweden.

The 1990 'tar' directive (90/239/EEC) wrote into law and established as a legitimate public health measure the strategy of reducing tar yields – and lending credibility to the concept of light and mild branding. This approach is now discredited in public health terms – however, this mistake was perpetuated in Article 3 and 5 of 2001/37/EC (the new directive superseding 90/239/EEC).

The new tobacco product directive (2001/37/EC) contains some good provisions (larger and bolder warning labels, ingredients disclosure, removal of misleading branding, review and update provisions) and some bad provisions (tar reduction, labelling with tar yield numbers). This is subject to challenge by tobacco companies (see British American Tobacco release, 24 August 2001).

Tobacco advertising

The 1989 'Television without frontiers' directive (89/552/EEC) banned advertising on TV but did not deal with the dominant form of TV advertising – televised sponsored events. The 1998 tobacco advertising directive (98/43/EC) was struck down by the European Court of Justice in October 2000 on account of its legal base (Case C-376/98) – the court argued that the Directive must contribute to 'eliminating appreciable distortions of competition' and 'eliminating obstacles to the free movement of goods and to the freedom to provide services'. The Court found the directive failed these tests.

In 2001, the Commission proposed a new advertising directive (COM/2001/0283 final) and this is formulated to act within the Commission's conservative view of the narrow boundaries of EU competence established by the treaty as interpreted by the European Court of Justice. The directive covers four areas of cross-border advertising (printed publications, Internet, radio and sponsorship), but does not include indirect advertising and will be easily circumvented by modern promotional techniques or moving promotional activity – such as

sports sponsorship – outside the EU. The German government has already threatened to challenge this directive if it has the effect of banning tobacco advertising in newspapers whose main circulation is within Germany.

Tobacco subsidies and public health funding

The European Union provides almost €1 billion to tobacco farmers through the Common Agricultural Policy (98/2848/EC). In contrast, expenditure on tobacco and public health is about 2-3% of this – the 'Europe Against Cancer' programme (see 646/96/EC) and the Tobacco Fund (see Regulation 2000/1648/EC which elaborates the operation of the fund established in Article 13 of 92/2075/EC – the tobacco subsidy regime).

Excise duties

The EU has applied limits governing the structure of tobacco duties (see directives 92/79/EEC on cigarettes, 92/80/EEC on products other than cigarettes and 95/59/EC). These may have had some effect in raising minimum duties, but their prime purpose is to stop the use of the excise tax system acting as a protectionist barrier to trade. A new proposal to restructure and raise minimum excise duties (COM/2001/0133 final) has been proposed by the Commission.

Weakness of health and consumer protection in the treaty

The fundamental weakness in EU tobacco policy is that the treaty article on public health (art. 152) does not allow binding EU legislation – directives or regulations. Public health legislation on tobacco has been shoehorned in as 'single market' legislation under art. 95. Consumer protection legislation is similarly constrained: art. 153 on consumer protection requires the use of art. 95 on the single market.

Dominance of free trade

Art. 95 of the treaty establishes the single market and does require 'a high level of health and consumer protection'. However, the ECJ emphasised that the primary purpose must be to remove barriers to trade.

A particular concern is the possible use of treaty provisions on the free movement of goods and services (art. 28) to undo national public health legislation. For example, national advertising legislation could be challenged as a barrier to entry.

Art. 30 allows a public health defence but the burden of proof is on the public health authority to show the measure is 'proportionate'; 'such prohibitions or restrictions shall not, however, constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States'.

This is not hypothetical – there are developments in this area:

- Complaints to the Commission about the French 'Loi Evan' and other national legislation.

- Swedish alcohol case (Case C-405/98) (a challenge to Sweden's ban on alcohol legislation). This appears to leave the matter to the Swedish courts to decide if the ban is justified in health terms.
- A potential Commission challenge to UK Customs over border controls designed to stop cross-Channel bootlegging. This could open the way for increased bootlegging and make the UK's tax policy harder to defend.

International negotiating positions: the EU forces the lowest common denominator

The position of the EU in the Framework Convention on Tobacco Control (FCTC) negotiations has been obstructive. For two reasons, the EU tends to drag its position down to the level of the least progressive member state. First, the member states *must* negotiate common EU positions where there is EU legislation in force. In the FCTC the EU has simply put forward positions that are already agreed within the EU, though it could agree more progressive positions if member states could agree them. Second, art. 300 of the treaty requires co-ordinated positions, even where there is no Community competence. In both cases, the EU negotiators have been drawn down to a position acceptable to the least progressive country – Germany.

European Union policy on smokeless tobacco

A statement in favour of evidence-based regulation for public health

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Summary

1. **Public health case**. We believe that the partial ban applied to *some* forms of smokeless tobacco in the European Union should be replaced by regulation of the toxicity of *all* smokeless tobacco. We hold this view for public health reasons: smokeless tobacco is substantially less harmful than smoking and evidence from Sweden suggests it is used as a substitute for smoking and for smoking cessation. To the extent there is a 'gateway' it appears not to lead to smoking, but away from it and is an important reason why Sweden has the lowest rates of tobacco-related disease in Europe. We think it is wrong to deny other Europeans this option for risk-reduction and that the current ban violates rights of smokers to control their own risks. For smokers that are addicted to nicotine and cannot or will not stop, it is important that they can take advantage of much less hazardous forms of nicotine and tobacco – the alternative being to "quit or die"... and many die. While nicotine replacement therapies (NRT) may have a role in harm reduction, tobacco-based harm-reduction options may reach more smokers and in a different, market-based, way. Chewing tobacco is not banned or regulated in the European Union but is often highly toxic, and our proposal would be likely to remove more products from the market than it permitted.

2. **Regulatory options**. We believe that the European Union policy on smokeless tobacco should adapt to new scientific knowledge and that the European Commission should bring forward proposals to amend or replace Article 8 of directive 2001/37/EC with a new regulatory framework. Canada has developed testing regimes for tobacco constituents and these could be readily adapted to the European situation. A review of EU policy in this area is required no later than December 2004, and we believe the Commission should expedite the part of its review that deals with harm reduction and regulation of tobacco products other than cigarettes so as to reconsider its policy on smokeless tobacco. We held this view before Swedish Match brought its legal proceedings to challenge EU legislation and we will continue to hold these view if its action fails.

Public health arguments

3. **Purpose of tobacco control**. The ultimate purpose of tobacco control campaigning and organisations should be clearly stated: in our view it is to reduce the burden of disease and death, mostly from cancer, cardio-vascular disease and lung disease, arising from tobacco use. The aim is not *in itself* to campaign against tobacco. Because of the dominance of the cigarette market, in most situations those two strategies coincide. However, there may be some situations where they conflict – where this is the case, we give priority to reducing disease. Such a case arises where two conditions are met:

    a) Where the use of a tobacco product is substantially less hazardous than cigarettes;

    b) Where that tobacco product may substitute for cigarette use or facilitate increased smoking cessation at individual and population level.

    This is the situation with oral tobacco products, such as 'snus', a form of oral tobacco widely used in Sweden and to a lesser extent in some other North European countries. New products are also emerging on the US market, which may also be targeted in this way. For this reason, there is a strategic question about how the tobacco control community should respond to such products. This is brought into a sharper focus in the European Union because of legal challenges to EU regulation in this area, and a commitment to review policy by the end of 2004.

4. **Position of addicted smokers**. It is also important that we are realistic about the situation of many tobacco users. Tobacco-delivered nicotine is powerfully addictive and many users cannot or will not give up. Though addiction is a type of disease in its own right, the aspiration to tackle both the addiction and the physical harm by complete tobacco cessation may only work for a subset of users. The attempt to tackle both addiction and harm, may end in tackling neither. For some, for example those with certain mental health conditions, there may be therapeutic benefits derived from nicotine or tobacco. For others, it is poverty and the ubiquity of tobacco in their communities that create a powerful barrier to individual cessation. We also know that the strength of addiction (as measured by nicotine intake) can increase with poverty. There are over 1.2 billion tobacco users world wide – increasing at about 80,000 per day. In

the European Union there are almost 100 million smokers, and smoking kills 550,000 EU citizens per year. We believe it is essential that every option be considered for reducing this toll. That includes harm reduction and product regulation strategies based on reducing the damage done to people that continue to use tobacco or nicotine for whatever reason.

5. **Harm caused by smokeless tobacco**. Smokeless tobacco is *not* harmless. For example, smokeless tobacco products used on the Indian sub-continent and some products in the United States cause oral cancer. In India, smokeless tobacco is a major cause of oral cancer. But the evidence shows that any link between smokeless tobacco in the form of Swedish snus and oral cancer is not established[1] [2]. The largest review, Nilson (1998)[3], concluded that although:

> *...20% of all grown-up Swedish males use moist snuff, it has not been possible to detect any significant increase in the incidence of cancer of the oral cavity or pharynx - the prevalence of which by international standards remains low in this country."*

There are other health effects that arise in the oral cavity – such as lesions and gingivitis – and a cancer risk from products other than Swedish snus must be anticipated. Smokeless tobacco may also be associated with cardiovascular disease, though the evidence is contradictory and far from clear. A literature review commissioned by ASH[4], concluded:

> *Smoking increases the risk of myocardial infarction, sudden death, stroke and peripheral artery disease of the legs by 2-4 times. Whether or not snuff use is associated with an increased risk of myocardial infarction and sudden death is still controversial. If there is an excess risk, it is very much smaller than for smoking. For stroke or peripheral artery disease, there is no scientific information on possible risks of snuff use.*

However, for oral tobacco to play a role in harm reduction it is not necessary to show that it does not cause cancer – it just needs to be substantially less hazardous than smoking. Even allowing for cautious assumptions about the health impact, snus – and other oral tobaccos - are *a very substantially less dangerous way to use tobacco than cigarettes.* Smokeless tobaccos are not associated with major lung diseases, including COPD and lung cancer, which account for more than half of smoking-related deaths in Europe. If there is a CVD risk, which is not yet clear, it appears to be a substantially lower CVD risk than for smoking. Smokeless tobacco also produces no environmental tobacco smoke (ETS) and therefore eliminates an important source of disease in non-smokers and children. These are very substantial benefits in reduced risk to anyone that switches from smoking to smokeless tobacco and we believe the pubic health community has a moral obligation to explore this strategy. It is likewise ethically wrong to actively *deny* users the option to reduce their risk in this way.

6. **Addictiveness and nicotine delivery**. Smokeless tobacco use is an effective delivery system for nicotine and is therefore addictive. Addictiveness is in itself a bad characteristic compared to not using the product at all. However, it is the nicotine delivery characteristics of smokeless tobacco that make it both addictive and a viable alternative to cigarette use for many users – it is capable of delivering a satisfactory nicotine dose. Smokeless tobacco use does not match the arterial nicotine 'bolus' (sharp spike) delivered by smoking, but still creates a peak venous blood-nicotine level that exceeds all NRT products (including the nasal spray) and is similar to smoking. The fact that it more closely matches the nicotine delivery profile of smoking may be one reason why users find it more effective that NRT as an alternative to smoking.

7. **Risks to users**. The risk to the user arising from use of a smokeless tobacco product varies by product and is to some extent uncertain - notably in the area of heart disease (though *at worst*

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[1] Schildt E-B, Eriksson M, Hardell L, Magnuson A. Oral snuff, smoking habits and alcohol consumption in relation to oral cancer in a Swedish case-control study. *Int J Cancer* 1998;**77**:341-6.

[2] Lewin F, Norell SE, Johansson H, Gustavsson P, Wennerberg J, Biörklund A, *et al.* Smoking tobacco, oral snuff, and alcohol in the etiology of squamous cell carcinoma of the head and neck. A population-based case-referent study in Sweden. *Cancer* 1998;**82**:1367-75.

[3] Nilsson R. A qualitative and quantitative risk assessment of snuff dipping. *Regul Toxicol Pharmacol* 1998;28:1-16

[4] Asplund, K. Snuffing, smoking and the risk for heart disease and other vascular diseases. Department of Medicine, University Hospital, Umeå, Sweden, 2002 [PDF]

the heart disease impact appears to be substantially less than smoking). However, we are confident that the evidence base suggests that it is reasonable to formulate the overall relative risk as follows: *on average Scandinavian or American smokeless tobaccos are at least 90% less hazardous than cigarette smoking*. In a spectrum of risk, snus is *much* closer to NRT than it is to cigarette smoking. Further, the actual risk can be controlled through regulation - for example by setting maximum thresholds for specific carcinogens or other toxins such as heavy metals. These data were not readily available at the time the ban was originally implemented in the early 1990s and therefore justify consideration of a change of approach in response to new knowledge.

8. **Risks associated with *banning* smokeless tobacco**. It might be argued that removing a ban on a product with known dangers, however low, can only increase risks. This is not the case because bans on smokeless tobacco also carry risks. It is quite possible that a ban on smokeless tobacco would mean more tobacco users use cigarettes because the opportunities to switch to or start on smokeless tobacco are denied. To the extent that the ban promotes cigarette use, it carries risks. There is no evidence to show that the *status quo* in European Union policy represents an optimum public health outcome or that the policy does not increase tobacco-related harm.

9. **Evidence from Sweden**. Evidence from Sweden suggests snus plays a positive public health role as a substitute for smoking and as an aid to smoking cessation. It is impossible to be definitive about this, because it is impossible to run a controlled trial on a whole nation. However, consider the following:
   - Sweden has the lowest levels of tobacco-related mortality in the developed world by some distance – approximately half the tobacco related mortality of the rest of the EU[5].
   - Sweden has the lowest male smoking prevalence in Europe (16% daily) and low female (c. 22%) prevalence.
   - However, it has comparable male *tobacco* prevalence and total consumption to neighbours Norway and Denmark - suggesting the big difference is in the *type* of tobacco used, rather than overall propensity to use tobacco or consume nicotine.
   - About half of tobacco in Sweden is now consumed as snus - this share has steadily grown since 1970s.
   - 33% of ex-smokers report use of snus - almost twice the number that report use of a pharmaceutical treatment (17%). Among males who have used a single aid to stop daily smoking, and succeeded to do so, some 70% had used snus and some 30% had used some kind of NRT.
   - There are far more ex-smokers among snus users, than ex-snus users among smokers - a substantial population study has been conducted by Lars Ramstrom with funding from the National Institute of Public Health in Sweden and the data has been presented at conferences and is in the public domain, though not yet published[6]. A published study by Rodu also showed similar results[7].
   - It is possible – though difficult to test – that snus use has contributed to 'denormalisation' of smoking and to the unacceptability of ETS. This may be a factor in low rates of smoking among women (who do not use snus very much) and acceptability of smoke-free places.

10. **Reasons for low rates of tobacco mortality in Sweden**. An important explanation for the low rates of tobacco-related mortality in Sweden is the contribution made by the high use of smokeless tobacco. It is difficult to conclude anything other than a positive public health role for snus in Sweden, though there remains doubt over the magnitude of the effect. There are no other convincing explanations for low smoking prevalence in Sweden, combined with relative

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5 Peto R. et al. Mortality from smoking in developed countries 1950-2000. Oxford. 1994.

6 Ramström LM, Snus, the Swedish oral smokefree tobacco - patterns of use: a gate leading to smoking or a way out. Paper presented at the 4th European Conference of Society for Research on Nicotine and Tobacco, Santander, October 5, 2002.

7 Rodu B et al. Impact of smokeless tobacco use on smoking in northern Sweden, Journal of Internal Medicine, 2002;252 398-404.

high tobacco use. The population data from Sweden is much clearer now than when the ban was introduced and again justifies a reconsideration of policy at the European level.

11. **Human and consumer rights**. There is an emerging literature on the 'human rights' dimension to this problem, stressing the right of smokers to good information and the choice of risk reduction strategies[8]. Through the ban, the EU is actively preventing smokers having access to a product *at least* 90% less dangerous than cigarettes, but that is clearly an effective substitute for at least some people (and for many people in Sweden). It is important to consider where the EU draws its moral (and legal) authority to make such 'life-or-death' choices on behalf of its citizens - especially as, on the basis of Swedish evidence, it appears to be making the wrong choices.

12. **How would smokeless tobacco be used outside Sweden?** There is legitimate doubt about whether snus or similar would be used in the same way in other member states as in Sweden, or to the same extent. However, that is unknowable in advance and the ban explicitly rules it out. By banning we know how it will be used – either not at all, or on a black market. We cannot really know what would happen until it is available, marketed and a suitable regulatory regime and tax structure in place - these are all variables that would affect its use. What we do know is that it has the potential to be used to reduce harm. If it looked as though there was an emerging overall negative impact (unlikely in our view) policy drivers such as taxation and modifications of the product standards could be used to trim demand. Even if a small number – relative to Sweden – used it, there may still be a considerable public health gain. An important area for further research is how consumers might respond to the introduction of new tobacco products that are positioned as less hazardous than cigarettes.

13. **Gateway effects.** There is concern that smokeless tobacco will function as a lead-in to smoking for people that would not otherwise smoke. Such 'gateway effects' are always contentious, and they are hard to demonstrate for the simple reason that we do not know what smokeless users would have done in the absence of smokeless tobacco - they may have simply moved straight to smoking. Gateways can act in the opposite direction too – they can be 'exits' rather than 'entrances'. Smokers may move to smokeless tobacco or use smokeless tobacco to quit, where they would otherwise have continued to smoke. Starters on smokeless tobacco may continue as smokeless users but otherwise have started with cigarettes, so that smokeless tobacco is a diversion from smoking. In both the US and Sweden, most smokeless tobacco use *cannot* be a gateway to smoking, either because smokeless users never started smoking or because they started smoking first. For the minority who started using smokeless before cigarettes they may or may not have had their smoking caused by smokeless use.

14. **Exit or entrance gateway?** Understanding the order in which tobacco users take up different products is an important and necessary factor in establishing a gateway effect and whether the gateway is an exit from or entrance to smoking, but it is not in itself sufficient to establish a gateway from smokeless to cigarettes. The basic problem is that it is difficult to know whether those that start with smokeless tobacco would otherwise have started on cigarettes in the absence of smokeless tobacco. The data from Sweden suggest that the gateway is more likely to be an 'exit' from smoking than an 'entrance'. Among Swedish males with a primary use of snus no more than 20% ever started smoking, while 45% of other males did become smokers[6]. In addition to this compelling evidence from the pattern of transitions, Sweden has the lowest rate of male smoking in Europe, combined with high levels of snus use. There is no other credible explanation for such low male smoking prevalence than the displacement and cessation of smoking through smokeless tobacco use. In total therefore, the Swedish data suggest that uptake of snus use prevents rather than promotes smoking and therefore contributes a net public health benefit. There have been studies in the United States that claim to show a gateway effect from smokeless tobacco use to smoking for a minority of smokeless users. However, these studies or related commentary have generally drawn causal inferences based on observation of transitions between often poorly defined categories of tobacco use, and sometimes from groups that are unrepresentative of the general population, such as the military. Psychosocial predictors of smoking initiation (school performance, parental smoking, risk taking etc.) can be used to assess which smokeless tobacco users might otherwise have

[8] Kozlowski L. Harm reduction, public health, and human rights: Smokers have a right to be informed of significant harm reduction options. Nicotine and Tobacco Research 2002:4;4 suppl 2. 55-60 [PDF]

been smokers. When these confounding factors are taken into account, the data do not show that initial smokeless tobacco use adds to the propensity to become a smoker[9 10].

15. **Unintended population effects**. There are numerous other potential population effects under discussion: will there be reduced cessation, increased relapse, wider use etc? Though some of these ideas are plausible, all such theories are at present contentious and with minimal or no supporting evidence. To take one example: does smokeless undermine the propensity to quit smoking by helping smokers survive the discomfort of smoke-free policies?. For snus to be shown to be dissipating the pressure to quit caused by smoke-free policies (and therefore have a negative impact on public health) we would need to assess the following contributory factors:

    a) How much combined daily snus and smoking use is there? (Only 3% among men in Sweden compared to 17% using snus only daily). If the combined use is not daily, it is unlikely to be used in overcoming smoke-free restrictions.

    b) How much does smoke-free contribute to smoking cessation? There is clearly an effect. One estimate suggests that completely smoke-free workplaces in the UK would reduce consumption by eight percent. This is one of the most important tobacco control measures, but it is still only one factor of many (price, health, media campaigns, etc) in causing smokers to quit.

    c) How much would availability of smokeless tobacco reduce (or increase) likelihood of quitting due to smokefree places? (Note: the magnitude *and* sign of this effect is unknown). Some assume that it is withdrawal that drives smoking cessation arising from smoke-free areas and therefore smokeless tobacco would remove the pressure to quit created by repeated temporary withdrawal. However, it could easily be 'denormalisation' of smoke due to reduced smoke. In which case smokeless might contribute to cessation.

    d) Is it right to deny people products so that they are forced to feel discomfort in smoke-free areas because this makes them more likely to quit - the ethical point is important.

16. **Role of surveillance**. In general we believe there is too little surveillance of the tobacco market and its impacts on health in Europe. In a comprehensive surveillance regime, any adverse trends that developed in the use of smokeless tobacco or other tobacco products could be detected and addressed with new regulation – such as taxation, marketing restrictions, labelling or product standards. Note that it is impossible to be absolutely certain about the outcome of a change in policy on smokeless tobacco, just as it is impossible to be certain that not changing policy is the best course. However, a surveillance regime would create some safeguards.

17. **Should the "precautionary principle" apply?** Some have argued that because there is not complete knowledge of how smokeless tobacco would be used or all its health effects, we should invoke the precautionary principle (PP) and keep it banned until there is a complete evidence base. Though this sounds reasonable at first take, it is actually a misuse of the PP. The PP is designed for use where there is some concern that a human activity is causing damage (usually to the environment) and scientific uncertainty about whether it is happening or the magnitude of the effect might otherwise be used as a reason not to act to mitigate or control the activity. The PP usually challenges those defending the *status quo* with uncertainties about the impact of change. The situation with smokeless tobacco is completely different to those situations where the precautionary principle is typically invoked. It may be that the *status quo* in tobacco use, the dominance of cigarettes, is causing the most harm and that the ban on oral tobacco is *increasing* the harm – that would almost certainly be the case if the experience of Sweden was generalised to Europe as a whole. So one can easily see the ban as problematic

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[9] O'Connor RJ, Flaherty BP, Kozlowski LT and Quinio BA, Regular smokeless tobacco use is not a predictor of smoking onset when psychosocial predictors are included in the model: an analysis of the TAPS Longitudinal Survey. Poster for Annual Conference of Society for Research on Nicotine and Tobacco, New Orleans, February 22, 2003

[10] Kozlowski LT, O'Connor RJ, Quinio BA, and Flaherty BP, Most smokeless tobacco use is not a causal gateway to cigarettes: using order of product use to evaluation causation in a national US sample. Paper for Annual Conference of Society for Research on Nicotine and Tobacco, New Orleans, February 22, 2003.

and invoke the precautionary principle on the basis of what is known about Sweden as a reason to act to remove the ban.

18. **Why not use NRT?** It is sometimes claimed that anything that can be done with smokeless in harm reduction terms could equally be done with NRT – and with virtually no risk. This view misunderstands two crucial differences between NRT and smokeless tobacco. The first is the nicotine delivery profile – smokeless tobacco far more closely matches cigarettes[11] and therefore can more easily be an acceptable substitute for addicted users. The NRT nasal spray comes close but this is difficult to use and not popular. There may be other tobacco-related sensory effects that are important and not present in NRT. The success of any harm reduction strategy would depend on the numbers of people that made a switch – and that in turn would depend on the consumer acceptability of the product. The second difference is the position of smokeless tobacco in a market place: smokeless tobacco would be occupying a different cultural space. Switching to smokeless tobacco is not a 'medical intervention' rather it is what concerned smokers may do as a way of changing their tobacco use.

19. **Characterising the two sides of the debate.** Many health advocates are uncomfortable with the concept that a certain class of tobacco products could play a role in a health strategy and fear that such strategies may be divisive. They characterise the debate as 'pro-snus' versus 'anti-snus'. However, there is a substantial body of informed and independent opinion that sees the value of harm reduction strategies based on smokeless tobacco. For them the debate is not "pro-snus versus anti-snus" but they would frame it as "a smoker's right to options for harm reduction" versus "health professional's authoritarian insistence that the only valid choice for smokers is to quit or die as an addicted cigarette user" – or to shorten this: "harm reduction" versus "quit or die". In practice there is a spectrum of views about the evidence and how to act in the face of uncertainties.

20. **Pro- or anti-tobacco industry?** Both sides claim they are taking an anti-tobacco industry stance. The "quit or die" grouping simply asserts that smokeless tobacco is made by the tobacco industry. The "harm reduction" side recognises that the tobacco industry is heterogeneous and developing all the time. They believe that smokeless tobacco is a viable competitor to the hegemony of the cigarette makers, that it will disrupt the market and usher in new forms of regulations that the biggest tobacco companies will be hard-pressed to satisfy with their conventional cigarette designs. The "harm reduction" grouping sees the "quit or die" grouping as unwitting and naïve allies of Big Tobacco – Philip Morris and British American Tobacco – cigarette companies that do not make smokeless tobacco.

Regulation of smokeless tobacco in Europe and the legal challenge

21. **Regulation of smokeless tobacco in the EU.** Smokeless tobacco in the European Union is now regulated under directive 2001/37/EC[12]. This retains provisions originally introduced in directive 92/41/EEC. Under its treaty of accession, Sweden is exempted from this ban and this exemption is reflected in the directive as below. The 2001 directive states:

> ***Article 2.4.*** *"tobacco for oral use" means all products for oral use, except those intended to be smoked or chewed, made wholly or partly of tobacco, in powder or in particulate form or in any combination of those forms, particularly those presented in sachet portions or porous sachets, or in a form resembling a food product.*
>
> ***Article 8.*** *Member States shall prohibit the placing on the market of tobacco for oral use, without prejudice to [the exemption granted for Sweden].*

22. **Legal challenges**. This position is now facing two legal challenges – from a German tobacco distributor backed by Swedish Match, and by Swedish Match directly through a judicial review of the UK government's implementation of these directives that will be referred to the European Court of Justice. The case made by Swedish Match argues the EU's actions are unlawful, unreasonable, unfair, unjustified, disproportionate and arbitrary, as follows:

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[11] Holm H, Jarvis MJ, Russell MAH, Feyerabend C. Nicotine intake and dependence in Swedish snuff takers. *Psychopharmacology* 1992;108(4):507-511.

[12] Directive 2001/37/EC Official Journal L 194, 18/07/2001 P. 0026 – 0035 [EURLEX]

a) Inadequate legal base because the ban is a public health measure with no single market justification;

b) Total prohibition is disproportionate to achieving single market or public health aims It draws on the case of the advertising directive Case C-376/98 in which a complete ban was imposed as a single market measure. The successful defence of 2001/37/EC (see Case 491/01) was in part because this regulated but does not prohibit trade;

c) The ban is arbitrary and discriminatory as it does not include chewing tobacco;

d) No reasons have been given for the ban and this breaches a general duty in breach of Article 253 of the treaty;

e) The ban violates the company's property rights under European Convention on Human Rights and European Charter of Fundamental Rights of the European Union;

f) The ban violates the EU treaty provisions on free movement of goods (Article 28/29);

g) The EU has not considered new scientific evidence.

23. **Has Swedish Match got a case?** We believe the regulation of smokeless tobacco products in the European Union *is* arbitrary and disproportionate, and impossible to justify as a single market measure or a health measure. The current regulation is absurd, as it applies a complete ban to oral tobacco products that are sucked, but no ban or even regulation to oral tobacco products that are chewed. Only meaningless regulation is applied to smoked tobacco as long as they are cigarettes, and no regulation to cigars or hand-rolling tobacco. It is impossible to justify the logic applying polar extremes of regulation to different products depending on what the user does with it once it is placed in the mouth (no regulation if you chew, complete ban if you suck). It is arbitrary and disproportionate because it does not prohibit cigarettes, which are substantially more toxic (*at least* 10 times more toxic) than snus.

24. **Burden of proof regarding health claims**. Although we make a case based on public health *benefits* above, showing a positive public health impact beyond reasonable doubt would not be the issue in the ECJ. The burden of proof would be on the EU to show that there was a case for a ban by showing an additional health impact. The directive 2001/37/EC also acknowledges a lower risk for smokeless tobacco products by requiring weaker warnings than for cigarettes (Article 5.4 of 2001/37/EC), in those situations where smokeless tobacco is permitted in the EU and a weaker warning than was required in the previous directive.

25. **What would happen instead of a ban?** We believe that the ban should be replaced by regulation. This is an opportunity to shape the smokeless tobacco market and ensure that if such products are used, they are placed on the market with a high level of protection for human health and the consumer and to ensure that the worst products are either removed from the market or do not come in. Regulation should apply to all smokeless tobacco, including chewing tobaccos that are currently allowed on the market unregulated. It could also apply to the tobacco intended for smoking. The highly toxic chewing tobaccos available in India are actually permitted in the EU at present, whereas much less dangerous products are like snus are banned. A rational regulatory approach would reverse this situation, and effectively ban the most toxic smokeless tobacco products.

26. **What regulatory standards could be used?** A regulatory approach could involve setting maximum standards for a range of target toxins implicated in the main tobacco-related diseases. The Canadian government has introduced legislation implementing a measuring and disclosure regime for all tobacco products[13], including smokeless, and this requires extensive testing of tobacco product constituents. The methodologies available for measuring tobacco constituents are appended to this paper at Annex 1. Note that these measurements are also required for smoking tobacco as well as smokeless tobacco. Such standards could be adapted for Europe by the European Committee for Standardisation (CEN - *Comité Européen de Normalisation)* and used in EU regulation.

27. **Other standards issues**. Other approaches to a standard might relate the proportion of toxins to the quantity of active drug nicotine and might also regulate additives. Some of the contaminants also change with age of the product – and shelf-life restrictions might be also

[13] Health Canada. *Tobacco Reporting Regulations*. June 2000. [Health Canada]

imposed. It would require products to be tested to an agreed methodology. In addition, it would be necessary for health claims to be subject to some sort of official scrutiny and backed by evidence - or for EU-approved information to be specified for packaging. Such standards could also be applied to smoking tobacco – cigarettes, cigars, pipe and hand-rolling tobacco – on the basis that there is no reason to allow tobacco to be placed on the market that is more toxic simply because the intention is to burn and multiply the toxicity considerably.

28. **Example of a standard.** Voluntary, market-based, toxicity standards do exist. For example, this is the Gothiatek standard (used by Swedish Match – see table)[14]

Toxin	Limit
Nitrite	3.5 mg/kg
TSNA	5 mg/kg
NDMA	5 ug/kg
BaP	10 ug/kg
Cadmium	0.5 mg/kg
Lead	1.0 mg/kg
Arsenic	0.25 mg/kg
Nickel	2.25 mg/kg
Chromium	1.5 mg/kg
ug = microgram or 10^{-6}g. mg/kg ~ parts per million (ppm). ug/kg is equivalent to parts per billion (ppb). Limits based on 50% water content - double the limits for dry weight equivalents.	

29. **Impact of regulation.** The Gothiatek standard is quite exacting, and would rule out most products on the market – it might be possible to taper its introduction to allow time for adjustment of growing, manufacturing and curing processes. If this standard were applied to all smokeless tobacco products, it would certainly take more tobacco products off the market in the EU than it allows on. Many of these products have high levels of TSNA, but are not regulated or tested at all – simply (and absurdly) because they are intended to be chewed. If applied to smoking tobacco too, it could cause disruption for the cigarette industry, and begin reducing toxins in *all* tobacco.

30. **Problems of regulation.** The main problems with regulation would be the burdens of testing and verification. However, these should fall on manufacturers – as is the case with cigarettes. For small manufacturers, for example firms exporting from the Indian sub-continent, the application of *any* standards would be a barrier to trade, but one that could be justified on health grounds. There is a problem with an absence of ISO standards for measuring toxic constituents for smokeless tobacco, though the measuring techniques are simple and readily available. However, measuring standards do exist for the main toxic constituents in tobacco and are in use in Canada – see Annex 1.

31. **European Commission review of policy will happen anyway.** The Commission is required to revisit policy on smokeless tobacco in its review of the effectiveness of 2001/37/EC under article 11 of that directive. The Commission is required to review the directive "*in the light of developments in scientific and technical knowledge*" with special heed to several important regulatory issues which include:

> *- tobacco products which may have the potential to reduce harm*
> *- development of standards concerning products other than cigarettes...*

Furthermore, the Commission should take proper scientific advice so that it can produce evidence based proposals:

> *...the Commission shall be assisted by scientific and technical experts in order to have all the necessary information available*

The review should also include legislative proposals as necessary.

[14] See www.gothiatek.com - the full standard available here [Gothiatek].

That report shall be accompanied by any proposals for amendments to this Directive which the Commission deems necessary to adapt it to developments in the field of tobacco products…

32. **Is the European Union's current position based on scientific advice?** To our knowledge, the EU did not revisit the scientific advice for Article 8 the 2001 directive – though much new data had become available. The Commission relied on advice from its Cancer Experts Committee to underpin much of the 2001 directive, but this committee did not give a view on smokeless tobacco[15]. This is important because the ECJ does not usually see its role as judging scientific advice, but if there is no scientific argument backing the ban then it will prove less of an obstacle to Swedish Match in the ECJ. Part of its case is that the EU provided no reasons for its ban and the recitals to the 2001 directive simply refer to the existing practice. In support of its case, it is quite possible that Swedish Match could call witnesses from the tobacco control community.

33. **Next steps – begin the review.** It would make sense to expedite the review under Article 11 as it applies to smokeless tobacco and convene the necessary experts to give advice. The Commission can either conclude that the policy is sound, in which case it will have built its evidence base for defending the action in the European Court of Justice, if it proceeds to a full hearing. It could also decide that its policy needs to change, in which case it could introduce a legislative proposal. That may avoid a potentially wasteful legal process and is more likely to create a policy that works for public health. An adverse ECJ ruling may also establish principles that constrain the Commission and limit its options for regulation of smokeless tobacco. The Commission (and member states) will have to do the work to defend the case in the ECJ anyway, and we believe that longer-term policy on smokeless tobacco will be formed during this period rather than in whatever formal consultation process is established for the review under Article 11 – probably in 2004.

34. **Public health community.** We hope that this paper will stimulate debate and thinking within the public health community and that over time we can come to a consensus on the way ahead. We urge a thorough examination of the evidence and arguments, and a determined focus on reducing disease. This is both a scientific and ethical issue and where there is uncertainty we are obliged to use judgement informed by evidence. Though there is an understandable reluctance to see any kind of ban reversed, it is important that we give primacy to the health of smokers, many in difficult circumstances and heavily addicted to nicotine, and this may involve us in some uncomfortable choices. All the authors of this statement approach the subject with an open mind and are receptive to any arguments and evidence – we hope others will take a similar approach.

Conclusion

35. **Benefits of proposed approach.** We support the replacement of the ban on oral tobacco with an approach that regulates the toxicity of all smokeless (and smoking) tobacco products. Our approach has the following advantages:
    a) It would create a legally defensible, fair and rational policy – in which public health is given primacy consistent within the framework of EU law.
    b) It could create public health benefits through smoking cessation and smoking substitution.
    c) It gives smokers an extra strategy for controlling their risk and eliminating ETS risk, and thereby respects their consumer and human rights.
    d) It would apply toxicity controls to the currently unregulated chewing products such as gutkha and paan available in the European Union and currently unregulated.
    e) It could have benefits beyond Europe if a good regulatory model is developed for controlling toxicity of smokeless tobacco – for example by establishing regulatory norms in the WHO Framework Convention on Tobacco Control.
    f) It opens the dominant cigarette makers to competition from tobacco products that do far less harm.

[15] Europe Against Cancer Programme High Level Cancer Experts Committee Consensus Conference on Tobacco Helsinki, 2 October 1996 [Europa]

Annex 1. Canadian standards for testing tobacco constituents

SCHEDULE 1
(Section 1 and subsection 12(3))

OFFICIAL METHODS FOR THE COLLECTION OF DATA ON CONSTITUENTS

Item	Constituent	Official Method
1.	(*a*) Nicotine (*b*) Nornicotine (*c*) Anabasine (*d*) Myosmine (*e*) Anatabine	Official Method T-301, *Determination of Alkaloids in Whole Tobacco*
2.	Ammonia	Official Method T-302, *Determination of Ammonia in Whole Tobacco*
3.	(*a*) Glycerol (*b*) Propylene glycol (*c*) Triethylene glycol	Official Method T-304, *Determination of Humectants in Whole Tobacco*
4.	(*a*) Nickel (*b*) Lead (*c*) Cadmium (*d*) Chromium (*e*) Arsenic (*f*) Selenium (*g*) Mercury	Official Method T-306, *Determination of Ni, Pb, Cd, Cr, As, Se and Hg in Whole Tobacco*
5.	Benzo[a]pyrene	Official Method T-307, *Determination of Benzo[a]pyrene in Whole Tobacco*
6.	Nitrate	Official Method T-308, *Determination of Nitrate from Whole*
7.	(*a*) N-nitrosonornicotine (*b*) 4-(N-nitrosomethylamino)-l-(3-pyridyl)-1-butanone (*c*) N-nitrosoanatabine (*d*) N-nitrosoanabasine	Official Method T-309, *Determination of Nitrosamines in Whole Tobacco*
8.	Triacetin	Official Method T-311, *Determination of Triacetin in Whole Tobacco*
9.	Sodium propionate	Official Method T-312, *Determination of Sodium Propionate in Whole Tobacco*
10.	Sorbic acid	Official Method T-313, *Determination of Sorbic Acid in Whole Tobacco*
11.	Eugenol [2- Methoxy-4-(2-propenyl)-phenol]	Official Method T-314, *Determination of Eugenol in Whole Tobacco*

Q.22/25 REASONS WHY CIGARETTES MORE ENJOYABLE

FORMER USERS OF SMOKELESS/CHEWING TOBACCO

	TOTAL	AT-LAN-TA	FLO-RIDA	AGE 18-34	AGE 35+	SMOKELESS TOBACCO TYPE PREVIOUSLY USED: TOTAL	FINE CUT	ROUGH CUT	LEAFY PLUG	SKOAL BAN-DITS	CIGARETTE USAGE: CURRENT SMOKERS	CURRENT NON-SMOKERS: FORMER SMOKERS	NEVER SMOKED	EDUCATION: HIGH SCHOOL OR LESS	COLLEGE OR MORE	INCOME: UNDER $30M	$30M AND OVER
(FORMER USERS)	85 100.0	24 100.0	61 100.0	37 100.0	48 100.0	85 100.0	9 100.0	1 100.0	53 100.0	18 100.0	2 100.0	53 100.0	23 100.0	9 100.0	61 100.0	23 100.0	62 100.0	17 100.0
DOESN'T MAKE ME SICK/ DON'T GET SICK TO STOMACH	3 3.5		3 4.9		3 6.3	3 3.5			1 1.9	2 11.1		3 5.7			2 3.3	1 4.3	2 3.2	1 5.9
DOESN'T GIVE ME HEART-BURN/INDIGESTION																		
STOPS ME FROM SMOKING/ TRYING TO QUIT SMOKING																		
RELAXES ME/CALMS MY NERVES (USE IT TO RELAX)	4 4.7		4 6.6	2 5.4	2 4.2	4 4.7			4 7.5			4 7.5			3 4.9	1 4.3	3 4.8	1 5.9
ALL OTHER HEALTH MENTIONS	1 1.2		1 1.6		1 2.1	1 1.2				1 5.6		1 1.9			1 1.6		1 1.6	
OTHER COMMENTS																		
LASTS LONGER	1 1.2		1 1.6	1 2.7		1 1.2			1 1.9			1 1.9				1 4.3	1 1.6	
HABIT/I'VE ALWAYS USED IT	2 2.4	1 4.2	1 1.6	2 5.4		2 2.4			2 3.8			2 3.8			1 1.6	1 4.3	1 1.6	1 5.9
TOO JUICY/DISLIKE THE JUICE																		
LIKE THE FEELING OF SOMETHING IN MY MOUTH																		
MORE SATISFYING/GET MORE PLEASURE FROM IT/SATISFIES ME/ENJOY IT MORE	4 4.7	3 12.5	1 1.6	2 5.4	2 4.2	4 4.7		1 100.0	3 5.7			4 7.5			4 6.6		2 3.2	1 5.9
NO REASON/JUST PREFER IT	2 2.4		2 3.3	1 2.7	1 2.1	2 2.4			2 3.8			2 3.8			1 1.6	1 4.3	2 3.2	

Q.22/25 REASONS WHY CIGARETTES MORE ENJOYABLE

FORMER USERS OF SMOKELESS/CHEWING TOBACCO

	TOTAL	AT-LANTA	FLO-RIDA	AGE 18-34	AGE 35+	SMOKELESS TOBACCO TYPE PREVIOUSLY USED: TOTAL	FINE CUT	ROUGH CUT	LEAFY PLUG	SKOAL BANDITS	CIGARETTE USAGE: CURRENT SMOKERS	CURRENT NON-SMOKERS: FORMER SMOKERS	CURRENT NON-SMOKERS: NEVER SMOKED	EDUCATION: HIGH SCHOOL OR LESS	EDUCATION: COLLEGE OR MORE	INCOME: UNDER $30M	INCOME: $30M AND OVER
(FORMER USERS)	85 100.0	24 100.0	61 100.0	37 100.0	48 100.0	85 100.0	9 100.0	1 100.0	53 100.0	18 100.0	2 100.0	53 100.0	23 100.0	9 100.0	61 100.0	23 100.0	62 100.0	17 100.0
INCONVENIENT TO SPIT/ HAVE TO FIND A PLACE TO SPIT	2 2.4		2 3.3	1 2.7	1 2.1	2 2.4			1 1.9	1 5.6		2 3.8			2 3.3		1 1.6	
CAN KEEP WORKING WHILE USING IT																		
CAN USE IT ANYWHERE/ MORE PLACES (ANYTIME)	4 4.7	2 8.3	2 3.3	2 5.4	2 4.2	4 4.7			3 5.7	1 5.6		4 7.5			4 6.6		2 3.2	1 5.9
NOT AS MESSY/CLEANER	7 8.2	3 12.5	4 6.6	4 10.8	3 6.3	7 8.2	1 11.1		5 9.4	1 5.6		7 13.2			6 9.8	1 4.3	4 6.5	3 17.6
CONVENIENT/MORE CONVENIENT	1 1.2		1 1.6		1 2.1	1 1.2			1 1.9			1 1.9				1 4.3	1 1.6	
ALL OTHER CONVENIENCE MENTIONS	1 1.2		1 1.6		1 2.1	1 1.2				1 5.6		1 1.9			1 1.6		1 1.6	
HEALTH BENEFITS (NET)	10 11.8	1 4.2	9 14.8	4 10.8	6 12.5	10 11.8			7 13.2	3 16.7		10 18.9			7 11.5	3 13.0	7 11.3	3 17.6
NO SIDE EFFECTS (SUB-NET)	5 5.9	1 4.2	4 6.6	2 5.4	3 6.3	5 5.9			3 5.7	2 11.1		5 9.4			3 4.9	2 8.7	3 4.8	2 11.8
WON'T HARM ME/NOT (AS) BAD FOR ME/ BETTER FOR ME																		
DOESN'T STAIN TEETH	2 2.4	1 4.2	1 1.6	2 5.4		2 2.4			2 3.8			2 3.8			1 1.6	1 4.3	1 1.6	1 5.9
WON'T HURT LUNGS/CAUSE LUNG CANCER																		
NO COUGHING/DOESN'T MAKE ME COUGH																		

Q.22/25 REASONS WHY CIGARETTES MORE ENJOYABLE

FORMER USERS OF SMOKELESS/CHEWING TOBACCO

	TOTAL	ATLANTA	FLORIDA	AGE 18-34	AGE 35+	SMOKELESS TOBACCO TYPE PREVIOUSLY USED: TOTAL	FINE CUT	ROUGH CUT	LEAFY PLUG	SKOAL BANDITS	CIGARETTE USAGE: CURRENT SMOKERS	CURRENT NON-SMOKERS: FORMER SMOKERS	CURRENT NON-SMOKERS: NEVER SMOKED	EDUCATION: HIGH SCHOOL OR LESS	EDUCATION: COLLEGE OR MORE	INCOME: UNDER $30M	INCOME: $30M AND OVER
(FORMER USERS)	85 100.0	24 100.0	61 100.0	37 100.0	48 100.0	85 100.0	9 100.0	1 100.0	53 100.0	18 100.0	2 100.0	53 100.0	23 100.0	9 100.0	61 100.0	23 100.0	62 100.0	17 100.0
CIGARETTES MORE ENJOYABLE	40 47.1	10 41.7	30 49.2	21 56.8	19 39.6	40 47.1	2 22.2	1 100.0	30 56.6	6 33.3	1 50.0	40 75.5			28 45.9	12 52.2	27 43.5	11 64.7
TASTE (NET)	7 8.2	1 4.2	6 9.8	5 13.5	2 4.2	7 8.2			6 11.3		1 50.0	7 13.2			4 6.6	3 13.0	4 6.5	3 17.6
TASTES GOOD/BETTER/LIKE TASTE BETTER	4 4.7		4 6.6	3 8.1	1 2.1	4 4.7			3 5.7		1 50.0	4 7.5			2 3.3	2 8.7	3 4.8	1 5.9
STRONG/STRONGER TASTE	1 1.2	1 4.2			1 2.1	1 1.2			1 1.9			1 1.9			1 1.6		1 1.6	
ALL OTHER TASTE MENTIONS	2 2.4		2 3.3	2 5.4		2 2.4			2 3.8			2 3.8			1 1.6	1 4.3		2 11.8
CONVENIENCE (NET)	17 20.0	6 25.0	11 18.0	10 27.0	7 14.6	17 20.0	2 22.2		13 24.5	2 11.1		17 32.1			13 21.3	4 17.4	10 16.1	6 35.3
EASY TO USE (SUBNET)	2 2.4	1 4.2	1 1.6	1 2.7	1 2.1	2 2.4			2 3.8			2 3.8			1 1.6	1 4.3	1 1.6	1 5.9
DON'T NEED MATCHES/ DON'T HAVE TO ALWAYS LIGHT UP																		
EASY/EASIER TO USE	2 2.4	1 4.2	1 1.6	1 2.7	1 2.1	2 2.4			2 3.8			2 3.8			1 1.6	1 4.3	1 1.6	1 5.9
HANDY	1 1.2	1 4.2		1 2.7		1 1.2			1 1.9			1 1.9			1 1.6			1 5.9
DON'T NEED HANDS/HANDS ARE FREE/NOT TIED UP																		
NO SPITTING/DON'T NEED TO SPIT USING CIGARETTES	8 9.4	3 12.5	5 8.2	6 16.2	2 4.2	8 9.4	2 22.2		6 11.3			8 15.1			7 11.5	1 4.3	5 8.1	3 17.6

Q.22/25 REASONS WHY SMOKELESS/CHEWING TOBACCO MORE ENJOYABLE

FORMER USERS OF SMOKELESS/CHEWING TOBACCO

	TOTAL	AT-LAN-TA	FLO-RIDA	AGE 18-34	AGE 35+	SMOKELESS TOBACCO TYPE PREVIOUSLY USED: TOTAL	FINE CUT	ROUGH CUT	LEAFY PLUG	SKOAL BAN-DITS	CIGARETTE USAGE: CURRENT SMOK-ERS	CURRENT NON-SMOKERS: FORM-ER SMOK-ERS	NEVER SMOK-ED	EDUCATION: HIGH SCH-OOL OR LESS	COL-LEGE OR MORE	INCOME: UN-DER $30M	$30M AND OVER
(FORMER USERS)	85	24	61	37	48	85	9	1	53	18	2	53	23	9	61	23	62	17
	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
MISCELLANEOUS	1		1		1	1			1			1			1		1	
	1.2		1.6		2.1	1.2			1.9			1.9			1.6		1.6	
DON'T KNOW																		

MARKETING INFORMATION SYSTEMS, INC.
TOBACCO PRODUCTS IN-STORE TEST #834684

TABLE 18A

Q.22/25 REASONS WHY SMOKELESS/CHEWING TOBACCO MORE ENJOYABLE

FORMER USERS OF SMOKELESS/CHEWING TOBACCO

	TOTAL	AT-LAN-TA	FLO-RIDA	AGE 18-34	AGE 35+	SMOKELESS TOBACCO TYPE PREVIOUSLY USED: TOTAL	FINE CUT	ROUGH CUT	LEAFY PLUG	SKOAL BAN-DITS	CIGARETTE USAGE: CUR-RENT SMOK-ERS	CURRENT NON-SMOKERS: FORM-ER SMOK-ERS	CURRENT NON-SMOKERS: NEVER SMOK-ED	EDUCATION: HIGH SCH-OOL OR LESS	EDUCATION: COL-LEGE OR MORE	INCOME: UN-DER $30M	INCOME: $30M AND OVER
(FORMER USERS)	85 100.0	24 100.0	61 100.0	37 100.0	48 100.0	85 100.0	9 100.0	1 100.0	53 100.0	18 100.0	2 100.0	53 100.0	23 100.0	9 100.0	61 100.0	23 100.0	62 100.0	17 100.0
DOESN'T MAKE ME SICK/ DON'T GET SICK TO STOMACH																		
DOESN'T GIVE ME HEART-BURN/INDIGESTION																		
STOPS ME FROM SMOKING/ TRYING TO QUIT SMOKING	1 1.2		1 1.6	1 2.7		1 1.2	1 11.1				1 1.9			1 1.6		1 1.6	
RELAXES ME/CALMS MY NERVES (USE IT TO RELAX)	1 1.2	1 4.2		1 2.7		1 1.2			1 1.9		1 1.9			1 1.6		1 1.6	
ALL OTHER HEALTH MEN-TIONS																		
OTHER COMMENTS																		
LASTS LONGER																		
HABIT/I'VE ALWAYS USED IT																		
TOO JUICY/DISLIKE THE JUICE																		
LIKE THE FEELING OF SOMETHING IN MY MOUTH	1 1.2	1 4.2		1 2.7		1 1.2			1 1.9		1 1.9			1 1.6		1 1.6	
MORE SATISFYING/GET MORE PLEASURE FROM IT/SAT-ISFIES ME/ENJOY IT MORE																		
NO REASON/JUST PREFER IT																		

MARKETING INFORMATION SYSTEMS, INC.
TOBACCO PRODUCTS IN-STORE TEST #834684

TABLE 18A

Q.22/25 REASONS WHY SMOKELESS/CHEWING TOBACCO MORE ENJOYABLE

FORMER USERS OF SMOKELESS/CHEWING TOBACCO

	TOTAL	AT-LAN-TA	FLO-RIDA	AGE 18-34	AGE 35+	SMOKELESS TOBACCO TYPE PREVIOUSLY USED: TOTAL	FINE CUT	ROUGH CUT	LEAFY PLUG	SKOAL BAN-DITS	CIGARETTE USAGE: CURRENT SMOK-ERS	CURRENT NON-SMOKERS: FORM-ER SMOK-ERS	CURRENT NON-SMOKERS: NEVER SMOK-ED	EDUCATION: HIGH SCH-OOL OR LESS	EDUCATION: COL-LEGE OR MORE	INCOME: UN-DER $30M	INCOME: $30M AND OVER
(FORMER USERS)	85	24	61	37	48	85	9	1	53	18	2	53	23	9	61	23	62	17
	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
INCONVENIENT TO SPIT/ HAVE TO FIND A PLACE TO SPIT																		
CAN KEEP WORKING WHILE USING IT																		
CAN USE IT ANYWHERE/ MORE PLACES (ANYTIME)																		
NOT AS MESSY/CLEANER																		
CONVENIENT/MORE CONVENIENT																		
ALL OTHER CONVENIENCE MENTIONS																		
HEALTH BENEFITS (NET)	4	1	3	4		4	2		2			4			4		3	1
	4.7	4.2	4.9	10.8		4.7	22.2		3.8			7.5			6.6		4.8	5.9
NO SIDE EFFECTS (SUB-NET)	2		2	2		2	1		1			2			2		1	1
	2.4		3.3	5.4		2.4	11.1		1.9			3.8			3.3		1.6	5.9
WON'T HARM ME/NOT (AS) BAD FOR ME/ BETTER FOR ME	1		1	1		1	1					1			1		1	
	1.2		1.6	2.7		1.2	11.1					1.9			1.6		1.6	
DOESN'T STAIN TEETH																		
WON'T HURT LUNGS/CAUSE LUNG CANCER	1		1	1		1			1			1			1			1
	1.2		1.6	2.7		1.2			1.9			1.9			1.6			5.9
NO COUGHING/DOESN'T MAKE ME COUGH	1		1	1		1			1			1			1			1
	1.2		1.6	2.7		1.2			1.9			1.9			1.6			5.9

Q.22/25 REASONS WHY SMOKELESS/CHEWING TOBACCO MORE ENJOYABLE

FORMER USERS OF SMOKELESS/CHEWING TOBACCO

	TOTAL	AT-LAN-TA	FLO-RIDA	AGE 18-34	AGE 35+	SMOKELESS TOBACCO TYPE PREVIOUSLY USED: TOTAL	FINE CUT	ROUGH CUT	LEAFY PLUG	SKOAL BAN-DITS	CIGARETTE USAGE: CUR-RENT SMOK-ERS	CURRENT NON-SMOKERS: FORM-ER SMOK-ERS	CURRENT NON-SMOKERS: NEVER SMOK-ED	EDUCATION: HIGH SCH-OOL OR LESS	EDUCATION: COL-LEGE OR MORE	INCOME: UN-DER $30M	INCOME: $30M AND OVER
(FORMER USERS)	85 100.0	24 100.0	61 100.0	37 100.0	48 100.0	85 100.0	9 100.0	1 100.0	53 100.0	18 100.0	2 100.0	53 100.0	23 100.0	9 100.0	61 100.0	23 100.0	62 100.0	17 100.0
SMOKELESS MORE ENJOYABLE	6 7.1	2 8.3	4 6.6	5 13.5	1 2.1	6 7.1	2 22.2		4 7.5			6 11.3			6 9.8		5 8.1	1 5.9
TASTE (NET)	2 2.4	1 4.2	1 1.6	2 5.4		2 2.4			2 3.8			2 3.8			2 3.3		1 1.6	1 5.9
TASTES GOOD/BETTER/LIKE TASTE BETTER	2 2.4	1 4.2	1 1.6	2 5.4		2 2.4			2 3.8			2 3.8			2 3.3		1 1.6	1 5.9
STRONG/STRONGER TASTE																		
ALL OTHER TASTE MENTIONS																		
CONVENIENCE (NET)	1 1.2	1 4.2		1 2.7		1 1.2			1 1.9			1 1.9			1 1.6		1 1.6	
EASY TO USE (SUBNET)	1 1.2	1 4.2		1 2.7		1 1.2			1 1.9			1 1.9			1 1.6		1 1.6	
DON'T NEED MATCHES/ DON'T HAVE TO ALWAYS LIGHT UP	1 1.2	1 4.2		1 2.7		1 1.2			1 1.9			1 1.9			1 1.6		1 1.6	
EASY/EASIER TO USE																		
HANDY																		
DON'T NEED HANDS/HANDS ARE FREE/NOT TIED UP																		
NO SPITTING/DON'T NEED TO SPIT USING CIGARETTES																		

Q.21/24 WHICH TOBACCO PRODUCT IS MORE ENJOYABLE

FORMER USERS OF SMOKELESS/CHEWING TOBACCO

	TOTAL	AT-LAN-TA	FLO-RIDA	AGE 18-34	AGE 35+	SMOKELESS TOBACCO TYPE PREVIOUSLY USED: TOTAL	FINE CUT	ROUGH CUT	LEAFY PLUG	SKOAL BAN-DITS	CIGARETTE USAGE: CUR-RENT SMOK-ERS	CURRENT NON-SMOKERS: FORM-ER SMOK-ERS	CURRENT NON-SMOKERS: NEVER SMOK-ED	EDUCATION: HIGH SCH-OOL OR LESS	EDUCATION: COL-LEGE OR MORE	INCOME: UN-DER $30M	INCOME: $30M AND OVER
(FORMER USERS)	85	24	61	37	48	85	9	1	53	18	2	53	23	9	61	23	62	17
	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
CURRENT SMOKER	53	12	41	28	25	53	7	1	36	7	1	53			35	17	37	13
	62.4	50.0	67.2	75.7	52.1	62.4	77.8	100.0	67.9	38.9	50.0	100.0			57.4	73.9	59.7	76.5
SMOKELESS/CHEWING TOBACCO	6	2	4	5	1	6	2		4			6			6		5	1
	7.1	8.3	6.6	13.5	2.1	7.1	22.2		7.5			11.3			9.8		8.1	5.9
CIGARETTES	40	10	30	21	19	40	2	1	30	6	1	40			28	12	27	11
	47.1	41.7	49.2	56.8	39.6	47.1	22.2	100.0	56.6	33.3	50.0	75.5			45.9	52.2	43.5	64.7
DK/NA	7		7	2	5	7	3		2	1		7			1	5	5	1
	8.2		11.5	5.4	10.4	8.2	33.3		3.8	5.6		13.2			1.6	21.7	8.1	5.9

Q.20/19 NUMBER OF PACKS SMOKED IN A WEEK

FORMER USERS OF SMOKELESS/CHEWING TOBACCO

	TOTAL	AT-LAN-TA	FLO-RIDA	AGE 18-34	AGE 35+	SMOKELESS TOBACCO TYPE PREVIOUSLY USED: TOTAL	FINE CUT	ROUGH CUT	LEAFY PLUG	PLUG	SKOAL BAN-DITS	CIGARETTE USAGE: CUR-RENT SMOK-ERS	CURRENT NON-SMOKERS: FORM-ER SMOK-ERS	NEVER SMOK-ED	EDUCATION: HIGH SCH-OOL OR LESS	COL-LEGE OR MORE	INCOME: UN-DER $30M	$30M AND OVER
(FORMER USERS)	85 100.0	24 100.0	61 100.0	37 100.0	48 100.0	85 100.0	9 100.0	1 100.0	53 100.0	18 100.0	2 100.0	53 100.0	23 100.0	9 100.0	61 100.0	23 100.0	62 100.0	17 100.0
13 PACKS																		
14 PACKS	6 7.1	4 16.7	2 3.3	5 13.5	1 2.1	6 7.1	3 33.3	1 100.0	2 3.8			6 11.3			6 9.8		3 4.8	3 17.6
15 PACKS	1 1.2		1 1.6	1 2.7		1 1.2			1 1.9			1 1.9				1 4.3		1 5.9
16 PACKS																		
17 PACKS																		
18 PACKS																		
19 PACKS																		
20 OR MORE PACKS	1 1.2		1 1.6		1 2.1	1 1.2				1 5.6		1 1.9			1 1.6		1 1.6	
DK/NA																		
AVERAGE	8.38	9.83	7.95	8.29	8.48	8.38	10.00	14.00	7.83	8.71	7.00	8.38			8.34	8.59	8.16	9.31
STD DEV	3.47	3.21	3.43	3.61	3.30	3.47	3.96		2.74	5.23		3.47			3.85	2.57	3.49	3.45
STD ERR	.48	.93	.54	.68	.66	.48	1.50		.46	1.98		.48			.65	.62	.57	.96

Q.20/19 NUMBER OF PACKS SMOKED IN A WEEK

FORMER USERS OF SMOKELESS/CHEWING TOBACCO

						SMOKELESS TOBACCO TYPE TYPE PREVIOUSLY USED					CIGARETTE USAGE			EDUCATION		INCOME	
				AGE								CURRENT NON-SMOKERS					
	TOTAL	ATLANTA	FLORIDA	18-34	35+	TOTAL	FINE CUT	ROUGH CUT	LEAFY PLUG	SKOAL BANDITS	CURRENT SMOKERS	FORMER SMOKERS	NEVER SMOKED	HIGH SCHOOL OR LESS	COLLEGE OR MORE	UNDER $30M	$30M AND OVER
(FORMER USERS)	85 100.0	24 100.0	61 100.0	37 100.0	48 100.0	85 100.0	9 100.0	1 100.0	53 100.0	18 100.0	2 100.0	53 100.0	23 100.0	9 100.0	61 100.0	23 100.0	62 100.0	17 100.0
CURRENT SMOKER	53 62.4	12 50.0	41 67.2	28 75.7	25 52.1	53 62.4	7 77.8	1 100.0	36 67.9	7 38.9	1 50.0	53 100.0			35 57.4	17 73.9	37 59.7	13 76.5
1 PACK																		
2 PACKS																		
3 PACKS	3 3.5		3 4.9	3 8.1		3 3.5	1 11.1		2 3.8			3 5.7			2 3.3	1 4.3	3 4.8	
4 PACKS	3 3.5		3 4.9	1 2.7	2 4.2	3 3.5			2 3.8	1 5.6		3 5.7			3 4.9		3 4.8	
5 PACKS	3 3.5	1 4.2	2 3.3	1 2.7	2 4.2	3 3.5			1 1.9	2 11.1		3 5.7			3 4.9		1 1.6	1 5.9
6 PACKS	3 3.5		3 4.9	2 5.4	1 2.1	3 3.5			2 3.8	1 5.6		3 5.7			2 3.3		2 3.2	
7 PACKS	17 20.0	3 12.5	14 23.0	10 27.0	7 14.6	17 20.0	1 11.1		15 28.3		1 50.0	17 32.1			10 16.4	7 30.4	10 16.1	7 41.2
8 PACKS	5 5.9	2 8.3	3 4.9	2 5.4	3 6.3	5 5.9	1 11.1		4 7.5			5 9.4			4 6.6	1 4.3	5 8.1	
9 PACKS	1 1.2		1 1.6	1 2.7		1 1.2			1 1.9			1 1.9				1 4.3	1 1.6	
10 PACKS	8 9.4	2 8.3	6 9.8	1 2.7	7 14.6	8 9.4	1 11.1		5 9.4	1 5.6		8 15.1			3 4.9	5 21.7	6 9.7	1 5.9
11 PACKS	1 1.2		1 1.6		1 2.1	1 1.2				1 5.6		1 1.9			1 1.6		1 1.6	
12 PACKS	1 1.2		1 1.6	1 2.7		1 1.2			1 1.9			1 1.9				1 4.3	1 1.6	

Q.19/18 AMOUNT OF CIGARETTE SMOKING COMPARED TO YEAR AGO

FORMER USERS OF SMOKELESS/CHEWING TOBACCO

	TOTAL	AT-LAN-TA	FLO-RIDA	AGE 18-34	AGE 35+	SMOKELESS TOBACCO TYPE PREVIOUSLY USED: TOTAL	FINE CUT	ROUGH CUT	LEAFY PLUG	SKOAL BAN-DITS	CIGARETTE USAGE: CUR-RENT SMOK-ERS	CURRENT NON-SMOKERS: FORM-ER SMOK-ERS	NEVER SMOK-ED	EDUCATION: HIGH SCH-OOL OR LESS	COL-LEGE OR MORE	INCOME: UN-DER $30M	$30M AND OVER
(FORMER USERS)	85	24	61	37	48	85	9	1	53	18	2	53	23	9	61	23	62	17
	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
CURRENT SMOKER	53	12	41	28	25	53	7	1	36	7	1	53			35	17	37	13
	62.4	50.0	67.2	75.7	52.1	62.4	77.8	100.0	67.9	38.9	50.0	100.0			57.4	73.9	59.7	76.5
MORE	16	3	13	13	3	16	3		11	1	1	16			10	6	11	5
	18.8	12.5	21.3	35.1	6.3	18.8	33.3		20.8	5.6	50.0	30.2			16.4	26.1	17.7	29.4
THE SAME	26	5	21	7	19	26	3	1	16	5		26			15	10	16	7
	30.6	20.8	34.4	18.9	39.6	30.6	33.3	100.0	30.2	27.8		49.1			24.6	43.5	25.8	41.2
LESS	11	4	7	8	3	11	1		9	1		11			10	1	10	1
	12.9	16.7	11.5	21.6	6.3	12.9	11.1		17.0	5.6		20.8			16.4	4.3	16.1	5.9
DK/NA																		

Q.17 REGULAR BRAND OF CIGARETTES

FORMER USERS OF SMOKELESS/CHEWING TOBACCO

	TOTAL	ATLANTA	FLORIDA	AGE 18-34	AGE 35+	SMOKELESS TOBACCO TYPE PREVIOUSLY USED: TOTAL	FINE CUT	ROUGH CUT	LEAFY PLUG	SKOAL BANDITS	CIGARETTE USAGE: CURRENT SMOKERS	CURRENT NON-SMOKERS: FORMER SMOKERS	CURRENT NON-SMOKERS: NEVER SMOKED	EDUCATION: HIGH SCHOOL OR LESS	EDUCATION: COLLEGE OR MORE	INCOME: UNDER $30M	INCOME: $30M AND OVER
(FORMER USERS)	85	24	61	37	48	85	9	1	53	18	2	53	23	9	61	23	62	17
	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
M - MENTHOL																		
UR - ULTRA LOW REGULAR	2	2			2	2			2			2			1	1		1
	2.4	8.3			4.2	2.4			3.8			3.8			1.6	4.3		5.9
LR - LOW REGULAR	17	4	13	10	7	17	3	1	9	2	1	17			9	7	9	7
	20.0	16.7	21.3	27.0	14.6	20.0	33.3	100.0	17.0	11.1	50.0	32.1			14.8	30.4	14.5	41.2
FR - FULL FLAVOR REGULAR	18	6	12	9	9	18	3		12	3		18			14	4	15	2
	21.2	25.0	19.7	24.3	18.8	21.2	33.3		22.6	16.7		34.0			23.0	17.4	24.2	11.8
R - REGULAR																		
K - KING SIZE	33	7	26	20	13	33	4		25	3	1	33			20	13	23	8
	38.8	29.2	42.6	54.1	27.1	38.8	44.4		47.2	16.7	50.0	62.3			32.8	56.5	37.1	47.1
H - HUNDREDS/120'S	20	5	15	8	12	20	3	1	11	4		20			15	4	14	5
	23.5	20.8	24.6	21.6	25.0	23.5	33.3	100.0	20.8	22.2		37.7			24.6	17.4	22.6	29.4

Q.17 REGULAR BRAND OF CIGARETTES

FORMER USERS OF SMOKELESS/CHEWING TOBACCO

	TOTAL	ATLANTA	FLORIDA	AGE 18-34	AGE 35+	SMOKELESS TOBACCO TYPE PREVIOUSLY USED: TOTAL	FINE CUT	ROUGH CUT	LEAFY PLUG	SKOAL BANDITS	CIGARETTE USAGE: CURRENT SMOKERS	CURRENT NON-SMOKERS: FORMER SMOKERS	NEVER SMOKED	EDUCATION: HIGH SCHOOL OR LESS	EDUCATION: COLLEGE OR MORE	INCOME: UNDER $30M	INCOME: $30M AND OVER
(FORMER USERS)	85 100.0	24 100.0	61 100.0	37 100.0	48 100.0	85 100.0	9 100.0	1 100.0	53 100.0	18 100.0	2 100.0	53 100.0	23 100.0	9 100.0	61 100.0	23 100.0	62 100.0	17 100.0
NON FILTER RED PACK	3 3.5		3 4.9		3 6.3	3 3.5			3 5.7			3 5.7			1 1.6	2 8.7	2 3.2	1 5.9
BROWN & WILLIAMSON (MASTER NET)=======	6 7.1	1 4.2	5 8.2	1 2.7	5 10.4	6 7.1			4 7.5	2 11.1		6 11.3			6 9.8		4 6.5	
BARCLAY (NET)	1 1.2	1 4.2			1 2.1	1 1.2			1 1.9			1 1.9			1 1.6			
KINGS REGULAR	1 1.2	1 4.2			1 2.1	1 1.2			1 1.9			1 1.9			1 1.6			
KOOL (NET)	4 4.7		4 6.6	1 2.7	3 6.3	4 4.7			3 5.7	1 5.6		4 7.5			4 6.6		4 6.5	
FILTER KINGS	2 2.4		2 3.3		2 4.2	2 2.4			2 3.8			2 3.8			2 3.3		2 3.2	
MILD KINGS	1 1.2		1 1.6		1 2.1	1 1.2				1 5.6		1 1.9			1 1.6		1 1.6	
ULTRA 100'S	1 1.2		1 1.6	1 2.7		1 1.2			1 1.9			1 1.9			1 1.6		1 1.6	
VICEROY (NET)	1 1.2		1 1.6		1 2.1	1 1.2				1 5.6		1 1.9			1 1.6			
KINGS	1 1.2		1 1.6		1 2.1	1 1.2				1 5.6		1 1.9			1 1.6			
UM - ULTRA LOW MENTHOL	1 1.2		1 1.6	1 2.7		1 1.2			1 1.9			1 1.9			1 1.6		1 1.6	
LM - LOW MENTHOL	3 3.5		3 4.9	1 2.7	2 4.2	3 3.5			2 3.8	1 5.6		3 5.7			2 3.3	1 4.3	3 4.8	
FM - FULL FLAVOR MENTHOL	12 14.1		12 19.7	7 18.9	5 10.4	12 14.1	1 11.1		10 18.9	1 5.6		12 22.6			8 13.1	4 17.4	9 14.5	3 17.6

Q.17 REGULAR BRAND OF CIGARETTES

FORMER USERS OF SMOKELESS/CHEWING TOBACCO

	TOTAL	AT-LAN-TA	FLO-RIDA	AGE 18-34	AGE 35+	SMOKELESS TOBACCO TYPE PREVIOUSLY USED: TOTAL	FINE CUT	ROUGH CUT	LEAFY PLUG	SKOAL BAN-DITS	CIGARETTE USAGE: CUR-RENT SMOK-ERS	CURRENT NON-SMOKERS: FORM-ER SMOK-ERS	CURRENT NON-SMOKERS: NEVER SMOK-ED	EDUCATION: HIGH SCH-OOL OR LESS	EDUCATION: COL-LEGE OR MORE	INCOME: UN-DER $30M	INCOME: $30M AND OVER
(FORMER USERS)	85	24	61	37	48	85	9	1	53	18	2	53	23	9	61	23	62	17
	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
KINGS IN THE RED PACK	3	1	2	1	2	3			2	1		3			2	1	3	
	3.5	4.2	3.3	2.7	4.2	3.5			3.8	5.6		5.7			3.3	4.3	4.8	
100'S	2		2	1	1	2	1			1		2			2		2	
	2.4		3.3	2.7	2.1	2.4	11.1			5.6		3.8			3.3		3.2	
LIGHTS KINGS	2		2	2		2			2			2			1	1		2
	2.4		3.3	5.4		2.4			3.8			3.8			1.6	4.3		11.8
LIGHTS 100'S	2		2		2	2			1	1		2			1		1	
	2.4		3.3		4.2	2.4			1.9	5.6		3.8			1.6		1.6	
LORILLARD (MASTER NET)	5	2	3	3	2	5			5			5			3	2	4	1
	5.9	8.3	4.9	8.1	4.2	5.9			9.4			9.4			4.9	8.7	6.5	5.9
KENT (NET)	2	2		1	1	2			2			2			1	1	1	1
	2.4	8.3		2.7	2.1	2.4			3.8			3.8			1.6	4.3	1.6	5.9
REGULAR (SUB NET)	2	2		1	1	2			2			2			1	1	1	1
	2.4	8.3		2.7	2.1	2.4			3.8			3.8			1.6	4.3	1.6	5.9
KINGS	1	1		1		1			1			1			1		1	
	1.2	4.2		2.7		1.2			1.9			1.9			1.6		1.6	
II 100'S	1	1			1	1			1			1				1		1
	1.2	4.2			2.1	1.2			1.9			1.9				4.3		5.9
NEWPORT (NET)	3		3	2	1	3			3			3			2	1	3	
	3.5		4.9	5.4	2.1	3.5			5.7			5.7			3.3	4.3	4.8	
KINGS	3		3	2	1	3			3			3			2	1	3	
	3.5		4.9	5.4	2.1	3.5			5.7			5.7			3.3	4.3	4.8	
AMERICAN TOBACCO (MASTER NET)	3		3		3	3			3			3			1	2	2	1
	3.5		4.9		6.3	3.5			5.7			5.7			1.6	8.7	3.2	5.9
PALL MALL (NET)	3		3		3	3			3			3			1	2	2	1
	3.5		4.9		6.3	3.5			5.7			5.7			1.6	8.7	3.2	5.9

Q.17 REGULAR BRAND OF CIGARETTES

FORMER USERS OF SMOKELESS/CHEWING TOBACCO

	TOTAL	AT-LAN-TA	FLO-RIDA	AGE 18-34	AGE 35+	SMOKELESS TOBACCO TYPE PREVIOUSLY USED: TOTAL	FINE CUT	ROUGH CUT	LEAFY PLUG	SKOAL DAN-DITS	CIGARETTE USAGE: CUR-RENT SMOK-ERS	CURRENT NON-SMOKERS: FORM-ER SMOK-ERS	NEVER SMOK-ED	EDUCATION: HIGH SCH-OOL OR LESS	COL-LEGE OR MORE	INCOME: UN-DER $30M	$30M AND OVER
(FORMER USERS)	85 100.0	24 100.0	61 100.0	37 100.0	48 100.0	85 100.0	9 100.0	1 100.0	53 100.0	18 100.0	2 100.0	53 100.0	23 100.0	9 100.0	61 100.0	23 100.0	62 100.0	17 100.0
100'S REGULAR	3 3.5		3 4.9		3 6.3	3 3.5			2 3.8	1 5.6		3 5.7			2 3.3	1 4.3	2 3.2	1 5.9
PARLIAMENT (NET)	1 1.2	1 4.2		1 2.7		1 1.2			1 1.9			1 1.9			1 1.6			1 5.9
LIGHTS 100'S	1 1.2	1 4.2		1 2.7		1 1.2			1 1.9			1 1.9			1 1.6			1 5.9
REYNOLDS (MASTER NET)	16 18.8	2 8.3	14 23.0	8 21.6	8 16.7	16 18.8	4 44.4		9 17.0	3 16.7		16 30.2			10 16.4	5 21.7	11 17.7	4 23.5
BRIGHT (NET)	1 1.2		1 1.6		1 2.1	1 1.2			1 1.9			1 1.9			1 1.6		1 1.6	
100'S MENTHOL	1 1.2		1 1.6		1 2.1	1 1.2			1 1.9			1 1.9			1 1.6		1 1.6	
SALEM (NET)	4 4.7		4 6.6	3 8.1	1 2.1	4 4.7	1 11.1		3 5.7			4 7.5			2 3.3	2 8.7	3 4.8	1 5.9
KINGS	3 3.5		3 4.9	2 5.4	1 2.1	3 3.5	1 11.1		2 3.8			3 5.7			2 3.3	1 4.3	2 3.2	1 5.9
LIGHTS 100'S	1 1.2		1 1.6	1 2.7		1 1.2			1 1.9			1 1.9				1 4.3	1 1.6	
VANTAGE (NET)	2 2.4	1 4.2	1 1.6	1 2.7	1 2.1	2 2.4	2 22.2					2 3.8			1 1.6	1 4.3	1 1.6	1 5.9
KINGS REGULAR	1 1.2		1 1.6	1 2.7		1 1.2	1 11.1					1 1.9				1 4.3	1 1.6	
100'S REGULAR	1 1.2	1 4.2			1 2.1	1 1.2	1 11.1					1 1.9			1 1.6			1 5.9
WINSTON (NET)	9 10.6	1 4.2	8 13.1	4 10.8	5 10.4	9 10.6	1 11.1		5 9.4	3 16.7		9 17.0			6 9.8	2 8.7	6 9.7	2 11.8

Q.17 REGULAR BRAND OF CIGARETTES

FORMER USERS OF SMOKELESS/CHEWING TOBACCO

	TOTAL	ATLANTA	FLORIDA	AGE 18-34	AGE 35+	SMOKELESS TOBACCO TYPE PREVIOUSLY USED: TOTAL	FINE CUT	ROUGH CUT	LEAFY PLUG	SKOAL BANDITS	CIGARETTE USAGE: CURRENT SMOKERS	CURRENT NON-SMOKERS: FORMER SMOKERS	CURRENT NON-SMOKERS: NEVER SMOKED	EDUCATION: HIGH SCHOOL OR LESS	EDUCATION: COLLEGE OR MORE	INCOME: UNDER $30M	INCOME: $30M AND OVER
(FORMER USERS)	85	24	61	37	48	85	9	1	53	18	2	53	23	9	61	23	62	17
	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
CURRENT SMOKER	53	12	41	28	25	53	7	1	36	7	1	53			35	17	37	13
	62.4	50.0	67.2	75.7	52.1	62.4	77.8	100.0	67.9	38.9	50.0	100.0			57.4	73.9	59.7	76.5
PHILIP MORRIS (MASTER NET)	23	7	16	16	7	23	3	1	15	2	1	23			15	8	16	7
	27.1	29.2	26.2	43.2	14.6	27.1	33.3	100.0	28.3	11.1	50.0	43.4			24.6	34.8	25.8	41.2
BENSON & HEDGES (NET)	3		3	1	2	3			1	1		3			2	1	2	1
	3.5		4.9	2.7	4.2	3.5			1.9	5.6		5.7			3.3	4.3	3.2	5.9
100'S MENTHOL	2		2	1	1	2			1	1		2			2		1	1
	2.4		3.3	2.7	2.1	2.4			1.9	5.6		3.8			3.3		1.6	5.9
100'S LIGHTS REGULAR	1		1		1	1						1				1	1	
	1.2		1.6		2.1	1.2						1.9				4.3	1.6	
MARLBORO (NET)	15	6	9	13	2	15	3	1	10		1	15			10	5	12	3
	17.6	25.0	14.8	35.1	4.2	17.6	33.3	100.0	18.9		50.0	28.3			16.4	21.7	19.4	17.6
KINGS IN THE RED PACK	7	4	3	6	1	7	2		5			7			6	1	6	1
	8.2	16.7	4.9	16.2	2.1	8.2	22.2		9.4			13.2			9.8	4.3	9.7	5.9
100'S	2	1	1	1	1	2			2			2			2		2	
	2.4	4.2	1.6	2.7	2.1	2.4			3.8			3.8			3.3		3.2	
LIGHTS KINGS	2		2	2		2			1		1	2				2	1	1
	2.4		3.3	5.4		2.4			1.9		50.0	3.8				8.7	1.6	5.9
LIGHTS 100'S	2	1	1	2		2	1	1				2			2		2	
	2.4	4.2	1.6	5.4		2.4	11.1	100.0				3.8			3.3		3.2	
MENTHOL	2		2	2		2			2			2				2	1	1
	2.4		3.3	5.4		2.4			3.8			3.8				8.7	1.6	5.9
MERIT (NET)	4		4	1	3	4			3	1		4			2	2	2	2
	4.7		6.6	2.7	6.3	4.7			5.7	5.6		7.5			3.3	8.7	3.2	11.8
KINGS REGULAR	1		1	1		1			1			1				1		1
	1.2		1.6	2.7		1.2			1.9			1.9				4.3		5.9

Q.16 WHETHER OR NOT RESPONDENT CURRENTLY SMOKES CIGARETTES

FORMER USERS OF SMOKELESS/CHEWING TOBACCO

	TOTAL	AT-LAN-TA	FLO-RIDA	AGE 18-34	AGE 35+	SMOKELESS TOBACCO TYPE PREVIOUSLY USED: TOTAL	FINE CUT	ROUGH CUT	LEAFY PLUG	SKOAL BAN-DITS	CIGARETTE USAGE: CUR-RENT SMOK-ERS	CURRENT NON-SMOKERS: FORM-ER SMOK-ERS	CURRENT NON-SMOKERS: NEVER SMOK-ED	EDUCATION: HIGH SCH-OOL OR LESS	EDUCATION: COL-LEGE OR MORE	INCOME: UN-DER $30M	INCOME: $30M AND OVER
(FORMER USERS)	85	24	61	37	48	85	9	1	53	18	2	53	23	9	61	23	62	17
	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
YES, CURRENTLY SMOKE CIGARETTES	53	12	41	28	25	53	7	1	36	7	1	53			35	17	37	13
	62.4	50.0	67.2	75.7	52.1	62.4	77.8	100.0	67.9	38.9	50.0	100.0			57.4	73.9	59.7	76.5
NO, DO NOT SMOKE CIGARETTES	32	12	20	9	23	32	2		17	11	1		23	9	26	6	25	4
	37.6	50.0	32.8	24.3	47.9	37.6	22.2		32.1	61.1	50.0		100.0	100.0	42.6	26.1	40.3	23.5
DK/NA																		

MARKETING INFORMATION SYSTEMS, INC.
TOBACCO PRODUCTS IN-STORE TEST #834684

TABLE 12C

Q. 15 REASONS STOPPED USING SMOKELESS/CHEWING TOBACCO

FORMER USERS OF SMOKELESS/CHEWING TOBACCO

													CIGARETTE USAGE							
							SMOKELESS TOBACCO TYPE TYPE PREVIOUSLY USED						CURRENT NON-SMOKERS			EDUCATION		INCOME	
		AGE																	
	TOTAL	ATLANTA	FLORIDA	18-34	35+	TOTAL	FINE CUT	ROUGH CUT	LEAFY PLUG	SKOAL BANDITS	CURRENT SMOKERS	FORMER SMOKERS	NEVER SMOKED	HIGH SCHOOL OR LESS	COLLEGE OR MORE	UNDER $30M	$30M AND OVER
(FORMER USERS)	85 100.0	24 100.0	61 100.0	37 100.0	48 100.0	85 100.0	9 100.0	1 100.0	53 100.0	18 100.0	2 100.0	53 100.0	23 100.0	9 100.0	61 100.0	23 100.0	62 100.0	17 100.0
DION'T LIKE IT ANYMORE/ GOT TIRED OF IT	6 7.1	1 4.2	5 8.2	3 8.1	3 6.3	6 7.1			3 5.7	2 11.1	1 50.0	2 3.8	1 4.3	3 33.3	4 6.6	2 8.7	5 8.1	1 5.9
NO REASON/JUST STOPPED	6 7.1	2 8.3	4 6.6	3 8.1	3 6.3	6 7.1	2 22.2	1 100.0	3 5.7			4 7.5	1 4.3	1 11.1	4 6.6	2 8.7	3 4.8	3 17.6
MISCELLANEOUS	6 7.1	1 4.2	5 8.2	2 5.4	4 8.3	6 7.1	1 11.1		4 7.5	1 5.6		4 7.5	1 4.3	1 11.1	3 4.9	2 8.7	2 3.2	2 11.8
DON'T KNOW	4 4.7	1 4.2	3 4.9	1 2.7	3 6.3	4 4.7	1 11.1		2 3.8			3 5.7	1 4.3		1 1.6	3 13.0	3 4.8	1 5.9

MARKETING INFORMATION SYSTEMS, INC.
TOBACCO PRODUCTS IN-STORE TEST #834684

TABLE 12C

Q. 15 REASONS STOPPED USING SMOKELESS/CHEWING TOBACCO

FORMER USERS OF SMOKELESS/CHEWING TOBACCO

	TOTAL	AT-LAN-TA	FLO-RIDA	AGE 18-34	AGE 35+	SMOKELESS TOBACCO TYPE PREVIOUSLY USED: TOTAL	FINE CUT	ROUGH CUT	LEAFY PLUG	SKOAL BAN-DITS	CIGARETTE USAGE: CUR-RENT SMOK-ERS	CURRENT NON-SMOKERS: FORM-ER SMOK-ERS	CURRENT NON-SMOKERS: NEVER SMOK-ED	EDUCATION: HIGH SCH-OOL OR LESS	EDUCATION: COL-LEGE OR MORE	INCOME: UN-DER $30M	INCOME: $30M AND OVER
(FORMER USERS)	85	24	61	37	48	85	9	1	53	18	2	53	23	9	61	23	62	17
	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
MADE ME SICK/SICK TO STOMACH	4		4	2	2	4	1		2	1		4			2	2	4	
	4.7		6.6	5.4	4.2	4.7	11.1		3.8	5.6		7.5			3.3	8.7	6.5	
BAD FOR HEALTH/NOT GOOD FOR YOU	3	1	2		3	3				3		1	1	1	2	1	2	
	3.5	4.2	3.3		6.3	3.5				16.7		1.9	4.3	11.1	3.3	4.3	3.2	
ALL OTHER UNHEALTHY MENTIONS	4		4	1	3	4			4			2		2	1	3	3	1
	4.7		6.6	2.7	6.3	4.7			7.5			3.8		22.2	1.6	13.0	4.8	5.9
OTHER COMMENTS																		
STARTED SMOKING MORE/ PREFER CIGARETTES	13	7	6	7	6	13	1		12			10	3		11	2	12	1
	15.3	29.2	9.8	18.9	12.5	15.3	11.1		22.6			18.9	13.0		18.0	8.7	19.4	5.9
STARTED GOING TO CHURCH (PREACHING IN CHURCH)	3	1	2	1	2	3				3			3		2	1	2	
	3.5	4.2	3.3	2.7	4.2	3.5				16.7			13.0		3.3	4.3	3.2	
STOPPED PLAYING SPORTS/ BALL	2		2	1	1	2			1	1		1	1		1	1	1	1
	2.4		3.3	2.7	2.1	2.4			1.9	5.6		1.9	4.3		1.6	4.3	1.6	5.9
STOPPED USING ANY KIND OF TOBACCO/GAVE UP TOBACCO	2	1	1		2	2			1		1		2		2		2	
	2.4	4.2	1.6		4.2	2.4			1.9		50.0		8.7		3.3		3.2	
WIFE/GIRLFRIEND DISLIKED IT	6	4	2	5	1	6	1		5			5	1		6		4	1
	7.1	16.7	3.3	13.5	2.1	7.1	11.1		9.4			9.4	4.3		9.8		6.5	5.9
DOCTOR/DENTIST TOLD ME TO STOP	4	2	2	1	3	4			4			1	1	2	3	1	3	1
	4.7	8.3	3.3	2.7	6.3	4.7			7.5			1.9	4.3	22.2	4.9	4.3	4.8	5.9
TOO JUICY/DISLIKED THE JUICE	2		2	1	1	2			2			2			1	1	2	
	2.4		3.3	2.7	2.1	2.4			3.8			3.8			1.6	4.3	3.2	
STARTED DATING WOMEN/BE-CAME INTERESTED IN WO-MEN (BAD FOR LOVE-LIFE)	5		5	3	2	5	1		1	3		4	1		4	1	4	1
	5.9		8.2	8.1	4.2	5.9	11.1		1.9	16.7		7.5	4.3		6.6	4.3	6.5	5.9
TOO EXPENSIVE/COST ME TO MUCH	2	1	1		2	2				2			2		2		2	
	2.4	4.2	1.6		4.2	2.4				11.1			8.7		3.3		3.2	

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MARKETING INFORMATION SYSTEMS, INC.
TOBACCO PRODUCTS IN-STORE TEST #834684

TABLE 120

Q. 15 REASONS STOPPED USING SMOKELESS/CHEWING TOBACCO

FORMER USERS OF SMOKELESS/CHEWING TOBACCO

	TOTAL	ATLANTA	FLORIDA	AGE 18-34	AGE 35+	SMOKELESS TOBACCO TYPE PREVIOUSLY USED: TOTAL	FINE CUT	ROUGH CUT	LEAFY PLUG	SKOAL BANDITS	CIGARETTE USAGE: CURRENT SMOKERS	CURRENT NON-SMOKERS: FORMER SMOKERS	CURRENT NON-SMOKERS: NEVER SMOKED	EDUCATION: HIGH SCHOOL OR LESS	EDUCATION: COLLEGE OR MORE	INCOME: UNDER $30M	INCOME: $30M AND OVER
(FORMER USERS)	85 100.0	24 100.0	61 100.0	37 100.0	48 100.0	85 100.0	9 100.0	1 100.0	53 100.0	18 100.0	2 100.0	53 100.0	23 100.0	9 100.0	61 100.0	23 100.0	62 100.0	17 100.0
UNHEALTHY (NET)	25 29.4	5 20.8	20 32.8	11 29.7	14 29.2	25 29.4	2 22.2		15 28.3	7 38.9		16 30.2	6 26.1	3 33.3	18 29.5	7 30.4	18 29.0	3 17.6
SIDE EFFECTS (SUBNET)	18 21.2	4 16.7	14 23.0	10 27.0	8 16.7	18 21.2	2 22.2		11 20.8	4 22.2		13 24.5	5 21.7		15 24.6	3 13.0	13 21.0	2 11.8
EFFECTS ON MOUTH/TEETH (SUB-SUBNET)	11 12.9	3 12.5	8 13.1	8 21.6	3 6.3	11 12.9	1 11.1		7 13.2	3 16.7		8 15.1	3 13.0		10 16.4	1 4.3	8 12.9	2 11.8
STAINED MY TEETH	4 4.7	2 8.3	2 3.3	4 10.8		4 4.7			3 5.7	1 5.6		3 5.7	1 4.3		4 6.6		4 6.5	
MADE TEETH HURT	1 1.2		1 1.6	1 2.7		1 1.2			1 1.9			1 1.9			1 1.6		1 1.6	
BAD FOR TEETH	1 1.2		1 1.6	1 2.7		1 1.2			1 1.9			1 1.9			1 1.6		1 1.6	
CAUSES GUM CANCER/ GUM DISEASE	3 3.5	1 4.2	2 3.3	2 5.4	1 2.1	3 3.5	1 11.1		2 3.8			2 3.8	1 4.3		2 3.3	1 4.3	1 1.6	2 11.8
MADE TONGUE SORE/ SWOLLEN	1 1.2		1 1.6		1 2.1	1 1.2				1 5.6		1 1.9			1 1.6		1 1.6	
BURNED MY MOUTH	1 1.2		1 1.6	1 2.7		1 1.2			1 1.9			1 1.9			1 1.6		1 1.6	
MADE MOUTH SORE/ SWOLLEN	1 1.2		1 1.6		1 2.1	1 1.2				1 5.6		1 1.9			1 1.6		1 1.6	
MADE JAWS TIRED/JAWS HURT	1 1.2		1 1.6		1 2.1	1 1.2				1 5.6			1 4.3		1 1.6			
GAVE ME BAD BREATH/ BREATH SMELLED	2 2.4	1 4.2	1 1.6	2 5.4		2 2.4			1 1.9	1 5.6		1 1.9	1 4.3		2 3.3		2 3.2	
GAVE ME HEARTBURN/ INDIGESTION	4 4.7	1 4.2	3 4.9		4 8.3	4 4.7			2 3.8	1 5.6		2 3.8	2 8.7		4 6.6		2 3.2	

MARKETING INFORMATION SYSTEMS, INC.
TOBACCO PRODUCTS IN-STORE TEST #834684

TABLE 12G

Q. 15 REASONS STOPPED USING SMOKELESS/CHEWING TOBACCO

FORMER USERS OF SMOKELESS/CHEWING TOBACCO

	TOTAL	AT-LAN-TA	FLO-RIDA	AGE 18-34	AGE 35+	SMOKELESS TOBACCO TYPE PREVIOUSLY USED: TOTAL	FINE CUT	ROUGH CUT	LEAFY PLUG	SKOAL BAN-DITS	CIGARETTE USAGE: CURRENT SMOKERS	CURRENT NON-SMOKERS: FORMER SMOKERS	CURRENT NON-SMOKERS: NEVER SMOKED	EDUCATION: HIGH SCHOOL OR LESS	EDUCATION: COLLEGE OR MORE	INCOME: UNDER $30M	INCOME: $30M AND OVER
(FORMER USERS)	85 100.0	24 100.0	61 100.0	37 100.0	48 100.0	85 100.0	9 100.0	1 100.0	53 100.0	18 100.0	2 100.0	53 100.0	23 100.0	9 100.0	61 100.0	23 100.0	62 100.0	17 100.0
TASTE (NET)	7 8.2	1 4.2	6 9.8	7 18.9		7 8.2	1 11.1		6 11.3			7 13.2			4 6.6	3 13.0	5 8.1	2 11.8
DISLIKED TASTE/BAD TASTE	2 2.4		2 3.3	2 5.4		2 2.4			2 3.8			2 3.8			1 1.6	1 4.3	1 1.6	1 5.9
DISLIKED TABACCO TASTE	1 1.2		1 1.6	1 2.7		1 1.2			1 1.9			1 1.9			1 1.6		1 1.6	
BITTER TASTE	1 1.2		1 1.6	1 2.7		1 1.2	1 11.1					1 1.9			1 1.6		1 1.6	
BITTER AFTERTASTE	1 1.2		1 1.6	1 2.7		1 1.2			1 1.9			1 1.9				1 4.3	1 1.6	
PREFERRED CIGARETTE TASTE/TASTE OF CIGARETTE SMOKE	2 2.4	1 4.2	1 1.6	2 5.4		2 2.4			2 3.8			2 3.8			1 1.6	1 4.3	1 1.6	1 5.9
ALL OTHER TASTE MENTIONS																		
INCONVENIENCE (NET)	11 12.9	5 20.8	6 9.8	3 8.1	8 16.7	11 12.9			10 18.9	1 5.6		9 17.0	2 8.7		8 13.1	3 13.0	7 11.3	4 23.5
INCONVENIENT TO SPIT/HAD TO FIND A PLACE TO SPIT	5 5.9		5 8.2		5 10.4	5 5.9			4 7.5	1 5.6		4 7.5	1 4.3		3 4.9	2 8.7	4 6.5	1 5.9
DISLIKED SPITTING/DON'T NEED TO SPIT USING CIGARETTES	1 1.2		1 1.6		1 2.1	1 1.2			1 1.9			1 1.9			1 1.6		1 1.6	
MESSY/TOO MESSY/NOT CLEAN	4 4.7	4 16.7		2 5.4	2 4.2	4 4.7			4 7.5			3 5.7	1 4.3		3 4.9	1 4.3	1 1.6	3 17.6
ALL OTHER INCONVENIENCE MENTIONS	1 1.2	1 4.2		1 2.7		1 1.2			1 1.9			1 1.9			1 1.6		1 1.6	

Q.12/14 LENGTH OF TIME USING REGULAR BRAND

FORMER USERS OF SMOKELESS/CHEWING TOBACCO

	TOTAL	ATLANTA	FLORIDA	AGE 18-34	AGE 35+	SMOKELESS TOBACCO TYPE PREVIOUSLY USED: TOTAL	FINE CUT	ROUGH CUT	LEAFY PLUG	SKOAL BANDITS	CIGARETTE USAGE: CURRENT SMOKERS	CURRENT NON-SMOKERS: FORMER SMOKERS	CURRENT NON-SMOKERS: NEVER SMOKED	EDUCATION: HIGH SCHOOL OR LESS	EDUCATION: COLLEGE OR MORE	INCOME: UNDER $30M	INCOME: $30M AND OVER
(FORMER USERS)	85 100.0	24 100.0	61 100.0	37 100.0	48 100.0	85 100.0	9 100.0	1 100.0	53 100.0	18 100.0	2 100.0	53 100.0	23 100.0	9 100.0	61 100.0	23 100.0	62 100.0	17 100.0
DK/NA	2 2.4		2 3.3		2 4.2	2 2.4						1 1.9	1 4.3		1 1.6	1 4.3	2 3.2	
MEAN	10.25	8.43	10.99	2.93	16.14	10.25	2.03	5.00	7.64	16.46	13.00	6.77	14.06	21.00	10.38	9.85	12.50	2.12
STD DEV	14.23	11.09	15.27	3.29	16.70	14.23	1.77		11.65	16.40	7.00	10.11	14.63	23.10	13.93	15.33	15.80	2.08
STD ERR	1.56	2.26	1.99	.54	2.46	1.56	.59		1.60	3.87	4.95	1.40	3.12	7.70	1.80	3.27	2.04	.50

Q.12/14 LENGTH OF TIME USING REGULAR BRAND

FORMER USERS OF SMOKELESS/CHEWING TOBACCO

				AGE		SMOKELESS TOBACCO TYPE TYPE PREVIOUSLY USED					CIGARETTE USAGE			EDUCATION		INCOME	
	TOTAL	ATLANTA	FLORIDA	18-34	35+	TOTAL	FINE CUT	ROUGH CUT	LEAFY PLUG	SKOAL BANDITS	CURRENT SMOKERS	CURRENT NON-SMOKERS: FORMER SMOKERS	CURRENT NON-SMOKERS: NEVER SMOKED	HIGH SCHOOL OR LESS	COLLEGE OR MORE	UNDER $30M	$30M AND OVER
(FORMER USERS)	85 100.0	24 100.0	61 100.0	37 100.0	48 100.0	85 100.0	9 100.0	1 100.0	53 100.0	18 100.0	2 100.0	53 100.0	23 100.0	9 100.0	61 100.0	23 100.0	62 100.0	17 100.0
23 YEARS	1 1.2		1 1.6		1 2.1	1 1.2			1 1.9					1 11.1	1 1.6		1 1.6	
25 YEARS	1 1.2		1 1.6		1 2.1	1 1.2			1 1.9			1 1.9			1 1.6		1 1.6	
26 YEARS	1 1.2	1 4.2			1 2.1	1 1.2				1 5.6			1 4.3			1 4.3		
30 YEARS	1 1.2		1 1.6		1 2.1	1 1.2				1 5.6		1 1.9			1 1.6		1 1.6	
34 YEARS																		
35 YEARS	1 1.2	1 4.2			1 2.1	1 1.2			1 1.9				1 4.3		1 1.6		1 1.6	
39 YEARS	1 1.2		1 1.6		1 2.1	1 1.2			1 1.9				1 4.3		1 1.6		1 1.6	
40 YEARS	1 1.2	1 4.2			1 2.1	1 1.2				1 5.6			1 4.3		1 1.6		1 1.6	
45 YEARS	1 1.2		1 1.6		1 2.1	1 1.2				1 5.6		1 1.9			1 1.6		1 1.6	
47 YEARS																		
58 YEARS	1 1.2		1 1.6		1 2.1	1 1.2				1 5.6				1 11.1		1 4.3	1 1.6	
65 YEARS	1 1.2		1 1.6		1 2.1	1 1.2			1 1.9					1 11.1	1 1.6		1 1.6	
70 YEARS																		

MARKETING INFORMATION SYSTEMS, INC.
TOBACCO PRODUCTS IN-STORE TEST #834684

TABLE 8

Q.12/14 LENGTH OF TIME USING REGULAR BRAND

FORMER USERS OF SMOKELESS/CHEWING TOBACCO

	TOTAL	AT-LAN-TA	FLO-RIDA	AGE 18-34	AGE 35+	SMOKELESS TOBACCO TYPE PREVIOUSLY USED: TOTAL	FINE CUT	ROUGH CUT	LEAFY PLUG	SKOAL BAN-DITS	CIGARETTE USAGE: CUR-RENT SMOK-ERS	CURRENT NON-SMOKERS: FORM-ER SMOK-ERS	NEVER SMOK-ED	EDUCATION: HIGH SCH-OOL OR LESS	COL-LEGE OR MORE	INCOME: UN-DER $30M	$30M AND OVER
(FORMER USERS)	85	24	61	37	48	85	9	1	53	18	2	53	23	9	61	23	62	17
	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
MORE THAN 6 YEARS - 8 YEARS (NET)	1		1	1		1			1			1				1		1
	1.2		1.6	2.7		1.2			1.9			1.9				4.3		5.9
7 YEARS																		
8 YEARS	1		1	1		1			1			1				1		1
	1.2		1.6	2.7		1.2			1.9			1.9				4.3		5.9
MORE THAN 8 YEARS - 12 YEARS (NET)	10	2	8		10	10			6	4		9	1		9		7	
	11.8	8.3	13.1		20.8	11.8			11.3	22.2		17.0	4.3		14.8		11.3	
10 YEARS	7	2	5		7	7			5	2		7			7		5	
	8.2	8.3	8.2		14.6	8.2			9.4	11.1		13.2			11.5		8.1	
11 YEARS	2		2		2	2				2		2			1		1	
	2.4		3.3		4.2	2.4				11.1		3.8			1.6		1.6	
12 YEARS	1		1		1	1			1				1		1		1	
	1.2		1.6		2.1	1.2			1.9				4.3		1.6		1.6	
MORE THAN 12 YEARS (NET)	17	5	12	1	16	17			9	7	1	4	8	5	13	4	16	
	20.0	20.8	19.7	2.7	33.3	20.0			17.0	38.9	50.0	7.5	34.8	55.6	21.3	17.4	25.8	
15 YEARS	3		3		3	3			2	1			2	1	2	1	3	
	3.5		4.9		6.3	3.5			3.8	5.6			8.7	11.1	3.3	4.3	4.8	
16 YEARS																		
18 YEARS	1		1	1		1			1			1				1	1	
	1.2		1.6	2.7		1.2			1.9			1.9				4.3	1.6	
19 YEARS																		
20 YEARS	3	2	1		3	3			1	1	1		2	1	3		3	
	3.5	8.3	1.6		6.3	3.5			1.9	5.6	50.0		8.7	11.1	4.9		4.8	

MARKETING INFORMATION SYSTEMS, INC.
TOBACCO PRODUCTS IN-STORE TEST #834684

Q.12/14 LENGTH OF TIME USING REGULAR BRAND

FORMER USERS OF SMOKELESS/CHEWING TOBACCO

	TOTAL	AT-LAN-TA	FLO-RIDA	AGE 18-34	AGE 35+	SMOKELESS TOBACCO TYPE PREVIOUSLY USED: TOTAL	FINE CUT	ROUGH CUT	LEAFY PLUG	SKOAL BAN-DITS	CIGARETTE USAGE: CURRENT SMOKERS	CURRENT NON-SMOKERS: FORMER SMOKERS	NEVER SMOKED	EDUCATION: HIGH SCHOOL OR LESS	EDUCATION: COLLEGE OR MORE	INCOME: UNDER $30M	INCOME: $30M AND OVER
(FORMER USERS)	85	24	61	37	48	85	9	1	53	18	2	53	23	9	61	23	62	17
	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
LESS THAN 1 YEAR (NET)	19	5	14	14	5	19	3		14	2		15	2	2	14	5	13	6
	22.4	20.8	23.0	37.8	10.4	22.4	33.3		26.4	11.1		28.3	8.7	22.2	23.0	21.7	21.0	35.3
3 MONTHS OR LESS	12	4	8	9	3	12	2		10			11		1	9	3	6	6
	14.1	16.7	13.1	24.3	6.3	14.1	22.2		18.9			20.8		11.1	14.8	13.0	9.7	35.3
MORE THAN 3-6 MONTHS	1		1	1		1				1			1		1		1	
	1.2		1.6	2.7		1.2				5.6			4.3		1.6		1.6	
MORE THAN 6 MONTHS - 1 YEAR	6	1	5	4	2	6	1		4	1		4	1	1	4	2	6	
	7.1	4.2	8.2	10.8	4.2	7.1	11.1		7.5	5.6		7.5	4.3	11.1	6.6	8.7	9.7	
MORE THAN 1 YEAR TO 2 YEARS (NET)	13	5	8	7	6	13	4		8	1		8	4	1	9	4	6	6
	15.3	20.8	13.1	18.9	12.5	15.3	44.4		15.1	5.6		15.1	17.4	11.1	14.8	17.4	9.7	35.3
MORE THAN 1 YEAR - 1 1/2 YEARS	3	1	2	1	2	3	2		1			1	2		2	1	1	1
	3.5	4.2	3.3	2.7	4.2	3.5	22.2		1.9			1.9	8.7		3.3	4.3	1.6	5.9
MORE THAN 1 1/2 YEARS - 2 YEARS	10	4	6	6	4	10	2		7	1		7	2	1	7	3	5	5
	11.8	16.7	9.8	16.2	8.3	11.8	22.2		13.2	5.6		13.2	8.7	11.1	11.5	13.0	8.1	29.4
MORE THAN 2 YEARS - 4 YEARS (NET)	13	4	9	7	6	13	1		10	2		9	4		8	5	10	3
	15.3	16.7	14.8	18.9	12.5	15.3	11.1		18.9	11.1		17.0	17.4		13.1	21.7	16.1	17.6
3 YEARS	9	2	7	3	6	9			7	2		6	3		5	4	6	3
	10.6	8.3	11.5	8.1	12.5	10.6			13.2	11.1		11.3	13.0		8.2	17.4	9.7	17.6
4 YEARS	4	2	2	4		4	1		3			3	1		3	1	4	
	4.7	8.3	3.3	10.8		4.7	11.1		5.7			5.7	4.3		4.9	4.3	6.5	
MORE THAN 4 YEARS - 6 YEARS (NET)	10	3	7	7	3	10	1	1	5	2	1	6	3	1	7	3	8	1
	11.8	12.5	11.5	18.9	6.3	11.8	11.1	100.0	9.4	11.1	50.0	11.3	13.0	11.1	11.5	13.0	12.9	5.9
5 YEARS	6	2	4	4	2	6		1	4	1		3	2	1	4	2	6	
	7.1	8.3	6.6	10.8	4.2	7.1		100.0	7.5	5.6		5.7	8.7	11.1	6.6	8.7	9.7	
6 YEARS	4	1	3	3	1	4	1		1	1	1	3	1		3	1	2	1
	4.7	4.2	4.9	8.1	2.1	4.7	11.1		1.9	5.6	50.0	5.7	4.3		4.9	4.3	3.2	5.9

Q.11/13 NUMBER OR PACKAGES OF REGULAR BRAND USED IN A TYPICAL WEEK

FORMER USERS OF SMOKELESS/CHEWING TOBACCO

	TOTAL	AT-LAN-TA	FLO-RIDA	AGE 18-34	AGE 35+	SMOKELESS TOBACCO TYPE PREVIOUSLY USED: TOTAL	FINE CUT	ROUGH CUT	LEAFY PLUG	SKOAL BAN-DITS	CIGARETTE USAGE: CURRENT SMOK-ERS	CURRENT NON-SMOKERS: FORM-ER SMOK-ERS	CURRENT NON-SMOKERS: NEVER SMOK-ED	EDUCATION: HIGH SCH-OOL OR LESS	EDUCATION: COL-LEGE OR MORE	INCOME: UN-DER $30M	INCOME: $30M AND OVER
(FORMER USERS)	85 100.0	24 100.0	61 100.0	37 100.0	48 100.0	85 100.0	9 100.0	1 100.0	53 100.0	18 100.0	2 100.0	53 100.0	23 100.0	9 100.0	61 100.0	23 100.0	62 100.0	17 100.0
REGULAR BRAND COMES IN A PACKAGE	18 21.2	2 8.3	16 26.2	2 5.4	16 33.3	18 21.2				18 100.0		7 13.2	9 39.1	2 22.2	15 24.6	2 8.7	14 22.6	
2 PACKAGES OR LESS (NET)	15 17.6	1 4.2	14 23.0	2 5.4	13 27.1	15 17.6				15 83.3		6 11.3	7 30.4	2 22.2	13 21.3	2 8.7	12 19.4	
1 PACKAGE	10 11.8	1 4.2	9 14.8	1 2.7	9 18.8	10 11.8				10 55.6		4 7.5	4 17.4	2 22.2	8 13.1	2 8.7	7 11.3	
2 PACKAGES	5 5.9		5 8.2	1 2.7	4 8.3	5 5.9				5 27.8		2 3.8	3 13.0		5 8.2		5 8.1	
MORE THAN 2 PACKAGES - 4 PACKAGES (NET)	1 1.2	1 4.2			1 2.1	1 1.2				1 5.6			1 4.3		1 1.6		1 1.6	
3 PACKAGES	1 1.2	1 4.2			1 2.1	1 1.2				1 5.6			1 4.3		1 1.6		1 1.6	
MORE THAN 4 PACKAGES (NET)																		
5 PACKAGES																		
6 PACKAGES																		
7 PACKAGES																		
DK/NA	2 2.4		2 3.3		2 4.2	2 2.4				2 11.1		1 1.9	1 4.3		1 1.6		1 1.6	
AVERAGE	1.44	2.00	1.36	1.50	1.43	1.44				1.44		1.33	1.63	1.00	1.50	1.00	1.54	
STD DEV	.61	1.00	.48	.50	.62	.61				.61		.47	.70		.63		.63	
STD ERR	.15	.71	.13	.35	.17	.15				.15		.19	.25		.17		.18	

Q.10/12 NUMBER OF FOIL POUCHES OF REGULAR BRAND USED IN TYPICAL WEEK

FORMER USERS OF SMOKELESS/CHEWING TOBACCO

	TOTAL	ATLANTA	FLORIDA	AGE 18-34	AGE 35+	SMOKELESS TOBACCO TYPE PREVIOUSLY USED: TOTAL	FINE CUT	ROUGH CUT	LEAFY PLUG	SKOAL BANDITS	CIGARETTE USAGE: CURRENT SMOKERS	CURRENT NON-SMOKERS: FORMER SMOKERS	CURRENT NON-SMOKERS: NEVER SMOKED	EDUCATION: HIGH SCHOOL OR LESS	EDUCATION: COLLEGE OR MORE	INCOME: UNDER $30M	INCOME: $30M AND OVER
(FORMER USERS)	85 100.0	24 100.0	61 100.0	37 100.0	48 100.0	85 100.0	9 100.0	1 100.0	53 100.0	18 100.0	2 100.0	53 100.0	23 100.0	9 100.0	61 100.0	23 100.0	62 100.0	17 100.0
MORE THAN 8 POUCHES (NET)	2 2.4		2 3.3		2 4.2	2 2.4			2 3.8				1 4.3	1 11.1	2 3.3		2 3.2	
9 POUCHES																		
10 POUCHES																		
12 POUCHES	2 2.4		2 3.3		2 4.2	2 2.4			2 3.8				1 4.3	1 11.1	2 3.3		2 3.2	
15 POUCHES																		
18 POUCHES																		
DK/NA	1 1.2		1 1.6	1 2.7		1 1.2			1 1.9			1 1.9				1 4.3		1 5.9
AVERAGE	3.19	3.28	3.15	2.27	4.12	3.19			3.19			2.74	4.30	3.86	3.47	2.56	3.23	2.92
STD DEV	2.62	2.02	2.88	1.65	3.04	2.62			2.62			2.16	2.76	3.68	2.90	1.66	2.83	1.80
STD ERR	.36	.48	.49	.32	.60	.36			.36			.36	.87	1.39	.48	.41	.45	.52

Q.10/12 NUMBER OF FOIL POUCHES OF REGULAR BRAND USED IN TYPICAL WEEK

FORMER USERS OF SMOKELESS/CHEWING TOBACCO

	TOTAL	AT-LAN-TA	FLO-RIDA	AGE 18-34	AGE 35+	SMOKELESS TOBACCO TYPE PREVIOUSLY USED: TOTAL	FINE CUT	ROUGH CUT	LEAFY PLUG	SKOAL BAN-DITS	CIGARETTE USAGE: CUR-RENT SMOK-ERS	CURRENT NON-SMOKERS: FORM-ER SMOK-ERS	NEVER SMOK-ED	EDUCATION: HIGH SCH-OOL OR LESS	COL-LEGE OR MORE	INCOME: UN-DER $30M	$30M AND OVER
(FORMER USERS)	85	24	61	37	48	85	9	1	53	18	2	53	23	9	61	23	62	17
	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
REGULAR BRAND COMES IN A FOIL POUCH	53	18	35	27	26	53			53			36	10	7	36	17	39	13
	62.4	75.0	57.4	73.0	54.2	62.4			100.0			67.9	43.5	77.8	59.0	73.9	62.9	76.5
2 POUCHES OR LESS (NET)	28	8	20	17	11	28			28			23	1	4	19	9	21	7
	32.9	33.3	32.8	45.9	22.9	32.9			52.8			43.4	4.3	44.4	31.1	39.1	33.9	41.2
1 POUCH	17	4	13	12	5	17			17			14	1	2	11	6	14	3
	20.0	16.7	21.3	32.4	10.4	20.0			32.1			26.4	4.3	22.2	18.0	26.1	22.6	17.6
2 POUCHES	11	4	7	5	6	11			11			9		2	8	3	7	4
	12.9	16.7	11.5	13.5	12.5	12.9			20.8			17.0		22.2	13.1	13.0	11.3	23.5
MORE THAN 2 POUCHES - 4 POUCHES (NET)	13	5	8	7	6	13			13			5	7	1	7	6	10	3
	15.3	20.8	13.1	18.9	12.5	15.3			24.5			9.4	30.4	11.1	11.5	26.1	16.1	17.6
3 POUCHES	6	3	3	4	2	6			6			2	3	1	4	2	6	
	7.1	12.5	4.9	10.8	4.2	7.1			11.3			3.8	13.0	11.1	6.6	8.7	9.7	
4 POUCHES	7	2	5	3	4	7			7			3	4		3	4	4	3
	8.2	8.3	8.2	8.1	8.3	8.2			13.2			5.7	17.4		4.9	17.4	6.5	17.6
MORE THAN 4 POUCHES - 6 POUCHES (NET)	4	3	1	1	3	4			4			2	1	1	4		2	1
	4.7	12.5	1.6	2.7	6.3	4.7			7.5			3.8	4.3	11.1	6.6		3.2	5.9
5 POUCHES	3	3		1	2	3			3			2	1		3		1	1
	3.5	12.5		2.7	4.2	3.5			5.7			3.8	4.3		4.9		1.6	5.9
6 POUCHES	1		1		1	1			1					1	1		1	
	1.2		1.6		2.1	1.2			1.9					11.1	1.6		1.6	
MORE THAN 6 POUCHES - 8 POUCHES (NET)	5	2	3	1	4	5			5			5			4	1	4	1
	5.9	8.3	4.9	2.7	8.3	5.9			9.4			9.4			6.6	4.3	6.5	5.9
7 POUCHES	4	1	3		4	4			4			4			3	1	3	1
	4.7	4.2	4.9		8.3	4.7			7.5			7.5			4.9	4.3	4.8	5.9
8 POUCHES	1	1		1		1			1			1			1		1	
	1.2	4.2		2.7		1.2			1.9			1.9			1.6		1.6	

Q.9/11 NUMBER OF CANS OF REGULAR BRAND USED IN A TYPICAL WEEK

FORMER USERS OF SMOKELESS/CHEWING TOBACCO

	TOTAL	AT-LAN-TA	FLO-RIDA	AGE 18-34	AGE 35+	SMOKELESS TOBACCO TYPE PREVIOUSLY USED: TOTAL	FINE CUT	ROUGH CUT	LEAFY PLUG	SKOAL BAN-DITS	CIGARETTE USAGE: CURRENT SMOK-ERS	CURRENT NON-SMOKERS: FORM-ER SMOK-ERS	CURRENT NON-SMOKERS: NEVER SMOK-ED	EDUCATION: HIGH SCH-OOL OR LESS	EDUCATION: COL-LEGE OR MORE	INCOME: UN-DER $30M	INCOME: $30M AND OVER
(FORMER USERS)	85 100.0	24 100.0	61 100.0	37 100.0	48 100.0	85 100.0	9 100.0	1 100.0	53 100.0	18 100.0	2 100.0	53 100.0	23 100.0	9 100.0	61 100.0	23 100.0	62 100.0	17 100.0
DK/NA	1 1.2		1 1.6		1 2.1	1 1.2	1 11.1					1 1.9				1 4.3	1 1.6	
AVERAGE	1.36	1.00	1.57	1.50	1.00	1.36	1.38	1.00			1.50	1.50	1.00		1.22	2.00	1.50	1.25
STD DEV	.48		.49	.50		.48	.48				.50	.50			.42		.50	.43
STD ERR	.15		.19	.18		.15	.17				.35	.18			.14		.20	.22

Q.9/11 NUMBER OF CANS OF REGULAR BRAND USED IN A TYPICAL WEEK

FORMER USERS OF SMOKELESS/CHEWING TOBACCO

	TOTAL	AT-LAN-TA	FLO-RIDA	AGE 18-34	AGE 35+	SMOKELESS TOBACCO TYPE PREVIOUSLY USED: TOTAL	FINE CUT	ROUGH CUT	LEAFY PLUG	SKOAL BAN-DITS	CIGARETTE USAGE: CURRENT NON-SMOKERS: CUR-RENT SMOK-ERS	FORM-ER SMOK-ERS	NEVER SMOK-ED	EDUCATION: HIGH SCH-OOL OR LESS	COL-LEGE OR MORE	INCOME: UN-DER $30M	$30M AND OVER
(FORMER USERS)	85 100.0	24 100.0	61 100.0	37 100.0	48 100.0	85 100.0	9 100.0	1 100.0	53 100.0	18 100.0	2 100.0	53 100.0	23 100.0	9 100.0	61 100.0	23 100.0	62 100.0	17 100.0
REGULAR BRAND COMES IN A CAN	12 14.1	4 16.7	8 13.1	8 21.6	4 8.3	12 14.1	9 100.0	1 100.0			2 100.0	9 17.0	3 13.0		9 14.8	3 13.0	7 11.3	4 23.5
3 CANS OR LESS (NET)	11 12.9	4 16.7	7 11.5	8 21.6	3 6.3	11 12.9	8 88.9	1 100.0			2 100.0	8 15.1	3 13.0		9 14.8	2 8.7	6 9.7	4 23.5
1 CAN	7 8.2	4 16.7	3 4.9	4 10.8	3 6.3	7 8.2	5 55.6	1 100.0			1 50.0	4 7.5	3 13.0		7 11.5		3 4.8	3 17.6
2 CANS	4 4.7		4 6.6	4 10.8		4 4.7	3 33.3				1 50.0	4 7.5			2 3.3	2 8.7	3 4.8	1 5.9
3 CANS																		
MORE THAN 3 CANS - 7 CANS (NET)																		
4 CANS																		
5 CANS																		
7 CANS																		
MORE THAN 8 CANS (NET)																		
10 CANS																		
12 CANS																		
14 CANS																		

Q.7/9 SMOKELESS TOBACCO USER TYPE

FORMER USERS OF SMOKELESS/CHEWING TOBACCO

	TOTAL	AT-LAN-TA	FLO-RIDA	AGE 18-34	AGE 35+	SMOKELESS TOBACCO TYPE PREVIOUSLY USED: TOTAL	FINE CUT	ROUGH CUT	LEAFY PLUG	SKOAL BAN-DITS	CIGARETTE USAGE: CUR-RENT SMOK-ERS	CURRENT NON-SMOKERS: FORM-ER SMOK-ERS	NEVER SMOK-ED	EDUCATION: HIGH SCH-OOL OR LESS	COL-LEGE OR MORE	INCOME: UN-DER $30M	$30M AND OVER
(FORMER USERS)	85 100.0	24 100.0	61 100.0	37 100.0	48 100.0	85 100.0	9 100.0	1 100.0	53 100.0	18 100.0	2 100.0	53 100.0	23 100.0	9 100.0	61 100.0	23 100.0	62 100.0	17 100.0
FINE CUT TOBACCO IN A CAN	9 10.6	2 8.3	7 11.5	6 16.2	3 6.3	9 10.6	9 100.0					7 13.2	2 8.7		7 11.5	2 8.7	5 8.1	3 17.6
ROUGH CUT TOBACCO IN A CAN	1 1.2	1 4.2		1 2.7		1 1.2		1 100.0				1 1.9			1 1.6		1 1.6	
LEAFY TOBACCO IN A FOIL POUCH	53 62.4	18 75.0	35 57.4	27 73.0	26 54.2	53 62.4			53 100.0			36 67.9	10 43.5	7 77.8	36 59.0	17 73.9	39 62.9	13 76.5
PLUG TOBACCO	18 21.2	2 8.3	16 26.2	2 5.4	16 33.3	18 21.2				18 100.0		7 13.2	9 39.1	2 22.2	15 24.6	2 8.7	14 22.6	
-- CELLOPHANE WRAPPER	16 18.8	1 4.2	15 24.6	2 5.4	14 29.2	16 18.8				16 88.9		6 11.3	8 34.8	2 22.2	14 23.0	1 4.3	13 21.0	
-- FOIL POUCH																		
-- DK/NA	2 2.4	1 4.2	1 1.6		2 4.2	2 2.4				2 11.1		1 1.9	1 4.3		1 1.6	1 4.3	1 1.6	
INDIVIDUAL PACKETS (SKOAL BANDITS)	2 2.4	1 4.2	1 1.6	1 2.7	1 2.1	2 2.4					2 100.0	1 1.9	1 4.3		1 1.6	1 4.3	1 1.6	1 5.9
DK/NA	2 2.4		2 3.3		2 4.2	2 2.4						1 1.9	1 4.3		1 1.6	1 4.3	2 3.2	

MARKETING INFORMATION SYSTEMS, INC.
TOBACCO PRODUCTS IN-STORE TEST #834684

TABLE 3

0.6/8 REGULAR BRAND OF SMOKELESS TOBACCO

FORMER USERS OF SMOKELESS/CHEWING TOBACCO

	TOTAL	AT-LAN-TA	FLO-RIDA	AGE 18-34	AGE 35+	SMOKELESS TOBACCO TYPE PREVIOUSLY USED: TOTAL	FINE CUT	ROUGH CUT	LEAFY PLUG	SKOAL BAN-DITS	CIGARETTE USAGE: CURRENT NON-SMOKERS: CUR-RENT SMOK-ERS	FORM-ER SMOK-ERS	NEVER SMOK-ED	EDUCATION: HIGH SCH-OOL OR LESS	COL-LEGE OR MORE	INCOME: UN-DER $30M	$30M AND OVER
(FORMER USERS)	85	24	61	37	48	85	9	1	53	18	2	53	23	9	61	23	62	17
	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
APPLE	2		2		2	2				2		1	1		2		2	
	2.4		3.3		4.2	2.4				11.1		1.9	4.3		3.3		3.2	
BLOOD HOUND	1		1		1	1				1			1		1		1	
	1.2		1.6		2.1	1.2				5.6			4.3		1.6		1.6	
BROWN MULE	4	1	3		4	4				4		1	3		4		3	
	4.7	4.2	4.9		8.3	4.7				22.2		1.9	13.0		6.6		4.8	
CANNONBALL																		
DAYSWORK	2		2		2	2				2		1		1	2		1	
	2.4		3.3		4.2	2.4				11.1		1.9		11.1	3.3		1.6	
RED MAN																		
LEVI GARRETT																		
BULL OF THE WOODS	3		3		3	3				3		3			2		2	
	3.5		4.9		6.3	3.5				16.7		5.7			3.3		3.2	
MISCELLANEOUS	4	1	3	1	3	4				4		1	3		3	1	3	
	4.7	4.2	4.9	2.7	6.3	4.7				22.2		1.9	13.0		4.9	4.3	4.8	
DON'T KNOW	2		2	1	1	2				2			1	1	1	1	2	
	2.4		3.3	2.7	2.1	2.4				11.1			4.3	11.1	1.6	4.3	3.2	

MARKETING INFORMATION SYSTEMS, INC.
TOBACCO PRODUCTS IN-STORE TEST #834684

TABLE 3

Q.6/8 REGULAR BRAND OF SMOKELESS TOBACCO

FORMER USERS OF SMOKELESS/CHEWING TOBACCO

												CIGARETTE USAGE						
				AGE		SMOKELESS TOBACCO TYPE TYPE PREVIOUSLY USED						CURRENT NON-SMOKERS			EDUCATION		INCOME	
	TOTAL	ATLANTA	FLORIDA	18-34	35+	TOTAL	FINE CUT	ROUGH CUT	LEAFY PLUG	SKOAL BANDITS		CURRENT SMOKERS	FORMER SMOKERS	NEVER SMOKED	HIGH SCHOOL OR LESS	COLLEGE OR MORE	UNDER $30M	$30M AND OVER
(FORMER USERS)	85 100.0	24 100.0	61 100.0	37 100.0	48 100.0	85 100.0	9 100.0	1 100.0	53 100.0	18 100.0	2 100.0	53 100.0	23 100.0	9 100.0	61 100.0	23 100.0	62 100.0	17 100.0
BEECHNUT	13 15.3	4 16.7	9 14.8	5 13.5	8 16.7	13 15.3			13 24.5			10 18.9	3 13.0		8 13.1	5 21.7	9 14.5	3 17.6
LEVI GARRETT	11 12.9	6 25.0	5 8.2	8 21.6	3 6.3	11 12.9			11 20.8			5 9.4	3 13.0	3 33.3	8 13.1	3 13.0	8 12.9	3 17.6
RED MAN	20 23.5	3 12.5	17 27.9	10 27.0	10 20.8	20 23.5			20 37.7			15 28.3	3 13.0	2 22.2	12 19.7	8 34.8	13 21.0	7 41.2
R.J. GOLD	1 1.2	1 4.2			1 2.1	1 1.2			1 1.9				1 4.3		1 1.6		1 1.6	
WORKHORSE																		
H.B. SCOTT																		
CHATTANOOGA CHEW	3 3.5	2 8.3	1 1.6	3 8.1		3 3.5			3 5.7			2 3.8		1 11.1	3 4.9		3 4.8	
DAYS WORK	1 1.2	1 4.2			1 2.1	1 1.2			1 1.9			1 1.9			1 1.6		1 1.6	
BROWN MULE	1 1.2	1 4.2			1 2.1	1 1.2			1 1.9					1 11.1	1 1.6		1 1.6	
BLOODHOUND	1 1.2		1 1.6		1 2.1	1 1.2			1 1.9			1 1.9			1 1.6		1 1.6	
MISCELLANEOUS	1 1.2		1 1.6		1 2.1	1 1.2			1 1.9			1 1.9			1 1.6		1 1.6	
DON'T KNOW	1 1.2		1 1.6	1 2.7		1 1.2			1 1.9			1 1.9				1 4.3	1 1.6	
PLUG TOBACCO	18 21.2	2 8.3	16 26.2	2 5.4	16 33.3	18 21.2				18 100.0		7 13.2	9 39.1	2 22.2	15 24.6	2 8.7	14 22.6	

MARKETING INFORMATION SYSTEMS, INC.
TOBACCO PRODUCTS IN-STORE TEST #834684

TABLE 3

Q.6/8 REGULAR BRAND OF SMOKELESS TOBACCO

FORMER USERS OF SMOKELESS/CHEWING TOBACCO

	TOTAL	AT-LANTA	FLO-RIDA	AGE 18-34	AGE 35+	SMOKELESS TOBACCO TYPE TYPE PREVIOUSLY USED: TOTAL	FINE CUT	ROUGH CUT	LEAFY PLUG	SKOAL BANDITS	CIGARETTE USAGE: CURRENT SMOKERS	CURRENT NON-SMOKERS: FORMER SMOKERS	CURRENT NON-SMOKERS: NEVER SMOKED	EDUCATION: HIGH SCHOOL OR LESS	EDUCATION: COLLEGE OR MORE	INCOME: UNDER $30M	INCOME: $30M AND OVER
(FORMER USERS)	85	24	61	37	48	85	9	1	53	18	2	53	23	9	61	23	62	17
	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
FINE CUT TOBACCO	11	3	8	7	4	11	9				2	8	3		8	3	6	4
	12.9	12.5	13.1	18.9	8.3	12.9	100.0				100.0	15.1	13.0		13.1	13.0	9.7	23.5
COPENHAGEN	3		3	2	1	3	3					3			1	2	2	1
	3.5		4.9	5.4	2.1	3.5	33.3					5.7			1.6	8.7	3.2	5.9
DENTAL																		
LEVI GARRETT	2	1	1		2	2	2					1	1		2			1
	2.4	4.2	1.6		4.2	2.4	22.2					1.9	4.3		3.3			5.9
SKOAL	3	1	2	3		3	3					2	1		3		2	1
	3.5	4.2	3.3	8.1		3.5	33.3					3.8	4.3		4.9		3.2	5.9
SKOAL BANDITS	2	1	1	1	1	2				2	1	1			1	1	1	1
	2.4	4.2	1.6	2.7	2.1	2.4				100.0	1.9	4.3			1.6	4.3	1.6	5.9
RAILROAD																		
MISCELLANEOUS	1		1	1		1	1				1				1		1	
	1.2		1.6	2.7		1.2	11.1				1.9				1.6		1.6	
ROUGH CUT TOBACCO	1	1		1		1		1			1				1		1	
	1.2	4.2		2.7		1.2		100.0			1.9				1.6		1.6	
HAWKEN	1	1		1		1		1			1				1		1	
	1.2	4.2		2.7		1.2		100.0			1.9				1.6		1.6	
KODIAK																		
LEAFY TOBACCO	53	18	35	27	26	53			53		36	10	7	36	17	39	13	
	62.4	75.0	57.4	73.0	54.2	62.4			100.0		67.9	43.5	77.8	59.0	73.9	62.9	76.5	
APPLE																		

2041074175

MARKETING INFORMATION SYSTEMS, INC.
TOBACCO PRODUCTS IN-STORE TEST #834684

TABLE 2

Q.5/6 LENGTH OF TIME USING SMOKELESS TOBACCO

FORMER USERS OF SMOKELESS/CHEWING TOBACCO

	TOTAL	AT-LAN-TA	FLO-RIDA	AGE 18-34	AGE 35+	SMOKELESS TOBACCO TYPE PREVIOUSLY USED: TOTAL	FINE CUT	ROUGH CUT	LEAFY PLUG	SKOAL BAN-DITS	CIGARETTE USAGE: CURRENT SMOK-ERS	CURRENT NON-SMOKERS: FORM-ER SMOK-ERS	NEVER SMOK-ED	EDUCATION: HIGH SCH-OOL OR LESS	EDUCATION: COL-LEGE OR MORE	INCOME: UN-DER $30M	INCOME: $30M AND OVER
(FORMER USERS)	85 100.0	24 100.0	61 100.0	37 100.0	48 100.0	85 100.0	9 100.0	1 100.0	53 100.0	18 100.0	2 100.0	53 100.0	23 100.0	9 100.0	61 100.0	23 100.0	62 100.0	17 100.0
56 YEARS																		
60 YEARS																		
66 YEARS																		
70 YEARS																		
73 YEARS																		
75 YEARS																		
DK/NA	2 2.4		2 3.3	2 5.4		2 2.4			2 3.8			2 3.8			2 8.7	1 1.6	1 5.9
AVERAGE	12.88	7.16	15.20	3.75	19.53	12.88	9.32	.50	9.17	27.49	.70	12.12	15.78	9.78	13.14	10.83	12.54	6.70
STD DEV	14.92	8.97	16.18	4.49	16.29	14.92	10.28		11.17	18.04	.20	14.42	17.25	8.96	15.68	11.27	14.21	11.12
STD ERR	1.64	1.83	2.11	.76	2.35	1.64	3.43		1.56	4.25	.14	2.02	3.60	2.99	2.01	2.46	1.82	2.78

2041074174

Q.5/6 LENGTH OF TIME USING SMOKELESS TOBACCO

FORMER USERS OF SMOKELESS/CHEWING TOBACCO

	TOTAL	AT-LAN-TA	FLO-RIDA	AGE 18-34	AGE 35+	SMOKELESS TOBACCO TYPE PREVIOUSLY USED: TOTAL	FINE CUT	ROUGH CUT	LEAFY PLUG	SKOAL BAN-DITS	CIGARETTE USAGE: CUR-RENT SMOK-ERS	CURRENT NON-SMOKERS: FORM-ER SMOK-ERS	NEVER SMOK-ED	EDUCATION: HIGH SCH-OOL OR LESS	COL-LEGE OR MORE	INCOME: UN-DER $30M	$30M AND OVER
(FORMER USERS)	85 100.0	24 100.0	61 100.0	37 100.0	48 100.0	85 100.0	9 100.0	1 100.0	53 100.0	18 100.0	2 100.0	53 100.0	23 100.0	9 100.0	61 100.0	23 100.0	62 100.0	17 100.0
23 YEARS	1 1.2		1 1.6		1 2.1	1 1.2			1 1.9			1 1.9			1 1.6		1 1.6	
25 YEARS	2 2.4		2 3.3		2 4.2	2 2.4			1 1.9	1 5.6		2 3.8			2 3.3		2 3.2	
28 YEARS	1 1.2	1 4.2			1 2.1	1 1.2			1 1.9					1 11.1	1 1.6		1 1.6	
29 YEARS																		
30 YEARS	1 1.2		1 1.6		1 2.1	1 1.2	1 11.1						1 4.3		1 1.6			
32 YEARS	1 1.2	1 4.2			1 2.1	1 1.2				1 5.6			1 4.3			1 4.3		
33 YEARS																		
35 YEARS	1 1.2		1 1.6		1 2.1	1 1.2			1 1.9			1 1.9			1 1.6		1 1.6	
40 YEARS	2 2.4		2 3.3		2 4.2	2 2.4				2 11.1		2 3.8			1 1.6			
45 YEARS	4 4.7		4 6.6		4 8.3	4 4.7			1 1.9	3 16.7		2 3.8	2 8.7		3 4.9	1 4.3	3 4.8	1 5.9
47 YEARS																		
50 YEARS	4 4.7		4 6.6		4 8.3	4 4.7			1 1.9	3 16.7		2 3.8	2 8.7		4 6.6		3 4.8	
55 YEARS																		

Q.5/6 LENGTH OF TIME USING SMOKELESS TOBACCO

FORMER USERS OF SMOKELESS/CHEWING TOBACCO

	TOTAL	AT-LAN-TA	FLO-RIDA	AGE 18-34	AGE 35+	SMOKELESS TOBACCO TYPE PREVIOUSLY USED: TOTAL	FINE CUT	ROUGH CUT	LEAFY PLUG	SKOAL BAN-DITS	CIGARETTE USAGE: CURRENT SMOK-ERS	CURRENT NON-SMOKERS: FORM-ER SMOK-ERS	CURRENT NON-SMOKERS: NEVER SMOK-ED	EDUCATION: HIGH SCH-OOL OR LESS	EDUCATION: COL-LEGE OR MORE	INCOME: UN-DER $30M	INCOME: $30M AND OVER
(FORMER USERS)	85 100.0	24 100.0	61 100.0	37 100.0	48 100.0	85 100.0	9 100.0	1 100.0	53 100.0	18 100.0	2 100.0	53 100.0	23 100.0	9 100.0	61 100.0	23 100.0	62 100.0	17 100.0
11 YEARS	1 1.2		1 1.6		1 2.1	1 1.2				1 5.6				1 11.1	1 1.6		1 1.6	
12 YEARS	2 2.4	1 4.2	1 1.6		2 4.2	2 2.4			2 3.8			2 3.8			1 1.6	1 4.3	1 1.6	1 5.9
MORE THAN 12 YEARS TO 15 YEARS (NET)-------	3 3.5	1 4.2	2 3.3	1 2.7	2 4.2	3 3.5			2 3.8	1 5.6		1 1.9	1 4.3	1 11.1	2 3.3	1 4.3	3 4.8	
13 YEARS	1 1.2	1 4.2		1 2.7		1 1.2			1 1.9				1 4.3		1 1.6		1 1.6	
15 YEARS	2 2.4		2 3.3		2 4.2	2 2.4			1 1.9	1 5.6		1 1.9		1 11.1	1 1.6	1 4.3	2 3.2	
MORE THAN 15 YEARS TO 21 YEARS (NET)---------	9 10.6	2 8.3	7 11.5	2 5.4	7 14.6	9 10.6	2 22.2		4 7.5	2 11.1		5 9.4	3 13.0	1 11.1	5 8.2	4 17.4	8 12.9	1 5.9
16 YEARS	1 1.2		1 1.6		1 2.1	1 1.2				1 5.6		1 1.9			1 1.6		1 1.6	
17 YEARS																		
18 YEARS	2 2.4		2 3.3	2 5.4		2 2.4	1 11.1		1 1.9			2 3.8				2 8.7	2 3.2	
19 YEARS																		
20 YEARS	6 7.1	2 8.3	4 6.6		6 12.5	6 7.1	1 11.1		3 5.7	1 5.6		2 3.8	3 13.0	1 11.1	4 6.6	2 8.7	5 8.1	1 5.9
MORE THAN 21 YEARS (NET) ----------	17 20.0	2 8.3	15 24.6		17 35.4	17 20.0	1 11.1		6 11.3	10 55.6		10 18.9	6 26.1	1 11.1	14 23.0	2 8.7	11 17.7	1 5.9
22 YEARS																		

Q.5/6 LENGTH OF TIME USING SMOKELESS TOBACCO

FORMER USERS OF SMOKELESS/CHEWING TOBACCO

	TOTAL	AT-LAN-TA	FLO-RIDA	AGE 18-34	AGE 35+	SMOKELESS TOBACCO TYPE PREVIOUSLY USED: TOTAL	FINE CUT	ROUGH CUT	LEAFY PLUG	SKOAL BAN-DITS	CIGARETTE USAGE: CUR-RENT SMOK-ERS	CURRENT NON-SMOKERS: FORM-ER SMOK-ERS	CURRENT NON-SMOKERS: NEVER SMOK-ED	EDUCATION: HIGH SCH-OOL OR LESS	EDUCATION: COL-LEGE OR MORE	INCOME: UN-DER $30M	INCOME: $30M AND OVER
(FORMER USERS)	85 100.0	24 100.0	61 100.0	37 100.0	48 100.0	85 100.0	9 100.0	1 100.0	53 100.0	18 100.0	2 100.0	53 100.0	23 100.0	9 100.0	61 100.0	23 100.0	62 100.0	17 100.0
6 MONTHS OR LESS	10 11.8	7 29.2	3 4.9	6 16.2	4 8.3	10 11.8	2 22.2	1 100.0	5 9.4		1 50.0	6 11.3	4 17.4		10 16.4		7 11.3	3 17.6
MORE THAN 6 MONTHS TO 1 YEAR	6 7.1	1 4.2	5 8.2	6 16.2		6 7.1	1 11.1		3 5.7	1 5.6	1 50.0	5 9.4	1 4.3		5 8.2	1 4.3	3 4.8	3 17.6
MORE THAN 1 YEAR TO 2 YEARS	8 9.4	3 12.5	5 8.2	5 13.5	3 6.3	8 9.4	1 11.1		7 13.2			4 7.5	2 8.7	2 22.2	5 8.2	3 13.0	7 11.3	1 5.9
MORE THAN 2 YEARS TO 3 YEARS	7 8.2		7 11.5	5 13.5	2 4.2	7 8.2	1 11.1		4 7.5	2 11.1		3 5.7	2 8.7	2 22.2	3 4.9	4 17.4	4 6.5	3 17.6
MORE THAN 3 YEARS TO 6 YEARS (NET)---------	14 16.5	6 25.0	8 13.1	8 21.6	6 12.5	14 16.5			13 24.5	1 5.6		11 20.8	2 8.7	1 11.1	11 18.0	3 13.0	11 17.7	2 11.8
4 YEARS	7 8.2	3 12.5	4 6.6	6 16.2	1 2.1	7 8.2			7 13.2			6 11.3	1 4.3		6 9.8	1 4.3	6 9.7	1 5.9
5 YEARS	5 5.9	2 8.3	3 4.9		5 10.4	5 5.9			4 7.5	1 5.6		4 7.5	1 4.3		3 4.9	2 8.7	3 4.8	1 5.9
6 YEARS	2 2.4	1 4.2	1 1.6	2 5.4		2 2.4			2 3.8			1 1.9		1 11.1	2 3.3		2 3.2	
MORE THAN 6 YEARS TO 9 YEARS (NET)---------	2 2.4		2 3.3	1 2.7	1 2.1	2 2.4			2 3.8			1 1.9	1 4.3		1 1.6	1 4.3	1 1.6	1 5.9
7 YEARS																		
8 YEARS	2 2.4		2 3.3	1 2.7	1 2.1	2 2.4			2 3.8			1 1.9	1 4.3		1 1.6	1 4.3	1 1.6	1 5.9
MORE THAN 9 YEARS TO 12 YEARS (NET)--------	7 8.2	2 8.3	5 8.2	1 2.7	6 12.5	7 8.2	1 11.1		5 9.4	1 5.6		5 9.4	1 4.3	1 11.1	5 8.2	2 8.7	6 9.7	1 5.9
10 YEARS	4 4.7	1 4.2	3 4.9	1 2.7	3 6.3	4 4.7	1 11.1		3 5.7			3 5.7	1 4.3		3 4.9	1 4.3	4 6.5	

Q.2 AGE/RACE OF RESPONDENT

FORMER USERS OF SMOKELESS/CHEWING TOBACCO

	TOTAL	AT-LAN-TA	FLO-RIDA	AGE 18-34	AGE 35+	SMOKELESS TOBACCO TYPE PREVIOUSLY USED: TOTAL	FINE CUT	ROUGH CUT	LEAFY PLUG	SKOAL BAN-DITS	CIGARETTE USAGE: CUR-RENT SMOK-ERS	CURRENT NON-SMOKERS: FORM-ER SMOK-ERS	NEVER SMOK-ED	EDUCATION: HIGH SCH-OOL OR LESS	COL-LEGE OR MORE	INCOME: UN-DER $30M	$30M AND OVER
(FORMER USERS)	85 100.0	24 100.0	61 100.0	37 100.0	48 100.0	85 100.0	9 100.0	1 100.0	53 100.0	18 100.0	2 100.0	53 100.0	23 100.0	9 100.0	61 100.0	23 100.0	62 100.0	17 100.0
35+ (UNSPEC)	1 1.2		1 1.6		1 2.1	1 1.2				1 5.6		1 1.9						
AVERAGE AGE	42.85	38.92	44.39	26.78	55.23	42.85	35.11	27.00	39.87	57.72	31.50	38.74	49.26	50.67	44.13	39.04	43.45	34.76
RACE																		
WHITE	70 82.4	23 95.8	47 77.0	31 83.8	39 81.3	70 82.4	9 100.0	1 100.0	44 83.0	12 66.7	2 100.0	41 77.4	22 95.7	7 77.8	48 78.7	21 91.3	48 77.4	16 94.1
BLACK	15 17.6	1 4.2	14 23.0	6 16.2	9 18.8	15 17.6			9 17.0	6 33.3		12 22.6	1 4.3	2 22.2	13 21.3	2 8.7	14 22.6	1 5.9
HISPANIC																		
REFUSED																		

MARKETING INFORMATION SYSTEMS, INC.
TOBACCO PRODUCTS IN-STORE TEST #834684

TABLE 1

Q.2 AGE/RACE OF RESPONDENT

FORMER USERS OF SMOKELESS/CHEWING TOBACCO

				AGE		SMOKELESS TOBACCO TYPE TYPE PREVIOUSLY USED					CIGARETTE USAGE: CURRENT NON-SMOKERS			EDUCATION		INCOME	
	TOTAL	ATLANTA	FLORIDA	18-34	35+	TOTAL	FINE CUT	ROUGH CUT	LEAFY PLUG	SKOAL BANDITS	CURRENT SMOKERS	FORMER SMOKERS	NEVER SMOKED	HIGH SCHOOL OR LESS	COLLEGE OR MORE	UNDER $30M	$30M AND OVER
(FORMER USERS)	85 100.0	24 100.0	61 100.0	37 100.0	48 100.0	85 100.0	9 100.0	1 100.0	53 100.0	18 100.0	2 100.0	53 100.0	23 100.0	9 100.0	61 100.0	23 100.0	62 100.0	17 100.0
18-34 (NET)	37 43.5	12 50.0	25 41.0	37 100.0		37 43.5	6 66.7	1 100.0	27 50.9	2 11.1	1 50.0	28 52.8	6 26.1	3 33.3	26 42.6	11 47.8	26 41.9	11 64.7
18-24	13 15.3	4 16.7	9 14.8	13 35.1		13 15.3	2 22.2		8 15.1	2 11.1	1 50.0	8 15.1	3 13.0	2 22.2	10 16.4	3 13.0	10 16.1	3 17.6
25-29	10 11.8	4 16.7	6 9.8	10 27.0		10 11.8	1 11.1	1 100.0	8 15.1			8 15.1	1 4.3	1 11.1	7 11.5	3 13.0	8 12.9	2 11.8
30-34	14 16.5	4 16.7	10 16.4	14 37.8		14 16.5	3 33.3		11 20.8			12 22.6	2 8.7		9 14.8	5 21.7	8 12.9	6 35.3
18-34 (UNSPEC)																		
35 OR OLDER (NET)	48 56.5	12 50.0	36 59.0		48 100.0	48 56.5	3 33.3		26 49.1	16 88.9	1 50.0	25 47.2	17 73.9	6 66.7	35 57.4	12 52.2	36 58.1	6 35.3
35-39	9 10.6	2 8.3	7 11.5		9 18.8	9 10.6	1 11.1		6 11.3	1 5.6		7 13.2	2 8.7		3 4.9	6 26.1	6 9.7	3 17.6
40-44	4 4.7	4 16.7			4 8.3	4 4.7			3 5.7		1 50.0	2 3.8	2 8.7		4 6.6		3 4.8	
45-49	3 3.5	1 4.2	2 3.3		3 6.3	3 3.5	1 11.1		1 1.9			2 3.8	1 4.3		2 3.3	1 4.3	2 3.2	1 5.9
50-54	4 4.7		4 6.6		4 8.3	4 4.7			3 5.7	1 5.6		3 5.7	1 4.3		4 6.6		4 6.5	
55-59	2 2.4	1 4.2	1 1.6		2 4.2	2 2.4			2 3.8				1 4.3	1 11.1	2 3.3		1 1.6	1 5.9
60-64	8 9.4		8 13.1		8 16.7	8 9.4			5 9.4	3 16.7		6 11.3	1 4.3	1 11.1	6 9.8	2 8.7	7 11.3	
65 OR OLDER	17 20.0	4 16.7	13 21.3		17 35.4	17 20.0	1 11.1		6 11.3	10 55.6		4 7.5	9 39.1	4 44.4	14 23.0	3 13.0	13 21.0	1 5.9