S. HRG. 108–470

IMPORTATION OF PRESCRIPTION DRUGS

HEARING

BEFORE THE

COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS UNITED STATES SENATE

ONE HUNDRED EIGHTH CONGRESS

SECOND SESSION

ON

EXAMINING PRESCRIPTION DRUG REIMPORTATION, FOCUSING ON EFFORTS TO REDUCE DRUG COSTS, PATIENT SAFETY CONCERNS, RECENT STATE ACTION, FRAUDULENT AND COUNTERFEIT DRUGS, AN INTERNATIONAL COMPARISON OF RISING PRESCRIPTION DRUG EXPENDITURES, AND S. 2328, TO AMEND THE FEDERAL FOOD, DRUG, AND COSMETIC ACT WITH RESPECT TO THE IMPORTATION OF PRESCRIPTION DRUGS

MAY 20, 2004

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C O N T E N T S

STATEMENTS

THURSDAY, MAY 20, 2004

ADDITIONAL MATERIAL

IMPORTATION OF PRESCRIPTION DRUGS

THURSDAY, MAY 20, 2004

UNITED STATES SENATE,
COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS,
Washington, D.C.

The committee met, pursuant to notice, at 10:17 a.m., in room SD–106, Dirksen Senate Office Building, Hon. Judd Gregg (chairman of the committee) presiding.

Present: Senators Gregg, Enzi, Alexander, Kennedy, Dodd, Mikulski, Murray, Reed, and Clinton.

OPENING STATEMENT OF SENATOR GREGG

The CHAIRMAN. Let's get started.

I appreciate the courtesy of the panel in delaying the hearing here for 15 minutes, as we were at a meeting earlier this morning with the Republican membership of the House and Senate and the President, so it was necessary to delay the meeting.

I want to get right into the hearing, and if Senator Kennedy comes in, I will yield to him for an opening statement.

Basically this hearing is about an issue which has captured the interest and participation of a large number of Americans, which is the question of purchasing drugs from foreign countries or over the Internet, and the issues which that has raised for us as a culture, which has always taken a tremendous amount of pride and made a great commitment to the safety and efficacy of the pharmaceutical products that are available to us.

The FDA, historically, has been one of the lead agencies in our Nation for protecting consumers and giving consumers the assurance that when they buy a product they will be taking to try to cure themselves, the product doesn't hurt or kill them. Its record is exemplary, obviously. There have been issues relative to how quickly they may have gotten through the process of approving products, but there has never been an issue around the fact that they have been very effective guardians of the safety and health of the American people, especially relative to the pharmaceuticals.

So the question of reimportation and the question of purchasing over the Internet has raised the whole issue of can it be done safely, and if it can be done safely, how it should be done. It also raises other questions dealing with the economics of research and development and the bringing on line of new medications.

But really, this hearing is going to focus more on the question of what is out there, what is being purchased, whether the processes in place today are safe, whether people buying things over the Internet are, through reimportation, putting themselves at risk

by purchasing products which may have been adulterated or counterfeited, and if so, how we could address that in a more structured way.

So I certainly appreciate the testimony of the witnesses today. The American people really are seeking the opportunity to go into other countries and purchase these drugs—certainly in New Hampshire, and I'm sure in most States that border Canada or Mexico, for that matter—and they certainly want to take the opportunity of using the Internet, which is a unique and wonderful tool that we now have available to us for commerce. But in pursuing those avenues, we want to make sure that they also are able to have a certain level of confidence, that what they are purchasing isn't going to hurt them. So I think it's important that we ask the people who are involved in this issue what is happening out there and what they recommend for addressing safety specifically.

With that, unless there are other opening statements—Senator Enzi, do you have anything you want to say?

Senator ENZI. I assume you were discouraging——

The CHAIRMAN. It was a rhetorical question.

[Laughter.]

Senator ENZI. I would ask that my full statement be made a part of the record.

The CHAIRMAN. Certainly.

[The prepared statement of Senator Enzi follows:]

PREPARED STATEMENT OF SENATOR ENZI

Importing prescription drugs from other countries will not solve the problem of rising drug prices. I won't support drug importation until we can ensure that the drugs that are imported are safe, effective, and will not compromise the integrity of our Nation's prescription drug supply or our world-leading pharmaceutical research.

Today, millions of Americans import prescription drugs from Canada and other countries, or purchase drugs from Internet pharmacies that operate from outside the United States. These Americans are taking their lives in their hands by going outside our closed drug distribution system and obtaining their prescription medicines from pharmacies and Internet sites that don't meet the high standards that we require domestically.

Right now, the Federal Government and State governments are looking the other way. We're not enforcing the laws on our books that prohibit drug importation, and we're just crossing our fingers and hoping that no one gets hurt. Some State and local governments are actually encouraging their employees and citizens to import drugs from Canada, while disclaiming any liability if someone is injured or dies as a result of taking unregulated imported drugs.

We can't keep this up indefinitely, so I commend Chairman Gregg for calling this hearing to consider the complex issues involved in opening our borders to imported prescription drugs. If the Senate is going to amend our laws to permit drug importation, the process must begin in this committee. As the committee begins to consider drug importation, I look forward to questioning our witnesses about some of the issues that concern me.

As we look into this issue, we must keep in mind that, whatever we decide to do on the importation of drugs, it won't make a big difference in how much we spend on our medications. The reason for that is simple. Canada's pharmaceutical market is less than one-tenth the size of ours. Our market is larger than the combined markets of Canada and all of Europe. We simply can't import enough medications from these price-controlled countries to make a significant impact on prices here, as the Congressional Budget Office has pointed out.

Clearly, there are many other ways for us to help Americans and keep their prescription medications available and affordable.

First, we need to set aside the politics of Medicare and work together to help seniors choose the Medicare drug discount card that is right for them. Low-income seniors especially deserve our help, since they will receive up to $600 in credit on their cards in 2004 and 2005 to help them pay for their prescriptions. Many of the cards are free, so there's no good reason why a senior shouldn't sign up for a drug discount card, which could save them from 20 to 35 percent off the retail prices of the medications they need.

Second, most of the major pharmaceutical companies have special patient-assistance programs for low-income Americans without health insurance. These noteworthy programs offer a supply of free or low-cost drugs to people who would otherwise not be able to afford their much-needed medications, and these programs are available to people of any age, not just seniors. Each of the manufacturers has its own program application, however, which complicates the sign-up process for patients who need drugs made by a number of different companies. The major pharmaceutical companies could help patients in need get into their patient-assistance programs more quickly if they were to develop a single uniform application and a simplified and streamlined application process.

Third, people should ask their pharmacists about generic drugs. The generic drugs available in the United States have the same active ingredients as their brand-name counterparts. They also are manufactured in FDA-inspected facilities, just like brand-name drugs. The difference is that generics usually cost from 30 to 60 percent less than their equivalent brand-name drugs. Nationwide, every 1 percent increase in the utilization of generic drugs yields $1.16 billion in savings in prescription drug costs per year.

Fourth, the Senate Republican Task Force on Health Care Costs and the Uninsured recently recommended expanding the Federal program that makes deeply discounted drugs available to patients of "safety-net" clinics and other healthcare facilities. Enacting this proposal would expand access to low-cost drugs for people who rely on our healthcare safety net.

Fifth, we need to eliminate unfair trade practices such as the drug price controls that many foreign governments employ, which force the American consumer to shoulder the burden of paying for the pharmaceutical research that benefits all consumers worldwide.

Those are just five ways that American citizens, pharmaceutical companies, and Congress could take action to make prescription drugs more affordable to more people. None of these ideas would require us to institute or import foreign price controls, nor would they threaten the safety of our drug distribution system, as I'm

afraid some of the legislative proposals introduced in this session of Congress would do.

Again, I commend Chairman Gregg for calling this hearing. If the Senate is to allow for the importation of prescription drugs, we ought not to rush this process to meet an artificial political timetable. The importation of prescription drugs raises serious questions about the safety of our Nation's drug supply and our ability to continue to reap the benefits of American pharmaceutical research and development. If we're going to open our borders to imported prescription drugs, we had better be certain about exactly what we're doing and how we're going to do it.

The CHAIRMAN. Senator Reed.

Senator REED. I ask that my statement be made a part of the record, Mr. Chairman.

[The prepared statement of Senator Reed follows:]

PREPARED STATEMENT OF SENATOR REED

Mr. Chairman, thank you for calling today's hearing on the issue of drug reimportation.

The escalating cost of prescription drugs continues to plague this Nation. Last November, the Congress passed the Medicare Modernization Act, which included a number of dramatic changes to this program, the most notable being the addition of a temporary drug discount card and beginning in 2006, the creation of a Medicare Part D drug benefit. I did not vote for this legislation because I felt that it did not provide an adequate drug benefit nor did it recognize Medicare's significant potential bargaining power.

The fact that there continues to be such strong interest in allowing for the importation of FDA-approved prescription drugs is an indication of how significant a burden drug costs have become, not only for frail elderly and disabled Medicare beneficiaries, but also for non-elderly Americans who lack drug coverage and are forced to pay often exorbitant prices for their medications. Even city and State Governments are encouraging employees to purchase medications from Canada as a way of restraining skyrocketing health care costs.

In light of this groundswell of interest, it is very appropriate that you have called today's hearing Mr. Chairman. It is imperative that as legislators, we carefully and thoughtfully explore the various theories on drug reimporation as well as take a long, hard, practical look at how it would work in the real world.

I hope today's hearing will also provide an opportunity to examine the already significant problem of drug counterfeiting in this country and what steps are being taken by the Food and Drug Administration (FDA) to crack down on such dangerous illegal enterprises. The FDA is the primary agency responsible for ensuring the safety of our Nation's food and drug supply, and as such, I will be very interested to learn about its efforts in this area.

Mr. Chairman, I believe that if we are to allow prescription drugs to be imported into this country there are a number of very important questions we must first address. I think the most obvious issue of concern to many is ensuring the safety of individually and commercially imported products.

We are fortunate that advancements in medicine have yielded remarkable breakthrough treatments that have the potential to extend or drastically improve the quality of one's life. Diseases that were once untreatable or treated through invasive procedures can now be tackled with a simple little pill. Yet, for many, these medical wonders remain out of reach because they cannot afford them. As a result, they are willing to risk that medications purchased overseas could possibly be counterfeit or adulterated because the alternative is not taking the medication at all and suffering the adverse health consequences that are certain to come with that choice. However, if we are to permit drug reimportation, we must be certain it can be done safely. The various legislative proposals that are currently pending take critical steps to address this very important aspect.

We also need to be mindful of what level of savings will be yielded through importation, particularly on the commercial side. What mechanisms will be in place to ensure that savings will be passed on to cash paying customers as well as consumers with insurance?

A final question that deserves our consideration pertains to supply. Americans make up a considerable share of the global market for prescription drugs. Clearly, large-scale reimportation is going to have an impact on drug supplies internationally. In terms of personal importation, the Dorgan bill takes constructive steps to ensure that manufacturers do not limit drug supplies overseas as a means of quelling U.S. importation.

However, on the commercial side, only a certain percentage of drugs available in the U.S. market would be from imported sources. The Congressional Budget Office estimates that between 10 and 15 percent of the U.S. prescription drug market would come from imports. The question becomes how these limited quantities would be allocated to consumers and whether or not they will have a meaningful impact on overall costs of medication in this country.

Mr. Chairman, let me again commend you for calling today's hearing and for providing a venue for these many important issues to be examined. I look forward to the testimony of the witnesses.

The CHAIRMAN. Thank you. I appreciate the courtesy of the members.

At this time I will submit the statements of Senators Frist, Harkin, Jeffords, and Edwards.

[The prepared statements of Senators Frist, Harkin, Jeffords, and Edwards follow:]

PREPARED STATEMENT OF SENATOR FRIST

Chairman Gregg, thank you for holding today's hearing. I commend you for the careful, deliberate approach you have taken with respect to importation. And I appreciate the opportunity you have provided for all of us to examine the important issues raised by legislative proposals to expand the importation of prescription drugs from foreign countries.

Senator Kennedy, you have also been a leader in this area. In the past, you have been extremely articulate in discussing the need to ensure that any changes in this area do not jeopardize the health and safety of American patients.

We are all searching for ways to provide consumers with affordable access to health care. In fact, that was a primary focus of the Senate Leadership Task Force on Health Care Costs and the Uninsured led by Senator Gregg, which issued its recommendations last week.

I want to remind my colleagues that this Congress already has taken important steps to make health care more affordable. The Medicare Modernization Act (MMA), which President Bush signed in December, includes a number of steps to make prescription drugs more affordable. For example, the MMA:

- Provides affordable, voluntary prescription drug coverage to all seniors and individuals with disabilities with a special emphasis on those with lower incomes and those with high, catastrophic drug costs;
- Includes a greater emphasis in the traditional fee-for-service Medicare program on prevention, chronic care, and disease management, which has the potential to save money and save lives;
- Authorizes the Agency for Health Care Research and Quality (AHRQ) to conduct research on the outcomes, clinical effectiveness, and appropriateness of prescription drugs and other health care items and services and to widely disseminate this information to patients, providers, and purchasers;
- Makes cheaper generic drugs available to consumers more quickly by closing loopholes in the Hatch-Waxman law;
- Provides all Americans with the opportunity to exercise greater control over their health care choices and dollars through tax-free Health Savings Accounts;
- Dramatically improves the pricing transparency of prescription drugs and attempts to drive down costs through competition by making retail prices widely available on the Centers for Medicare and Medicaid Services' "Price Compare" website; and
- Offers seniors immediate prescription drug savings of 10–25 percent through Medicare-approved prescription drug discount cards.

In fact, beginning next month—less than 6 months after this landmark legislation was signed into law—seniors will begin benefiting from lower prescription drug costs. Just yesterday, the Centers for Medicare and Medicaid Services released an analysis showing that Medicare beneficiaries qualifying for the transitional assistance program under the new Medicare law could save between 29 and 77 percent on their brand-name drug costs and as much as 92 percent on their generic drug costs combining the effects of discounts available with the cards and the effect of the $1,200 credit they have available to them over the next 18 months.

The recommendations of the Gregg Task Force are one attempt to build on these initial steps.

And, in fact, there is more to be done.

As we examine the factors driving overall health care inflation, we know that the rapidly rising cost of prescription drugs is a key culprit—both because of increased utilization and increased prices. Pharmaceutical costs have outpaced all categories of health spending in recent years and are expected to account for nearly 15 percent of all national health expenditures by 2011—up from 9.4 percent in 2000.

Thus, a greater focus on prescription drug costs is clearly appropriate. At the same time, none of us want to jeopardize the development of life-saving pharmaceutical treatments as we consider importation legislation and other policies intended to make health care and health coverage more affordable.

As we examine these policy proposals, we also must ensure that patients are not put at risk. As a physician who has dedicated my life to treating and healing patients, this is the most important consideration for me personally as I weigh the proposals before this committee and before the U.S. Senate.

How do we ensure that all Americans have access to *safe*, *effective*, and *affordabl*e prescription drugs?

Our challenge is to strike a balance among these sometimes competing priorities. In fact, it is the central challenge for us as we consider legislation to allow the importation and reimportation of prescription drugs into the United States.

Chairman Gregg, Senator Kennedy, I look forward to working with both of you, and the other members of this committee, as this process moves forward to ensure that we can strike the appropriate balance.

I look forward to hearing the testimony of our two panels and thank everyone for participating in this hearing today. At the end of the day, we must ensure that individuals not only receive the prescriptions they need and at the prices they can afford, but with the safety and efficacy they expect and deserve.

PREPARED STATEMENT OF SENATOR HARKIN

Mr. Chairman, we are here today to talk about the reimportation of prescription drugs from other countries back into the United States. In Iowa, people are always looking for ways to cut the costs of their prescription drugs. Constituents have told me about splitting pills, others have used mail order pharmacies in Canada or have traveled there. Still others have used pharmacies on the Internet. Some of these methods are not safe. But people do it because of one thing: cost.

A recent *Kaiser Family Foundation* report noted that 27 percent of Americans without insurance went without a prescribed medication last year. Even if you have insurance, coverage for prescription drugs has decreased and out-of-pocket costs have increased dramatically over the past decade. This is a problem for everyone—not just senior citizens.

I support reimportation with good safety measures in place. I believe Senator Dorgan and Senator Kennedy have put together a good bill to address the fundamental regulatory hurdles that must be cleared to make reimportation safe. We can't have people exposed to potentially harmful products without any oversight—the exact situation that exists today.

However, Mr. Chairman, I believe the calls for reimportation are really calls for lower drug prices in general. We will discuss prices today and some witnesses have talked about drug pricing in their testimony. Some will argue that unless prices—and profits—remain high for the pharmaceutical industry, investment in research and development will decline. In addition, arguments will be made that millions of people will suffer needlessly because future research

and development is not done. I think this holds us hostage to the pricing practices of the pharmaceutical industry. For example, a recent University of Wisconsin study found that the Top 10 drug companies only invest 13 percent of revenues in research and development. But they collect 23.6 percent of revenues in profit, and almost 35 percent of revenues are spent on marketing. No wonder they are the most profitable industry in the world.

People are suffering needlessly now because they can't get access to the same prescription drug prices as people in other countries. People's lives are at stake. Prescription drugs are not like other consumer products. They are not optional or discretionary. For people with HIV-AIDS, lack of access to drugs can mean debilitating illness and even death. For older Americans with chronic conditions—like Diabetes or Congestive Heart Failure—lack of access to drugs means unnecessary hospital stays, and drastic changes in the quality and length of their lives. It's not like buying a car—the customer can't walk away from the deal with his health in tact. So the choices that we make here in Washington . . . the choices that the Bush administration and the pharmaceutical industry makes . . . are fateful choices. And let's be clear, the prices as they are today cost countless lives here at home.

I fully appreciate the need to preserve the pharmaceutical industry's ability to perform research and development. The Federal Government, through taxpayer money, already supports this through rich tax incentives and investment in biomedical research at the National Institutes of Health. Likewise, I certainly do not dispute the industry's right to make a profit. But we are quickly coming to the point where the pursuit of reasonable profits turns into flat out profiteering. Diseases are viewed as marketing opportunities, not as scourges to be eliminated as rapidly and as cost-effectively as possible.

Lower prices matter because without them, millions of people don't have access to the pharmaceuticals they need to remain healthy, contributing members of our society. Without them, they are denied their health. And, even worse, we all pay. Taxpayer dollars are wasted on hospitalizations that could have been prevented. Chronic diseases that could have been controlled and treated become major medical problems. Until we choose a different course—until we choose to allow reimportation, or choose to allow the Secretary of Health and Human Services to negotiate lower drug prices on behalf of our Medicare beneficiaries—necessary care will remain out of reach for millions of Americans.

PREPARED STATEMENT OF SENATOR JEFFORDS

About 5 years ago, I was encouraged and optimistic when the Congress passed and President Clinton signed the first reimportation legislation, a bill I had introduced called the Medical Equity and Drug Safety, or the "MEDS" Act. It was designed to allow safe, FDA-approved medicines, that are manufactured in plants approved by FDA and sold abroad, to be purchased by American pharmacists and wholesalers and reimported into the United States. We worked closely with the FDA in developing this law. We sought the agency's advice about provisions that were necessary to

ensure the safety and quality of these medicines. We accepted that advice and included stringent controls in the MEDS Act.

President Clinton supported and signed the MEDS Act. Then-presidential candidate, George W. Bush, supported it during his campaign. But since then, the goal-posts have moved. We are now being told that what FDA had advised us would work to ensure safety, will now no longer work. That the controls FDA advised us to include in the MEDS Act are now inadequate.

Mr. Chairman, I can accept that the MEDS Act was not flawless. I can accept that there were some disagreements about whether and how it could work. But few disagreed with the notion that it should work. No one has argued that Americans should continue to pay prices higher than those by other consumers in other countries. This concept of reimportation is not a partisan issue. It is supported by Democrats, Republicans and Independents in both the House and the Senate. All of whom are looking for the right answer.

As of today, we have no fewer than four initiatives in the House of Representatives, three bills introduced in the Senate and at least one more waiting in the wings that would provide for the reimportation of prescription drugs. Virtually all have been criticized for a number of reasons ranging from safety concerns to the imposition of price controls; for either going too far, or not far enough. Clearly, we have an opportunity to address this issue this year and the proponents of these measures deserve our praise for working to resolve outstanding problems. But I believe all these efforts could succeed with just a little more help.

So today I would argue that FDA must stop telling us what will not work, and must now tell us what will work. The agency needs to stop obfuscating and confusing the issue with stories about counterfeit, fake or unsafe drugs. We are interested in knowing how to ensure that the safe, effective medicines that are available on the world market, can be made available here. I hope, that the witness from the FDA, can begin to tell us what is necessary: what regulatory authority and what level of resources are needed to make this program available. We can then take that advice, write the necessary law and get to the matter at hand: that is making sure that Americans have better access to more fairly priced medicine.

Mr. Chairman, I want to commend you and Senator Kennedy for holding this hearing and I am continuing my commitment to work with you and our colleagues to solve this vexing problem. I look forward to hearing from our witnesses, especially those that can contribute to the solutions and not just recite the litany of problems that all of us already know—and know all too well.

PREPARED STATEMENT OF SENATOR EDWARDS

Thank you, Mr. Chairman, for convening this hearing. As we all know, Americans are suffering from skyrocketing drug prices. People from all over the country have told me heart-wrenching stories of having to choose between paying for their prescriptions and putting food on their table. In a country as great as ours, people should never have to make this choice.

Today, this committee meets to discuss the safe and effective reimportation of prescription drugs. Safe and effective reimportation

of drugs would be a very helpful step in helping reduce drug costs. We already know that a safe system to bring drugs in from Canada and other countries will give our seniors much better savings than the new Medicare Drug Card.

Americans must have access to affordable prescription drugs here at home. But all too often, that is not the case. The reality is that prescription drug costs continue to rise at more than twice the rate of inflation. As a result, many Americans are forced to go without their medication. Some of them end up in the emergency room, potentially worse off then they were before.

Last year, we had a chance to do something about this with the Medicare Prescription Drug bill. We had a chance to allow the government to negotiate lower drug prices. But the drug companies were against it, and it was defeated. We had the chance to enact a meaningful benefit for seniors. But big insurance companies claimed they needed subsidies from the government to compete with the Medicare program. So instead of giving seniors a full drug benefit, the Medicare bill gave billions away to HMOs and drug companies.

Truly, the political power of the drug lobby and HMO lobby is a thing to behold. They have hundreds of lobbyists all over Washington doing everything they can to make sure we keep drug prices high. They achieved a spectacular success with the Medicare bill. And you can bet that the drug companies will continue to do everything they can to stop reimportation as well.

Many of my colleagues and I stood up to the drug lobby and opposed this bill. We voted against this $530 billion piece of legislation because it helps HMOs and drug companies more than it helps ordinary Americans. Despite our efforts to include provisions that would lower drug costs, the bill passed and is now law.

We are seeing the effects of this legislation now, as the drug discount card program is being unveiled. Unfortunately, it is more of the same. It is an overly complicated system that will give most seniors no additional help over the current system.

Mr. Chairman, Americans deserve to buy drugs at reasonable prices. No one should have to make a choice between filling their prescriptions and feeding their family. I am gratified that so many of my Democratic and Republican colleagues support reimportation. I urge them to pass legislation that includes strict safety measures to ensure that Americans receive FDA-approved drugs from registered pharmacies and wholesalers.

We shall proceed to Mr. Taylor, who is here representing the FDA. He is the Associate Commissioner for Regulatory Affairs at the U.S. Food and Drug Administration. He is joined by other members of the Food and Drug Administration.

Mr. Taylor, tell us what you think and how we should address this issue.

STATEMENT OF JOHN M. TAYLOR, ASSOCIATE COMMISSIONER FOR REGULATORY AFFAIRS, U.S. FOOD AND DRUG ADMINISTRATION; ACCOMPANIED BY WILLIAM K. HUBBARD, ASSOCIATE COMMISSIONER FOR POLICY AND PLANNING, U.S. FOOD AND DRUG ADMINISTRATION

Mr. TAYLOR. Thank you, Mr. Chairman.

Mr. Chairman and members of the committee, I am John M. Taylor, Associate Commissioner for Regulatory Affairs at the Food and Drug Administration. With me is Mr. William K. Hubbard, Associate Commissioner for Policy and Planning. In addition to my remarks, Mr. Hubbard will be presenting some examples of products that highlight the safety concerns that we will be discussing today.

We appreciate having this opportunity to discuss with you issues relating to the importation of prescription drugs into the United States and proposals that would legalize the importation of these drugs beyond what is currently allowed by law.

FDA shares with Congress its concern for senior citizens and other patients who have difficulty paying for prescription drugs. That is why the administration worked closely with Congress to enact the new Medicare prescription drug law, and that is why FDA has made it a priority for its medical and scientific experts to establish and expand programs that promote access to innovative treatments and affordable medications.

FDA has taken a number of important steps to lower the cost of prescription drugs, including an unprecedented effort to speed up the development and approval of generic drugs, which typically cost 50 to 70 percent less than their brand-name counterparts. Last year, FDA published a final rule to improve access to generic drugs that will save Americans over $35 billion in drug costs over the next 10 years. The agency has also taken steps to improve the development process for innovator drugs, increase the efficiency of drug development, and reduce regulatory costs.

FDA is also working to prevent adverse events through new rules to require bar coding of drugs and improve the tracking of adverse events, with the goal of preventing billions of dollars in unnecessary health care costs each year.

FDA continues, however, to have serious public health concerns about the importation of drugs outside the current safety system established by Congress under the Federal Food Drug and Cosmetic Act. When it comes to buying drugs absent our existing regulatory procedures, FDA has consistently concluded that it is unable to endorse a "buyer beware" approach. Currently, new drugs marketed in the United States, regardless of whether they are manufactured here or in a foreign country, must be approved by FDA based on demonstrated safety and efficacy. They must be produced in inspected manufacturing plants that comply with good manufacturing practices, and the shipment and storage of these drugs must be properly documented and, where necessary, inspected.

Unfortunately, the drug supply is under unprecedented attack from a variety of progressively more sophisticated threats. This is evident in the recent increase in efforts to introduce counterfeit drugs into the U.S. market. FDA's counterfeit drug investigations have risen four-fold since the late 1990s. Although once a rare event, we are now seeing greater numbers of counterfeit finished drugs being manufactured and distributed by well-funded and elaborately organized networks.

At the same time, inadequately regulated foreign Internet sites have also become portals for unsafe and illegal drugs. For example, FDA recently worked with domestic and international authorities

to shut down a website advertising "FDA approved" and safe "European" birth control pills and other drugs, but actually importing ineffective, counterfeit products.

Evidence strongly suggests that the volume of these foreign drug importations is rising steadily, presenting an ever more difficult challenge for agency field personnel at ports-of-entry, mail facilities, and international courier hubs.

Consumers are exposed to a number of potential risks when they purchase drugs from foreign sources or from sources that are not operated by pharmacies properly licensed under State pharmacy laws. These outlets may dispense expired, subpotent, contaminated or counterfeit drug products, the wrong or a contraindicated product, an incorrect dose, or medication unaccompanied by adequate directions for use. The drugs may not have been packaged and stored under proper conditions to prevent degradation, and there is no assurance that these products were manufactured under good manufacturing practice standards.

When consumers take such medications, they face the risk of dangerous drug interactions and/or suffering adverse events, some of which can be life-threatening. More commonly, if the drugs are subpotent or ineffective, patients may suffer complications from the illnesses that their prescriptions were intended to treat, without ever knowing the true cause.

To help assess the extent of the problem posed by imported drugs, FDA and Customs conducted import blitzes at four international mail facilities last summer. We found that 88 percent of the products we examined were unapproved or otherwise illegal. Examples of the potentially hazardous products encountered during the blitz included: drugs never approved by FDA, drugs withdrawn from the market, drugs with inadequate labeling, drugs inappropriately packaged, drugs requiring close physician monitoring, and controlled substances.

At a time when FDA faces more challenges than ever in keeping America's supply of prescription drugs safe and secure, legislation to liberalize drug importation without providing concomitant enhancements in our authorities and resources could seriously compromise the safety and effectiveness of our drug supply.

Successive versions of legislation introduced in the House and Senate have achieved mixed results in providing FDA with the authority and resources needed to assure the safety of imported drugs. But we still see some very basic safety issues with these bills. Chief among these is our concern about provisions to legalize the practice of individual consumers importing drugs on their own from foreign sources. Even if personal importation is limited to Canada, the volume of imported drugs that could result from enactment of the personal importation provisions could overwhelm our already burdened regulatory system.

We do not believe that FDA or any other agency has the ability to assess and properly regulate the millions of small individual packages of drugs that will enter the country each year if personal importation is legalized. Currently, the volume of incoming packages is far beyond the ability of FDA and Customs to properly process. Codification of personal importation would merely exacerbate this problem, as we estimate that tens of millions of small drug

parcels will enter the United States through international mail facilities and private courier hubs. Neither FDA nor Customs, at current staffing levels, would be able to inspect these packages.

Even if such resources could be provided, a mere visual inspection is not adequate to ensure a product's safety. Due to the sheer volume of these packages, it would be impossible to replicate the current regulatory system that relies not only on the inspection of incoming drug shipments at the border, but on the ability of FDA and Customs to track the drugs from the manufacturer to the pharmacy shelf.

In short, legalizing personal importation will endorse the sale of drugs to U.S. consumers from foreign Internet pharmacies, when we know there are already many illicit operators of websites that are selling phony or unapproved medications. When substantial numbers of individual consumers import their own drugs from foreign sources, there is no way for FDA to make meaningful decisions as to the safety or efficacy of such products.

Other concerns relate to the workability of provisions for commercial importation. We caution against the creation of highly complex regulatory systems that are insufficiently funded. Fees to regulate entities should be determined by straightforward means. Funding for such a program should take into account the need for the expenditure of significant new resources for criminal investigations. Where new gateways are created for drugs to enter the United States, some criminal elements will try to exploit these channels and attempt to bring in counterfeit and other unsafe medications. Due to the new pathways by which drugs would enter the country, it would become more difficult to detect fraudulent behavior, and the safety of U.S. consumers may depend to a large degree on intensive investigative activities, as well as the actions of numerous foreign regulatory bodies and border agencies.

While we believe it is a positive step to provide some mechanism for FDA review of foreign products, we note that merely identifying two drugs as pharmaceutically similar would not necessarily ensure true therapeutic equivalence or substitutability between those products. We are concerned about the possibility that drugs with differences that could lead to different therapeutic results or allergic reactions could be sold along side the U.S. version of the drug, or carry the same labeling as the U.S. drug.

Under this system, consumers would have no way to know whether the drug they purchase at their local drugstore would be the U.S. version approved by FDA, or one of up to 20 foreign versions of the drug. They would also have no way of knowing the true composition of the drug, whether it contained a substance harmful to them, or whether the drug would act the same way within the body as the original FDA-approved drug.

Finally, we are concerned that legislation which would mandate unreasonable timetables for implementation would compromise FDA's ability to ensure the safety or quality of the drugs proposed for import.

FDA firmly believes that we can and should do a better job of making safe and innovative drugs more affordable in the United States, but to succeed, we need to find safe and affordable solutions that do not put consumers at risk. The standards for drug review

and approval in the United States are the best in the world, and the safety of our drug supply mirrors these high standards. We believe that U.S. consumers should not have to settle for less.

FDA would urge Congress to ensure that any change to our drug regulation system does not require consumers to give up the "gold standard" in drug safety that they have come to rely on. FDA's scientists, doctors, health care experts and regulators must be empowered to protect us from bad medicine. We owe it to patients today and tomorrow to make our medical future brighter, healthier, and more affordable.

Thank you for this opportunity to testify.

[The prepared statement of Mr. Taylor follows:]

PREPARED STATEMENT OF JOHN M. TAYLOR, J.D.

INTRODUCTION

Mr. Chairman and members of the committee, I am John M. Taylor, Associate Commissioner for Regulatory Affairs at the U.S. Food and Drug Administration (FDA or the Agency). With me is Mr. William K. Hubbard, Associate Commissioner for Policy and Planning at FDA. We appreciate having this opportunity to discuss with you the issues relating to the importation of prescription drugs into the United States and proposals that would legalize the importation of these drugs beyond what is currently allowed by law.

At FDA, our statutory responsibility is to assure the American public that the drug supply is safe, secure, and reliable. For more than 60 years, the Federal Food, Drug, and Cosmetic (FD&C) Act has ensured that Americans can be confident that, when they use an FDA-approved drug, the medicine will be safe and effective and will work as intended in treating their illness and preventing complications. In carrying out this responsibility, FDA also works to do all we can under the law to make medicines accessible and help doctors and patients to use them as effectively as possible, through such steps as expanding access to generic medicines, reducing the time and cost of showing that new medicines are safe and effective, and providing up-to-date information for health professionals and patients to obtain the benefits and avoid the risks associated with powerful medicines. That is the primary mission of the thousands of dedicated staff, including leading health care experts, doctors, economists and scientists who work tirelessly at FDA in public service for the American people. FDA has concerns about unapproved, imported pharmaceuticals whose safety and effectiveness cannot be assured because they are outside the legal structure and regulatory resources provided by Congress. We have also taken steps within the law to improve the availability of affordable medicines and reduce drug costs, without compromising safety. In my testimony today I look forward to having the opportunity to engage in a constructive dialog about the issue of importing prescription drugs as well as discussing steps to provide greater access to more affordable prescription medications.

REDUCING DRUG COSTS

FDA shares with Congress its great concern for senior citizens and other patients who have difficulty paying for prescription drugs. That is why the Administration worked with Congress to enact the new Medicare prescription drug law. And that is why FDA has made it a priority for its medical and scientific experts to establish and expand programs that promote access to innovative treatments to help Americans live healthier lives and assure that Americans have access to medications and treatments that they can afford.

FDA has taken a number of significant steps to provide greater access to affordable prescription medications, including unprecedented steps to lower drug costs by helping to speed the development and approval of low-cost generic drugs after legitimate patents have expired on branded drugs. Generic drugs typically cost 50 to 70 percent less than their brand-name counterparts. On June 18, 2003, FDA published a final rule to improve access to generic drugs and lower prescription drug costs for millions of Americans. These changes will save Americans over $35 billion in drug costs over the next 10 years. Elements of this rule were codified as part of the recently enacted Medicare law and, with FDA's technical assistance, the law added additional mechanisms to enhance generic competition in the marketplace.

In addition, last year Congress provided an increase of $8 million for FDA's generic drug program, the largest infusion of resources into this program ever. This increase in the generic drug budget enables FDA to hire additional expert staff to review generic drug applications more quickly and initiate targeted research to expand the range of generic drugs available to consumers. Improvements in the efficiency of review procedures have led to significant reductions in approval times for generic drugs since 2002, and consequently will save consumers billions more by generally reducing the time for developing generic drugs and making them available.

The Agency has also taken steps to help improve the development process to help lower the high cost of developing new drugs. In particular, FDA is continuing to improve the methods by which assistance and advice is provided to sponsors regarding what we believe are the best approaches to develop new therapies and maximize the prospects for swift FDA approval. These ongoing efforts are designed to provide sponsors with the best possible information and thus increase the efficiency of the development process. We expect that reforms in drug and biologic manufacturing requirements should help reduce manufacturing costs by 20 percent. FDA has identified several priority disease areas, such as cancer, diabetes and obesity, and new technologies including gene therapy, pharmacogenomics and novel drug delivery systems that are good candidates for efforts to clarify regulatory pathways and clinical endpoints.

FDA is also working to prevent adverse events through new rules that would require bar coding for drugs and better ways to track adverse events automatically with the goal of preventing billions of dollars in unnecessary health care costs each year. FDA's final rule requiring bar coding of drugs is estimated to have net economic benefits of approximately $3.5 billion per year. Avoiding such preventable medical complications will also help reduce health care costs, while enhancing quality and safety. In addition, the agency is striving to promote electronic prescribing, to improve quality and reduce prescription costs as well.

IMPORTATION OF PRESCRIPTION DRUGS

Sixty-five years ago, Congress responded to widespread instances of unsafe drugs by directing FDA to create a system for assuring that Americans have a drug supply they can trust will not harm them. Over 40 years ago, Congress required that legal drugs be proven to be effective as well, because modern medicines—when they are produced, distributed, prescribed, and used properly—should not only be safe but also should prevent the many complications and side effects of diseases. More recently, in 1988, Congress enacted the Prescription Drug Marketing Act (PDMA) to establish additional safeguards to prevent substandard, ineffective, or counterfeit drugs from entering the United States. Under PDMA, it is illegal for anyone other than the drug's original manufacturer to reimport a prescription drug into the United States that was manufactured in the United States. This law was enacted with strong bipartisan support because of high-profile cases of unsafe and ineffective drugs entering the United States in large volumes. In one instance, over 2 million unapproved and potentially unsafe and ineffective Ovulen-21 "birth control" tablets from Panama were distributed throughout the United States. In another case, a counterfeit version of Ceclor, a widely used antibiotic at the time, found its way into the U.S. drug distribution from a foreign source. Over the years, FDA's dedicated professional staff has employed PDMA and other authorities to build a drug safety infrastructure to ensure that Americans enjoy the highest-quality drug supply in the world.

Unfortunately, the drug supply is under unprecedented attack from a variety of increasingly sophisticated threats. This is evident in the recent significant increase in efforts to introduce counterfeit drugs into the U.S. market. FDA has seen its number of counterfeit drug investigations increase fourfold since the late 1990's. Although counterfeiting was once a rare event, we are increasingly seeing large supplies of counterfeit versions of finished drugs being manufactured and distributed by well-funded and elaborately organized networks. At the same time, inadequately regulated foreign Internet sites have also become portals for unsafe and illegal drugs. For example, FDA recently worked with domestic and international authorities to shut down a website that was advertising "FDA-approved" and safe "European" birth control pills and other drugs, but was actually responsible for importing ineffective, counterfeit drugs. Evidence strongly suggests that the volume of these foreign drug importations is increasing steadily, presenting an increasingly difficult challenge for agency field personnel at ports-of-entry, mail facilities, and international courier hubs, and our laboratory analysts and border and law enforcement partners.

FDA is doing its best to use its limited international authorities to stop the increasing flow of violative drugs into this country, but the task is daunting. Each day, thousands of individual packages containing prescription drugs are imported illegally into the United States, simply because the sheer volume has grown to exceed the capability of FDA field personnel to properly process. FDA's Office of Regulatory Affairs has inspectors who work in the field who perform investigational work pertaining to imported prescription drugs, a job that is not limited to inspections at ports-of-entry.

SAFETY CONCERNS RELATING TO IMPORTATION

FDA remains concerned about the public health implications of unapproved prescription drugs from entities seeking to profit by getting around U.S. legal standards for drug safety and effectiveness. Many drugs obtained from foreign sources that either purport to be or appear to be the same as U.S.-approved prescription drugs are, in fact, of unknown quality. Consumers are exposed to a number of potential risks when they purchase drugs from foreign sources or from sources that are not operated by pharmacies properly licensed under State pharmacy laws. These outlets may dispense expired, subpotent, contaminated or counterfeit products, the wrong or a contraindicated product, an incorrect dose, or medication unaccompanied by adequate directions for use. The labeling of the drug may not be in English and therefore important information regarding dosage and side effects may not be available to the consumer. The drugs may not have been packaged and stored under appropriate conditions to prevent against degradation, and there is no assurance that these products were manufactured under current good manufacturing practice standards. When consumers take such medications, they face risks of dangerous drug interactions and/or of suffering adverse events, some of which can be life threatening. More commonly, if the drugs are subpotent or ineffective, they may suffer complications from the illnesses that their prescriptions were intended to treat, without ever knowing the true cause.

Patients also are at greater risk because there is no certainty about what they are getting when they purchase some of these drugs. Although some purchasers of drugs from foreign sources may receive genuine product, others may unknowingly buy counterfeit copies that contain only inert ingredients, legitimate drugs that are outdated and have been diverted to unscrupulous resellers, or dangerous sub-potent or super-potent products that were improperly manufactured. Furthermore, in the case of foreign-based sources, if a consumer has an adverse drug reaction or any other problem, the consumer may have little or no recourse either because the operator of the pharmacy often is not known, or the physical location of the seller is unknown or beyond the consumer's reach. FDA has only limited ability to take action against these foreign operators.

The Agency has responded to the challenge of importation by employing a risk-based enforcement strategy to target our existing enforcement resources effectively in the face of multiple priorities, including homeland security, food safety and counterfeit drugs. However, this system, as it works today, is already overwhelmed by the number of incoming packages, and this presents a significant ongoing challenge for the Agency.

Recent spot examinations of mail shipments of foreign drugs to U.S. consumers revealed that these shipments often contain dangerous or unapproved drugs that pose potentially serious safety problems. In 2003, inspectors found that the majority of the packages examined in these "blitzes" contained illegal, unapproved drugs. Last summer, FDA and Customs conducted blitz examinations on mail shipments at the Miami and New York (JFK) mail facilities in July, and the San Francisco and Carson, California, mail facilities in August. In each location, the agencies examined packages shipped by international mail over a 3-day time span. Of the 1,153 shipments examined, the overwhelming majority (1,019 packages, or 88 percent) contained unapproved drugs. The drugs arrived from many countries. For example, 16 percent entered the United States from Canada; 14 percent were from India; 14 percent came from Thailand, and 8 percent were shipped from the Philippines.

A second series of import blitz exams, conducted in November 2003, also revealed potentially dangerous, illegally imported drug shipments. Of the 3,375 products examined, 2,256 or 69 percent were violative. FDA found recalled drugs, drugs requiring special storage conditions and controlled substances. These blitz exams were performed at the Buffalo, Dallas, Chicago and Seattle international mail facilities and, for the first time, the private courier hubs at Memphis and Cincinnati. Canadian parcels appeared most frequently (80 percent of the mail parcels), while 16 percent were from Mexico, and the remaining 4 percent came from Japan, the Netherlands, Taiwan, Thailand and the United Kingdom.

Examples of the potentially hazardous products encountered during the exams include:

• Unapproved drugs such as (1) alti-azathioprine, an immunosupressant drug that can cause severe bone marrow depression and can be associated with an increased risk of infection and cancer development; and (2) human growth hormone, which can have serious side effects if used inappropriately or in excessive doses.
• Controlled substances—FDA and Customs found over 25 different controlled substances, including Diazepam; Xanax; Codeine; Valium, Lorazepam, Clonazepam and anabolic steroids.
• Drugs withdrawn from the U.S. market for safety reasons such as Buscapina, which appears to be the drug dipyrone, removed from the market in 1977 due to reports of association with agranulocytosis—a sometimes fatal blood disease.
• Improperly packaged drugs shipped loose in sandwich bags, tissue paper or envelopes.
• Animal drugs not approved for human use such as Clenbuterol, a drug approved for the treatment of horses but also known as a substance of abuse in the "body building" community and banned by the International Olympic Committee.
• Potentially recalled drugs—Serevent Diskus and Flovent Diskus medicines from Canada for the treatment of asthma. Shortly after the blitz, certain lots of the Canadian versions of these drugs were recalled in Canada.
• Drugs requiring risk management and/or restricted distribution programs—for example, Canadian-manufactured isotretinoin, which in the United States is subject to a stringent risk management plan, under which prescribers are required to screen, educate and monitor patients to avoid certain serious risks such as birth defects.
• Drugs with inadequate labeling such as those with missing dosage information or labeling that is not in English.

But its not just FDA that has identified both legal and safety concerns about importation of prescription drugs—so have many other professional regulators, including State pharmacy boards and most recently courts. On November 6, 2003, Federal District Court Judge Claire V. Eagan, U.S. District Court for the Northern District of Oklahoma, issued a decision in *United States* v. *RX Depot, Inc. and RX of Canada LLC*, granting a preliminary injunction to immediately prevent these defendants who operate business that import prescription drugs from Canada, because such unapproved drugs were a clear violation of the FD&C Act. In addition to her unequivocal findings of law, the Judge concluded that these companies could not assure the safety of the drugs they have been importing and, as a result, in violating the law, have put Americans at serious risk. The Judge concluded that "unapproved prescription drugs and drugs imported from foreign countries by someone other than the U.S. manufacturer does not have the same assurance of safety and efficacy as drugs regulated by the Food and Drug Administration." She continues: "Because the drugs are not subject to FDA oversight and are not continuously under the custody of a U.S. manufacturer or authorized distributor, their quality is less predictable than drugs obtained in the United States."

RECENT STATE ACTIONS

Despite this ruling and the concerns raised by the Agency, recently, several Governors and mayors have proposed to create systems whereby their employees and/or constituents could be directed to Canadian pharmacies for purchasing Canadian drugs. FDA has spoken with a number of such officials about our concerns, and many have declined to proceed and have turned to other legal, proven ways to safely reduce drug costs. However, some States and localities, including the State of Minnesota and the State of Wisconsin have proceeded to establish state-run websites linking citizens to entities dispensing drugs purportedly from Canada.

Recent research by the State of Minnesota pointed out significant problems related to purchasing non-FDA approved pharmaceuticals from foreign Internet pharmacies. Minnesota State health officials observed even Canadian pharmacies that participate in the Canadian Internet Pharmacy Association engaging in problematic practices during a single, voluntary, pre-announced "visit." The officials noted dozens of safety problems, such as:

(1) several pharmacies used unsupervised technicians, not trained pharmacists, to enter medication orders and to try to clarify prescription questions;

(2) one pharmacy had its pharmacists review 100 new prescriptions or 300 refill prescriptions per hour, a volume so high that it would have been impossible to assure safety;

(3) one pharmacy failed to label its products, instead it shipped the labels unattached in the same shipping container, even to patients who received multiple medications in one shipment; and

(4) drugs requiring refrigeration were being shipped unrefrigerated with no evidence that the products would remain stable.

At least one of the Canadian pharmacies visited by Minnesota health officials dispensed many drugs that apparently were not even of Canadian origin, and many of the drugs were obtained from prescriptions that had been written and rewritten across multiple Canadian provinces. These types of systematic safety problems would generally be clear regulatory violations that would not be tolerated under the comprehensive system of Federal and State regulation of drug safety in the United States.

Similar findings occurred when representatives of New Hampshire Gov. Craig Benson visited the Canadian Internet pharmacy known as CanadaDrugs.com, located in Winnipeg, Manitoba. The "terms of service" for CanadaDrugs.com requires purchasers to agree that they "will not be liable for damages arising from personal injury or death" from the use of drugs sold by the pharmacy. Under this practice, the consumer has no recourse for injuries arising from the use of drugs from this shipper. Additionally, the website allows patients to send in their prescriptions by fax, when the practice is illegal under the law in New Hampshire and other States. CanadaDrugs.com is "accredited" only by the Internet and Mail order Pharmacy Accreditation Commission, which is a voluntary body with no legal standing and no Federal or State regulatory or enforcement authority.

DRUG COUNTERFEITING

Counterfeiting of prescription drugs is a growing global concern. In fact, counterfeiting of drugs is commonplace in many countries. In the United States, Federal and State authorities have kept counterfeiting of drugs to a minimum because of our extensive system of laws, regulations and enforcement. As a result, Americans have a high degree of confidence in the drugs they obtain from their local pharmacy. In recent years, however, FDA has seen growing evidence of efforts by increasingly well-organized counterfeiters, backed by increasingly sophisticated technologies and criminal operations, intent on profiting from drug counterfeiting at the expense of American patients.

To respond to this emerging threat, FDA convened a Counterfeit Drug Task Force that received extensive comment and ideas from security experts, Federal and State law enforcement officials, technology developers, manufacturers, wholesalers, retailers, consumer groups, and the general public. Based on these comments, on February 18, 2004, FDA issued a report that contains specific steps that can be taken now and in the future to protect consumers from counterfeit drugs and secure the U.S. drug supply chain.

The report's framework describes how to strengthen our drug safety assurances against modern counterfeit threats through a multilayered strategy that includes modern anti-counterfeiting technologies. Promising developments such as "track and trace" technologies that cannot be faked like a paper drug pedigree, and verification technologies built not only into tamper-resistant drug packaging but also into the drugs themselves will make our job of verifying the legitimacy of drug products much easier. FDA is working to speed the availability of these anti-counterfeiting technologies, but these technologies have not yet been proven, and they are intended to complement and reinforce an underlying system for assuring the safety and effectiveness of prescription drugs.

Thus, anti-counterfeiting technologies hold great promise for strengthening our legal drug distribution system, but to be effective they must be used in conjunction with effective legal authorities.

INTERNATIONAL DRUG PRICES

As millions of Americans without good prescription drug coverage experience every day, the "list prices" they face for patented drugs when they walk into a drug store in the United States can be much higher than the price of drugs sold abroad. But these price differences do not result from a comparative advantage in the production of such goods abroad. Foreign "list" prices are lower in part because of price controls in foreign countries. While drug prices in the United States can be much lower than "list" for Americans with good drug insurance, in Canada, the Patented Medicine Price Review Board (PMPRB) limits both initial prices and price increases of patented medicines through a variety of "tests." Price controls at the provincial level also constrain prices.

Studies of patented drug prices often ignore how competition in the United States today, building on the measures described above to improve access and competition in generic drugs, effectively lowers generic drug prices so that many are far lower than drug prices abroad. Generic drugs comprise over half of all U.S. prescriptions, a much higher percentage than in most other countries. Furthermore, low generic prices are fully compatible with strong incentives for research and development of new drug products, because generics are allowed in the United States only after patents expire. The U.S. policy has meant that patent law and competition, not price controls, are the primary mechanism by which to affect incentives for innovation.

Competition in the United States has provided U.S. consumers with some of the lowest priced generic drugs in the world. For example, recent studies examined the prices for seven drugs that are the biggest selling chronic-use drugs for which the first U.S. entry of a generic version occurred in the last 10 years (alprazolam, clonazepam, enalapril, fluoxetine, lisinopril, metformin, and metoprolol). Five of the seven U.S. generic drugs were found to be significantly cheaper than the generic version of the same drug available in Canada. Five of the same seven generics were also more expensive in Australia than in the United States, with some prices being many times greater than the comparable U.S. price.

Many countries could do more to encourage innovation in health care by changing the way their dollars are being spent, to get more value for their citizens. First, most countries need more competition when it comes to generic drugs, which should be made available quickly and used more widely and at lower prices as soon as legitimate drug patents expire. Regulation of generics should not restrict prices and choices; it should focus on promoting free and fair generic drug competition, including lower prices for patients that use generic drugs. The bottom line is that it can be possible to redirect billions of dollars in drug spending, through greater use of less expensive generic drugs, permitting greater financial rewards for developing and providing access to valuable new drugs quickly. This approach encourages innovation without spending more money. If the savings from more competitive generic prices and wider use of generic drugs are applied to providing better rewards for innovative new drugs, this approach could reduce the inequities in new drug prices across countries, while improving global incentives to develop better drugs.

The international community has started making progress toward greater fairness in drug pricing, with the potential to reduce the excessive burden on American consumers, who currently pay about half of all drug costs worldwide. For example, an agreement under TRIPS last year will help make very low-cost medicines available to developing countries for urgent public health threats, such as AIDS. In conjunction with this agreement, many developed nations agreed not to "reimport" these low cost medicines, in recognition of the fact that the price of medicines in a country should reflect that country's ability to pay. The United Kingdom and France are also taking steps toward increasing payments for innovative new medicines. The fact that significant savings are possible in other developed countries from greater use and more competition involving generic drugs means that it is possible to achieve fairer new drug prices worldwide with less burden on American consumers, without other countries having to spend more.

IMPORTATION PROPOSALS

At a time when FDA faces more challenges than ever in keeping America's supply of prescription drugs safe and secure, legislation to liberalize drug importation without providing concomitant enhancements in FDA's authorities and resources to assure the safety of these imports could compromise the safety and effectiveness of our drug supply. Depending upon the specifics of the legislation, the volume of importation that could result from enactment of these bills could overwhelm our regulatory system. Many of these bills fail to provide FDA with adequate authority or resources to establish and regulate the major new "legal" channels for incoming foreign drugs—manufactured, distributed, labeled, and handled outside of our regulatory system—or even to ensure their safety. Some of these proposals would even limit FDA's existing authorities. They would impose unprecedented restrictions on FDA's ability to inspect and test drugs, and FDA's authority to block the distribution of drugs we think are unsafe.

Today, FDA drug approvals are manufacturer-specific, product-specific, and include many requirements relating to the product, such as manufacturing location, formulation, source and specifications of active ingredients, processing methods, manufacturing controls, container/closure system, and appearance. Under section 801 of the FD&C Act, only manufacturers may import drugs into the United States. The drugs must be produced in FDA inspected facilities. These facilities and the drugs produced in them are currently covered by the U.S. regulatory system, and

it is legal to import these drugs. It is important that in considering legislation to allow expanded importation of drugs by persons other than the manufacturer, Congress should not bypass the protections provided by FDA's drug approval process and by State regulation of firms that dispense drugs within their jurisdictions.

We want to be clear that our objections to legislative proposals that would create large, legal channels for drugs to enter our drug supply without assurances of safety are based on concerns that they will create substantial drug safety problems without clear, large-scale, long-term benefits. FDA has particularly raised concerns about legislative proposals that would create such channels by weakening our existing safety protections rather than providing the necessary resources or additional authorities to enable the Agency to assure drug safety and security. Furthermore, our economic experts as well as many others have raised concerns about the limitations of potential longer-term benefits and savings that could be realized from imported drugs. The Congressional Budget Office has estimated that the savings from even a broad, multiple-country importation proposal would be only about 1 percent, while savings from importing drugs from Canada only would be "negligible." Even the Canadian Internet pharmacy operators have said that they cannot provide safe drugs for Americans on a large scale. These are important concerns, but that does not mean that we are opposed to undertaking a thorough effort to determine whether and how importation could be accomplished safely. But this cannot be accomplished by fiat or with a presumption of safety.

Some Members of Congress are working on the difficult challenge of identifying the resources and authorities necessary to assure safety for certain types of imported drugs. This is a much more constructive approach than simply declaring imported drugs to be legal or restricting FDA's authorities to keep the U.S. drug supply safe. To help determine whether and what specific authorities and resources would provide for the safe importation of drugs, the conference report of the new Medicare law gave the Secretary of Health and Human Services specified requirements for a study of drug importation. Among these requirements, the conference report asked the Secretary to "identify the limitations, including limitations in resources and in current legal authorities, that may inhibit the Secretary's ability to certify the safety of imported drugs" and to "estimate agency resources, including additional field personnel, needed to adequately inspect the current amount of pharmaceuticals entering the country."

MEDICARE IMPORTATION STUDY AND TASK FORCE

Last year, when Congress enacted the Medicare Modernization Act, it recognized these safety issues and included language that required that the Secretary certify the safety of prescription drugs prior to authorizing their importation. At the same time, Congress directed the Department to conduct a comprehensive study and prepare a report to Congress on whether and how importation could be accomplished in a manner that assures safety. The Department is currently working on that analysis and has created an intergovernmental task force to steer this effort to completion by the Congressional deadline later this year.

The taskforce includes representatives from FDA, the Centers for Medicare and Medicaid Services, Customs and Border Protection, and the Drug Enforcement Administration. The taskforce has brought together a wide variety of health care stakeholders to discuss the risks, benefits and other key implications of importing drugs into the United States, and to offer recommendations to the Secretary on how to best address this issue in order to advance the public health. The statutory language and the conference report provide detailed, comprehensive requirements for the importation study.

As an integral part of the study process, the task force held a series of six meetings to gather information and viewpoints from consumer groups, health care professionals, health care purchasers, industry representatives and international trade experts, and a public docket for comments was opened as well. This process affords Congress and the Administration an opportunity to fully address the complex public health, economic and legal questions in order to make appropriate and effective recommendations about importation of prescription drugs and the associated fundamental changes to the FD&C Act and in safety resources that may be required.

CONCLUSION

The standards for drug review and approval in the United States are the best in the world, and the safety of our drug supply mirrors these high standards. The employees of FDA constantly strive to maintain these high standards. However, a growing number of Americans are obtaining prescription medications from foreign sources. U.S. consumers often seek out Canadian suppliers, sources that purport to

be Canadian, or other foreign sources that they believe to be reliable. Often, the imported drugs arriving through the mail, through private express couriers, or by passengers arriving at ports-of-entry are unapproved drugs that may not be subject to any reliable regulatory oversight. FDA cannot assure the safety of drugs purchased from such sources.

The vigilance of FDA and Customs inspectors is an important tool in detecting imported products that violate the FD&C Act. Given the available resources and competing priorities facing these agencies, however, experience shows that inspectors are unable to visually examine many of the parcels containing prescription drug products that arrive through the mail and private courier services each day. The growing volume of unapproved imported drugs, which often are generated from sales via the Internet, presents a formidable challenge.

FDA firmly believes that we can and should do a much better job of making safe and innovative drugs more affordable in the United States, but to succeed we need to find safe and affordable solutions that, when implemented, do not put consumers at risk. We appreciate and support the bipartisan commitment to making drugs more affordable for seniors and other consumers and are working hard to achieve the goals of safety and affordability. We believe that Americans should not have to settle for less.

We all agree more needs to be done to continue to address the high cost of prescription medicines. But we must be cautious and deliberate as we consider proposals to accomplish this goal. FDA would urge that Congress ensure that any changes to our drug regulation system do not require American citizens to give up the "gold standard" in drug safety that has become a hallmark in this country. FDA's scientists, doctors, health care experts and regulators must be empowered to protect us from bad medicine. We owe it to patients today and tomorrow to make our medical future brighter, healthier and more affordable.

Thank you for the opportunity to testify. I look forward to responding to any questions you may have.

The CHAIRMAN. Mr. Taylor, I know that Mr. Hubbard is going to testify, but before he does, Senator Kennedy has joined us and I didn't know if the Senator wanted to make an opening statement.

OPENING STATEMENT OF SENATOR KENNEDY

Senator KENNEDY. Thank you very much, Mr. Chairman. We were on guard waiting for the President, who is up meeting with a number of our good Republican friends, and we were just uncertain as to the exact moment that this hearing was going to start. So I appreciate the courtesy to make a brief opening comment here.

First of all, thank you very much for having this hearing because it is a hearing of enormous importance. It affects the quality of health for millions of our citizens and it's an issue that, in many instances, involves life and death to many of our citizens. I think there are ways of trying to address this issue, so I thank you very much for having the hearing.

I wanted to indicate that in our audience today we have a number of senior citizens who have come here because they know how important the issue is. We especially welcome Joybelle Poole, who has come all the way from Sandusky, OH because this issue is important to her. She is a retired nurse, has four grown children, and like other Americans, struggling to make ends meet. She has found a way to get her drugs from Canada and they cost her $151 for a 90-day supply. In the United States, it costs her $660. So she knows that every patient should have access to the same kind of savings.

If I could, Joybelle is out there, so if she could just stand so I could see her. She is there in the back. Thank you very much.

[Applause.]

I will be brief, Mr. Chairman, but this is very important. The current rules on the importation or reimportation of FDA-approved drugs manufactured in FDA-approved plants are indefensible and unsustainable. They prohibit anyone except a drug manufacturer from importing drugs into the United States, and they create a shameful double standard in which the Canadians, Europeans and other foreign patients can buy American drugs at affordable prices, while drug companies charge exorbitant prices to the American consumer. This chart over here indicates the dramatic contrast that exists between what is paid for in the United States and what is paid for in these other countries.

The central issue is fairness for millions of Americans struggling to afford the soaring costs of prescription drugs. Americans understand fairness. They know it's wrong when American patients buy the same prescription drug and pay 60 percent more than the British or the Swiss, two-thirds more than the Canadians, 80 percent more than the Germans, and twice as much as the Italians.

Prescription drugs, as I mentioned, often mean the difference between sickness and health, or life and death, for millions of Americans. Drug companies are consistently the most profitable industry in the Nation; yet, they overcharge countless families. It is wrong that patients have to go without the drugs they need because this administration won't stand up to the industry.

The bipartisan legislation introduced by Senators Dorgan, Snowe, McCain, Daschle, myself and many others on this committee, will at long last give American patients a fair deal. Our proposal will legalize safe imports of U.S.-approved drugs manufactured in U.S.-approved plants. It will enable U.S. consumers to buy FDA-approved drugs at the same fair prices as they are sold abroad.

The drug companies and the Bush administration argue that imported drugs threaten the health of American consumers because of the possibility of counterfeiting or adulteration. Under our bill, this argument can't pass the laugh test.

A quarter of the drugs Americans use today are already legally imported into the United States. The American people have no idea how large a share of the pills they take are outsourced, produced for U.S. drug makers in plants overseas, where wages are far cheaper. The catch is that the law allows it. Drugs can be legally imported only by the drug companies themselves, who then sell them at a high U.S. price.

If the drug companies can import drugs at low prices, why can't patients import them at low prices, too? Our legislation sets up ironclad safety procedures to guarantee that every drug imported legally into the United States is the same FDA-approved drug originally manufactured in an FDA-approved plant, whether the drug is manufactured abroad and shipped to the United States, or whether it is manufactured in the United States, shipped abroad and then imported back into the United States.

Under the bill, the FDA is given new legal authority and resources to enforce the law. In fact, under this legislation, the procedures to prevent counterfeiting or adulteration of drugs shipped into the United States are actually stronger than the protections

against counterfeiting of drugs manufactured for the domestic market.

But legalizing the safe importation of drugs is only half the battle to bring fairness to the prices consumers pay. Legalization is meaningless unless it is backed up by strong measures to prevent drug manufacturers from subverting the law. Already, large American companies are retaliating against imports from Canada by limiting the amount of drugs they will sell to Canada, or denying drugs to pharmacies that resell them to American patients.

Our legislation also includes strict rules to close the loopholes that drug companies use to evade the law. Violations will be considered unfair trade practices under the Clayton Act, and violators will be subject to treble damages.

Year in and year out, drug company profits are the highest of any industry in the United States. Yet, year in and year out, patients are denied lifesaving drugs because those astronomical profits are obtained by equally astronomical prices, prices that drug companies can't charge anywhere else in the world because no other country in the world would tolerate such high prices.

It is time to end the shameful price-gouging here at home. It is time for basic fairness, and it is time for Congress to act.

Finally, Mr. Chairman, we have the situation where militarily we protect the Straits of Ormuz, the Straits of Malacca, the Suez Canal, the Panama Canal, because of international trade—and the taxpayers pay for that.

We are doing the same thing with regard to the drug industry. The hard working American taxpayers are paying, through the NIH, for the basic research, which I am a very strong supporter of. We are in the time of the life sciences. I think the breakthroughs are going to be extraordinary and I strongly support it, and reject even the administration's cutting back on much of that research. But for the American taxpayers to have to pay double, which they are, paying one time in terms of research and then paying the higher prices, when we are effectively subsidizing every other country, including western Europe, is bad health policy, bad economics, and that has to be altered and has to be changed. We believe we have legislation that could best address that.

I thank the witnesses for their courtesy in letting me make a brief statement at this time, and I thank the chair very much, as well.

The CHAIRMAN. Thank you, Senator.

[The prepared statement of Senator Kennedy follows:]

PREPARED STATEMENT OF SENATOR KENNEDY

I commend our Chairman, Senator Gregg, for holding this hearing on this issue of such basic importance to patients and their families.

This is the biggest rip-off of Middle America since Enron. Big drug companies are swelling their bloated bottom line by pricing good health care beyond the reach of average Americans—and it's time for a change.

The current rules on importation or reimportation of FDA-approved drugs manufactured in FDA-approved plants are indefensible and unsustainable. They prohibit anyone except a drug manu-

facturer from importing drugs into the United States. They create a shameful double standard in which Canadians, Europeans and other foreign patients can buy American drugs at affordable prices, while drug companies charge exorbitant prices to American patients.

The central issue is fairness for millions of Americans struggling to afford the soaring cost of prescription drugs. Americans understand fairness. They know it's wrong when American patients buy the same prescription drug and pay 60 percent more than the British or Swiss, two-thirds more than Canadians, 80 percent more than Germans, and twice as much as Italians.

Prescription drugs often mean the difference between sickness and health—or even life and death—for millions of Americans. Drug companies are consistently the most profitable industry in the Nation, yet they overcharge countless families. It's wrong that patients have to go without the drugs they need because the Bush Administration won't stand up to the pharmaceutical industry.

Bipartisan legislation introduced by Senators Dorgan, Snowe, McCain, Daschle, myself, and others will, at long last, give American patients a fair deal. Our proposal will legalize safe imports of U.S.-approved drugs manufactured in U.S.-approved plants. It will enable U.S. consumers to buy FDA-approved drugs at the same fair prices as they are sold abroad.

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ing the amount of drugs they will sell to Canada, or denying drugs to pharmacies that resell them to American patients.

Our legislation also includes strict rules to close the loopholes that drug companies use to evade the law. Violations will be considered unfair trade practices under the Clayton Act, and violators will be subject to triple damages.

Year in and year out, drug company profits are the highest of any industry in the United States. Yet year in and year out, patients are denied life-saving drugs because those astronomical profits are obtained by equally astronomical prices—prices that drug companies can't charge anywhere else in the world because no other country in the world would tolerate such high prices.

It's time to end the shameful price-gouging here at home. It's time for basic fairness. It's time for Congress to act.

I look forward to the testimony of our distinguished witnesses.

PHARMACEUTICAL MARKET ACCESS AND DRUG SAFETY ACT

I. IMPORTABLE DRUGS

Drugs must be approved by the Food and Drug Administration and manufactured in an FDA-inspected plant.

Drugs must be patient-administered, and not a controlled substance, an infused or injected drug, a biologic, or a drug inhaled during surgery.

II. COMMERCIAL IMPORTATION BY PHARMACIES AND DRUG WHOLESALERS

Allows importation by licensed pharmacies and wholesalers from Canada within 90 days of enactment and from the current European Union members, Australia, New Zealand, Japan, and Switzerland beginning 1 year from enactment.

Requires registration of wholesalers and pharmacies with FDA, and levies capped fees to support the costs of the program. Registration may only be of those entities that are fully licensed in accordance with applicable State and Federal law to act as pharmacies or wholesalers of prescription drugs.

Importers and all resellers of imported products must provide a *full chain-of-custody (pedigree)*, tracking possession of drugs from the point of manufacture to the sale to the consumer.

Drugs must be re-labeled in English to comply with FDA requirements. The FDA will provide approved labeling information to importers.

FDA may stop the importation of a drug that has been determined to be counterfeit, contaminated, or is otherwise adulterated. FDA may require use of approved anti-counterfeiting technologies to verify the chain-of-custody of a drug.

The bill says that importation, sale, and use of drugs is not patent infringement.

III. IMPORTATION BY INDIVIDUALS

Immediately upon enactment, an individual may import up to a 90-day supply of a prescription drug from Canada for their personal use or for the personal use of a family member. Once FDA

has issued regulations, a Canadian pharmacy registered under the Act may ship drugs to individuals for personal use. Registered Canadian pharmacies must be approved by FDA, frequently inspected, and they must validate a U.S. prescription, review health and medication history, and track shipments.

The bill also allows individual Americans who travel outside the United States to bring back with them for their personal use a 90-day supply of medicine from Australia, current countries in the European Union, Japan, New Zealand, or Switzerland, or a 14-day supply of medicine from other foreign countries.

The bill continues the FDA's current "compassionate use" policy of allowing importation for patients with special needs.

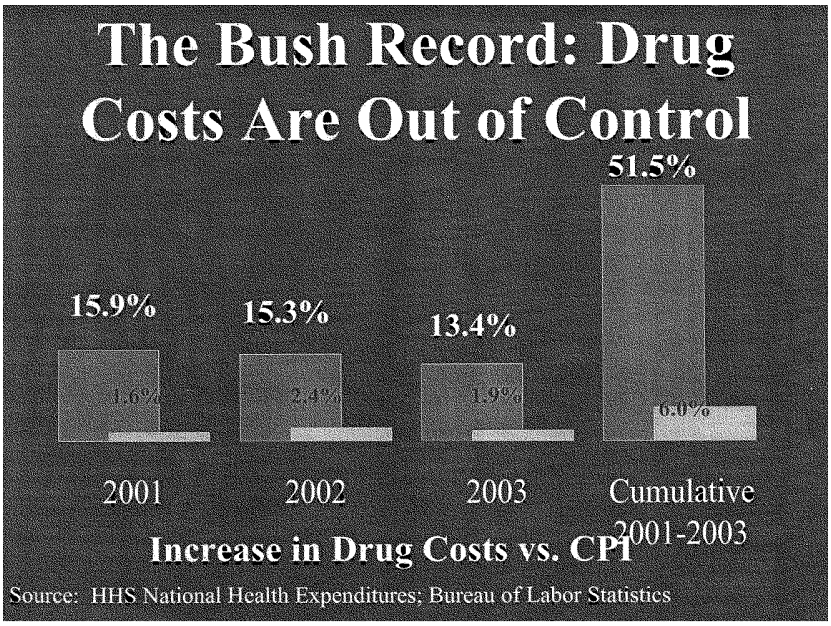
IV. "GAMING" THE SYSTEM

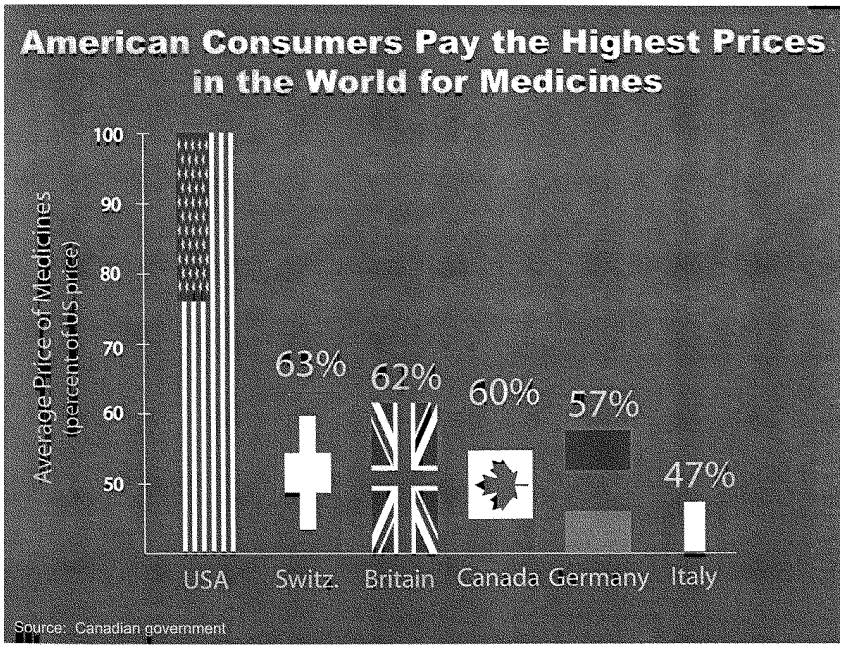
The bill protects those selling or using drugs imported under the program by preventing a drug company from taking actions that would thwart drug importation. An individual who takes such an action against a pharmacist, wholesaler, or consumer to hinder importation of prescription drugs will be in violation of the Clayton Act, and treble economic damages may be awarded.

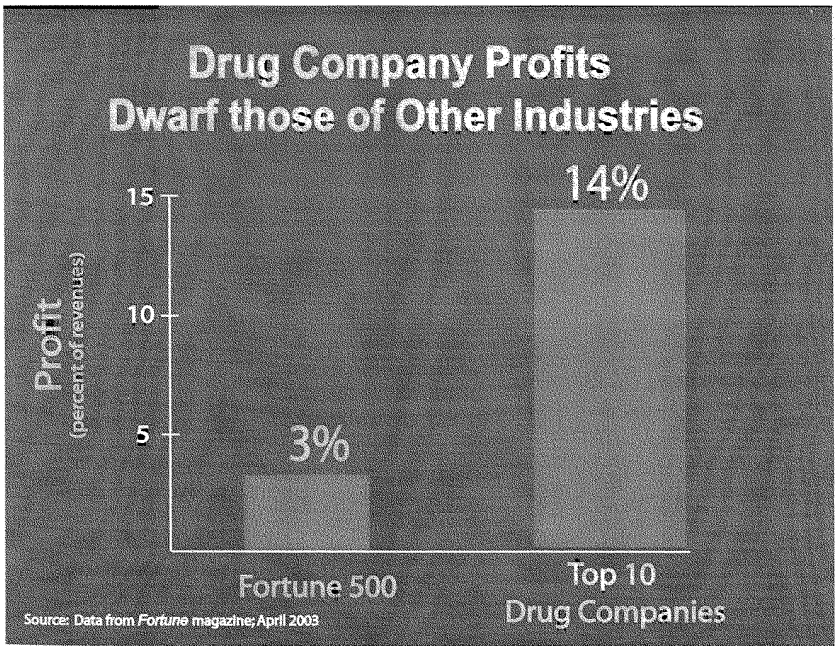
The proposal includes features to prevent a drug manufacturer from blocking importation of drugs by changing the color, dosage form, or place of manufacture of the drug so that it is no longer FDA-approved. Drug manufacturers that make these kinds of changes would be required to notify the FDA, and the FDA would be given the authority to take the steps needed to approve the drug.

V. LIMITING UNSAFE DRUG IMPORTS

Customs could seize and destroy drugs imported by individuals from foreign exporters that are not registered with FDA. FDA would provide the individual whose drugs were seized with a simple notice explaining how the individual can import drugs from registered Canadian exporters safely and legally.


The Bush Record: Drug Costs Are Out of Control
15.9%
15.3%
13.4%
51.5%
1.6%
2.4%
1.9%
0.0%
2001
2002
2003
Cumulative 2001-2003
Increase in Drug Costs vs. CPI
Source: HHS National Health Expenditures; Bureau of Labor Statistics


American Consumers Pay the Highest Prices in the World for Medicines
Average Price of Medicines (percent of US price)
100
90
80
70
60
50
63%
62%
60%
57%
47%
USA
Switz.
Britain
Canada
Germany
Italy
Source: Canadian government



The CHAIRMAN. Mr. Hubbard.

STATEMENT OF WILLIAM K. HUBBARD, ASSOCIATE COMMISSIONER FOR POLICY AND PLANNING, FDA

Mr. HUBBARD. Thank you, Mr. Chairman.

We certainly understand, as you noted, Mr. Chairman, that drug prices are of concern to many Americans, and we're not in denial at all about that being a problem in some cases.

FDA's mission, as you stated, is safety. That has been our concern, that if you open up the borders to these drugs, it needs to be done with great care and perhaps take into account the sorts of concerns that FDA has. What we would like to do is show you some of those concerns today.

I have given the members a little handout of six exhibits that I would like to walk through to describe that, if I may.

[The FDA exhibits follow:]

Exhibit 1

Exhibit 2

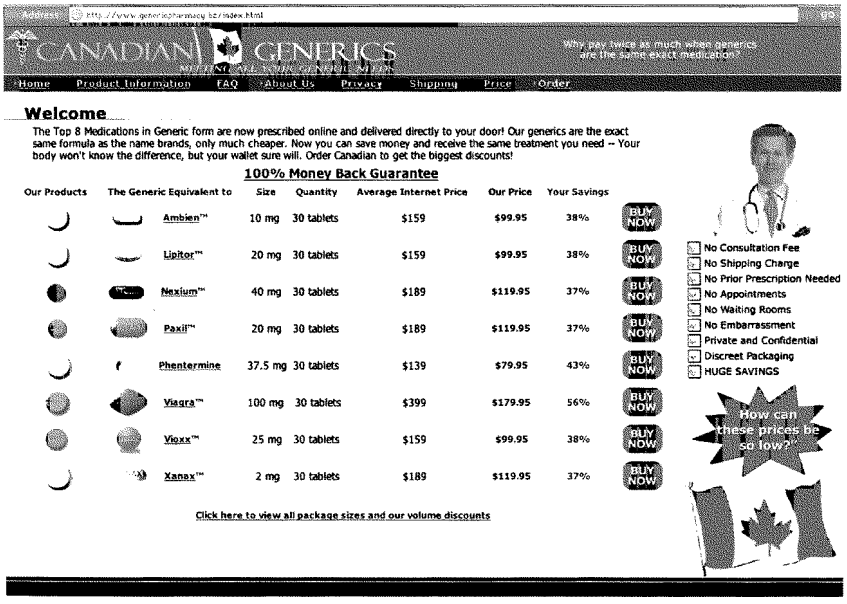


Exhibit 3

Undissolved Calcium Tablets

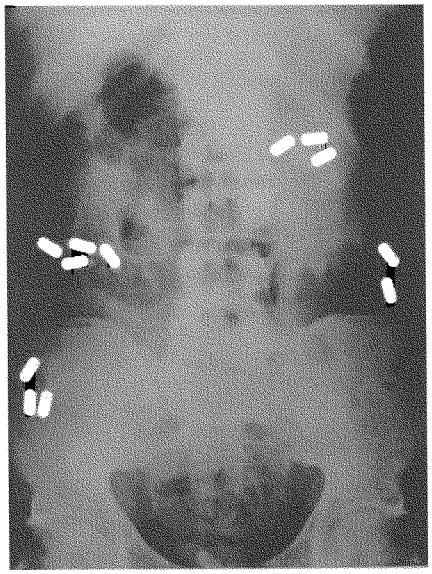


Exhibit 4

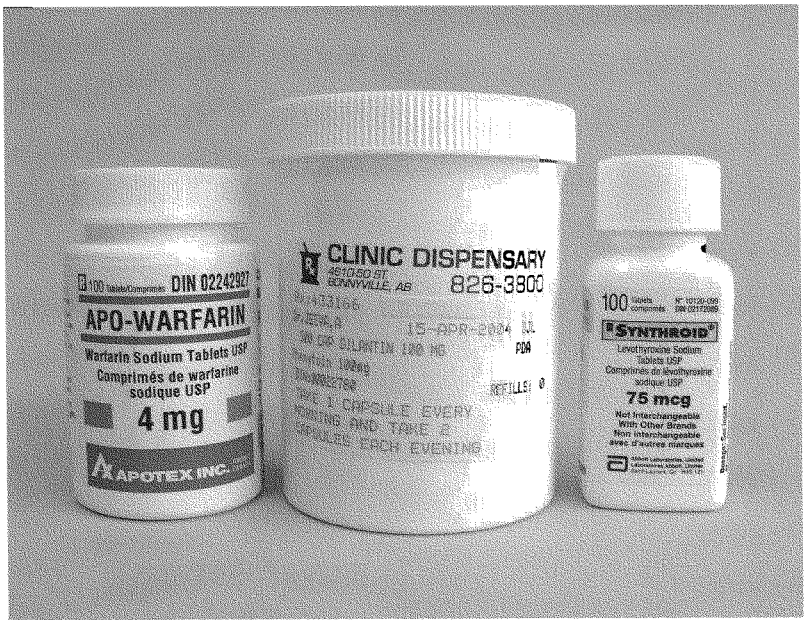


Exhibit 5

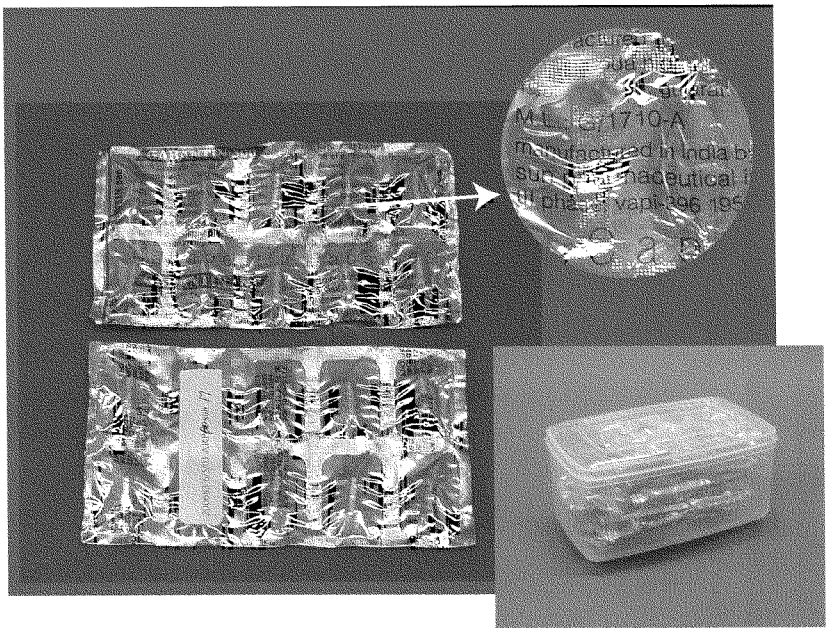
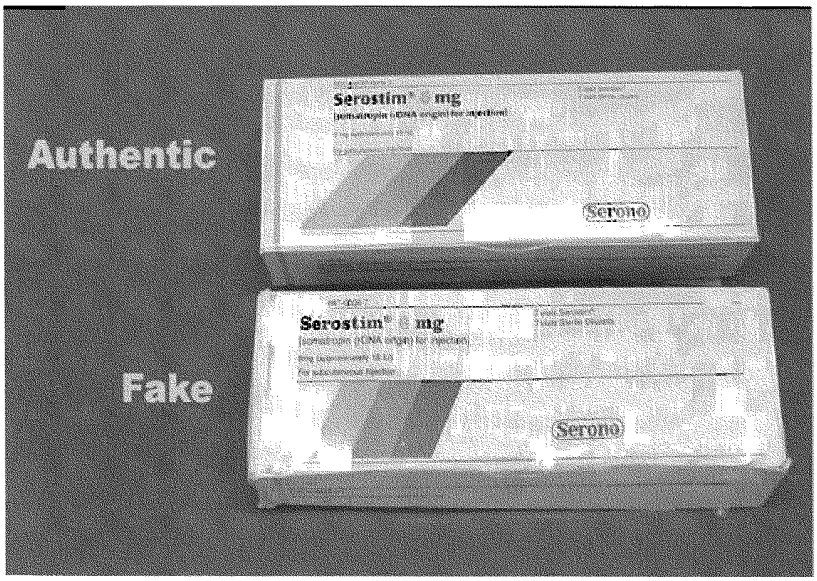


Exhibit 6



Mr. Hubbard. These are drugs that Americans bought from Canada. We see this every day. I would be glad to pass this up to the dais if you would like to see them. These are actual Canadian drugs that American citizens bought over the Internet.

Of course, as you see from the first exhibit, these come in huge volumes now. This is a mailroom at one of the 12 international mail facilities. The packages come off the planes and go on to conveyor belts, and for drugs they are segregated into these bins for examination. The volume currently is perhaps 5 million. We have perhaps a dozen or so inspectors at these facilities to look at all these drugs. So we are overwhelmed now with the inability to open all of these packages and make any reasonable safety judgments about these drugs. This is what it looks like.

We are concerned that a further opening of the borders will exacerbate what we already fear is an unsafe situation. Let me explain a little bit more about some of those safety issues.

The second exhibit—and there is a poster over here against the wall—is of a website offering to sell cheaper generic drugs from Canada. We got it through a "spam" e-mail. We noted that these drugs did not have generic versions, so we investigated to determine where the server was, where the computer was, that set this site up. It turned out to be in China, a province called Dandong Province bordering North Korea. So we thought these might be Chinese counterfeits because counterfeiting of drugs is fairly common in that part of the world.

So we made an order. We put a prescription together and bought Ambien and Lipitor and Viagra. It arrived a few days later like this, and then it had a return address not in China but Miami, FL, but a postmark from Dallas, TX and a phone number for reorder. So we called the phone number and asked the phone company where it was, and they said it was in Belize. So we called the people there. They said, "Where are you?," and we said, "We're in the United States," called back and got another person and were told they were in Belize. Then we asked the credit card company, "Who did you pay for this drug?" They said, "Well, we paid a company on the Island of St. Kitts."

Now, what I'm trying to give an example of is that we don't know where this business is, but we do know there are no Canadian generics of these drugs. We also know that this business is hard to find. It is obviously not a legitimate business selling legitimate drugs. The patients that receive these drugs are obviously getting some sort of fake knockoffs.

Now, proponents of importation would say, "Well, these drugs shouldn't be allowed in." These would not be allowed in under our bills. But our concern, Mr. Chairman, is that our investigators tell us that they can make some minor change in the way this business operates and stay in business. For instance, by establishing a mail drop in Canada, perhaps faking the return address. That would require a lie. But this whole thing is a lie. So these people have no intention of being concerned about whether they are going to lie or not.

We do need to make sure that you understand that these sorts of criminal activities are very difficult to police now, and if we open the borders, our concern is that that becomes even worse.

Let me give you another example of our concern, if I may. It is often stated that these drugs in other countries are the same. We point out that sameness is a very important thing to us because chemical equivalence is not all you need to show a drug.

What I have given you here is an x-ray. This is of a woman who was given a drug that is a calcium pill for osteoporosis. But the drug was not the same as the one the doctor told her to get because it didn't dissolve. It was improperly made. So she was essentially eating rocks. As you can see, these are pills going through her digestive system. They never dissolved in her body, never entered her blood stream, never had any therapeutic effect. But if you took those pills and crushed them with a hammer and did a chemical analysis, it would say it's the same as the U.S.-made drug. It is not the same. This drug would be useless to you, but it will be the same when you do that chemical analysis.

Now, on a similar note, we have three more here that are very commonly ordered by Americans. These are drugs of warfarin, dilantin and synthroid. The issue here is that some drugs need to be very carefully titrated. If you get a little bit too much of warfarin, if this product, which may be a perfectly safe product in Canada, is a little different from the product that the doctor has carefully titrated for the patient in the United States, and the patient gets a little too much, they run a risk of fatal bleeding. And if they get a little too little, they run a risk of blood clots.

For the drug in the middle, a similar thing. A little too much and you're going to have a serious central nervous system effect, and too little and you're going to have a potential for seizures.

These drugs in Canada may be perfectly fine. If the patient went to Canada and was prescribed these drugs and went on these drugs, and the doctor carefully titrated them, they may be fine. But for the patient to start on the American drug and then go to the Canadian drug in our view is posing a serious risk.

The next example is another control we have. We call it transshipment. This is the issue of people in third world countries using Canadian pharmacies and wholesalers to send drugs to our citizens. This is a case of an elderly gentleman in Michigan who ordered a drug from what he thought was a Canadian pharmacy selling American drugs through Canada. He got this drug made in India.

Now, we have seen cases in which third world pharmaceutical manufacturers are saying to these Canadian pharmacies, when your supply starts running low, let us know. We can meet all your needs because we can make all you want here in India, Pakistan and Indonesia.

I don't think the proponents of importation are trying to access those drugs. They are trying to access American-made drugs that have been FDA approved. This drug is not FDA approved, and in our view, is an unsafe product. But transshipment, in our view, is a legitimate concern and I would urge you to think about that as you craft legislation in this area.

The last point I would make is these are counterfeit drugs. The bottom one is counterfeit and the top one is authentic. You can't tell the difference. So to ask the FDA inspectors at the border to open these packages that come in from Canadian pharmacies and visually look at that package and say, "Have I got a good drug here?," he's going to run into these kinds of examples, where he's not going to know.

If I took this to a manufacturer, he wouldn't know. He would have to do sophisticated testing. Obviously, you can't do that with 5 million or 20 million or even 50 million packages that might be coming in under personal importation.

So I hope these examples give you some sense of our concerns, that the theory of good American drugs being in Canada and coming back sounds good from a safety point of view, but in the real world that we work in, we see a lot of dangers out there that would need to be controlled if legislation were to happen in this area.

With that, thank you for giving me the time, Mr. Chairman. Mr. Taylor and I will take questions.

The CHAIRMAN. Thank you.

We will work on a 5-minute timeframe here for questions.

I think, Mr. Taylor, you said that you did four spot checks of mail drops and you found 88 percent of the drugs coming through were counterfeit, adulterated or not appropriate; is that correct?

Mr. TAYLOR. Yes. We did a series of blitzes at the mail facilities last year, in order to help both us and Customs better assess the type of products that were coming into the country. What I said was that we had found a myriad of products that pose potential risks to the consumer, including products that were unapproved, and in some cases, people have said, "Well, an unapproved drug is unapproved in name only and still has the same therapeutic effects."

But one of the products that we found at the mail facility was warfarin, the very product that Bill Hubbard just talked about. It does have potential safety issues because, if the potency is not right, then obviously the benefits that it is supposed to provide are diminished.

We also found a large number of controlled substances, including animal drugs that, quite frankly, are used by body builders and others, and are the favorites of adolescents who want to become larger and stronger.

We found drugs that were withdrawn from the market for safety reasons. We found drugs that were potentially recalled. We had one instance where there was a recall in Canada that occurred for a particular medication. Because we believed that some people were probably purchasing that product over the Internet, we put out a talk paper to the American public, warning them about this potential Canadian recall for the foreign version product. When we did the blitz, we were able to corroborate that, indeed, some people were purchasing this product and receiving it in the mail.

We also found products that were improperly packaged. The continuum ranged from products that were just coming over in a plain plastic bag, to products that had foreign language labeling that neither a physician nor a consumer could possibly understand, thereby making it difficult to use the——

The CHAIRMAN. I don't want to cut you off, but my time is limited.

Mr. TAYLOR. Okay.

The CHAIRMAN. And I think you made that point very well.

I guess my question is this. Is there a way to track imported drugs so that you know whether the pharmaceutical product that

came out of an FDA-approved facility and was packaged and sent to Canada comes back here? Is there some way to do that?

Mr. TAYLOR. Well, to do so, quite frankly, is to put together a model that kind of replicates the current system we have in place in regards to foods. I mean, a couple of years ago Congress gave the agency enhanced authority regarding imported foods, including registration requirements, prior notice, as well as other tools that allowed us to better target products that are coming from overseas and assess the risk and make better decisions as to whether or not to detain a product or not.

The CHAIRMAN. So if we used the template of the authorities we have given you relative to food and applied it to importation of drugs, you might be able to address that?

Mr. TAYLOR. Right, as well as the template we currently have in existence for products that are imported. You can import products into the United States legally if these products come from FDA-inspected facilities, that are manufactured products approved by the agency, and we determine whether or not the active ingredient is proper—and that goes to the issue of whether or not the product works well within the body. We ensure that the product moves properly from the point of entry all the way to the pharmacy shelf and are able to track the product so that, if something happened or led to a recall, we would be able to track the product back.

Those are the kind of steps that we think, if you were going to look at a way to ensure safety, those are some of the things that should be considered.

The CHAIRMAN. What sort of increase in resources would you need to effectively do that, and would you consider a fee system of obtaining those resources?

Mr. TAYLOR. We think that the resource needs are quite extreme. We would need to have people not only—we need to enhance our presence not only at the borders, at the mail facilities, but we would need to enhance our ability to do foreign inspections overseas to determine whether or not the products are manufactured properly. We would need to enhance our resources in order to do any type of enforcement follow up or any kind of criminal cases that might result. We might need to enhance our resources in order to look at the products to make sure they are, indeed, safe.

So we're talking about a substantial number of resources to ensure that any of these legislative proposals are done in a way that ensures what the American consumer is getting is safe and works as intended.

The CHAIRMAN. Thank you.

Senator Kennedy.

Senator KENNEDY. Thank you, and thank you both for testifying.

I know I speak for all of those who are cosponsoring and sponsoring this legislation, that we are eager to work with the FDA to ensure that we have the best in terms of safety. In more recent days we have actually engaged the FDA to try to get their recommendations and their suggestions. You quite properly point out we have the safest system in the world at the present time, but there are still a lot of troubles, as you mentioned here, that need addressing.

Many of us feel that the kinds of protections that we have in the existing proposed legislation will address a number of those items,

because we will have the adequately inspected licensed exporter, licensed importers. We will have the requirements of pedigrees to ensure the kind of safety and security measures that are necessary in terms of the passage of these various kinds of items in the system.

You also remind us about the importance of additional resources, which I think is a given. We obviously have inspectors now that go to plants and FDA inspect all over the world. They do that on a regular basis, but this would mean there would probably be an expansion. But we have taken the concepts that we have accepted, and our committee had accepted—in PADUFA, for example, with the prescription drug, which has worked very, very well. We have extended that concept with the medical device legislation, which is in the process of working as well. It has a few glitches that still have to be addressed, but at least it is working as well, to see if we can't follow that kind of model to try and get the additional resources for the agency to be able to do this, and make sure we are going to have, with this kind of expanded opportunity and availability, not only the best in terms of security in the new legislation, but also address some of the very important issues that you have raised here today.

I would like to just ask if you are willing to continue to work with us—this panel, Mr. Taylor and others—in terms of addressing some of these issues as we move this process along. I think we have solid safety provisions in this. These have been the kind of safety provisions that we will have later on the second panel with Phil Lee, who has been the Assistant Secretary of Health under two administrations, and also has been the Chancellor at the University of California at San Francisco, and dean of one of our great medical schools. We also have the support of Dr. Kessler, of course, who has been the head of the FDA, was up at Yale, now out at San Francisco at the University of California.

So we have attempted to try and get the best in terms of safety and security, because that is a key issue. This is going to be a key item as we are considering this. But to have the kind of strong support that we have had from Dr. Lee and Dr. Kessler—I would ask, Mr. Chairman, that Dr. Kessler's letter be put in the record at an appropriate place. There are 24 other groups that have supported this legislation, and I ask that their letters of support also be included at an appropriate place.

The CHAIRMAN. Well, this isn't a hearing on the legislation, but we will accept it.

[The referred to letters follow:]

RESPONSE TO QUESTIONS OF SENATOR KENNEDY BY DAVID KESSLER, M.D.

May 19, 2004.

Hon. EDWARD M. KENNEDY,
United States Senate,
Washington, DC 20510.

DEAR SENATOR KENNEDY: Thank you for the opportunity to respond to your questions about S. 2328, the Pharmaceutical Market Access and Drug Safety Act of 2004. As a former Commissioner of Food and Drugs, and a current leader of one of the Nation's leading centers for medical research and treatment, I share your concern over the affordability of prescription drugs, and support your efforts to ensure that less costly prescription drugs purchased overseas are safe and effective.

Question 1. Does S. 2328 ensure the safety of drugs imported to the United States? In particular, are there adequate assurances that drugs imported by registered pharmacies and wholesalers and exported to individuals from registered pharmacies in Canada will not be counterfeit and will meet the conditions of approval of the Food and Drug Administration?

Answer 1. It is essential that prescription drugs purchased by Americans are safe and effective. I am certain that FDA, given the proper authority, mandate, and support can ensure the safety of drugs imported into the United States. S. 2328 provides a sound framework for assuring that imported drugs are safe and effective. Most notably, it provides additional resources to the agency to run such a program, oversight by FDA of the chain of custody of imported drugs back to FDA-inspected plants, a mechanism to review imported drugs to ensure that they meet FDA's approval standards, and the registration and oversight of importers and exporters to assure that imported drugs meet these standards and are not counterfeit. As the legislation progresses, I'm sure that adjustments to this sound framework can be made to accommodate legitimate concerns of FDA or other experts and ensure that the legislation works as intended.

Question 2. Will the user fees provided for in S. 2328 provide adequate resources for FDA to police the importation of drugs under the bill?

Answer 2. FDA must be given new and adequate resources to carry out the responsibilities it would have under S. 2328, As commissioner, I oversaw the implementation of the 1992 Prescription Drug User Fee Act (PDUFA). PDUFA has proven that users fees can be an effective means of funding critical agency programs. User fees capped at 1 percent of the value of imported drugs as provided in S. 2328 would give substantial resources to FDA to police drug imports. For example, using CBO projections that 10–15 percent of drugs used in the United States might come in through imports, and assuming that the drugs will be half the price of domestic drugs, the user fee proposal in S. 2328 could result in up to $100 million in new resources for FDA, which would enable FDA to double the center for drugs field budget. It will be important, however, that the Congress work with FDA to ensure that as the drug import program evolves that FDA receives adequate, new funds to support the program.

Question 3. Does S. 2328 provide adequate protections against efforts by drug companies to stop drug importation, such as cutting off the supply of drugs to those entities that export drugs to the United States or changing drugs distributed overseas so that they do not meet the conditions of approval of FDA?

Answer 3. U.S. prescription drug companies have made their products available at substantially less cost in highly developed countries such as Canada, but have then acted to prevent U.S. citizens from importing these less costly versions of their products. The steps you have taken in S. 2328 are effective tools to prevent some of the industry practices that have been documented to date.

Question 4. Do you believe that innovation in the pharmaceutical industry will cease because of drug importation? How will it be affected?

Answer 4. Research and development funding is an expense that should be shared equally by the citizens of wealthy countries throughout the world. Innovation is the heart of the prescription drug industry. The leaders of the industry, its stockholders, and the continuing enormous investment in biomedical research that is occurring at leading institutions around the world will ensure that drug innovation not only continue but accelerates.

Again, thank you for the opportunity to assist you with this important endeavor.

Sincerely,

DAVID KESSLER, M.D.,
Dean, UCSF School of Medicine.

LEADERSHIP COUNCIL OF AGING ORGANIZATIONS (LCAO),
WASHINGTON, D.C., 20006,
May 19, 2004.

DEAR SENATOR: The undersigned members of the Leadership Council of Aging Organizations (LCAO) are writing in support of S. 2328, the Pharmaceutical Market Access and Drug Safety Act of 2004. We commend the bi-partisan group of original co-sponsors for their leadership on this issue.

S. 2328 will allow individuals to safely buy prescription drugs from Canada—and pharmacists and wholesalers to safely buy from the world's major industrialized nations—at prices that will be substantially lower than domestic prices. Most impor-

tantly, the bill gives the Food and Drug Administration (FDA) necessary resources to ensure the safety of the imported drugs, while also preventing attempts to thwart the intent of the bill by forms of market manipulation.

As representatives of senior organizations, we have long been concerned that the increasing cost of prescription drugs has caused millions of consumers to go without the medicines they have been prescribed and/or has forced them to cut dosage, thus deviating from recommended courses of treatment. The double-digit rate of drug inflation has also been a major strain on State Medicaid budgets, forcing many States to cut back on coverage.

Because the new Medicare law does so little to restrain the rate of drug inflation, its benefit to seniors will rapidly erode. For example, according to the Congressional Budget Office, the "doughnut hole" grows from $2,850 in 2006 to $5,044 in 2013, and the share of beneficiaries' income consumed by prescription drug costs will increase dramatically.

This bill will provide much-needed help to Medicare and Medicaid recipients. Individuals, States, State purchasing pools, and Medicare drug plans will all benefit. We urge you to co-sponsor this important bill. We look forward to working with you to pass S. 2328 this year.

Again, we thank the bi-partisan group of original co-sponsors for their leadership on this important national consumer issue.

Sincerely,

AFL-CIO; Alliance for Retired Americans; American Federation of Teachers; American Public Health Association; Association for Gerontology and Human Development in Historically Black Colleges and Universities; Association of Jewish Aging Services of North America; B'nai B'rith International; Eldercare America; Experience Works; Families USA; Gray Panthers; International Union, UAW; National Adult Day Services Association; National Association of Professional Geriatric Care Managers; National Association of Retired and Senior Volunteer Program Directors; National Association of Retired Federal Employees; National Association of Senior Companion Project Directors; National Association of State Long-Term Care Ombudsman Programs; National Association of State Units on Aging; National Committee to Preserve Social Security and Medicare; National Indian Council on Aging; National Seniors Center Law Center; OWL, the voice of midlife and older women; Volunteers of America.

ORGANIZATIONS SUPPORTING S. 2328—THE PHARMACEUTICAL MARKET AND DRUG SAFETY ACT

1. ActionAIDS
2. AFL-CIO
3. AFSCME
4. AIDS Survival Project
5. Alliance for Retired Americans
6. American Association on Mental Retardation
7. American Federation of Teachers
8. American Public Health Association
9. Association for Gerontology and Human Development in Historically Black Colleges and Universities
10. Association of Jewish Aging Services of North America
11. B'nai B'rith International
12. Boston Health Care for the Homeless
13. Citizen Action (Illinois)
14. Congress of California Seniors
15. Disability Rights Action Coalition for Housing (DRACH)
16. Eldercare America
17. Experience Works
18. Exponents
19. Families USA
20. Frontline Hepatitis Awareness
21. Gray Panthers
22. International Union, UAW
23. Minnesota Senior Federation
24. National Adult Day Services Association
25. National Association of Professional Geriatric Care Managers
26. National Association of Retired and Senior Volunteer Program Directors
27. National Association of Retired Federal Employees
28. National Association of Senior Companion Project Directors

29. National Association of State Long-Term Care Ombudsman Programs
30. National Association of State Units on Aging
31. National Committee to Preserve Social Security and Medicare
32. National Indian Council on Aging
33. National Seniors Center Law Center
34. NETWORK: A National Catholic Social Justice Lobby
35. OWL, the voice of midlife and older women
36. Provincetown AIDS Support Group
37. San Francisco AIDS Foundation
38. Senior Action Network
39. Service Employees International Union (SEIU)
40. Southeast Kansas Independent Living (SKIL)
41. Statewide Independent Living Council of Illinois (SILC of IL)
42. Tennessee AIDS Support Services, Inc. (Knoxville, TN)
43. Topeka Independent Living Resource Center, Inc. (TILRC)
44. TREA Senior Citizens League (TSCL)
45. Triad Health Project
46. Volunteers of America

Senator KENNEDY. My time is up, but knowing that we can continue to work with you on these issues of safety, which are very, very important, is enormously important. If there are additional ideas, we are obviously hopeful of getting them.

I thank the chair.

The CHAIRMAN. Senator Enzi.

Senator ENZI. Thank you, Mr. Chairman. I appreciate your holding this hearing.

I have been looking at this important issue and notice that Canada is only 10 percent of the U.S. market, so I am questioning how much of an impact we're going to have on them or they're going to have on us.

But one of the things I did notice was that the Canadian Internet pharmacies are largely based in Manitoba. Is there something about the law or regulations governing pharmacies in that province that is different from other places in Canada? Do either of you know?

Mr. HUBBARD. The Manitoba provincial government has been somewhat supportive of these pharmacies. They bring a lot of jobs and revenue into the province. Drug sales in Canada are very much decentralized at the provincial level, so there has been a surge of these international pharmacies in that particular province.

They exist in other provinces as well, but Manitoba has probably had 80 percent or more of the international pharmacies.

Senator ENZI. Thank you.

Since S. 2328 has come up, it does not require FDA approval on an imported drug. It creates a presumption of FDA approval under certain circumstances.

Could you describe the difference between actual FDA approval of a drug and a presumption of FDA approval of a drug? Either of you.

Mr. Taylor.

Mr. TAYLOR. I think what the bill attempts to do is to set up a standard of pharmaceutical—what it attempts to do is try and set up a construct that allows products that are sold in other countries to come into the United States based on a determination that they are pharmaceutically equivalent to the FDA-approved version,

which means they have the same ingredients, the same formulation, roughly the same potency.

The concern that we have is that pharmaceutical equivalence is not the same as therapeutic equivalence, and the reason that is important is because, as Mr. Hubbard stated earlier, two products can have the same active ingredients, can be manufactured in the same way, but still work differently within the body.

To illustrate the point, there are certain products that are terribly sensitive, and if the product does not dissolve properly into the blood stream, the product will not have the health benefits that one would expect. So that's the reason why we have engaged in a dialogue and provided some input on why we think the pharmaceutical equivalence is not as strong as a therapeutic equivalence standard that we use now to look at our generic drugs.

Senator ENZI. Thank you.

Following up on that, Mr. Hubbard, you had that great picture of the undissolved calcium tablets. I want more information on that. You said if you crushed them with a hammer, they would have the same active ingredients——

Mr. HUBBARD. The correct drug and this drug both contain calcium. It often comes from oyster shells or something like that. The intent is that it be bound with stabilizers or other binders of so-called inactive ingredients and crushed into a tablet form. Then when the individual swallows it, it reaches the stomach and begins to dissolve. Once that dissolution occurs, the active ingredient enters the blood stream and has a therapeutic effect. In this case, I think it basically goes to the bones and keeps bone loss from occurring.

This product apparently had improper binders and was crushed perhaps too—was compressed too hard, so that it would not dissolve in the stomach. But as I said, if you did a chemical analysis of it, you would find basically the same drug of the proper drug.

Senator ENZI. So under a presumption it would be approved——

Mr. HUBBARD. That's right. Unless there was a system in place to make sure that that difference was caught, then that would be viewed as an FDA-approved drug because it would be the same as an FDA-approved drug, chemically.

Mr. TAYLOR. Senator, we have had some counterfeit drug cases where the drugs are pharmaceutically equivalent. However, they were obviously not the FDA-approved drugs. They were merely marketed in a way to suggest that they were.

Senator ENZI. Another issue that has been brought up is having a full paper pedigree on drugs, whether they are imported or not, or perhaps electronic pedigrees.

Would it be easy for somebody to counterfeit a paper pedigree, would it be more difficult with an electronic one, or would it make any difference?

Mr. HUBBARD. A pedigree currently is nothing but a piece of paper, a document that says this drug was made here, sold to this wholesaler, and then sold to this pharmacy. Any of us could counterfeit that fairly easily.

Electronic pedigree, however, which the industry is developing, is much more difficult to copy, because you not only have to copy the electronic mechanism—in this case, probably a computer chip—but

you then have to find a way to break into the database and get it into the computer database that your fake product is a real product. That is going to be really hard. So electronic pedigrees are in the future and they will substantially help combat counterfeiting of drugs.

Senator ENZI. Thank you. My time has expired.

Thank you, Mr. Chairman.

The CHAIRMAN. Senator Reed.

Senator REED. Thank you, Mr. Chairman. And thank you, gentlemen, for your testimony.

We have talked a lot about counterfeit drugs, but I understand that the FDA has continued to delay a final rule related to the wholesale distribution of prescription drugs under the Prescription Drug Marketing Act, and part of that rule would be touching upon a voluntary trace and track system that could contribute to identifying the source of drugs.

If this is such a problem, why is the agency not moving more aggressively to promulgate a rule?

Mr. TAYLOR. Senator, as we noted in the report that the department put out this summer on counterfeit drugs, what we said in that report was that we felt the track and trace technology was a stronger approach for combating counterfeiting for the reasons that have been noted today, and we thought that was the approach that we were encouraging industry to adopt in the future. We have thrown our weight behind trying to ensure that that approach is developed and adopted, hopefully by 2007.

What we have done as a result of that is we have, as you have said, stayed the PMA rule relating to pedigrees. We originally stated because there were legal issues with the implementation of that reg that were brought to our attention. We sent a report to Congress highlighting these legal issues and have sought advice from Congress on how to resolve these issues.

In the meantime, what we have explored is a track and trace technology which we feel is a better approach in the future to ensuring that the drug supply chain remains secure.

Senator REED. Do you have the authority to mandate that track and trace system in order to protect the quality and the safety of drugs?

Mr. TAYLOR. We have not mandated——

Senator REED. Do you have the authority to do so, Mr. Taylor?

Mr. TAYLOR. I don't know. I would have to get back to you on that, sir.

Senator REED. That's an important question, I think, because one of the issues here is—and you have both testified very eloquently—is to ensure that quality is there, efficacy is there. One of the problems we seem to have is that we just don't know where these drugs are coming from. We don't know if it's the drug that it says it is on the label. But if we have a track and trace system, which you are confident in, it should be deployed as quickly as possible.

Mr. HUBBARD. If I may interject, we thought about the requirement but determined that the industry wants to move in this direction. For us to freeze the industry while we go do 2 or 3 years of rulemaking might actually take longer. We think the industry is working very quickly to put it in place.

Senator REED. The logic of that escapes me. If the industry is doing it, why would you freeze them if you say 3 years from now you're going to have to do it?

Mr. HUBBARD. We have learned from experience in bar coding, for instance, that they tend to wait and not invest in the technology until they see what FDA is going to require, so that they don't misjudge and invest in the wrong technology.

Senator REED. At least some might say that, as long as this situation is confused, as long as you can't effectively trace the source of pharmaceuticals, that is the strongest argument against importation. If that were to go away, then there is no argument left for the industry.

Would you comment on that?

Mr. HUBBARD. We have certainly said in our counterfeit report from last year that development of track and trace technology will make it much more possible to ascertain whether a given drug is the real drug or not, so we agree with you, that track and trace technology needs to be in place. Our report was very firm in saying the industry should put it in place, and we gave them actually a bit of a deadline of 2007. But it is a big investment for them and it will take some time to develop.

Senator REED. Mr. Taylor.

Mr. TAYLOR. We were very positive about track and trace technology in our report. But let me just raise a cautionary note. We also in that report were seeking input on other ideas that might be just as strong in securing the drug supply chain, because we should not look at any one approach or any one technology as fail safe.

One of the true lessons learned right now in regards to counterfeit drugs is that the technological capability of counterfeiters is increasing and they have become much more savvy. As a result, one of the things we emphasized in our counterfeit report is that it is not embracing just one approach, if you're an industry member or a part of the drug supply chain, but instead, using multiple tools, including track and trace, to ensure that if one part of your secure mechanism is breached, it would not make it easy for someone to counterfeit your product.

So what we advocated was looking at a comprehensive system, track and trace or something similar as a part of it, but I did not want to leave here advocating any one approach as being a fail safe approach because we have seen people overcome so far many of the technologies that have been introduced.

Senator REED. I appreciate that point, Mr. Taylor, and you will advise if you require any legal authority.

But as we debate these different techniques, the issue is not being addressed. Sometimes you just have to set a standard, as they do so often in industry, and industry rapidly adapts.

One final question, if I may. The Kennedy bill, which is an interesting piece of legislation, I am told does not set a standard of pharmaceutical equivalency. It requires that any imported drug be FDA approved under the same standard in section 506(a) that the manufacturer would have to meet.

I wonder if I could have your comments on that point.

Mr. TAYLOR. I think the distinction here is that, in regards to the approval of generic drugs, we look at the bioequivalency of the two products. What I mean by that is, using the example that Mr. Hubbard showed of the calcium in the chest cavity, what that bioequivalence or bioavailability or substitutability ensures is that the product works exactly like the FDA-approved innovator drug. Bioavailability is a crucial component of that.

The concern that we have articulated in regards to this bill is that the standard that is used does not capture bioequivalency. It talks about potency, which goes to the strength of the drug, but that is not the same as ensuring that the product provides the very benefits that it is intended to provide.

Senator REED. Thank you very much, Mr. Taylor and Mr. Hubbard.

Thank you, Mr. Chairman.

The CHAIRMAN. Senator Alexander.

OPENING STATEMENT OF SENATOR ALEXANDER

Senator ALEXANDER. Thank you, Mr. Chairman. Thank you for your testimony.

Under current Federal law, importation of drugs is allowed if the Secretary of Health and Human Services says that it may be done in a safe and effective way. We have had two well-respected Secretaries of the Department of HHS over the last 12 years.

How often have they exercised their authority to allow the importation of drugs?

Mr. TAYLOR. They have not, to date. The implementation of those pieces of legislation would be triggered by the certification of the Secretaries. As you noted, both Secretary Shalala and Secretary Thompson——

Senator ALEXANDER. So over the entire 8 years of the Clinton administration and so far in the Bush administration, Secretary Shalala and Secretary Thompson, neither one have exercised the authority they now have for importation?

Mr. TAYLOR. Senator, if I recall, it was Senator Jeffords' bill that first put out this authority. I think that was in 1999 or 2000, so it hasn't been——

Senator ALEXANDER. Right. So far they have not——

Mr. TAYLOR. So far, that's absolutely right.

Senator ALEXANDER. Why did they say they didn't do it?

Mr. TAYLOR. Because they felt they could not certify that the piece of legislation would allow safe and effective products to make their way to the U.S. consumer.

Senator ALEXANDER. Would it be possible now for the administration to adopt its own procedures for allowing the importation of drugs without legislation from Congress under this preexisting authority?

Mr. HUBBARD. If I may, Senator, the legislation you referred to is still on the books.

Senator ALEXANDER. I understand.

Mr. HUBBARD. The Secretary could theoretically certify today, but the Secretary has determined he can't do that.

Senator ALEXANDER. What I'm asking is, why do we need another law if you already have a law saying you can do it, and the

only reason you are not doing it is because two administrations have said it can't be done in a safe and effective way?

Mr. HUBBARD. I think Secretary Thompson has noted that FDA currently does have the resources and authority to oversee a safe importation system.

Senator ALEXANDER. So you need more money and a larger system to try to set up a safe way to do that?

Mr. HUBBARD. That is what he has said.

Senator ALEXANDER. May I ask one other question.

Senator Kennedy mentioned research. One of the great things about our government is that we fund a lot of research, $19 billion a year for various types of research just to our universities, but there are different kinds of research.

Do you know how much money drug companies spend on research for new products in the United States each year?

Mr. TAYLOR. Sir, I personally do not.

Senator ALEXANDER. Do you suppose you could help me get that figure?

Mr. TAYLOR. Sure.

Mr. HUBBARD. I think it is in the range of $25- or $30 billion a year.

Senator ALEXANDER. Isn't the kind of research the Federal Government funds at universities and at energy laboratories different from the kind of research that drug companies do in developing specific products for market?

Mr. HUBBARD. It is generally noted that NIH and NSF and others fund more basic research on how disease might occur, whereas drug companies do what is often called applied research, which is actually turning basic research into a product that can treat disease, such as, in this case, a pharmaceutical.

Senator ALEXANDER. So if I were worried about a stroke or infected with HIV or had Parkinson's disease, I might hope that the NIH sponsored research would be the basic research, but that the $25–$30 billion that the drug companies spend would take the basic research and bring it along and bring it to market?

Mr. HUBBARD. That is generally what happens, yes.

Senator ALEXANDER. How much of that kind of research is spent in countries outside of the United States by private companies? Do you know anything about that?

Mr. TAYLOR. I don't know, but——

Senator ALEXANDER. Would you assume it is not much?

Mr. TAYLOR. Senator, I wouldn't presume. I mean, we can certainly——

Senator ALEXANDER. Could you supply that? I would like to have a fair and honest idea, if we create a system that sets the price of drugs at about the cost of distribution, what will happen to the $25- or $30 billion that drug companies use for research to bring new innovations to market.

Mr. TAYLOR. We would certainly be happy to get back to you on these questions.

Senator ALEXANDER. I would appreciate that.

Thank you, Mr. Chairman.

The CHAIRMAN. Senator Murray.

Senator MURRAY. Thank you, Mr. Chairman. I would like to submit my full statement for the record.

The CHAIRMAN. Absolutely.

[The prepared statement of Senator Murray follows:]

PREPARED STATEMENT OF SENATOR MURRAY

Mr. Chairman: Access to quality, effective and affordable prescription drugs should not come down to finding the best deal on the Internet.

I share the frustrations of my colleagues regarding the excessive price the American consumer must pay for many drug treatments.

It hardly seems fair to have American consumers paying 50 percent or even 100 percent more than Canadians or Europeans pay for the same drug.

I recognize that American consumers often have faster access to new drug therapies and have more choices as well. But, unfortunately, for seniors and the uninsured, there is no choice. They simply go without.

Reimportation may offer a mechanism for greater price competition in this country. But, we should not allow the rush to import drugs reduce our high safety standards.

We often take it for granted that we have one of the safest drug supplies in the world—from drug approval to manufacturing and distribution. The FDA standard is truly the gold standard.

As members of this committee know, getting the drug to the patient is not just about having the drug approved. There are a number of safeguards to ensue the integrity of the product.

I am also concerned that the focus on reimportation or importation of prescription drugs as a savings mechanism for seniors and the uninsured can take the focus off what we should be talking about.

We should be talking about an affordable, prescription drug benefit within Medicare that does not have coverage gaps or limitations and that offers a seamless benefit as part of the Medicare defined benefit package.

We should also be talking about access to quality, affordable health care, including prescription drugs for the 44 million uninsured.

I look forward to the testimony of today's witnesses and hope that this committee will take the time to ensue that we do not jeopardize patient safety in the rush to reimport drugs.

Senator MURRAY. Thank you very much for your testimony. I think all of us are concerned about the price of drugs, and I certainly live in a border State where many of my constituents tell me they drive to Canada to get drugs.

One of the things I often hear from them is why are we so worried about this issue of safety. We don't know of a lot of Canadians who are dying because they got the wrong kind of drug.

What is your response to them on that?

Mr. TAYLOR. Well, I think it is in two parts. One is that the reason we're concerned about safety is because our job is not to wait until people are harmed. Our job is to try to prevent harm from occurring. Even though we do not necessarily expect acute harm from some of these products, based on some of the products that

we have seen, both in the blitz that I noted earlier and in our counterfeit drug cases, one of the concerns is that, even though these products might not initially harm you, they might not be delivering the benefits that were promised when someone sought the use of the product.

For example, in the counterfeit Lipitor case that led to the recall of 250,000 bottles last summer, our concern was that the product was manufactured in a way so that it probably was not going to deliver the cholesterol lowering benefits that were promised.

We have had other situations where products were manufactured in a way so that they have an active ingredient, just like the FDA-approved product, but because the active ingredient is either subpotent or superpotent, the product will not work as intended. The patient might never be harmed, but they will not get the therapeutic benefits that——

Senator MURRAY. Is that happening a lot in Canada today? Are we seeing a lot of those kinds of drugs sold, or is this just because our constituents go up there, they purchase something in a drug store that is then inspected and bring it back different than re-importation?

Mr. TAYLOR. Well, our general concern is because the breadth and number of products that are coming to the country make it more likely that you will see products that are of poor quality. We are unable to inspect every package. We don't know the origin of many of these products. We have had more than one occasion where a consumer has——

Senator MURRAY. But doesn't Canada know, if you're going up there to purchase it?

Mr. TAYLOR. In some cases, the Canadian government has stated that their authority does not extend to products that come into Canada that are intended for the U.S. consumer. So that is a gap in the regulatory——

Senator MURRAY. I think most people assume that the products they purchase in Canada have been inspected by Canadian authorities. You're saying to me, if they come in there from a third country to be exported, they are not?

Mr. TAYLOR. That is correct.

Senator MURRAY. So we would not know if products coming back were inspected if they were purchased someplace else and just came through Canada?

Mr. TAYLOR. Yes. Our general message is that in some cases the products will be perfectly fine. But the over-arching public health concern that FDA has articulated is that we simply don't know very much about the products that are being sold in——

Senator MURRAY. So you are not so worried about somebody going up and buying a product on a Canadian pharmacy shelf and bringing it back, as you are purchasing larger quantities that could perhaps not be made in Canada and inspected there?

Mr. TAYLOR. We are concerned about any instance where the purchasers—we are worried about any instance where the origin of these products is unclear. Many have drawn the distinction between walking to your pharmacy and purchasing a product there, versus purchasing a product over the Internet site. They have made that argument. But the bottom line is knowing the product

history and knowing the origin of the product, so that there is some assurance that the product will work as intended.

Senator MURRAY. Drugs that are manufactured in Canada for export only, are they subject to Canadian health inspection? If they are manufactured in Canada but not for consumption there but are for export, are they inspected?

Mr. HUBBARD. I don't know. I do know, Senator Murray, that a drug made in another country that is exported to Canada for reexport, say, to the United States, is generally not covered by their FDA, just as in this country, our FDA doesn't regulate a product that is transshipped to the United States.

Senator MURRAY. I assume, then, that the concern you have is that those products coming into this country would then have to be inspected by FDA and you don't have the capacity to do that?

Mr. TAYLOR. At this current time we certainly don't have the resources to do so. But our regulatory system, as set up right now, is geared to doing foreign inspections pursuant to the act's current provisions, which means that, as I noted earlier, we do inspections of those facilities that have a product approved and will be introduced in the United States, to make sure that it is manufactured properly. That is really the full bulwark of our foreign inspection regulatory system.

Senator MURRAY. Have you done any cost analysis of the House passed bill or any similar measures on what it would cost FDA to——

Mr. TAYLOR. In our discussions with Senate staff 2 days ago, we do have some getbacks regarding cost, but our current estimate is that we are talking about hundreds of millions of dollars to ensure that we have the appropriate resources in place to make sure that safe products are coming to the United States.

Senator MURRAY. Okay. Thank you very much.

The CHAIRMAN. Senator Mikulski.

Senator MIKULSKI. Thank you very much, Mr. Chairman. I, too, would ask unanimous consent that my statement go into the record.

The CHAIRMAN. Absolutely.

[The prepared statement of Senator Mikulski follows:]

PREPARED STATEMENT OF SENATOR MIKULSKI

Mr. Chairman, thank you for calling this important hearing today on reimportation of prescription drugs.

The ballooning cost of health care is one of the biggest problems facing American families, especially the skyrocketing cost of prescription drugs. In 2002 alone, prescription drug costs grew more than 15 percent. Last year, Americans spent $184 billion on prescription drugs. Families are being squeezed, and so are businesses. Rising health insurance costs mean employers pass on more of their costs to their employees in higher co-pays for prescription drugs and more out-of-pocket costs for patients, or they stop offering health insurance altogether.

Americans are paying more for their prescription drugs than anyone else in the world. This is unfair and offensive. Americans should not have to pay more for access to medicines that come from

innovation and research conducted right here in the United States, funded by taxpayer dollars.

That's why I'm proud to cosponsor the bipartisan Pharmaceutical Market Access and Drug Safety Act introduced by Senators Dorgan, Snowe and others. If passed, this legislation will help Americans get the same drugs for lower prices and put in place new safeguards against counterfeit drugs. It meets the day-to-day needs of Americans by helping them get the medicines they need at a price they can afford. This legislation would allow individual Americans to import drugs from Canada. It would also allow pharmacists and wholesalers to import drugs from 19 other industrialized countries.

Americans must have access to affordable drugs, but they must also be safe to use whether they are from this country or another country. The Food and Drug Administration (FDA) is the gold standard for approving safe and effective drugs. Congress must help ensure a strong safety standard for imported drugs. That's one of the reasons I'm supporting the Dorgan/Snowe legislation. While it opens the door to consumers to buy drugs from Canada, it also puts in place stronger and smarter tools to prevent unsafe drugs from reaching American consumers. To protect the health of the American public, the bill requires: tracking of drugs from manufacture to sale, frequent FDA inspections of importers and exporters, and additional resources for FDA to do the job. It also gives FDA the ability to ban imported drugs that are counterfeit, contaminated, or adulterated. These are important measures that must go hand-in-hand with reimportation itself.

Reimportation is just one tool to help make prescription drugs more affordable to Americans. To get a grip on drug costs, Congress must pursue a number of policies that combined will make a difference in the lives of American families. Last year, Congress helped improve access to lower-cost generic drugs. But last year's Medicare drug law doesn't do enough to get a grip on rising drug costs. In fact, Medicare is prohibited from using the purchasing power of the Federal Government to negotiate better prices for seniors. That's what VA does, and it works. VA negotiates discounts on drugs of 25 percent or more. That saves veterans money and it saves taxpayers money—$1.1 billion over the last 3 years. That's why I am fighting for legislation that encourages Medicare to negotiate lower prices.

I know that drug companies must have the resources to invest in research and development, so they can make the breakthroughs that lead to new treatments and cures. That's why I support entrepreneurship and extending the research and development (R&D) tax credit. But drug company bottom lines aren't the only lines that are important. What about the people standing in line at the pharmacy? The Federal Government must be on their side, making sure they can afford the medications they need.

I look forward to hearing from our witnesses today about how Congress should design the best framework to allow Americans access to safe, imported prescription drugs. I know there are several proposals on the table. I hope that this committee can take the best ideas and put them to work to lower drug costs for Americans.

Senator MIKULSKI. Mr. Chairman, thank you for organizing this hearing, because the cost to the American family for buying pre-

scription drugs, I believe, is at a national crisis. It is stressing not only our seniors who need them for a lifeline and chronic illness management, but also for young families. If you're a young woman who has MS or Lupus, you're having a hard time paying for your drugs. If you have a child with asthma, autism, juvenile diabetes or others, families of all ages are wondering how are they going to be able to afford the lifeline.

This is a national crisis. The Medicare bill we passed is really a hollow opportunity. The reason people are going to the Internet and crossing the border is out of desperation. So what we do know then is that where there is need, there will be greed, and where there is greed, there are scams and schemes. The way you deal with the scams and schemes is to come back and deal with the need, which is how can we get drug costs under control in our own country without shacking the emerging biotech companies as well as our pharmaceutical industry.

So that's what we need to come to grips with. We need to recognize at this hearing—and, really, I am very proud of FDA; it's headquartered in my own State—their vigor to protect the consumer from a safety standpoint. But if we don't come up with a framework to do it, it is still going to go on. People are either going to do it in the sunshine, in a regulated environment, or they're going to go underground, bootleg, and that is where we're going to get all kinds of very, very sad outcomes, like the wonderful Malone family has had to grapple with in their own lives. It is going to happen because drug costs are beyond the reach of many people each day.

Then that takes me to my question. We are talking about reimporting primarily from Canada, and I would like to focus on Canada. What does Canada tell us about this? Has FDA reached out to Canada? Has their trade representative reached out to Canada? Has our American Ambassador to Canada said, "Look, we've got folks coming in by bus, and we've got them coming in by the Internet. How can we ensure the safety and efficacy of our people?"

Have we engaged the Canadian government in helping us be able to do this?

Mr. HUBBARD. Many times, Senator Mikulski. In fact, we have had a number of discussions with Health Canada about whether they could assure the safety of drugs. What they tell us is, just as we might say to anyone if the situation were reverse, that Health Canada is responsible for assuring the safety of drugs for Canadian citizens. We have said, if you walk into a Canadian drug store, you are probably going to get a good drug.

But these Internet sales, these international pharmacies that sell across the border, are viewed by Health Canada as the responsibility of the American FDA. They cannot assure that those exported drugs will meet American standards.

Senator MIKULSKI. Do the Canadians manufacture drugs in their own country under an American patent drug, or do they import American drugs and, because of the Canadian nationalized system, buying in bulk and a variety of techniques in their own price controls, does the Canadian government manufacture the primary drugs? And we all know what the basic 40 or 50 are, that are being used safely in the management of chronic illness.

Mr. HUBBARD. I don't believe the government manufactures any drugs. However——

Senator MIKULSKI. I'm not talking about the government. I'm talking about, are drugs manufactured in a country that is a wonderful ally, a great neighbor, and shares our ethical framework around safety and efficacy?

Mr. HUBBARD. As we understand it, drugs in Canada come from a variety of sources. Some of them are American made drugs that were exported to Canada for sale there. Some are made by Canadian subsidiaries of American companies. Some are made by independent Canadian companies, and some are even imported from other countries.

Senator MIKULSKI. We then have a framework for getting those drugs back. In other words, those that go there that we make here, and those that are made under Canadian standards, which I think by the very nature of our long-standing relationship with Canada, we know that we could either count on them to have safety, because that is a value in their own country and so on, so we could do that, if we then even focused on that limitation; am I correct?

Mr. HUBBARD. You must understand, Senator, our problem is that people like this say they are good for people but they're not.

Senator MIKULSKI. Mr. Hubbard, I know what you said about the people like that. Mr. Hubbard, please. I'm not trying to be abrasive with you. I'm trying to pinpoint.

Now we have big broad brush issues to try to get at it. If we focused only on allowing those imports limited to the categories I just said, would we be on to something and then prohibit this type of regulation because of exactly what I said, the scammers, the schemers, who in their greed are preying on the American people?

We want to make sure the bad guys aren't doing back things to our people, so we're on the same broadband here. But if we limited maybe our focus to those drugs that are manufactured in this country, sent there and then sent back—that's what reimportation means. It means we're reimporting, and then also those that would be made in a Canadian facility that could be a subsidiary of an American company and so on.

What do you think about that?

Mr. TAYLOR. I think that to the extent that you are defining a set of permissible drugs, whether they be from Canada or somewhere else, the key will still be making sure that whatever construct is in place, that you're allowing the permissible drugs to come in but not allowing the impermissible ones to come in behind them. That goes to the resource issue, making sure that you have the appropriate personnel to ensure that the products that are coming in have the requisite safety.

So my response is, you know, you can set that up, but there still needs to be the infrastructure and the personnel to ensure the safety of those products that are deemed impermissible or outside the rubric that you have defined.

The CHAIRMAN. Thank you, Senator.

Senator MIKULSKI. I agree with that, and I would agree that that's a very important issue. But I think we can do better and I think we can be more creative in our thinking.

The CHAIRMAN. I think the Senator is going to want to look at the bill I introduce next week. Your questions are exactly on point as to what my bill does.

Senator Clinton.

Senator CLINTON. Thank you, Mr. Chairman.

I'm just trying to make sure I understand what our witnesses are telling us, along with my colleague and friend, Senator Mikulski. Am I hearing that if you had the resources and the authority that you think you need to conduct this kind of function, you would not have any objection to trying to do it?

Mr. HUBBARD. The administration has taken no position, but FDA has said, if we had the resources and authority, we could presumably set up a system in which you could allow safe imported drugs, or at least ameliorate the safety concerns, in a very substantial way.

Senator CLINTON. You made an analogy earlier to what FDA does in inspecting food. I think the FDA has claimed over the years, with good cause, that we do have the safest food supply in the world. Would you agree with that statement?

Mr. TAYLOR. I think we have a very safe one. I'm not sure it's the strongest, but I think we do a very good job in light of the increasing number of imports coming in. I think that our ability to do that job is enhanced by both the provisions in the Bioterrorism Act, in conjunction with the resources that were appropriated that allowed us to bring those provisions to life. We are currently implementing those now.

Senator CLINTON. Yet my understanding is we still only inspect 2 or 3 percent of the food that is imported into the country.

Mr. TAYLOR. That is correct.

Senator CLINTON. And we also have, according to the Centers for Disease Control, every year 76 million people getting sick, more than 300,000 are hospitalized, and 5,000 die from diseases caused by foods.

So even if you have an enhanced system that you think is doing a good job, there is still going to be problems. You keep working to try to improve that system to try to get the problems out of it so that you can make the food system even safer. Is that right?

Mr. TAYLOR. Correct.

Senator CLINTON. So from my perspective, part of what we are trying to do here, with the legislation that has been introduced and other legislation that is coming, is to begin that process with respect to importing or reimporting drugs. Because it is also the case, isn't it, that we have a large problem of counterfeiting right here in the United States. We have counterfeit drugs made in the United States and sold in the United States, isn't that right?

Mr. TAYLOR. That is right, Senator. But the difference is that our ability to address and investigate and identify and prosecute those counterfeiters is strengthened here in the United States because we have the jurisdictional ability to do so.

I'm not suggesting that counterfeits only exist overseas, but what I am saying is that when we identify a counterfeiter domestically, we have additional tools that enhance our ability to identify the counterfeiter and bring that counterfeiter to justice. We just simply now, when we discover the counterfeiting is occurring overseas, we

often have to work with the regulatory authorities overseas or work with the Customs posts or embassies overseas. It just presents a greater challenge.

Senator CLINTON. I think that one of the areas that we need to explore as we begin to open this up is how we enhance cooperation. I know that the European Union has already adopted a technology to secure pharmaceutical packages. It costs very little per package, and it is state-of-the-art anticounterfeiting. So I think there are things we can learn from other places in the world as we try to figure out how to exist in this global market.

Because as my colleagues have said, we're going to have a flood of drugs and supplements and all kinds of things coming into our country because people can get on the Internet. You're not going to look at every package that is delivered everywhere in the world.

Let me also ask with respect to Mr. Hubbard's question. You claim that drugs imported under the proposal might not be bioequivalent—and that's the calcium pill that doesn't dissolve. Isn't it true that any drug that is different than the U.S. drug must be approved by the FDA under section 506(a)?

Mr. HUBBARD. Yes, Senator. If you're speaking of one of the bills that is before the committee, that is anticipated. There would be a review. I think our concern would be that there would be a huge resource cost and questions about our ability to deal with all that data.

Senator CLINTON. I understand that. Of course, the FDA came into being in response to the problems at the beginning of the last century, and we created it because we had adulterated foods, we had adulterated drugs, and we had to do what needed to be done in the 20th century to deal with those problems.

Well, now we're in the 21st century. We have new problems. We are going to have to give you new resources, new authorities, in order to deal with what is a problem. Whether we pass this legislation or not, it is not going to go away. You are still going to be dealing with a flood of imported and counterfeited drugs and other kinds of supplements that are coming in.

You know, I think what we're looking for is as positive an attitude from the FDA as we can get. You are the experts. You are the ones trying to keep our food supply and our pharmaceuticals safe. But we have to think for the future. We can't continue to keep doing business the way we have done. It is not going to work. People are going to get those drugs, whether they go by car or get it in the mail. So we need a new system, and we need your help to develop that new system.

Mr. TAYLOR. Senator, as you know, the Secretary has been asked to look at and consider many of these issues in response to the conference report that was attached to the Medicare prescription drug plan. To help him do so, he has convened a task force that has held listening sessions and public meetings, and these are some of the very issues that that group is looking at and considering.

Senator CLINTON. Look, Mr. Taylor, we might as well just put it on the table. We know that the pharmaceutical industry does not want this done, and we know how much influence they have within our Government. Whatever administration, whoever is at the FDA, it is a constant battle. We are well aware of that.

What we are looking for is to try to at least even the playing field a little bit, as difficult as that might be, and to try to provide some of the additional authorities and resources so that the FDA can get into the 21st century.

I mean, I don't think the pharmaceutical industry can withstand the onslaught of counterfeiting that is going to occur because people are desperate. I don't think they can stand the onslaught of reimportation because people are desperate.

Finally, you know, we have no evidence of anyone being hurt by drugs obtained from Canada. And yet we have 30 percent of our seniors who have not filled a prescription because they can't afford it. So we need to look at this in the broader context. I would wish that the drug industry and the FDA would be partners in our trying to do our job, which is to protect people, but also provide affordable, safe pharmaceuticals to take care of the needs of the American people.

It is not fair any longer for the American taxpayer, consumer and patient to be at the bottom of an inverted triangle supporting the drug research and development for the entire world. That's not fair. So we're looking for some kind of solution here. We understand the problems and we think we can solve this.

[Applause.]

The CHAIRMAN. It is the tradition of this committee that we don't have demonstrations during the committee hearings, but we appreciate the statement from the Senator from New York.

The gentleman from Connecticut.

Senator DODD. Thank you, Mr. Chairman.

Let me first of all ask unanimous consent as well, that my opening statement be included in the record.

The CHAIRMAN. Without objection.

[The prepared statement of Senator Dodd follows:]

PREPARED STATEMENT OF SENATOR DODD

Mr. Chairman, I would like to thank you for holding today's hearing on such an important topic—the importation of Food and Drug Administration (FDA)-approved prescription drugs.

As we have discussed time and time again, in this committee and elsewhere, our Nation's health care costs are exploding. Americans pay more for health care—by far—than any other nation.

The fact that health care costs are so high places a particular burden on the 44 million uninsured Americans, and it also means that any efforts to provide coverage for the uninsured will be enormously costly to the American people. Therefore, reducing health care costs is a critical step in ensuring that everyone has access to appropriate care.

Prescription drugs are an absolutely integral part of our health care system. The advances in drug therapies over the last few decades have led to millions of lives improved and even saved. I am proud that many of these medicines are made in my home State of Connecticut.

However, prescription drugs are also a major driver of rising health care costs. Over the last 3 years, drug costs have increased by more than 50 percent. Our health care system cannot continue to bear these price increases.

It is essential that we seek opportunities to control prescription drug costs. I was extremely disappointed that such an opportunity was missed during our consideration of the Medicare Modernization Act. That law now prohibits the Federal Government from using its purchasing power to bargain for lower drug prices. This is something that I, and I'm sure many of my colleagues, will be looking to change in the near future.

We are now faced with another opportunity to control prescription drug costs by allowing the importation of FDA-approved prescription drugs from Canada and other industrialized nations.

I have always taken the position that drug importation should be allowed as long as it is safe. I do not want lower prices to come at the cost of quality and safety for American consumers. I have looked at every importation proposal with these priorities in mind.

We now have a bipartisan proposal from Senator Dorgan, Senator Kennedy, and others, that I believe addresses many of the safety concerns that have been raised in the past. It gives the FDA the authority and resources necessary to make drug importation a safe proposition.

I want to make it clear that I am still analyzing this proposal, and I am looking forward to hearing what today's witnesses have to say about it. But my current thinking is that it seems to meet the safety requirements.

Once safety is addressed, this really becomes an issue about what is best and what is fair for American consumers. At the moment, Americans pay significantly more for prescription drugs than those in other industrialized nations.

Based on that inequity, it is my belief that we should insist on an open market for prescription drugs, just as there is for almost every product that we trade internationally.

At the same time, we should continue to take steps to ensure fair trade practices for prescription drugs, just as we do for other products. But this should be done in conjunction with, and not in lieu of, importation.

Again Mr. Chairman, thank you for holding this hearing. I am hopeful that in the very near future Congress will pass legislation to allow importation so that Americans have access to affordable prescription drugs. I look forward to working with all of my colleagues on this issue.

Senator DODD. Let me commend my colleagues, and thank the witnesses as well. And I thank the Chairman for holding a hearing on this subject matter.

It has been said before, but certainly deserves being repeated, I think all of us here on this side of the table have a tremendous amount of respect for what the industry has been able to produce and do—extending lives, the quality of lives. Certainly, we are all very, very grateful for the tremendous innovations that have occurred and an industry that has made a huge difference in the lives of people. It's important to state that, because we certainly take great pride in the fact that the United States has led the way and the pharmaceutical industry has provided a tremendous amount of new products on line that have made a huge, huge difference for people.

What you are hearing here, though, from Senator Mikulski, Senator Clinton and others, is an expression of the frustrations that we hear every day when we go back to our States. When you're talking about 44 million Americans that have no health insurance at all, and as Senator Clinton just pointed out, people are medicating themselves by taking prescriptions and deciding to cut pills in half or to extend the time over when they actually take the prescriptions, which is dangerous.

We talk about products coming in that are dangerous because we don't know where they're coming from. People self-medicating is dangerous, and that is going on all across the country today. It isn't just people are without health insurance. People on Medicare, Medicaid, are doing this because they have to make choices between food—you have heard this over and over again—rents, basic costs, every single day they are faced with these incredible choices. It's dangerous and we truly have to enter the 21st century in how we deal with all of this.

Obviously, the costs here are tremendously high, and we all know that. So we are torn between wanting to see products come on line to make a difference in people's lives, knowing that is not done for free. We all know that, that it is expensive to do it. We have had people talk about profitability and the amounts that get invested in research and the like, and that is a legitimate debate.

But then with the cost of doing this we ought to have the product available, and yet we have it unavailable for the very practical reason that people just can't afford it, and then limit their ability to seek other sources that could be legitimate sources for those products.

As Senator Mikulski said, people are going to do this. They are going to self-medicate and they are also going to find resources that they think are going to save their lives or make their lives more liveable. Whatever they have to do, they are going to do it. Our job is to see if, No. 1, we can't come up with a reasonable cost on these products, and also provide them with the kind of assurances that we do in so many other areas every single day.

As this globalization occurs economically, we are using products every single day that require some safety standards and some precautions. We are seeing automobiles introduced into this country being made offshore, and what kind of safety standards do we provide for the American consumer when they drive an automobile that has been produced in a foreign country. You can go down a long list of things we use every single day. We know there are lax areas of protection that occur in a number of these areas. So this is an important hearing.

I am interested in the written statement you made—and I think this is Mr. Taylor—let me quote your statement here. You were talking about the importation proposals on page 9 of your testimony. I'm quoting from it here now. You say, "Some of these proposals would even limit FDA's existing authorities. They would impose unprecedented restrictions on FDA's ability to inspect and test drugs, and FDA's authority to block the distribution of drugs we think are unsafe."

Can you be more specific? Since you made that claim here, what specific proposals do that, and how do they do that?

Mr. TAYLOR. Well, to keep it short, there have been proposals in the past that have sought, in order to facilitate greater importation, have actually sought to weaken the actual provisions of the act that exists now. That's what I was getting to on that point. That doesn't happen to be the case in Senator Kennedy's bill, but there have been proposals in the past that have tinkered with the current statute and, therefore, would prevent or weaken our ability to stop products that we think are still potentially problematic.

Senator DODD. Specifically, you're talking about the proposal now being introduced by Senator Dorgan, Senator Kennedy, Senator Snowe and, I think, Senator Collins.

Mr. TAYLOR. That statement does not relate to the Senator Kennedy/Dorgan bill. That related to proposals that have been used and floated in the past.

Senator DODD. One more question. This goes to the issue that Senator Clinton was raising, and Senator Mikulski was raising.

Correct me if I'm wrong on this, but this is what I am told is the case, that a licensed wholesaler, licensed by the Canadian government, and a licensed retailer licensed by the Canadian government, those companies can only handle products that have been approved by Health Canada; is that statement true or not? I'm asking the question. I don't know the answer.

Mr. HUBBARD. It's theoretically true. We believe some of the drugs coming from those businesses are not regulated by Health Canada, but that is besides the point, I guess.

Senator DODD. Is that the law, though? The law says that those——

Mr. HUBBARD. We think so, yeah.

Senator DODD. So we can assume, except when obviously people may abuse the system, but assuming that that's the case, then those products would be relatively safe, if they have been licensed by Health Canada, since I gather from your statements we have a lot of respect for how Health Canada regulates its products.

Mr. TAYLOR. Yes, that's absolutely right. By no means should any of our statements be interpreted to disparage Health. We think they do have a very strong drug approval system. However, the issue that we are concerned about is that their strong drug approval and drug distribution system is focused on ensuring that the products that make their way to Canadian consumers are safe and effective, just like our laws and our resources are geared towards. But the problem is that their focus isn't on ensuring that products come from Canada, so there is a regulatory gap.

Senator DODD. I understand. My point is, I just want to narrow in on this particular area, that licensed wholesalers, licensed retailers, those products, they only can sell products that have been approved by Health Canada, and that we have a lot of respect for Health Canada's ability to make judgments on the efficacy and safety of products that are licensed by these particular wholesalers and retailers.

Mr. TAYLOR. Sir, I can get back——

Senator DODD. But they're not transshipped is my point.

Mr. TAYLOR. Sure. I mean, I can get back to you and explain specifically what the Canadian requirements are, but I can tell you that, yes, we do have a great deal of respect for Canadian——

Senator DODD. These wouldn't be transshipped products then?

Mr. HUBBARD. We are concerned that some of the products may be transshipped. That was one of the concerns we raised in our opening remarks.

Senator DODD. That's not the point. If they are licensed to sell, they wouldn't be transshipped products, is that correct?

Mr. HUBBARD. In theory. But again, we are concerned that is not fact.

Mr. TAYLOR. In theory, that's correct.

Senator DODD. Okay. Thank you, Mr. Chairman.

The CHAIRMAN. Thank you.

We thank the panel. We especially thank the FDA for the exceptional job you do in protecting the American consumer, both in the food and drug area. We appreciate your work and look forward to working with you as we move down this road. We are obviously going to be developing legislation in this area and your input is absolutely critical to make sure that the FDA can handle the responsibility and feel comfortable with it.

Mr. TAYLOR. Thank you.

Mr. HUBBARD. Thank you.

The CHAIRMAN. Our next panel includes three witnesses. We have Dr. John Vernon, an economist and with the Finance Department at the University of Connecticut, where he also holds an appointment in the School of Business Center for Healthcare and Insurance Studies. His research focuses on the interface between industry and regulation, pharmaceutical innovation.

Dr. Philip Lee, who has a long history of participation in health issues. He is now a Professor of Human Biology at Stanford. He was Chancellor of the University of California, San Francisco, and he was Assistant Secretary for Health, Department of Health and Human Services under the Johnson administration.

And Mr. Tim Malone, and his wife is also here. Mr. Malone had a very unfortunate experience, obviously, in losing his son. He wanted to tell us about what happened.

Why don't we begin with Dr. Lee, and then Dr. Vernon, and then Mr. and Mrs. Malone.

STATEMENTS OF PHILIP LEE, M.D., CONSULTING PROFESSOR, PROGRAM IN HUMAN BIOLOGY, STANFORD UNIVERSITY, AND PROFESSOR OF SOCIAL MEDICINE [EMERITUS], SCHOOL OF MEDICINE, UNIVERSITY OF CALIFORNIA, SAN FRANCISCO

Dr. LEE. Mr. Chairman, thank you for the opportunity to testify.

Much of what I was going to say—and you have it in my written testimony—has been covered in the Q&A with the FDA. I would say that I have carefully reviewed the legislation and, in my view, it provides the necessary, provided the resources are made available, the necessary authorities for the FDA to provide the adequate protections we need if we expand imports as proposed in S. 2328.

FDA, as we all know, is the gold standard. I think there is one other factor in the legislation, that it does prohibit drug companies from manipulating the system in order to circumvent the price benefits that would accrue to American patients who purchase drugs either through their pharmacy or if they did it with a Canadian

pharmacy directly. I think the legislation, in fact, will reduce rather than increase the likelihood of counterfeit drugs entering the United States. Also, I think it will provide some downward pressure on prices.

Now, in my testimony I deal with the patient safety and quality, safety and effectiveness issues. I deal fairly extensively with the fraud issues and counterfeit drug issues which are very important. I think that Dr. McClellan, when he was FDA Commissioner, initiated the task force and they produced an excellent report. It outlines a series of steps. The legislation really dovetails very closely with the FDA-proposed rule in the Federal Register on the 1988 legislation, particularly with respect to tracing, tracking, and identification. Those, I think, have been covered.

This RFID, the radio frequency identification system, is one that is now most frequently talked about. From my standpoint, it looks very, very promising, and hopefully can be implemented within the next several years. There is a lot of progress being made.

Clearly, other things need to be done, the kind of single packaging that we see now with many over-the-counter drugs, where each capsule or each pill is in its separate package. That kind of protection is also an added benefit and the FDA is obviously working on that as well. They have worked very aggressively with industry to move this forward.

Again, in section 8 of the proposed legislation, I think we have very specific language that makes certain that the pedigree would be there, and that the track and trace technology in lieu of pedigree would be authorized. I think those are important provisions.

The rising prices, of course, there have been a lot of comments on that. I would say only one thing, expenditures have been projected to increase in the United States from $207 billion in 2004, $233.6 billion in 2005, to $519.8 billion by 2013. So we need to have some means. This happens because, No. 1, we are using more drugs, using more new drugs, and the price of drugs has increased. In the United States in particular we are using more new drugs, and the prices have increased more than in other countries.

Of course, for the patient, for the man or woman who goes to their physician and gets the prescription, which in this country is assured by the FDA of being safe and effective, one of their considerations is price. Many people, as has been pointed out in earlier comments, can't afford the drugs these days.

Also in the testimony, in a fair amount of detail, with pharmaceutical research and development, I have suggested in my testimony an approach that might be taken to studying this problem, looking not just at the research and development expenditures but the marketing, advertising and administrative expenditures. As profits have increased, we have noticed expenditures in recent years in those areas have gone up and R&D has not been in recent years nearly as productive as it was as recently as 4 or 5 years ago. So we are in a period where I think we need some more analysis.

Professor Vernon has done an excellent economic analysis based on certain assumptions, and has also in his written articles made some caveats for what he is suggesting in his testimony.

One area that I didn't cover in my testimony in detail is direct to consumer advertising. There is an area where the industry is in-

vesting increasing amounts, and I think for every dollar and a half they invest in direct to consumer advertising, it brings in about four dollars in profits. My own view is that this needs to be examined very carefully to determine does that benefit the patient? Does the direct to consumer advertising, which then gets patients to go in and see their doctor and ask for a particular drug, brand name drugs, is that a benefit to the patient? I think some of these issues need a more thorough examination.

We need to also understand why has innovation slowed recently. What's happening? Industry critics say we are developing too many "me too" drugs and not enough new molecular entities. That certainly appears to be the case. Less than a third, about a third of the drugs that are approved, are new molecular entities that really are some significant advance. So I would say this is an area that needs more study, and I think that certainly can be undertaken.

I would just conclude by saying that this is only part of the answer. Other steps need to be done. Mr. Taylor mentioned the efforts the FDA has made with respect to generic drugs, and we are seeing in the United States a greater use of generics than in any other country. Patients need to be aware of the fact that if they go to Canada to purchase a drug, it may be more expensive than the generic equivalent. They need to ask the doctor if they can get a generic drug that is equivalent, not only chemically but biologically equivalent, and therefore presumably therapeutically equivalent.

Another thing that we could do much more of is what we call academic detailing, where you have very well-trained clinical pharmacists to advise physicians about particular conditions in the drugs instead of just the detail people coming from the pharmacists. For 20 years, research has been done which documents the value of that approach.

With that, Mr. Chairman, I would simply say I support the proposed legislation, S. 2328, and would be pleased to answer any questions.

The CHAIRMAN. Thank you, Dr. Lee.

[The prepared statement of Dr. Lee follows:]

PREPARED STATEMENT OF PHILIP R. LEE, M.D.

Mr. Chairman, Senator Kennedy, and members of the committee. I am pleased to appear today and testify in favor of the Pharmaceutical Market Access and Drug Safety Act of 2004 (S. 2328). The legislation addresses several important issues that were not addressed in the Medicare Prescription Drug Improvement and Modernization Act. Specifically, S. 2328 gives the Secretary of the Department of Health and Human Services the authority to implement a system for the importation of prescription drugs from Canada within 90 days of enactment and, beginning 1 year after enactment, from the members of the European Union as of January 1, 2003, Australia, New Zealand, Japan, and Switzerland. Moreover, it provides a rigorous licensing and inspections regime to assure that drugs imported under the program meet the FDA gold standard of safety and effectiveness. Unlike other legislative initiatives in this area, it also assures that drug companies will not be able to manipulate the rules to prevent a significant amount of drugs being imported into the United States. Without such rules, a program of importation and reimportation would likely have little or no impact on U.S. prices.

After carefully reviewing the legislation, I conclude that it will reduce rather than increase the likelihood of counterfeit drugs entering the U.S. supply chain from abroad and that drugs imported under the program will meet FDA standards for safety and effectiveness. Moreover, it will provide downward pressure on prices paid by U.S. consumers without leading to a reduction in drug innovation.

Let me deal with the issues of patient safety and drug product quality, safety and effectiveness. Then, I will deal with the issues of drug prices, costs, and cost effectiveness.

PATIENT SAFETY AND DRUG QUALITY, SAFETY, AND EFFECTIVENESS

Last year, prior to enactment of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA 2003), the House of Representatives, by a margin of 243 to 186, passed a bill to allow individual patients, pharmacists, and drug wholesalers to import prescription drugs from Canada and European countries if they had been approved for use in this country by the FDA. Before final action, the House-Senate conference committee rejected this approach and reaffirmed the current policy, which permitted importation only if the Secretary of the Department of Health and Human Services certified that drugs imported under the program authorized by the bill would be safe. Neither Secretary Shalala nor Secretary Thompson has been willing to grant such certifications. The MMA, while including a new prescription drug benefit (Part D) for Medicare, did not permit the importation of drugs from Canada and Europe. The MMA did, however, request a report to Congress on importation.

To assist in examining the issues related to importation, Secretary Thompson established the Task Force on Drug Importation, chaired by Dr. Richard Carmona, the Surgeon General of the U.S. Public Health Service, and including Dr. William Raub, the DHHS Deputy Assistant Secretary for Science, and Dr. Mark McClellan, the former FDA Commissioner and currently the Administrator of the Centers for Medicare and Medicaid Services.

The Task Force has held five listening sessions, drawing on a wide range of experts. I have had the opportunity to review some of the transcripts and the testimony of some of the witnesses in full. These documents should be carefully reviewed by the committee staff because they deal with a number of issues of concern to this committee.

The Pharmaceutical Market Access and Drug Safety Act of 2004 (S. 2328) deals with the quality, safety, and effectiveness issues very directly. The act would require that importable drugs must be approved by the Food and Drug Administration (FDA) and manufactured in an FDA inspected plant. In addition, the drug must be administered by the patient; it cannot be injected or infused; and it must not be a drug inhaled during surgery or a controlled substance.

These requirements are essential to any expansion of drug imports, and I believe they deal with the drug quality and safety issues. The process and elements of FDA approval were described by Dr. Carl Peck, former Director of the FDA Center for Drug Evaluation and Research (1987–1993) in his testimony for the DHHS Task Force on Drug Importation on April 27, 2004. The importance of the FDA requirements for safety and effectiveness were also stressed by Pamela Wilkinson, Vice President of Regulatory Affairs/Serono Laboratories, Inc. I agree and do not believe it necessary to repeat their statements in detail. Suffice it to say, the FDA is the gold standard for assuring drug quality, safety and effectiveness. Drugs imported under the Pharmaceutical Market Access and Drug Safety Act of 2004 (S. 2328) are required by the legislation to meet these standards, and I believe that the regime of licensing and inspection established by the legislation will assure that they will in fact meet these standards.

FRAUDULENT AND COUNTERFEIT DRUGS

Let me turn to a related safety and quality issue—fraudulent and counterfeit drugs entering the United States if current policies are modified to permit greater imports into the United States.

I have had a long-standing interest in this problem. In 1990, in an article in the *International Journal of Health Services*, my late colleagues, Dr. Milton Silverman and, Mia Lydecker, and I wrote an article, "The Drug Swindlers" that described the problem of counterfeit drugs internationally. We developed the story more fully in the chapter, "The Drug Swindlers," in our book, *Bad Medicine*, published by Stanford University Press in 1992. After our 1990 article, the story was reported in the November 12, 1990 *Newsletter* of the Pharmaceutical Manufacturers Association and it received international coverage in the magazine *Newsweek* ("The Pill Pilots" November 5th, 1990).

Based on our studies, we noted that many drug experts were alarmed by the rapidly expanding growth of counterfeit drugs. I should note that in 1990 and 1992, we did not include China among the countries with serious problems. I have been very concerned about the increase of the problem in recent years, but I am encouraged by the possibilities for dealing with the problem.

Let me elaborate. A number of pharmaceutical industry officials and trade association representatives have expressed concern that counterfeiting may increase with legislation allowing imports. On reading their statements before the DHHS Task Force on Drug Importation, I do not believe that they were speaking about the Pharmaceutical Market Access and Drug Safety Act of 2004 (S. 2328). I believe the act provides clear policies to prevent this.

The issue of fraudulent and counterfeit drugs has concerned Congress and the FDA since the enactment of the Prescription Drug Marketing Act (PDMA) of 1988. The act was amended in 1992, but its benefits have not been realized. The Food and Drug Administration published a Federal Register Notice on February 19, 2004 delaying the final rule published in the Federal Register on December 3, 1999 on certain requirements in the final rule relating to wholesale distribution of prescription drugs. There have been multiple earlier delays in this final rule. In this most recent revision delaying the final rule until December 1, 2006, the FDA states:

> FDA is working with stakeholders through its counterfeit drug initiative to facilitate widespread, voluntary adoption of track and trace technologies that will generate a *de facto* electronic pedigree, including prior transaction history back to the original manufacturer, as a routine course of business. If this technology is adopted, it is expected to help fulfill the pedigree requirements of the PDMA and obviate and resolve many of the concerns that have been raised with respect to the final rule by ensuring that an electronic pedigree travels with the drug product all the time.

On February 18th, the FDA held a press conference to announce the release of its report *Combating Counterfeit Drugs*. At the press conference, Secretary Thompson noted:

> We have started to see a tremendous increase in the volume and, more importantly, the sophistication of counterfeit and other unsafe drugs entering our supply (Young 2004, p. 645).

The then-FDA Commissioner, Mark McClellan described the electronic track and trace technologies that would soon be able to provide a high level of confidence that a drug was manufactured safely and distributed under proper conditions. The report is an excellent one and describes the FDA's current strategy, with an emphasis on the track and trace technologies and the authentication technologies that should be in use by 2007.

The plan is very well thought out, but it did not describe the resources that will be needed, in both the private and public sectors to implement the plan, nor did it deal with the issue of assuring the safety and effectiveness of drugs during the period before these standards are widely adopted.

Section 8, Wholesale Distribution of Drugs (S. 2328) deals with this issue and is aligned with the FDA Strategy. It amends section 503(c) of the FFDCA to require a pedigree in interstate commerce, including drugs exported from the United States and imported drugs, and allows FDA to require anti-counterfeiting or track and trace technology in lieu of pedigree. A pedigree is a statement of origin of the drug with information about all previous transactions. This is an important provision in S. 2328. Further, these actions are very appropriate in view of recent developments.

In testimony before the HHS Task Force on Drug Importation, officials of Eli Lilly, Pfizer, and Johnson and Johnson all commented on the issue of counterfeit drugs, with the problem increasing in the United States since 1998. John Theriault, Vice President, Global Security, Pfizer, Inc. had appeared before the Senate Special Committee on Aging in July 2002, to describe the problem and the steps taken by Pfizer to counter the problem. He noted in his testimony to the Task Force on April 5, 2004:

> It is widely accepted that China is the major source of counterfeit pharmaceutical products marketed throughout the world. Before 1998, the United States and other developed countries were not particularly concerned about counterfeit pharmaceuticals. The security departments of major pharmaceutical companies devoted few, if any, resources to the problem. It was one of the widely accepted "truths" of counterfeiting that it was a problem only in China, India, and less developed countries.

Between 2001 and 2003, the problem seems to have grown rapidly, including Europe, Asia, the Middle East, and the Americas. According to John Dempsey, Executive Director of Trade Relations and Brand Security for Ortho Biotech, the FDA has initiated 73 counterfeit drug investigations since October 1996, the majority in the last two and a half years, resulting in 44 arrests, 27 convictions, with a number of criminal investigations still ongoing. He added, "The Pharmaceutical Security Institute's 2003 report states that there was a 60 percent increase in the incidence of

prescription drug counterfeiting in 2003. They have documented 264 incidents of counterfeiting in 2003" (p. 24 of 38).

Clearly the problem is a serious one throughout the world. I believe that the FDA's proposed system of modern protection against counterfeit drugs is supported by the Pharmaceutical Market Access and Drug Safety Act (S. 2328) and that S. 2328 would provide the necessary authority for the FDA to deal with the problem. Thus, rather than making American consumers less safe, S. 2328 would make American patients safer.

Let me add a word of caution about the track and trace technologies. These are based on radiofrequency identification (RFID) tagging of products by manufacturers, wholesalers, and retailers. This appears to be the best approach available and there is an enormous literature on this topic. A web search of this issue for pharmaceuticals leads to more than 100,000 "hits," and there are professional journals and trade publications solely devoted to RFID.

I believe two issues still need to be fully addressed: (1) security and (2) privacy, particularly when large databases link products purchased by individual patients. I am not an expert in either of these areas, but this committee may wish to review the whole matter after it receives the Secretary's report on importation.

Let me turn from drug quality, safety, and effectiveness to drug prices and expenditures and the forces that are compelling Congress to revisit the issue of the importation of prescription drugs from Canada and Europe.

RISING PRESCRIPTION DRUG EXPENDITURES: INTERNATIONAL COMPARISONS

According to the Directorate for Education, Employment, Labor, and Social Affairs (OECD):

> Total expenditure on pharmaceutical goods represents between 0.7 and 2.2 percent of GDP across OECD countries, with a mean around 1.2 percent. Expenditure on pharmaceuticals represents between 8 and 29 percent of total health expenditure with a mean around 15.4 percent. Although relatively small this order of magnitude is still significant, since in most countries more than half of pharmaceutical expenditures is reimbursed by public funds (Jacobzone 2000, p. 11).

The costs in all the countries reflect both the price of drugs and the use of drugs. The price is a reflection of the number of both new, brand name drug products and the generic products on the market and in use.

In recent years, the price of prescription drugs has been rising rapidly. Before 1981, prescription drug prices tended to rise more slowly in the United States than did the consumer price index (CPI)—in many years, substantially more slowly. Since 1981, the CPI for prescription drugs has risen more rapidly, sometimes triple the CPI for all items (Smith 2004). Price increases in the 1990's and in the early 21st century have been particularly striking.

Spending for retail prescription drugs rose from $2.7 billion in 1960 to $15 billion in 1982 to $48.2 billion in 1992 and $162.4 billion in 2002. The average annual rate of growth was 7.8 percent in 1980, 11.7 percent in 1982, 12.4 percent in 1992, and 15.6 percent in 2002. As a percent of health spending retail drugs rose from 4.9 percent in 1980 to 10.5 percent in 2002, and as a percent of gross domestic product from 0.43 percent to 1.55 percent (Smith 2004, p. 161).

Annual increases in spending for prescription drugs in the United States are projected to increase to $207.9 billion in 2004, $233.6 billion in 2005, and $519.8 billion by 2013 (Heffler 2004). It is small wonder that the cost of prescription drugs is of concern to patients, health plans, and State and Federal officials. A number of factors have contributed to the rapid increase in prescription drug costs throughout the developed world, including increased consumption of drugs, shifting of consumption from older, less costly drugs to newer drugs, and increased drug prices. Notably, the United States ranks well above the industrialized world on all dimensions. Our per capita consumption of drugs is higher, and the prices we pay for the drugs we consume are higher. From the point of view of the individual patient, whose goal is to treat illness or maintain health by following the instructions of his doctor, the prices of the drugs prescribed for him is the most important factor.

NATIONAL POLICIES TO CONTROL EXPENDITURES

There are two basic approaches to controlling drug expenditures: policies to control prices and policies to manage drug utilization (Morgan et al. 2003).

Strategies for Controlling Expenditures

In a critical review of the regulation of the market for pharmaceuticals, Maynard and Bloor (2003) make the point that the pharmaceutical market, like all markets,

is regulated by government, private agencies (e.g., trade associations) or industry self-regulation. They also note that three objectives of regulation are often cited: (1) expenditure control, (2) quality, and (3) access.

The construct of regulatory interventions includes three categories: (1) influencing patients, (2) influencing doctors, and (3) influencing industry. To influence patients, the emphasis has been on multi-tiered co-payment structures and increasing the amount of deductibles and premium. In addition, shifting drugs from prescription to over-the-counter status shifts costs to patients from third party payers. Also, direct-to-consumer advertising, a practice that is sanctioned only in the United States and New Zealand, attempts to directly influence patients' choice of brand name drug products.

Policies designed to influence doctors largely have been based on feedback to physicians about their prescribing behavior and the costs of the drugs they prescribe. These policies have been ineffective when compared to the role played by the pharmaceutical manufacturers in promoting their brand name drugs, particularly their newer drugs to physicians. There is no doubt that drug promotion by manufacturers influences physician prescribing behavior, and it is seldom to prescribe the most cost-effective drugs.

Formularies and generic substitution also are used, but they have more impact on cost than modifying physician behavior. One of the most detailed studies of the use of a formulary was carried out by the program in the Veterans Health Administration (VHA) in the United States. In 1995, the VHA established its own pharmacy benefit manager, the VHA Pharmacy Benefits Management Strategic Health Care Group that implemented a national formulary, including closed, open and preferred contracts (Huskamp et al. 2003). Although only a small number of drugs were included in the closed contracts the aggregate savings over the 2-year study period was $82.1 million for the five classes of drugs that were closed at some point during the study period.

European countries and Canada use a mix of policies to control drug costs. Policies that focus on controlling price predominate. Policies to control utilization have been much less widespread. A wide variety of programs to limit prices have been followed, including "reference pricing," negotiation of rates as condition for being included in government insurance programs, and profit limitation.

PRICE LIMITATION AND PHARMACEUTICAL RESEARCH AND DEVELOPMENT

For the past 35 years, ever since the publication of the Final Report of the DHEW Task Force on Prescription Drugs, I have heard the argument that policies designed to impose government price controls or any other measure to reduce drug prices in the United States will reduce industry profits, which in turn will lead to a decrease in R&D investment by the pharmaceutical industry and a decrease in the number of innovative prescription drugs introduced, resulting in more disease, disability, and premature death. The argument has been made over and over, particularly by the Pharmaceutical Manufacturers Association (PMA) and its successor, the Pharmaceutical Research and Manufacturers of America (PhRMA), as well as by many economists.

Few studies have systematically examined the growth of drug industry sales relative to profits and spending on R&D and drug promotion. Previous analyses of relative revenue allocation indicate that more dollars are spent on marketing, advertising, and administration (MAA) than on R&D. This allocation of revenue raises doubts about the link between drug prices and R&D spending voiced during the Medicare benefit debate. Studies also indicate that the pharmaceutical firms have among the highest returns on revenue of any U.S. business, with profits outpacing other research-intensive industries like medical devices and telecommunications (Fortune 2004). If profits and spending on drug promotion are increasing more rapidly than R&D investments, then R&D is not the only industry expenditure that could be reduced.

New drug innovation also is critical to any drug pricing debate. While some analysts assert that constrained drug prices would limit innovation, recent trends suggest that slowing research productivity and increasing drug prices have gone together. In 2002 the FDA approved only 17 new molecular entities (NMEs) for U.S. sale, a fraction of the 56 NMEs approved in 1996.

In a recent analysis of the decline in the development of antimicrobial agents, Spellberg, Brass, Miller, and Edwards at the Division of Infectious Diseases, Harbor-UCLA Research and Education Institute and the David Geffen School of Medicine, UCLA and Powers from the Center for Drug Evaluation and Research, FDA found a significant decline in the number of antimicrobial agents approved by the FDA during the past 20 years. They concluded:

> Despite the critical need for new antimicrobial agents, the development of these agents is declining. Solutions encouraging and facilitating the development of new antimicrobial agents are needed.

The development of new antimicrobial agents are needed especially for naturally occurring and emerging infectious diseases, including infections caused by agents of bioterrorism.

How to account for slowed innovation amidst rising drug revenues? Industry critics say drug companies increasingly develop "me-too" drugs; these incrementally modified drugs (IMDs) usually offer only marginal therapeutic benefits, but may be heavily promoted to increase market share (Angell 2000). A prior analysis of FDA approvals concluded that only about one-third of new drugs were truly innovative (NIHCM 2002). The rest were "me-too" drugs, which contain active ingredients similar to those already available in marketed products. Since both NMEs and IMDs may offer medical or economic benefits over existing therapies, the number of NME approvals does not necessarily reflect the quality of new drug innovation. An analysis of drug innovation would expand current knowledge by examining the chemical novelty and the anticipated therapeutic advantage of new drugs and the changing rates of innovation relative to industry sales and profits.

Such a study would add to the literature by examining pharmaceutical industry spending and innovation over time. Earlier analyses were limited because they examined few drug companies and provided figures for only 1 year (Families USA 2001, 2002). A separate study used Food and Drug Administration (FDA) data to evaluate innovation over time, but did not consider concomitant changes in R&D or MAA spending (NIHCM 2002). Recent research has examined R&D spending and innovation in the context of drug development decisions, but these studies used data from a trade organization and did not consider marketing, advertising, or administration costs (Cockburn 2004, Croghan 2004, DeMasi 2003).

When the prescription drug benefit was enacted in December 2003, the Congressional Budget Office estimated it would cost $395 billion over the next 10 years. The White House now projects the cost to be $534 billion. With such an enormous outlay of Federal dollars for prescription drugs, taxpayers and policymakers should have a systematic understanding of how manufacturers allocate revenues and what level of innovation is derived from R&D investments. This knowledge can inform future dialogue over the appropriate role of government in drug price negotiations.

Such a study could contribute to evaluating the assertion that Federal drug price negotiation would inhibit the development of new therapies. It would explore the relationships among R&D investments and patterns of innovation and suggest evolving industry priorities regarding drug research, development, advertising, and marketing.

ONLY PART OF THE ANSWER

The Pharmaceutical Market Access and Drug Safety Act of 2004 (S. 2328) is only part of the answer to the rapidly rising expenditures for prescription drugs.

The first step that can be taken without any new legislative authority is the greater use of generic drugs. A recent study by Fischer and Avorn (2003) reported:

> Analysis of state-by-state Medicaid prescription drug spending in 2000 identified potential savings of $229 million that could be realized from greater use of generic drugs. If the best available prices from each State had been used, savings would have increased to $450 million. The majority of savings were concentrated in a small group of medications, including clozapine, alprazolan, and levothyroxine" (p. 1051).

The potential for generic drugs has long been recognized. The reasons that they are not prescribed more frequently by physicians or dispensed by pharmacists are many. It was not until the 1970's that State laws prohibiting the substitution of a generic name drug product that was chemically, biologically, and clinically equivalent to a brand-name drug product were abolished.

While the generic name drugs have a greater market share in the United States than anywhere in the industrialized world, and they will usually be less expensive than brand name drug products imported from Canada or Europe, they are still underutilized. This is not a new problem. Fifteen years ago, Professor Helene Lipton and I discussed the issue in our book, *Drugs and the Elderly*, emphasizing the need for greater physician awareness and the removal of financial disincentives for pharmacists to dispense generics.

One important factor has been the detailing of brand name drug products to physicians by the pharmaceutical companies and the recent dramatic increase in direct-to-consumer advertising of prescription drugs (expenditures now approach $3 billion per year). One approach to better informing physicians is the use of academic detail-

ing (a program in which today's highly trained clinical pharmacists provide one-on-one, evidence-based, objective information on drug quality, safety, effectiveness, and costs to prescribing physicians). Studies reported by Avorn and Soumerai (1983) in the early 1980s demonstrated the benefits of this type of educational outreach in improving clinical decision-making. Many studies since then have confirmed their earlier observations.

Much more needs to be done using this approach with both physicians and pharmacists.

In summary, Mr. Chairman, I have carefully reviewed the Pharmaceutical Market Access and Drug Safety Act of 2004, and I encourage the committee to support it and Congress to enact it.

I have been concerned with issues related to prescription drug policy for the past 39 years, including during both my years of Federal service and as a faculty member of the School of Medicine, UCSF.

I believe that the bill provides strong assurances of the safety and quality of imported drugs. It contains appropriate provisions related to counterfeit drugs, and it provides patients, physicians, pharmacists and wholesalers the opportunity to add a tool—the importation of prescription drugs—to help deal with the problem of the rapidly rising costs of drugs. We all recognize that it is only one of the tools available; others include greater generic prescribing and dispensing and the use of academic detailing to better inform physicians about the many new drugs in the market place.

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The CHAIRMAN. Dr. Vernon.

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Mr. VERNON. Mr. Chairman and members of the committee, I wish to thank you for the opportunity to testify today on the issue of pharmaceutical reimportation.

My name is John Vernon and I am a professor in the Department of Finance and in the Center for Healthcare and Insurance Studies in the School of Business at the University of Connecticut. I have a Ph.D. in economics from City University of London and a Ph.D. in health policy and management from the Wharton School at the University of Pennsylvania. I also hold bachelor's and master's degrees in economics from Duke University and North Carolina State University, respectively.

My testimony today will be quite narrow and focused. I will not discuss whether drugs imported from Canada or elsewhere are safe, nor will I discuss the potential economic benefits that importing drugs from price-regulated markets may produce through ex-

panding access. While both of these issues deserve careful analysis and attention, they lie outside the domain of my research and expertise. Instead, this morning I will limit my testimony to the potential long-run economic costs associated with legalizing reimportation, which may be viewed as importing foreign price controls on to the U.S. pharmaceutical marketplace.

Because informed policy debate must always weigh the benefits of a proposed policy against its costs, and because the costs associated with regulated drug prices in the United States will occur many years into the future, my colleagues and I have undertaken several research studies that attempt to estimate what these long-run costs would be. We calculate them to be quite substantial, and in the trillions of dollars.

I would like to begin by clarifying an important point: reimporting patented pharmaceuticals from outside the United States is not a free trade issue. This is a common misunderstanding. The rationale for free trade is based on the doctrine of comparative advantage, where countries specialize in the production of goods and services for which they are, comparatively speaking, low-cost producers, and then trade freely with other countries doing the same thing.

Free trade is good for the economy and it is good for society. But pharmaceutical prices in Canada and elsewhere are lower because drug prices are regulated in those markets and not because those countries have a comparative advantage in the production of pharmaceuticals.

It is imperative to understand that the real issue at hand is intellectual property rights. If patented pharmaceuticals are imported from abroad, the U.S. patent system is circumvented and price controls will indirectly be imposed on pharmaceuticals in the United States. Please allow me to clarify this point.

Once a new pharmaceutical or molecular entity has been discovered, researched and then developed, which typically takes 12 to 15 years, and all the safety, efficacy and other clinical data are collected and analyzed, the marginal manufacturing cost of a single pill is quite small. This is because the final product of all the R&D is essentially just new information and knowledge, information that has taken many years and hundreds of millions of dollars to obtain.

In the absence of intellectual property rights, and the ability of pharmaceutical firms to price their products significantly above marginal manufacturing costs, no investor or firm would spend the time and money to discover and develop this information. Thus, there must be a sizable reward to induce these R&D activities.

The research I will summarize today represents an attempt to measure the long-run costs associated with imposing foreign drug prices on the U.S. market. Importantly, while economic theory predicts it is unlikely this would occur through legalized reimportation alone, because this is the implicit intent of the policy, our analyses are based on this scenario.

Measuring the costs associated with foregone future innovation is indeed a very difficult task. There are many variables that can affect the outcome. However, because there is an overwhelming tendency for public policy debate to focus on the short-run benefits

of lower, regulated drug prices, it is critical that efforts also be undertaken to estimate what the corresponding costs would be in terms of lower levels of innovation in the future. Only then can the benefits be weighed against the costs to determine if the policy is, indeed, a good one.

It is well known that the allocation of resources to investment activities depends on the expected costs and future returns of those investment activities. Pharmaceutical R&D is no exception. The effect of a policy permitting the large-scale reimportation of price-regulated pharmaceuticals from abroad, if successful, or if accompanied by direct price controls, will be to significantly diminish the expected returns associated with pharmaceutical R&D. Rational firm managers, acting on behalf of their shareholders, will divert resources away from pharmaceutical R&D and into other, now relatively more attractive investment activities.

Pharmaceutical R&D will unambiguously decline. What is uncertain, however, is by how much R&D will decline. This will depend on two things primarily: the success and scale of the reimportation policy or price control scheme, and the sensitivity of R&D investment to expected pharmaceutical profitability. For the purposes of our research, we assumed that the policy would achieve its objective and the result would be pharmaceutical prices and profit margins in the United States that are comparable to those found outside the United States.

To quantify the sensitivity of R&D to pharmaceutical prices and profitability in our research, we employed a variety of methodological techniques, including standard retrospective statistical analyses of industry and firm-level data and prospective simulation analyses.

Interestingly enough, our findings were strikingly consistent across methods and studies and suggest that such a policy, if successful, would reduce R&D by approximately 25 to 30 percent. For our base case analyses, we used the low-end figure of 25 percent. Depending on the study and method, this figure may reflect either a one-time drop in R&D, with no impact on the future growth rate of R&D investment, or a decline in the growth rate of R&D by between 1 and 2 percentage points only, with no one-time effect.

Then, using results from recent studies on the growth rate of industry R&D, and the cost of capital for pharmaceutical R&D, we calculated the present value of foregone R&D using standard methods. Finally, we combined this measure with estimates of the productivity of pharmaceutical R&D to translate this policy-induced decline in R&D into human life years and lives lost, and then finally into dollars, using standard estimates of the value of a human life year.

Our findings predict that a policy successfully reducing pharmaceutical prices, and profit margins, to the levels observed in markets where governments regulate drug prices will impose a cost of approximately 79 million life years, 1 million lives, or about $8 trillion.

To place the latter figure into context, consider that the 2003 GDP for the U.S. economy was roughly $11 trillion. This cost estimate seems reasonable when compared to the recent findings by University of Chicago economists Kevin Murphy and Robert Topel,

that a permanent 10 percent reduction in mortality from cancer and heart disease would have a value of $10 trillion to Americans.

In conclusion, I wish to emphasize that the research I have summarized looks at only one aspect of the policy issue: the long-run costs of foregone innovation. Informed policy debate must consider all aspects and consequences of legalized importation, or of regulating drug prices in the United States. This being said, however, the present value costs of such a policy to future generations appears to be quite significant.

[The prepared statement of Mr. Vernon follows:]

PREPARED STATEMENT OF JOHN A. VERNON, PH.D.

Mr. Chairman and members of the committee, I wish to thank you for the opportunity to testify today on the issue of pharmaceutical reimportation. My name is John Vernon and I am a professor in the Department of Finance and in the Center for Healthcare and Insurance Studies in the School of Business at the University of Connecticut. I have a Ph.D. in economics from City University, London and a Ph.D. in Health Policy and Management from the Wharton School of Business at the University of Pennsylvania. I also hold bachelors and masters degrees in economics from Duke University and North Carolina State University, respectively.

My testimony today will be quite narrow in focus. I will not discuss whether drugs imported from Canada or elsewhere are safe, nor will I discuss the potential economic benefits that importing drugs from price-regulated markets (such as Canada and the EU) may produce through expanded access to existing medicines. While both of these issues deserve careful analysis and attention, they lie outside the domain of my research and expertise. Instead, this morning, I will limit my testimony to the potential long-run economic costs of legalizing reimportation, which can be viewed as importing foreign price controls to the U.S. pharmaceutical market.

Because informed policy debate must always weight the benefits of a proposed policy against its costs, and because the costs associated with regulated drug prices in the United States will occur many years into the future (through reduced levels of pharmaceutical innovation), my colleagues, Carmelo Giaccotto, Joseph Golec, and Rexford Santerre, and I have undertaken several research studies that attempt to estimate these long-run costs. We calculate them to be quite substantial, and in the trillions of dollars.

I would like to begin by clarifying an important point: reimporting patented pharmaceuticals from outside the United States is not a free trade issue. This is a common misunderstanding. The rationale for free trade is based on the doctrine of comparative advantage: where countries specialize in the production of goods and services for which they are, comparatively speaking, low-cost producers, and then trade freely with other countries doing the same thing. Free trade is good for the economy and good for society. But pharmaceutical prices in Canada and elsewhere are lower because drug prices are regulated in those markets, and not because those countries have a comparative advantage in the production of pharmaceuticals (in the absence of price regulation, it is likely that prices would still be lower outside the United States because of lower real income levels). It is imperative to understand that the real issue at hand is intellectual property rights. If patented pharmaceuticals are imported from abroad, the U.S. patent system is circumvented, and price controls will be indirectly imposed on pharmaceuticals in the United States. Please allow me to clarify this point.

Once a new pharmaceutical or molecular entity has been discovered, researched and then developed (which typically takes 12–15 years), and all the safety, efficacy, and other clinical data are collected and analyzed, the marginal manufacturing cost of a single pill is quite small. This is because the final product of all the R&D is essentially just new information and knowledge: information that has taken many years and hundreds of millions of dollars to obtain. In the absence of intellectual property rights, and the ability of pharmaceutical firms to price their products significantly above marginal manufacturing costs, no investor or firm would spend the time and money to discover and develop this information. Thus, there must be a sizable reward to induce these R&D activities. As is, only 3 out of 10 new products generate returns in excess of average R&D costs (Grabowski and Vernon, 2000).

This being said, however, once a product has been brought to market, pricing above marginal cost results in an underutilization of the new product (from a social welfare perspective). Clearly, then, a tradeoff exists between providing incentives for

research and development (R&D), and thus innovation, and consumer access to today's medicines: this is the balance the U.S. patent system tries to strike.

While there is nothing sacrosanct about the current structure of the U.S. patent system for pharmaceuticals, or indeed the existing rate (and stock) of R&D investment, what is immediately apparent is that allowing importation of prescription drugs from price-regulated markets, while possibly expanding access to medicines already developed, effectively circumvents the U.S. patent system and allows foreign governments to set the price of pharmaceuticals in the United States. If successful, the result will be to significantly diminish the incentives to invest in R&D, which in turn will reduce the future supply of new drugs.

The research I will summarize today represents an attempt to measure the long-run costs associated with imposing foreign drug prices on the U.S. market. While economic theory predicts it is unlikely this would occur through legalized reimportation alone, because this is the implicit intent of the policy, our analyses are based on this scenario.

Measuring the costs associated with forgone future innovation is indeed a difficult task: there are many variables that can affect the outcome. However, because there is an overwhelming tendency for public policy debate to focus on the short-run benefits of lower (regulated) drug prices, it is critical that efforts be undertaken to estimate what the corresponding costs would be in terms of lower levels of innovation. Only then can the benefits be weighted against the costs to determine if the policy is a good one. Obviously, our research focuses on only one component of the economics of importation and price regulation: the long-run costs. As such, our analyses must not be viewed as a complete cost-benefit analysis.

It is well known that the allocation of resources to investment activities depends on the expected costs and future returns of those investment activities. Pharmaceutical R&D is no exception. The effect of a policy permitting the large-scale reimportation of price-regulated pharmaceuticals from abroad, if successful, or if accompanied by direct price controls, will be to significantly reduce the expected returns associated with pharmaceutical R&D. Rational firm managers, acting on behalf of their shareholders, will divert resources away from pharmaceutical R&D and into other, now relatively more attractive, investment activities. Pharmaceutical R&D will decline. What is uncertain, however, is by how much R&D will decline. This will depend on two things: (1) the "success" and scale of the reimportation policy, or price control scheme, and (2) the sensitivity of R&D investment to expected pharmaceutical profitability. For the purposes of our research we assumed that the policy would achieve its objective, and the result would be pharmaceutical prices (profit margins) in the U.S. that are comparable to those found outside the U.S.

To quantify the sensitivity of R&D to pharmaceutical prices and profitability in our research, we employed a variety of methodological techniques, including standard retrospective statistical analyses of industry and firm-level data and prospective simulation analyses (Vernon, 2003, 2004; Giaccotto, Santerre and Vernon, 2004). Interestingly enough, our findings were strikingly consistent across methods and studies, and suggest that such a policy, if successful, would reduce R&D by approximately 25 to 30 percent. For our base case analyses we used the low-end figure of 25 percent (Golec and Vernon, 2004). Depending on the study and method, this figure may reflect either a one-time drop in R&D, with no impact on the future growth rate of R&D investment, or a decline in the growth rate of R&D by between 1–2 percentage points only, with no one-time effect. The two effects generate the same estimate. It seems likely, however, that both effects would occur, at least to some degree, but in estimating the long-run costs of forgone innovation, we adopted a conservative approach, and assumed a single effect (Golec & Vernon, 2004).

Then, using results from recent studies on the growth rate of industry R&D (Scherer, 2001) and the cost of capital for pharmaceutical R&D (DiMasi, Hansen, and Grabowski, 2003; Myers and Shyam-Sunder, 1996) we calculated the present value of forgone R&D using standard methods. Finally, we combined this measure with estimates of the productivity of pharmaceutical R&D (Lichtenberg, 2002, 2003) to translate this policy-induced decline in R&D into human life years and lives lost, and then into dollars using standard estimates of the value of a human life year (Cutler and McClellan, 2001). Our findings predict that a policy successfully reducing pharmaceutical prices (and profit margins) to the levels observed in markets where governments regulate drug prices will impose a cost of approximately 79 million life years, one million lives, or about $8 trillion (Golec and Vernon, 2004).

To place the later figure into context, consider that the 2003 GDP for the U.S. economy was roughly $11 trillion. This cost estimate seems reasonable when compared to the recent findings by University of Chicago economists, Kevin Murphy and Robert Topel, that a permanent 10 percent reduction in mortality from cancer and heart disease would have a value of $10 trillion dollars to Americans.

In conclusion, I wish to emphasize that the research I have summarized looks at only one aspect of the policy issue: the long run costs of forgone innovation. Informed policy debate must consider all aspects and consequences of legalizing importation, or of regulating drug prices in the United States. This being said, however, the present value costs of such a policy to future generations appear to be quite significant.

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The CHAIRMAN. Thank you very much, Dr. Vernon.

We will now hear from Mr. Malone, and Mrs. Malone, if she wishes to comment. Obviously, you have experienced an incredible tragedy and the sympathy of this committee goes out to you. We very much appreciate your being willing to come and tell us your story relative to your son, Jim.

TIM AND MARGARET MALONE, LIVERMORE, CALIFORNIA, PARENTS OF JAMES MALONE [DECEASED]

Mr. MALONE. Thank you, Senator. We are not professional speakers, but I would like to thank you and the committee for giving us this opportunity to tell our story and to spread the word and, hopefully, to save some lives.

I am pleased to be here today, but also very sad. I want to tell you about our son, James, and how he died, because he ordered prescription drugs over the Internet.

Our son James was a bright 24-year-old, working part time, and just finishing his 2-year degree at Los Positas College in Livermore, CA. James lived at home with us, his parents, in Livermore, and planned to move to Sacramento to attend California State University in September of this year.

During the last few months before his death, James was understandably under a lot of stress, particularly for a shy person, with final exams at school, his work, and making plans to move away to attend a 4-year college. He also worked out regularly at the gym. We believe this is why James was ordering drugs, primarily muscle relaxants and anti-anxiety drugs, on the Internet.

What we didn't know at the time is there is a tragic problem with these Internet medication orders. Almost any drug manufactured by pharmaceutical companies, even controlled substances, are available via Internet websites. All that is needed is Internet access and a credit card.

When James searched on the Internet for medical information on how to relieve back pain and muscle spasms, and help with his anxiety disorder, he found not only was there no prescriptions required, but there was no evaluation or consultation on the kinds of medications, the strength, form, or dosage taken, or cautions about the interactions with other drugs. We believe this is what killed our son. He mixed medications, fell asleep, and stopped breathing.

Some of the drugs that James received by UPS from Internet orders, with return addresses in India and Pakistan, were Darvacet, Diazepam—which is valium—codeine, soma, a muscle relaxant, and others.

As we struggled to make sense of our son's death, and tried to understand how this could happen, we tried to determine the actual source of these drugs, how and where they were manufactured, and how they are distributed. James receives shipments via UPS from India and Pakistan, with no documentation or dosing instructions. The sparse writing on the blister packs holding the pills, the individual wrapping, was in a foreign language and alphabet, probably Farsi. However, some of the shipments of drugs also contained the name brand of well–known pharmaceutical companies.

We also discovered the manner in which these credit card transactions were processed. Like most Internet orders, only a credit card number and expiration date were required. However, for these controlled substance drug orders, the websites required purchasers to go through a third party company to process the order. This made it almost impossible for terrified parents like ourselves to find the actual distributors of these drugs.

Mrs. MALONE. Mr. Chairman and Senators, since James' death, we have continued to receive packages of dangerous, high potency drugs. These were apparently shipped after he died. We continue to receive 10, 20, or 30 offers a day on his computer, on my husband's computer, and on my own, for as wide variety of controlled medications, even though we have tried to contact the apparent sources and have requested that they stop sending solicitations.

Not only are these e-mails still coming, but the sophisticated spam blockers can't stop it, since the senders use a variety of techniques, such as intentionally misspelling words, leaving spaces in the middle of words, and using special characters to make sure the e-mail gets through.

We are concerned about the source of these drugs, both from a quality control perspective, and are they what the packaging says

they are, as well as the potential for mislabeling, purposefully tampering, or outright fraudulence, such as aspirin marketed as cancer medication or cholesterol lowering pills.

And no longer do addicts need to drive to a certain part of town to obtain drugs from the friendly local drug dealer on the corner. People with addictions can now order from the comfort of their own homes and have it delivered overnight by a reputable delivery service, in a plain brown wrapper. The neighbors need never know.

Our goal in speaking out publicly about our son's death is to help others realize the deadly results that can happen, and do happen, from the seemingly innocuous practice of ordering medications on the Internet. This could happen to your mother or grandmother; it could happen to your daughter or son, or your best friend, who is trying to save a few dollars on medication or avoid another costly trip to the doctor's office to obtain a prescription with instructions on how to use it safely.

We are also concerned about the Internet drug companies, or their ever-changing distributors, who are in the market solely to make money. Making money in and of itself is not a bad thing, but it becomes questionable when it is earned at the expense of our loved ones' lives. To determine the source of these deadly drugs, we would ask that there be accountability, that laws be enacted to allow investigators to follow the money trail and to ascertain who is raking in these profits.

We are asking that legislation be enacted to regulate the ability of companies to sell medications indiscriminately, without verification of age, medical condition, or prescription. We are asking that legislation be enacted so that when medications are purchased over the Internet, complete information is provided about strength, dosage, and especially deadly drug interactions.

Finally, we are asking that legislation be enacted so that companies manufacturing these drugs are clearly identified, and the law should require monitoring of these medications for purity, quality, and truth in packaging. We would like to see serious fines and jail time for those circumventing these laws, using phony names, and overseas companies and accounts, and third-party payment requirements to mask who is profiting from these sales.

Mr. MALONE. For James, he honestly and naively thought that he could take care of his own medical needs by doing the research on the net, that he could trust the information provided him by these medical sites. You could put a key word into AOL under "pain" and get solicitations on 20 percent off morphine this month. I have examples of that.

Buying the recommended drugs to treat his ailments, James assumed that what was presented on these official-looking websites was true and accurate information, but that if there were no dosage and interaction information on the medications, that they must be safe to take. As we now know, he was dead wrong.

Thank you for your time. If you have any questions or if anyone would like to follow up later, I would be glad to make myself available.

The CHAIRMAN. Thank you very much, Mr. and Mrs. Malone. It was very courageous of you to come forward. You have done a tre-

mendous public service, considering the trauma that you have been through, well beyond the call of citizenship. We appreciate it.

Mrs. MALONE. Thank you.

The CHAIRMAN. Following up on your thoughts there on what type of legislation we should pass, almost all of what you have outlined I would have no problem with. I guess the question is, if the product was manufactured in India and transshipped through Canada and the credit card company was in Belize, as we heard earlier, we don't have much of a legislative reach.

Were any of the products that your son took manufactured in the United States, to your knowledge?

Mr. MALONE. Not that we have been able to determine yet. We were able to trace the distributor for virtually all of the drugs, even though he went to different websites, to one distributor in Florida. So if we could focus enforcement, that might be an area to look at, because we have more control over U.S. companies.

But again, some of the packages that we saw in his room after he died had names of major pharmaceutical companies on them. I would think maybe that would be an avenue to——

The CHAIRMAN. Have you determined whether those were counterfeited names or whether they were real names, or haven't you been able to determine that?

Mr. MALONE. We are pursuing an investigation of this, but it appears from what we have been able to determine so far that they seem to be legitimate.

The CHAIRMAN. Obviously, you have put a lot of time into this, and I certainly understand your commitment to do that, in your investigating did you find that these products had been transshipped through other countries to our country? Do you know if any of them came through Canada?

Mr. MALONE. I don't know for sure, but in one particular case some valium that we received in the original factory packaging showed it was manufactured in Pakistan by a major pharmaceutical company, and then transshipped—I guess that would be the term—handled through a third party, a distributor based in Florida. Then they would control the Internet website and manage the orders.

The CHAIRMAN. This Internet website, did it have an access number that allowed you to actually physically talk to someone?

Mrs. MALONE. Sir, we've got quite a bit of backup information available. We have been working through Joseph Califano, Jr., with a detective agency in New York City. They have come out to our home, spoken with us, and done quite a bit of investigative research. We can make the information available to you or others that would be of interest.

The CHAIRMAN. That would be great.

What is your recommendation to people who decide that they want to try to self-prescribe, or just want to go on the Internet, from your experience?

Mrs. MALONE. My first recommendation would be that there would be a prescription required if it's a controlled substance, that it not be just available like you're ordering a pair of shoes.

Mr. MALONE. I think the danger here that we are talking about is not necessarily product quality control, quality assurance, be-

cause these drugs may very well be exactly what they say they are, but it is the ease with which you can get controlled substances just with a credit card and Internet access. I'm not sure what would prevent that, but I think that needs to be taken into consideration.

I'm in high tech. I am reluctant to regulate the Internet or to tax it, that kind of thing. But something has to be done because people believe, the common citizen believes that they are protected, that there are Federal laws that protect them from buying these prescription drugs, even if they are doing it over the Internet. And they're not.

The CHAIRMAN. You're right. That is what we're going to try to address. We thank you for taking the time to come and present your very unfortunate situation. It is obviously educational and will be valuable as we develop legislation.

Dr. Vernon, your conclusion of an obviously in-depth analysis of the trade offs between lower prices, which are price controlled basically, and research was that that would have about an $8 trillion cost and it would affect about a million people. Is that an annual number or is that a 10-year number?

Mr. VERNON. Actually, that is a present value. It takes into account the entire future and discounts back towards the present, to today, and puts it in terms of today's dollars.

I would point out that that is what we consider to be our most reasonable point estimate, that there is a very wide range of estimates that we came up with, depending on the assumptions employed.

The CHAIRMAN. You characterized reimportation as essentially reimporting foreign price controls of an American made product, is that right?

Mr. VERNON. That is correct.

The CHAIRMAN. And you are assuming that a 10-percent price control on a foreign product would cause—on an American made product, whether the price control was put in place in Canada or whether we actually put in price controls—that a 10 percent reduction in the cost of that product was what you were using as your basis?

Mr. VERNON. The basis was what manufacturers would experience would be profitability similar to what they generate off their foreign sales in foreign countries.

The CHAIRMAN. So I guess the bottom line of my question is, what is the price-control number that you are assuming for American-made products which are now price-controlled, which would lead to a significant reduction in research and the effect on life?

Mr. VERNON. We actually don't have a specific percentage reduction in the average price of pharmaceuticals in the United States. Our analysis is just based on it being similar and very comparable to the prices found outside the United States.

The CHAIRMAN. In other words, if you went to a price-control system in the United States, similar to the price-control system in Canada, this would cause a loss of $8 trillion and would affect a million lives?

Mr. VERNON. That was the basis for our analysis, that is correct, Senator.

The CHAIRMAN. I have been rejoined by Senator Kennedy. I may have to leave here in a few minutes, so if you could——

Senator KENNEDY. Are you going to leave me in charge, Mr. Chairman? I remember when—

[Laughter.]

Senator KENNEDY. Thank you. I apologize to the witnesses. We were dealing with the defense authorization bill and I needed to be on the floor for a few moments. But I have had the opportunity to review the testimony prior to the hearing.

Dr. Lee, you heard the testimony from Mr. Taylor from the FDA on our first panel. Don't the problems with importation happening now make a compelling case that we need to provide a safe way for individuals to import prescription drugs? For example, S. 2328 provides a safe way for individuals to get the drugs from Canada and would identify who the safe suppliers are and assure that a physician has prescribed the medicine, and that it is a truly FDA-approved product.

So isn't S. 2328 the obvious solution to this kind of a problem?

Dr. LEE. Well, I would certainly agree with that in terms of the authority. Certainly, as people have pointed out earlier, the resources necessary to implement must be provided, and I think that is a critical element.

It is clear that the FDA is currently not being given adequate resources to deal with the counterfeiting issue, so that I think we have to look at that. But I would say that, absolutely, that is absolutely correct.

Senator KENNEDY. The point I think we have to make is that, even though we have the best system around, you are still seeing and hearing from the witnesses the challenges that they are facing. I think we address a good part of those challenges in the legislation.

Also, you were the Assistant Secretary for Health twice, and in that capacity you have had the responsibility for supervising the activities at FDA. You have also been chancellor of one of the Nation's great medical research universities and are recognized as an expert on public health.

I want to underline that part of your testimony that says our legislation would assure the safe importation of prescription drugs, and a similar statement I have entered into the record from David Kessler, the former Commissioner of the FDA. I recognize that there may need to be some fine tuning of the legislation, but don't you agree that the many safeguards in this bill should really put to rest those who claim to be concerned that this legislation will expose Americans to unsafe and counterfeit drugs?

Dr. LEE. I agree with that. I do detail that in greater detail in my testimony.

Senator KENNEDY [presiding]. Dr. Vernon, you have had some scary sounding estimates for the number of lives that could be lost over the next 50 years if drug industry profits go down.

Just yesterday we read in the Wall Street Journal about the impact of relatively small increases in copayments, causing patients to cut back on drugs that their doctors prescribe.

Have you calculated the loss of life that we are experiencing every day because patients are unable to afford needed drugs?

Mr. VERNON. No, I have not, but certainly those are important costs that need to be considered.

Senator KENNEDY. You're absolutely right, because I see earlier that a number of our colleagues pointed out the kinds of situations that I have seen in my own State. I still have a searing memory of having a hearing in Quincy, MA, where both the husband and wife needed the same drug, but they had limited resources and agreed they would get the full prescription as long as they could, and then they would divide it between themselves, hopefully knowing they couldn't survive without it, and hoping that they would pass it together. It was one of the memorable kinds of meetings that blazed in my soul, and that sort of choice is being made every single day. I know others have spoken eloquently of it and I think it is a matter of importance and we should certainly think about that, too.

Dr. Lee, in your reaction to Dr. Vernon's paper, do you think, if drug prices went down a bit, we would see reductions in research and development and the invention of needed drugs?

I have a chart over here. It shows a number of things. One, it shows profitability, but it also shows the investment in research. This is according to Fortune 500, the top six companies per industry. Hold it up, please.

This is the drug companies smaller share profits in R&D than other research-based industries. Pharmaceuticals, 68 percent; chemicals, 80; semiconductors, 97; software, 167; and 203 in aerospace and defense. This is according to Fortune 500, the annual 10(k) reports.

I know it makes a difference, obviously, in what you're dealing with in terms of the gross, but if you are looking at the gross, you also see the pharmaceutical industry is one of the most profitable industries. I have another chart, but let's accept that to be the case.

You talk about the $24 billion, approximately—it has always been very difficult to get that figure. But it does seem they spend a lot in terms of the advertising and other kinds of payments in the industry. You have the basic rationale that the pharmaceutical companies are not going to be successful unless they innovate, unless they research. There is no reason for them to exist.

So if they are going to cut way back in their research and not be able to produce new products, they are going to go out of business, effectively. They are going to have to make a judgment on whether they are going to continue the research on that or have more advertising, or more profits, for their industry. Because if they don't research, they are going to go out of business.

It seems to me that it is logical to think they would find other ways of trying to save rather than cutting back on the research. But that has been something mentioned many, many times.

Dr. LEE. Senator Kennedy, if I may just add a word, much of the research money by the pharmaceutical companies goes for these "me too" products, which are not new molecular entities.

Second, they fund what many of us would call marketing as opposed to true clinical trials. They are called clinical trials, but in fact, they are efforts to market and those come under the research. So when you look at those expenditures, you have to look critically

at how much money really goes for new molecular entities that are innovative, that advance our knowledge and advance therapy.

I mentioned in my testimony the paper by the group at UCLA Harbor Hospital, about the lack of new antibacterial drugs. You know, there are virtually none coming on. There are a number that have come on with HIV drugs in the last 4 or 5 years, partly because NIH's investment spawned a great deal of that drug development, and a market for an HIV drug people take for the rest of their life. For an antibacterial drug, it is only a short time and they don't see the profit return, so they are making decisions that are purely profit-related and don't necessarily serve the public interest.

So I think we have to look in greater depth than is possible—I mean, Dr. Vernon did a very excellent economic analysis, but that is only part of the story. You have to look at what data was available to them, and they didn't look at the marketing expenses, they didn't look at the promotional expenses, which in fact, exceed those for research and development.

Senator KENNEDY. I can remember when we had hearings on the industry at another time the lack of interest and investment in drug resistant bacteria. This was something that was very evident. If you are looking over the general challenge that we are facing, in terms of health care—I mean, there are many, many different challenges, but certainly in the pharmaceutical area, this is key. I think the point you make about the "me too" drugs is absolutely correct. So this is something that is important to mention.

Let me just mention to Mr. and Mrs. Malone, I thank you for coming and appearing. It is always difficult to talk about these matters, but we thank you for your willingness to share. I think you are obviously motivated that we try and get this right, and that is why you are here. I think it is a great tribute to you both for being willing to go over this sad ground again. But it is enormously helpful. Obviously, the best way we can thank you is by trying to get it right.

Several of my colleagues and I have introduced a bill to allow drug importation, but the bill will not allow the importation of controlled substances. It will give Customs and FDA better authority to stop the illegally imported drugs at the border. It will allow the Government to stop credit card payments to the illegal offshore Internet and mail order pharmacies. It requires individual imports of drugs to come from licensed Canadian pharmacies that FDA regularly inspects, and the drugs are dispensed with a prescription from the patient's attending physician.

So I understand these are not all the proposals that you made in your testimony, but they are certainly some of them.

Mr. MALONE. Senator Kennedy, just one comment I could make on the prescription. That is key.

For example, through my health care I can get mail order drugs. I have to take my original prescription, mail that in, and then they contact my doctor and verify that it really is a prescription from him. There is that double check, that confirmation. That would solve a lot of issues, that model that insurance companies are using today.

Senator KENNEDY. That is very, very helpful.

As we mentioned, as other sponsors here on the committee have said, we are going to exhaust every avenue to ensure protection. We are concerned about the challenges that are out there now, which are exposing our population. We will work with the agency, we will work with others who are skilled practitioners, knowledgeable individuals, that can be helpful to us.

I was here when we passed the Medicare bill. I was here when it was defeated in 1964, and then 8 months later we passed it in 1965. Only 3 percent of all private insurance had pharmaceuticals at that time, so we didn't include it at that time. We had the physicians' fees and hospitalizations. We didn't have pharmaceuticals. That is the third leg on the stool. We committed to our people that we were going to deal with the health care issues, and that is as essential to many of our seniors as their hospital visits or visits to their doctors, and in many respects, more so.

Every day that we fail, we violate that pledge and that commitment. We have an opportunity to do something that can make a difference. We at least partially missed it, as I have said repeatedly on our Medicare bill. But we have an opportunity to do something with this legislation. We have to do it carefully and we have to make sure we have the resources necessary for the FDA to do it, and we have to clear up the existing kinds of challenges. But we are strongly committed to that and we welcome those that have been listening to our hearing, if they have ideas and suggestions, we will certainly look forward to hearing them.

Finally, I would just say that we are going to move ahead with this legislation. We have met with the Majority Leader. I have talked to the chairman, whose own legislation is going in. We want to work through the committee, and it is our desire to certainly do that. But we are running out of time in terms of this session, and this need is out there.

We have indicated to our leader that we are going to deal with this issue in the near future, because there is an extraordinary need, and every day that goes by without it, we are putting a health risk on our fellow citizens that we ought to be able to address. I think we can and have every intention to do so.

There being no further business, the committee will stand in recess, subject to the call of the chair.

[Additional material follows.]

ADDITIONAL MATERIAL

RESPONSE TO QUESTIONS OF SENATOR GREGG BY PHILIP R. LEE, M.D.

STANFORD UNIVERSITY,
July 19, 2004.

Hon. JUDD GREGG, *Chairman,*
Committee on Health, Education, Labor, and Pensions
U.S. Senate,
Washington, DC 20510–6300.

DEAR MR. CHAIRMAN: I am pleased to respond to your letter of May 26th (not received until July 7th) and respond to your questions as well as those of Senators Enzi and Jeffords. My replies are attached.

Question 1. You stated that, under S. 2328, importable drugs must be FDA approved and manufactured in an FDA-inspected plant. It is my understanding, however, that the bill would permit the importation of drugs with different active ingredients, "related" active ingredients, or different active ingredients [section 4.]; and allows FDA to waive virtually any approval condition for a personally imported drug, including whether the drug is FDA-approved or manufactured in an FDA-approved facility [section 5].

Answer 1. Mr. Chairman, it is my understanding of S. 2328 that a prescription drug cannot be imported by registered importers (e.g., pharmacies, groups of pharmacies, wholesalers) without the submission of an application to the FDA by the manufacturers and the FDA approving the drug for import. Section 804(g)(2)(C) requires that the manufacturer of the drug that may be imported to submit to the FDA a notice of any differences in the drug from conditions of approval of the U.S. label drug (such as a different formulation or different manufacturing plant) or that there are no differences. The FDA must then review those differences as if they were manufacturing changes to the U.S. label drug under section 506A of the Federal Food, Drug, and Cosmetic Act. Some of these changes require pre-approval or allow the FDA to require preapproval. Others may be implemented pending approval. Still others do not require approval. The FDA may also inspect the manufacturing plant if that is required. The drug to be imported may be imported only if the differences that would require preapproval are approved by the FDA, and importation is stopped if the difference is not approved.

S. 2328 also contemplates importation of drugs that differ from a U.S. label drug because of small variations in active ingredient, or because of differences in dose, strength, or route of administration. It facilitates importation of such drugs in section 804(g)(2)(G), which requires manufacturers to submit applications to FDA under section 505 of the Federal Food, Drug, and Cosmetic Act. Importation could occur only if FDA were to approve such an application, so the standard of FDA-approval is maintained.

Question 2. As you know, FDA's enforcement activities under S. 2328 would be funded by means of a user fee that would be capped at 1 percent of the total value of drugs imported annually into the United States. As such, the current $1 billion worth of drugs imported annually into the United States from Canada would generate a mere $10 million in fees.

Answer 2. I believe the user fees that would be authorized under S. 2328 would be adequate to cover the costs of the necessary inspections, the review process, and the development of regulations necessary to implement the Act. There are, for example, only 30 or 40 pharmacies in Canada that would likely export to the United States. This number of pharmacies, as well as wholesalers, plants in Canada could certainly be inspected with resources made available. When the imports are permitted from Europe, it is likely that the additional costs could be covered by the user fees imposed, especially if the number of domestic importers is a manageable number.

Question 3. S. 2328 does *not* require that imported drugs be kept separate from other drugs, or to disclose to the consumer whether or not a prescription drug is imported.

Answer 3. While current policy does not require that consumers be informed about the place of manufacture of their prescription drugs (whether imported by the manufacturer or produced domestically), I think this is a good idea. I believe the

patient's "right to know" is a good one and should be applied to drugs imported by manufacturers, pharmacies, or individuals.

Sincerely,

PHILIP R. LEE, M.D.,
Consulting Professor of Human Biology, Stanford University,
Professor of Social Medicine (Emeritus), Department of Medicine, and
Senior Advisor, Institute for Health Policy Studies, School of Medicine, UCSF.

QUESTIONS OF SENATOR GREGG TO JOHN M. TAYLOR, J.D.

Question 1. Is it fair to note a shift in tone in the agency's position on importation—from outright opposed to "we're willing to work with Congress to determine what resources and authorities could be provided to ensure that importation delivers only safe and affordable drugs to Americans?"

Question 2. If importation is automatically permitted from countries throughout Europe and the South Pacific, is 1 year sufficient time for the FDA to prepare?

SPECIFIC TO S. 2328 (KENNEDY-DORGAN)

Question 1. Can you identify the FDA's chief concerns with the bill?

Question 2. What critical safety features are missing from the bill?

Question 3. How much will the bill cost to implement?

QUESTIONS OF SENATOR GREGG TO JOHN A. VERNON, PH.D.

Question 1. CBO predicts that overall cost savings to U.S. consumers would produce, at most, a modest reduction in prescription drug spending—roughly 1 percent over 10 years. Do you agree?

Question 2. Under an importation program, what cost-savings would be available to individual consumers? What portion of potential savings would go to the middlemen who import?

Question 3. In your research model, you assume that the impact of large-scale importation will result in U.S. drug prices equal to the lowest prices in the world, adversely impacting pharmaceutical R&D spending. Based upon your research, what do you believe the impact on pharmaceutical R&D would be if importation accounted for 5 percent–10 percent of total U.S. drug sales?

QUESTIONS OF SENATOR FRIST TO JOHN M. TAYLOR, J.D. AND WILLIAM K. HUBBARD

May 25, 2004.

JOHN TAYLOR,
Associate Commissioner for Regulatory Affairs,
Food and Drug Administration,
Rockville, Maryland 20857.

WILLIAM K. HUBBARD,
Associate Commissioner for Policy and Planning,
Food and Drug Administration,
Rockville, Maryland 20857.

DEAR MR. TAYLOR AND MR. HUBBARD: Thank you for participating in the prescription drug importation hearing before the Senate Health, Education, Labor and Pensions (HELP) Committee last week. While I regret being unable to attend, I look forward to reviewing your testimony and your response to questions posed by the committee members.

Your testimony will prove extremely valuable as Congress continues to consider efforts to provide Americans with safe, effective, affordable prescription drugs. Because I was unable to attend the hearing, I have submitted the following questions for the record and would greatly appreciate your timely response to the following:

Question 1. In reviewing S. 2328, the legislation introduced by Senator Dorgan and others, I understand that the FDA must permit importation from Canada within 90 days following the date of enactment of the act. Do you believe that the FDA is ready to meet such a time frame for issuing regulations? What are the differences with respect to enforcing this law for food importation as compared to prescription drug importation?

The bioterrorism law Congress passed in 2001 provided FDA 18 months to issue regulations for just the registration of food exporters alone. The law also provided $100 million in the first year in additional authorized funding for FDA to assess the threats posed by efforts to intentionally adulterate food—and a food importing infrastructure was already in place.

Do you believe that S. 2328 provides FDA with the time frame and resources to ensure the safety of imported medicines? Do you believe that we should also consider extending resources to U.S. Customs and the U.S. Department of Homeland Security?

Question 2. In at least one of the bills before the committee, as I read it, the FDA must automatically permit importation from 19 additional countries beyond Canada 1 year following the date of enactment.

Does it concern you that this expansion to these additional countries would be automatic, and that it does not require prior review by the FDA as to (1) the impact of expanding the importation system beyond Canada and (2) whether importation from a particular country poses a public health risk?

Also, it is my understanding that the regulatory authorities in some of these countries may not be nearly as rigorous in ensuring safety and efficacy as those used by the FDA. Can you expand on this?

Question 3. Currently, FDA-approved generic drugs must meet a bioequivalency standard. As you have reviewed S. 2328, do you view the standards contained in that legislation as requiring imported drugs to meet a similar bioequivalency standard? The language of that bill seems to say that drugs must meet pharmaceutically equivalent standards, but not necessarily therapeutically equivalent standards. Is this an accurate reading?

Question 4. Last year the United States learned that a cow in Canada exhibited signs of bovine spongiform encephalopathy (BSE), commonly referred to as "Mad Cow" disease. In order to protect American consumers, the United States banned all beef imports from Canada. While the Secretary of the Department of Agriculture, Ann M. Veneman, believed the risk to Americans was low, the government nevertheless had the authority to take this extra precaution.

Would you agree that the FDA must possess similar authority with respect to prescription drugs (i.e., the authority to shut off importation from a particular country in the event of a public health risk)? Do you feel that the proposals before the committee provide such authority and is it sufficient?

Furthermore, I noticed on the FDA's website a list of recalls, market withdrawls, and safety alerts. What is FDA's current recall authority? Under S. 2328, would the FDA have recall authority and would the FDA be able to differentiate between a foreign and U.S.-approved product? How important is it for us to include recall authority, or some type of equivalent authority, in any legislation?

Question 5. Parenteral or "injectable" medications generally have very specific shipping and handling requirements such as refrigeration to ensure the product's safety and efficacy. Parenteral medications can be used to treat chronic and acute diseases such as diabetes.

Past legislation has recognized the inherent danger in allowing importation of products of this fragile nature, due to the high risk of improper storage or shipping, and disallowed their import into the U.S. In fact, there are reports of adverse events that have occurred as a result of improperly shipped parenterals from Canada. When considering importation legislation, should we consider any special limits on these types of medications? Are there other drugs that are particularly sensitive to conditions such as temperature whereby the FDA should have additional authority?

Question 6. Finally, all new drugs currently undergo a rigorous FDA approval and regulatory process. Can you briefly describe this process and how those standards may differ in comparison to the approval and distribution systems found in EU member countries such as Greece and Portugal? And if so, what are the implications for patient safety as we consider expanding the legal importation of drugs?

Once again, thank you for attention to these questions. I look forward to your response. If you have any questions, please contact Jennifer Romans of my staff at (202) 224–9598.

Sincerely,

WILLIAM H. FRIST, M.D.,
Majority Leader,
United States Senate.

RESPONSE TO QUESTIONS OF SENATOR ENZI BY PHILIP R. LEE, M.D.

Question 1. Dr. Lee, you testified that you believe importation will provide downward pressure on drug prices paid by American consumers. However, the Congressional Budget Office has estimated that importation from a broad set of industrialized countries—not just Canada—would only result in a 1 percent reduction in U.S. drug spending.

The CBO also pointed out foreign governments probably would respond to U.S. importation by taking actions to limit the volume of drugs diverted to the United States, out of a desire to prevent shortages or higher prices in their own countries.

What makes you so sure, then, that changing the law to allow importation would result in lower drug prices for most Americans?

Answer 1. I am not familiar with the report of the Congressional Budget Office (CBO) on the savings from the importation of prescription drugs. I was not aware of a CBO report on S. 2328 and would wait until that was available before commenting in more detail. Two anecdotes, however, have influenced my thinking. The people who currently import prescription drugs from Canada do so because they believe they save money, far beyond the 1 percent reported by the CBO. This is not surprising in view of the fact that the prices of prescription drugs in Canada are 40 percent below those in the United States. My second anecdote: in Israel, where parallel imports are authorized, it is the view of some that, while rarely used, they exert a downward pressure on prices.

Question 2. Dr. Lee, you endorse FDA approval as the "gold standard" for assuring drug quality, safety and effectiveness. I agree with you. However, the bill that you support, S. 2328, does not require FDA approval—it creates a "presumption" of FDA approval under certain circumstances.

Could you describe the difference between actual FDA approval of a drug and the presumption of FDA approval of a drug?

Answer 2. I believe the language of S. 2328, creating a new section 804 to the Federal Food, Drug, and Cosmetic Act does, in fact, require FDA approval of any prescription drug imported from registered exporters or by registered importers. It would make sense to eliminate the word, "presumption."

Question 3. Dr. Lee, the bill you support provides for drug importation to begin in 90 days. In contrast, the bioterrorism law for food importation allowed 18 months for the FDA to issue many parts of the regulations, even though the FDA already had some authority and an inspection infrastructure in place.

Here, the FDA has no authority and no real infrastructure in place, yet the bill you support would permit drug importation almost immediately.

Why do you believe the FDA would be ready to allow importation in 90 days?

Answer 3. Yes, I believe the FDA would be ready to allow importation in 90 days. The limited number of pharmacies in Canada, perhaps 30–40, that are likely to be registered exporters should make it feasible for the FDA to implement the provisions of S. 2328 that relate to the importation of approved prescription drugs from Canada within 90 days.

Question 4. You testified that drug companies spend more on marketing, advertising, and administration than on research and development. Having run a small business myself, I can tell you that businesses have a lot of administrative expenditures that aren't related to marketing or advertising, so lumping them together doesn't make much sense to me. Can you explain what you mean by administration?

Answer 4. In my testimony, I defined administrative costs as those costs that were defined by the companies in their SEC filings. In our review of SEC filings, my colleagues and I did not define administrative costs. It appears that different companies include different categories under administration.

Question 5. I also found some data from the business intelligence firm IMS Health that contradicts your assertion about drug company spending on advertising and promotion versus research. For instance, their data shows that the drug industry spent $30 billion on R&D in 2001, and $19 billion on all promotional activities, including direct-to-consumer advertising.

That $19 billion on promotional activities also includes free or heavily discounted drugs that companies offer through their patient assistance programs.

Can you explain the discrepancy between your assertion and these figures?

Answer 5. Unfortunately, I do not have access to IMS Health data, but the figures do seem to be very different than those reported to the SEC by the individual companies. For example, the report published by Families USA in July 2002, *Profiting from Pain: Where Prescription Drug Dollars Go*, included data for SEC filings. They reported on the manufacturers of the top 50 drugs prescribed to seniors. Families

USA reported that the revenues (net sales) were $166.678 billion, with marketing, advertising, and administration at $45.413 billion (27 percent), R&D at $19.076 billion (11 percent) and profit at $30.599 billion (18 percent) (see Table 1 in *Profiting from Pain: Where Prescription Drug Dollars Go*. A Report by Families USA. July 2002).

I cannot explain the IMS Health Data because I do not know how they defined R&D or promotion and what they included in those categories. The paper by Rosenthal et al. (*New England Journal of Medicine* (2002) 346: 498–505) suggests that in 2000 that spending for promotion of prescription drugs was $16 billion, a figure that comes close to the IMS Health Data suggested for 2001. Clearly the SEC filings include a good deal more under marketing, advertising and administration than prescription drug promotion to physicians.

In a recent article by Ma, Stafford, Cockburn, and Finkelstein ("A Statistical Analysis of the Magnitude and Composition of Drug Promotion in the United States in 1998" *Clinical Therapeutics*. (2003) 25(5): 1503–17.), the authors reported that the pharmaceutical industry spent $12.724 billion promoting its products in the United States. The expenditure included free drug samples provided to physicians ($6.002 billion), office promotion ($3.537 billion), direct-to-consumer advertising ($1.337 billion), hospital promotion ($0.705 billion) and advertising in medical journals ($0.540 billion). Again, this total for 1998 appears to match more closely the IMS Health figure than do the SEC filings by companies.

Question 6. Dr. Lee, you testified that most new drugs approved by the FDA are not clinical breakthroughs. You suggested that most new drugs are simply "me-too" products of marginal value to consumers.

Considering that the pharmaceutical research and development process takes on average between 12 and 15 years between the discovery of a potential drug and FDA approval of that drug, I find the "me-too" label hard to accept.

The "me-too" label suggests that companies are emulating the success of popular drugs already on the market. How many examples can you provide of successful innovative drugs aimed at particular conditions that were the object of "me-too" drugs developed after other companies saw the market potential for the originial innovative drug?

Furthermore, when there are multiple drugs aimed at a particular medical condition, the resulting competition generally brings lower prices for all drugs in that therapeutic class. Do you disagree with this assessment, and how many examples can you provide where this assessment does not hold true?

Answer 6. This is a complex issue, but the best recent analysis was carried out by the National Institute for Health Care Management Research and Education Foundation. The report, *Changing Patterns of Pharmaceutical Innovation* (Washington, D.C., NIHCM Foundation, May 2002, pg. 24) "characterizes the level of innovation of all new branded medicines that entered the U.S. market from 1989 to 2000, excluding vaccines and other biological products" (pg. 2). In the 12-year period from 1989 to 2000, the FDA approved 1,035 new drug applications. Of these, 361 (35 percent) were new molecular entities (NMEs), 674 (65 percent) were drugs containing active ingredients already available in marketed drug products. The FDA classifies these as incrementally modified drugs (IMDs). The remaining 116 (11 percent) were drugs that were identical to products already available on the U.S. market. These were called other drugs (other). It is the IMDs that are often referred to as "me too" products by industry critics. The vast majority (85 percent) of these drugs (IMDs) reviewed by the FDA received a standard rating. A priority rating was given when a drug appeared to provide clinical improvement over the drug products available on the market at the time of the New Drug Application (NDA). Only 15 percent of IMDs received a priority rating in contrast to 42 percent of NMEs, which received a priority rating. The authors of the report noted:

> Highly innovative drugs—medicines that contain new active ingredients and also provide significant clinical improvement are rare. Over the 12-year period examined, just 153 out of a total of 1,035 new drug approvals (or 15 percent) were for such drugs, priority NMEs (pg. 3).

During the late 1990's, the authors reported that while many new drugs entered the market, most of the growth came from the less innovative products. Standard IMDs accounted for 62 percent of the increase and priority NMEs for only 3 percent of the increase. These standard IMDs may be heavily promoted (see Angell M. "The Pharmaceutical Industry—To Whom Is it Accountable?" *New England Journal of Medicine* (2000). 342(25): 1902–1904.)

The spending for newly introduced prescription drugs, according to the NIHCM study, was driven by the standard rated new products. These products provide no significant improvement over existing products, yet they accounted for 67 percent

of the increase associated with new drugs and 44 percent of the total increased spending. The use of prescription drugs depends on physician prescribing and that is why the drug companies spend so much on promoting their products to physicians, including the billions of dollars of free samples given to physicians to encourage the use of their products. I don't believe that brand name prescription drug products represent a true market.

QUESTIONS OF SENATOR ENZI TO JOHN M. TAYLOR, J.D.

Question 1. There is a requirement in S. 2328 for a full paper pedigree for all drugs, whether imported or not.

My understanding is that the drug distribution system is moving toward the adoption of track-and-trace technologies using radiofrequency devices—in other words, an electronic pedigree.

Would it be easy for someone to counterfeit a paper pedigree? What would it take for someone to do so?

Question 2. Considering how much safer an electronic pedigree would be, and that the system is on track to have electronic pedigrees in use by 2007, shouldn't we wait for the new technology?

In other words, would we be exposing consumers to a much higher level of risk by allowing imported drugs to enter the country with nothing more than an easy-to-fake paper pedigree?

Question 3. Would you describe, to the best of your knowledge, the major differences between how Canada regulates prescription drugs for domestic consumption, and how Canada regulates drugs that are exported to other countries?

QUESTION OF SENATOR ENZI TO JOHN A. VERNON, PH.D.

Question 1. Dr. Vernon, the Congressional Budget Office sees little savings in drug importation, which suggests we ought to keep our drug distribution system closed to imports.

The CBO suggests that if we allow importation, foreign governments would act to limit exports from their countries to the U.S. to prevent shortages and protect their own price-control schemes. Is that a fair analysis?

QUESTIONS OF SENATOR DEWINE TO JOHN M. TAYLOR, J.D.

May 19, 2004.

Hon. JUDD GREGG, *Chairman,*
Health Education Labor and Pensions Committee,
U.S. Senate,
Washington, DC 20510.

DEAR CHAIRMAN GREGG: I kindly request that the following questions be submitted for the record for the Thursday, May 20, 2004 hearing on the "Importation of Prescription Drugs."

Several recently introduced Senate bills include provisions requiring a paper pedigree on all domestic prescription drug products distributed to retail pharmacies. I know the FDA has spent a lot of time studying drug counterfeiting and convened a task force to make recommendations about what should be done to address the problem. Specifically, your report titled "Combating Counterfeit Drugs" states:

> "Modern electronic technology is rapidly approaching the state at which it can reliably and affordably provide much greater assurances that a drug product was manufactured safely and distributed under conditions that did not compromise its potency. FDA has concluded that this approach is a much more reliable direction for assuring the legitimacy of a drug than paper recordkeeping requirements, which are more likely to be incomplete or falsified, and that it is feasible for use by 2007." (page ii of the Executive Summary)

In another section of the report, the FDA states:

> "At the time PDMA was enacted, the only way to pass on a pedigree for drugs was to use paper, which has posed practical and administrative challenges. RFID technology, which would provide a de facto electronic pedigree, could surpass the intent of PDMA and do so at a lower cost. In light of the rapid progress toward much more effective electronic pedigrees that can be implemented with-

in several years, FDA intends to continue to stay its regulations regarding certain existing pedigree requirements to allow suppliers to focus on implementing modern effective pedigrees as quickly as possible." (page iii of the Executive Summary)

I think the FDA's conclusions in this report make sense. Mr. Taylor, I think it would be helpful for the committee to have you elaborate on these points.

Question 1. Please explain what a paper pedigree is and why, as you say in your report, it is "more likely to be incomplete or falsified."

Question 2. What would be the relative difficulty of counterfeiting the paper pedigree as compared to counterfeiting the prescription drug, its label and its packaging?

Question 3. If a paper pedigree were required to accompany every prescription drug item delivered to retail pharmacies, can you give us an estimate of how many pedigrees would be provided to retail pharmacies on a daily basis?

Question 4. Please describe what would be required throughout the distribution chain—from the manufacturer through the distributor to retail pharmacy—in order to implement a paper pedigree requirement for all prescription drugs distributed to retail pharmacies. How would current administrative and operational procedures need to be changed? Can you estimate the costs associated with these changes?

Question 5. FDA indicated that paper pedigrees pose "practical and administrative challenges." Please provide the committee with examples of these challenges and, where possible, an analysis of their costs.

Thank you for the kind consideration of this request.

Very respectfully yours,

MIKE DEWINE.

RESPONSE TO QUESTIONS OF SENATOR JEFFORDS BY PHILIP R. LEE, M.D.

Question 1. Dr. Lee, welcome and thank you for coming back to testify once again before this committee and to commend you for your thoughtful statement.

As you mentioned, you have heard many of these same arguments over the past 35 years. In part, this is because the pharmaceutical industry has been so successful in pushing off legislation they did not want.

Carrots and sticks are the methods Congress has at hand to obtain support—or at least—compliance with some policies, and there at least two bills before the Senate that take these different approaches.

Given your long experience in these issues, I would be interested in your views of how, from a legislative point of view, we might finally move forward on this issue of reimportation?

Answer 1. I believe that the balanced approach that is represented in S. 2328 is a very reasonable approach to assure the high quality of prescription drugs available in the United States. The bill stimulates competition by providing citizens of the United States access to the prescription drugs that have been prescribed for them at lower prices than are currently available in the United States.

Question 2. In your statement you noted the increasing price of drugs and the increasing costs of drugs and I appreciate your clarifying the differences. The bottom line is that American consumers feel they are spending too much on medicines, especially compared to people in other countries.

On the other hand, some of these costs have been offset by reduced costs (and sometimes the eliminated costs) of treating diseases and hospitalizations.

You have seen first hand the impact of NIH funded research has had for example on the health expenditures of the Medicare program. I would appreciate hearing your views on how we might better balance our policy goals in this arena?

Answer 2. The cost of drugs differs from the price in that it reflects price and volume of use. An individual may pay a reasonable price for each pill, but if the medicine must be taken three times daily on a permanent basis, the cost on a monthly or annual basis may be quite high.

There are many treatments, such as those for congestive heart failure and asthma, that if applied appropriately in the ambulatory setting can result in dramatically lower costs of medical care because unnecessary hospitalizations are avoided. On the other hand, we also have the overuse of prescription drugs, such as antibiotics to treat the common cold, that not only do no good, but may result in antibiotic resistant organisms. We now have a very serious problem because of hospital-acquired infections with organisms that are resistant to virtually all antibiotics.

This may result in the death of patients, and it certainly adds to the costs of medical care.

There are many other areas where technological advances, such as laparoscopic surgery provide significant benefit to patients and reduce costs to the individual patient because inpatient hospital care is avoided. However, the number of procedures, such as removal of the gallbladder because of stones or chronic inflammation, has increased and thus the costs have risen. This is also true for many of the new imaging technologies. Unfortunately, many of these are performed unnecessarily, increasing the costs of care (and the radiologists' income) without benefit to patients.

The problems with prescription drugs are very serious. There is overuse (e.g., antibiotics), underuse (e.g., diuretics to treat hypertension), and misuse (many examples). Thirty-five years ago, we identified these problems in the Task Force Report on Prescription Drugs. In that report, we called for rational prescribing. Doctor Milton Silverman and I reemphasized this in our book, Pills, Profits, and Politics, published 30 years ago. The recommendations are still applicable today. I could actually write another book on the subject now and again emphasize many of the points that we made 30 years ago.

How to deal with the problems? The first steps we recommended many years ago began with physician education and far greater use of clinical pharmacists in hospitals and I would add now in ambulatory care settings. Hospitals need to adopt electronic medical records and every inpatient prescription should be made electronically to avoid the errors in handwritten prescriptions. The IOM Reports, *To Err Is Human* and *The Quality Chasm*, dealt with these and had a number of specific recommendations.

I think that medical students and residents should not receive gifts from drug companies, and all forms of promotion should be fully disclosed so that patients know that their doctors are receiving gifts from drug companies. An organization has been formed, "No Free Lunch," to address many of the issues related to promotion. The organization and its web site are under the direction of Bob Goodman, a general internist practicing in New York City.

Doctor Avorn at Harvard has proposed academic detailing to replace the commercial detailing that currently promotes prescribing of brand name products.

These are but a few suggestions. Others would be more regulatory, such as banning the use of antibiotics in agriculture to promote growth. New antibiotics, particularly to treat drug resistant organisms, should be limited to inpatient hospital use until the problem of hospital-acquired infection is under better control.

Question 3. I'm also especially interested in your views on how we might best incentivize research into New Molecular Entities as opposed to the "Me Too" drugs. Could you elaborate on your statement for the committee?

Answer 3. One step that might be taken—it would require action by Congress—would be to require that any new drug introduced demonstrate that it was more cost-effective than the drugs on the market. This idea would, of course, be strongly resisted by industry, but it would help to reduce the number of incrementally modified drugs that receive a standard rather than a priority rating by FDA in their reviews.

QUESTIONS OF SENATOR JEFFORDS TO JOHN A. VERNON, PH.D.

Question 1. In your statement you note that if reimportation is successful . . . "the result will be to significantly diminish the incentives to invest in R&D, which in turn will reduce the future supply of new drugs." That assertion raises a couple of questions.

The CATO Institute, which is dedicated in part to an open-market view of economics, has reached a very different conclusion than yours. CATO advocates in favor of reimportation arguing that it will require companies to review their international pricing strategies and truly negotiate, rather than just accept, prices for their products. This approach will lead to greater competition and let the markets better decide the true value of these products. Isn't the CATO hypothesis as valid as yours, and if not, why not?

Question 2. Pharmaco-economics is not my specialty area . . . but I believe that companies experience the greatest return on investment from truly breakthrough products, those that are known as "New Molecular Entities."

Less—but still profitable are those known as "Me Too" drugs that may be good for a companies bottom line but are of less value from a health perspective.

Your analysis leads me to wonder whether companies operating in a climate of fewer R&D resources wouldn't be more inclined to devote those scarce resources on

the newer more profitable breakthrough drugs. Has your research addressed that as a possible outcome resulting from a reimportation policy?

RESPONSE TO QUESTIONS OF SENATOR REED BY PHILIP R. LEE, M.D.

Question 1. Dr. Lee, you note in your testimony that the United States and New Zealand are the only two countries that allow direct-to-consumer (DTC) advertising. To what extent does DTC advertising contribute to increased utilization in these two countries?

Answer 1. A recent study by Harvard-based researchers, Meredith Rosenthal and colleagues, on the effects of direct-to-consumer (DTC) advertising and physician promotion activities on drug sales within five therapeutic drug classes found that for every 10 percent increase in DTC advertising, drug sales within classes studied increased on average by 1 percent (Rosenthal et al. 2003). In this study, the authors examined monthly data from August 1996 to December 1999 for five therapeutic classes of drugs (where at least one product had high DTC advertising expenditures and there was variation in advertising patterns within the therapeutic class). The five classes were: anti-depressants, antihyperlipidemics, proton pump inhibitors, nasal sprays, and antihistamines. By applying the price elasticity results from these five therapeutic classes to the aggregate changes in total sales and total DTC advertising spending for the 25 drug classes with the highest retail sales from 1999 to 2000, the authors estimated that changes in DTC advertising from 1999 to 2000 accounted for 12 percent (or $2.6 billion) of the total growth in drug spending in 2000. This means that each additional dollar spent on DTC advertising in 2000 yielded $4.20 in additional pharmaceutical sales in that year. This study demonstrates that DTC advertising, while not the only driver of increased drug expenditures, is an important contributor to increased growth in drug costs (Rosenthal et al. 2003).

Similarly, a study conducted by Findlay for the National Institute for Health Care Management Foundation examined which products were the major drivers of annual increases in retail drug costs and DTC advertising (Findlay 2001). Although Findlay did not separate out the effects of DTC advertising from the effects of drug company promotional practices aimed at physicians, the study found that heavily advertised drugs had more rapid increase in sales and disproportionately affected cost increases. Findlay concludes that "much of the sales increase for heavily advertised drugs came from a jump in the number of prescriptions. For the 50 most heavily advertised drugs, the number of prescriptions increased 24.6 percent. The number of prescriptions for all other drugs rose just 4.3 percent . . . Thus, the number of prescriptions for the 50 most heavily advertised drugs grew at a rate six times that for other drugs" from 1999 to 2000 (Findlay 2001, pg. 7).

A comprehensive and detailed analysis of available literature bearing on the association between DTCA spending and drug sales can be found in Dr. Barbara Mintzes' doctoral dissertation ("Direct-to-consumer Advertising of Prescription Drugs: Effects on Prescribing and Policy Implications." Center for Health Services and Policy Research, University of British Columbia, Vancouver, British Columbia, Canada, June 2003). Dr. Mintzes is a leading scholar and expert on the nature and impact of DTCA both in the United States and abroad. An excerpt from this dissertation is attached and includes a review of relevant data from New Zealand as well as other U.S. studies (see Attachment A).

Clearly, there is some evidence that direct-to-consumer advertising influences prescription drug expenditures and utilization. According to Dr. Barbara Mintzes, DTCA does contribute to increased sales of heavily advertised drugs. However, most of these analyses do not separate out fully the effects of DTCA from drug company promotional campaigns aimed at physicians (Mintzes 2003).

Question 2. A November 2003 Wharton study comparing average prices for pharmaceuticals in nine countries found that price differences were generally consistent with income differences between these nations. However, the study only examined manufacturer prices not retail prices. How much do retail prices vary across nations? Does the general correlation drug prices and per capita income as indicated in this study hold true at the pharmacy counter?

Answer 2. In answer to Senator Reed's second set of questions, I am not familiar with any literature that examines the Wharton study's correlation for retail drug prices and per capita income, but we are searching for additional information about retail price comparisons and hope to have a more complete answer soon.

As the Senator states, the Danzon and Furukawa study focuses on manufacturer prices, not retail prices. Regarding retail prices, the authors write "the general conclusion from these retail-price comparisons is that retail prices in the European countries that regulate pharmacy margins (France, Germany, and Italy) are much

higher, relative to U.S. prices, than their manufacturer prices; hence, differences measured at retail prices are smaller than differences at manufacturer prices" (Danzon and Furukawa 2003, pg. W3–530). The authors later state that "in fact, high regulated wholesale and retail pharmacy distribution margins in some foreign countries could contribute to their lower manufacturer prices" (Danzon and Furukawa 2003, pg. W3–530).

Two recent articles provide some comparative data of spending on pharmaceuticals across countries (Reinhardt et al. May/June 2002, Anderson et al. May/June 2003). For instance, using the most recent OECD data available (Anderson et al. May/June 2003) for the countries that Danzon and Furukawa examined (Canada, France, Germany, Italy, Japan, Mexico, United Kingdom, and United States):

Spending on Pharmaceuticals in Selected OECD Countries, 2000 (excerpted from Anderson, Reinhardt, Hussey, and Petrosyan. (May/June 2003) "It's the Prices, Stupid: Why the United States is So Different From Other Countries" *Health Affairs* 22 (3): 94).

Country	As percent of GDP, 2000	Spending per capita, 2000 (US$ PPP)*
Canada	1.4	385
France	1.9	473
Germany	1.4	375
Italy	1.8	459
Japan (1999)	1.2	313
Mexico (1999)	1.1	93
United Kingdom (1997)	1.1	253
United States	1.6	556

*PPP stands for purchasing power parity.

In addition to France and Italy, Portugal and Hungary also spend a greater percent of GDP on pharmaceuticals than the United States (2.0 percent and 1.8 percent respectively). All other OECD countries included in the analysis spend a smaller percentage of GDP on pharmaceuticals with Ireland the smallest percent (0.6 percent). While these data do not allow me to directly answer Senator Reed's questions regarding whether there is a correlation between retail drug prices and per capita income, they indicate that the United States spends a greater percentage of GDP on pharmaceuticals than most other OECD countries.

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ATTACHMENT A

From Mintzes B. (June 2003) "Direct-to-Consumer Advertising of Prescription Drugs: Effects on Prescribing and Policy Implications." Ph.D. Dissertation, Center

for Health Services and Policy Research, University of British Columbia, Vancouver, British Columbia, Canada.

2.4.5 RETROSPECTIVE DATA ANALYSES

Table 2.26 describes studies that have used administrative and sales databases to examine the association between DTCA spending and drug prescribing and sales.

Table 2.26.—Retrospective data analyses

Study	Main Outcomes Assessed	Methodology
National Institute of Health Care Management (NIHCM)1999–2001 reports on DTCA & retail prescription drug spending:		
Barents 1999	Factors affecting growth in prescription drug expenditures.	Data on DTCA from IMS Health and Competitive Media Reporting (CMR).
	Drug classes responsible for spending increases.	Data on retail spending, prescriptions, from Scott Levin.
	DTCA spending per class	
Findlay, 2000	Increase in retail drug spending in 1999 over 1998 levels attributable to top 25 DTCA drugs vs. other drugs.	Data on DTCA from IMS Health and CMR.
		Data on retail spending, prescriptions, from Scott Levin.
Findlay, 2001	Increase in retail drug spending in 2000 over 1999 levels attributable to top 50 DTCA drugs vs. other drugs.	Data sources/ methodology same as above.
Other reports:		
Rosenthal et al., 2002	Spending on DTCA vs. other forms of promotion: 1996–2000.	Data from IMS Health and CMR.
	Ad spending vs. sales 1996–2000	5 drug classes: antidepressants, antihistamines, statins, nasal sprays, PPI's.
Zachry et al., 2002	No. of diagnoses for conditions treated by DTCA drugs.	Data from CMR for ad spending.
	# Rx within drug class versus DTCA spending.	National Ambulatory Medical Care Survey (1992–1997) for diagnoses and prescriptions.
	# Rx vs. DTCA spending	Time series analysis.
PHARMAC, 2002	DTCA spend for 4 subsidized drugs vs. sales and # Rx, 1999–2001.	Data on DTCA from IMS Health.
	Volume & substitution effects	Spending and # of scripts, administrative data, New Zealand drug plan (PHARMAC).
Wosinska, 2001	# Rx for advertised drugs	1996–1999 data Blue Shield,.
	Effects of DTCA by drug formulary status ..	# Rx for lipid-lowering drugs.
	Product switching within class	Data on DTCA and drug detailing from CMR.
Eichner and Maronick, 2001	DTCA spending vs. sales	DTCA data from CMR, prescribing data Scott-Levin
	drugs for allergy, nail fungus, high cholesterol, depression.	1996–1998: 16 drugs -4 classes.
Basara, 1996	Increased prescribing and sales for Imitrex (sumatripan) vs. DTCA spending.	Four regional campaigns.
		Individual physician prescribing data from IMS Health.
		7 month time series analysis.

NIHCM: EFFECTS OF DTCA ON U.S. RETAIL DRUG SPENDING 1993–2000

The National Institute of Health Care Management (NIHCM), a non-profit foundation, published a report in July 1999 outlining factors affecting the growth in prescription drug expenditures in the U.S. between 1993 and 1998. Error! Bookmark not defined. This report highlights the importance of growth in spending on new drugs within four heavily advertised drug classes: oral antihistamines, antidepressants, lipid lowering drugs and anti-ulcerants. NIHCM followed this report with two additional analyses specifically examining the relationship between DTCA and annual increases in retail prescription drug expenditures, published in 2000[1] and 2001.[2] As these reports follow one another as a progressively more detailed examination of the same phenomenon, they are discussed in chronological order below.

BARENTS 1999

U.S. retail spending on prescription drugs increased from $50.6 billion in 1993 to an estimated $93.4 billion in 1998, an 84 percent increase over a 5-year period. Four categories of drugs accounted for 30.8 percent of this increase: oral antihistamines, antidepressants, lipid lowering drugs and anti-ulcerants. These categories include seven of the ten drugs most heavily advertised to the public in 1998.

Table 2.27.—Increase in Spending in four Therapeutic Classes, 1993 to 1998

Drug category	Increase in expenditures 1993–1998 [U.S. $ billions]	Percent of total increase in prescription drug costs
Antidepressants	$ 5.0	11.8%
Lipid lowering drugs	$ 3.4	8.0%
Anti-ulcerants	$ 2.7	6.4%
Oral antihistamines	$1.9	4.5%
Total—four categories	$13.1	30.8%

Adapted from: Barents Group,1999, Figure A, p2.

DTCA spending is highly concentrated. In 1998, U.S. $706.9 million, or 54 percent of total DTCA spending, went towards promoting ten products to the public. These ten drugs alone accounted for 22 percent of the total increase in retail pharmaceutical sales in the U.S. between 1993 and 1998.

Table 2.28.—The 10 Drugs with Highest DTCA Spending in 1998

Drug	1998 sales [US$ millions]	Share of 1998 retail sales	Therapeutic category	Share in therapeutic category	Spending on DTCA [US$ millions]
Claritin (loratadine)	2,140.0	2.3%	Antihistamine	62.2%	185.1
Propecia (finasteride)	72.7	0.1%	Baldness	41.4%	92.0
Zyrtec (cetirizine)	454.9	0.5%	Antihistamine	18.6%	75.6
Zyban (bupropion)	183.8	0.2%	Smoking cessation	82.8%	64.4
Pravachol (pravastatin)	953.6	1.0%	Lipid lowering	18.3%	59.7
Allegra (fexofenadine)	432.0	0.5%	Antihistamine	13.6%	52.5
Prilosec (omeprazole)	2,945.0	3.2%	Ulcer/reflux	44.7%	49.7
Zocor (simvastatin)	567.3	1.7%	Lipid lowering	30.1%	44.5
Evista (raloxifene)	99.8	0.1%	Osteoporosis	19.3%	42.3
Prozac (fluoxetine)	2,346.0	2.5%	Antidepressant	32.9%	41.1
Total above	11,195 (12.0% of total sales).	12.0%		Mean = 36.4%	$707 (53.9% of DTCA spend)

Adapted from: Barents Group 1999; Table 4, p13.

From January to June 1999, the top five drugs advertised on television, by spending, were treatments for: allergy, baldness, obesity, and allergic rhinitis (two products); the top five drugs in print advertisements were for: allergy, type II diabetes, impotence and high cholesterol.[3]

Higher prices per prescription were responsible for 64 percent of the 1993–1998 increase in retail prescription drug spending, according to NIHCM, and the use of new, costlier drugs was identified as the primary factor driving this increase. In 1998, the average price of drugs introduced in 1992 or later was $71.49, as compared to an average price of $30.47 for drugs introduced before 1992.

FINDLAY, 2000

In a follow-up analysis of the effects of DTCA on pharmaceutical costs, NIHCM found that the top 25 drugs promoted directly to consumers were responsible for a U.S. $7.2 billion increase in U.S. retail pharmaceutical costs in 1999 over 1998 costs, or 40.7 percent of the total $17.7 billion increase in retail drug spending. They also found that doctors wrote 34.2 percent more prescriptions for these 25 products in 1999 than 1998, as compared to a 5.1 percent increase in prescribing volume for all other prescription drugs.[2]

Table 2.29 describes the contribution to drug sales of the 10 products with top DTCA spending, representing 41 percent of total DTCA spending. Only four of these products were also on the 1998 top 10 list for DTCA spending: loratadine (Claritin), cetirizine (Zyrtec), omeprazole (Prilosec) and fexofenadine (Allegra). However, the degree of concentration in DTCA spending is similar, as is the proportion of total prescription drug sales (11 percent vs. 12 percent in 1998) represented by this small number of drugs. Additionally, they contributed to the annual increase in U.S. retail spending to a similar degree (approx. 20 percent versus 22 percent). This suggests a similar pattern of advertising spending as in 1998, highly concentrated on a few "blockbuster" drugs.

Table 2.29.—The 10 Drugs with Highest DTCA Spending in 1999

Drug	Indication	1999 DTCA Spending [US$ millions]	1999 sales [US$ millions]	Change in sales 1998–1911	Contribution to increased spending 1998–1999
Claritin (loratadine)	Allergy	137.1	2,591.1	+21.1%	2.6%
Prilosec (omeprazole)	Ulcer/reflux	79.4	3,649.4	+28.9%	4.1%
Xenical (orlistat)	Obesity	76.2	144.7	N/A*	0.8%
Zyrtec (cetirizine)	Allergy	57.1	551.5	+31.5%	0.8%
Lipitor (atorvastatin)	Lipid lowering	55.5	2,659.9	+55.7%	5.5%
Flonase (fluticasone)	Allergic rhinitis	53.5	489.5	+37.9%	0.8%
Nasonex (mometasone)	Allergic rhinitis	52.3	264.0	+116.1%	0.8%
Ortho tri-cyclen	Contraceptive	50.1	431.5	+58.2%	0.9%
Glucophage (metformin)	Diabetes	43.1	1,157.8	+48.7%	2.2%
Allegra (fexofenadine)	Allergy	42.8	423.9	+50.0%	1.0%
Top 10 DTCA drugs		647.1 (41% of DTCA spend).	12,363.3 (11% of total Rx drug sales).	Mean = 50.0%	19.5%

Adapted from: Findlay, 2000. Figure 3, page 4.
*Launched in this period.

FINDLAY, 2001

A follow-up NIHCM report in 2001 again examined the relationship between DTC advertised drugs and annual increases in retail drug sales.[2] In this report, Findlay examines the contribution of the 50 top DTCA drugs to sales. These 50 drugs represent almost all DTCA spending in 2000 (94.8 percent), and together they were responsible for U.S. $.9.9 billion, or 47.8 percent, of the $20.8 billion increase in retail spending over 1999 levels. They had combined sales of $41.3 billion, or 31.3 percent of total retail prescription drug sales.

Retail sales increased by 32 percent for these 50 drugs in 2000, as compared to an increase of 14 percent for all other drugs combined, and the number of prescriptions rose by 25 percent, as compared to a 4 percent increase in all other drugs.

Table 2.30.—The 10 Drugs with Highest DTCA Spending in 2000

Drug	Indication	2000 DTCA spending [US$ millions]	2000 sales [US$ millions]	Change in sales 1999–2000
Vioxx (rofecoxib)	Arthritis	160.8	1,518.0	+360.7%
Prilosec (omeprazole)	Ulcer/reflux	107.5	4,102.2	+12.4%
Claritin (loratadine)	Allergy	99.7	2,035.4	+14.9%
Paxil (paroxetine)	Antidepressant	91.8	1,808.0	+24.5%
Zocor (simvastatin)	Lipid lowering	91.2	809.4	+22.2%
Viagra (sildenafil)	Impotence	89.5	2,015.5	+31.2%
Celebrex (celecoxib)	Arthritis	78.3	618.7	+58.0%
Flonase (fluticasone)	Allergic rhinitis	73.5	1,120.4	+26.4%
Allegra (fexofenadine)	Allergy	67.0	113.2	+61.8%
Meridia (sibutramine)*	Obesity	65.0	652.7	-8.1%
Top 10 DTCA drugs		924.3 (41% of DTCA spending).	14,793.5 (11% of total Rx drug sales).	Mean = +60.4%

*Safety concerns prompting a market withdrawal in Italy may have affected sales.

Table 2.30 above presents the contribution to sales of the top 10 drugs, by DTCA spending during 2000. The proportion of total DTCA spending on just 10 products was 41 percent in 2000, as in 1999, and these 10 products again represented 11 per-

cent of the U.S. retail pharmaceutical market. The overlap between the year 2000 and 1999 "top 10" DTCA products was again 4 of the 10 products.

The three NIHCM reports summarized above indicate a strong association between annual increases in prescription drug spending and the most heavily advertised products. A small number of heavily advertised products contributed disproportionably to annual retail expenditures on prescription drugs, mainly through higher prescribing volume and sales, rather than through price increases. This is consistent with the expected direction of effect of DTCA, and suggestive of a causal effect. However, the authors were unable to distinguish between increased sales stimulated by DTCA alone, by promotion aimed at physicians alone, or by the combined effects of these two marketing techniques. Other factors may have also influenced prescribing volumes, such as publication of favourable trial results, or formulary inclusion by large managed care companies.

ROSENTHAL ET AL. 2002

Meredith Rosenthal and colleagues compared industry spending on DTCA to spending on promotion aimed at physicians between 1996 and 2000.[4] They also examined data on sales versus DTCA spending for five heavily advertised therapeutic classes, antidepressants, antihistamines, lipid-lowering drugs, corticosteroid nasal sprays and proton pump inhibitors. Table 2.31 presents an overview of U.S. promotional spending over this time period.

Table 2.31.—U.S. Spending on DTCA and Promotion Aimed at Physicians: 1996–2000

[Promotional Spending (in US$ millions)]

	1996	1997	1998	1999	2000
Estimated spending on promotion to physicians*	9,503	11,261	12,663	13,643	15,029
DTCA spending	791	1,069	1,316	1,848	2,467
Percent of DTCA spending on television ads	28%	29%	50%	61%	64%
Total estimated promotional spending	10,294	12,330	13,979	15,491	17,496
Percent of promotional spending on DTCA	8.3%	9.5%	10.4%	13.5%	16.4%
DTCA spending as a percent of sales	1.2%	1.5%	1.6%	1.8%	2.2%
Total promotional spending as a percent of sales	15.8%	17.2%	17.1%	15.2%	15.6%

Adapted from: Rosenthal et al, Table 1, p 500.

*Promotion to physician recalculated to include an estimated 13.5 percent on meetings and events, as described by Rosenthal et al. (p. 499; Methods., range 12–15 percent) Rosenthal et al. Table 1 omits this category

Although the industry spent much more on promotion aimed at physicians than on DTCA, the proportion devoted to DTCA increased continually over this time period. By 2000, spending on DTCA had more than tripled over 1996 levels. In 2000, the industry as a whole spent nearly twice as much on print DTCA as on print advertising in health professional journals.

Rosenthal et al. examined advertising intensity within five drug classes: antidepressants, antihistamines, lipid-lowering drugs, corticosteroid nasal sprays and proton pump inhibitors (PPI's). They found that spending on DTCA as a proportion of sales varied much more per drug class than spending on promotion aimed at physicians. In 1999, the category with the highest DTCA advertising intensity (11.6 percent of sales) was nasal sprays. In contrast, DTCA spending reached only 0.5 percent of sales for antidepressants. This was a 23-fold difference in advertising intensity. For promotion aimed at health professionals (omitting sponsored meetings and events), the highest advertising spending was also on nasal sprays, at 24.7 percent of sales. However, this was only a 2.8-fold difference in advertising intensity as compared to the category with the lowest spending among the five, lipid-lowering drugs (8.7 percent of sales).

ZACHRY ET AL. 2002

Zachry et al. carried out a retrospective data analysis to examine whether a relationship existed between prescriptions for an advertised drug, prescriptions for drugs within the same class, and frequencies of diagnoses for approved indications of advertised drugs and monthly advertising spending.[5] They combined data from the National Ambulatory Medical Care Survey (NAMCS) and information on monthly advertising spending obtained from Competitive Media Reporting. The NAMCS includes 195,577 consultations between 1992 and 1997, weighted to be representative of the U.S. population.

Zachry et al. only included drugs and drug classes advertised for at least 19 months within this time. From 1992–1997, 121 drugs within 48 drug classes were advertised to the U.S. public, with 80 percent of spending on full product advertising, and only 4.4 percent on "help-seeking" or disease-oriented ads that make no mention of brand name. Nineteen of these drugs, within 5 drug classes, met the study inclusion criteria. The five classes were: antihistamines, antihypertensives, acid-peptic disorder drugs, benign prostatic hypertension (BPH), and lipid lowering drugs.

For lipid-lowering drugs, spending was significantly associated with diagnoses: for each $1000 spent on DTCA for lipid-lowering drugs, 32 additional diagnoses and 41 prescriptions were generated. For antihistamines, a strong substitution effect was observed within the class, with every $1000 spent on DTCA for loratadine (Claritin) associated with 24 additional prescriptions for loratadine (Claritin), 20 fewer for terfenadine (Seldane) and 7 fewer for astemizole (Hismanal). No significant association was observed between spending on antihypertensives and BPH drugs and the number of diagnoses or prescriptions.

In two cases prescriptions for leaders within the class—loratadine (Claritin) and simvastatin (Zocor)—were positively associated with total spending within the class, as well as drug-specific spending.

The authors caution that causality cannot be assumed, and that DTCA expenditures accounted for a modest amount of variance (10–30 percent) associated with diagnoses and prescribing. However, this study represents the first published report to combine retrospective data on diagnoses and prescriptions with DTCA spending data. The differences the authors observed between drug classes are also consistent with market factors. For example, the majority of lipid-lowering drugs with strong sales performance are advertised to the U.S. public, and therefore both product-specific and class effects might be expected. However, most antihypertensives are not advertised to the public, and overall spending on DTCA within this class is lower than for lipid lowering drugs. This is consistent with the lack of association between monthly advertising spending and diagnoses or prescriptions within this class.

PHARMAC, 2002

In an unpublished report to the New Zealand Ministry of Health, New Zealand's public pharmaceutical management agency, PHARMAC, examined prescribing volumes and costs for four subsidized products that had been advertised to the New Zealand public between 1999 and 2001.[6] These were fluticasone (Flixotide), terbinafine (Lamisil), omeprazole (Losec) and eformoterol (Oxis Turbuhaler). This is the only analysis of the effects of DTCA on costs of publicly financed pharmaceuticals.

Table 2.32.—New Zealand DTCA Spending for Four Products During 2001

Product	Total DTCA Spending (CDN $ equiv)	Print	TV	Radio
Flixotide (fluticasone)	$1,469,173	6%	94%	
Lamisil (terbinafine)	$613,589	19%	81%	
Losec (omeprazole)	$867,352	15%	75%	10%
Oxis Turbuhaler (eformoterol)	$998,006	12%	88%	

Source: PHARMAC, 2002. Adapted from: Table 1, page 4.

During the period from 1999 to 2001, the number of prescriptions grew for all four products. Table 2.33, below, provides information on the number of prescriptions per year and cost differences had prices remained stable (standardized to May 2002 prices).

Table 2.33.—Increases in Expenditure and Script Numbers From 1999–2001

No. of prescriptions/year				2001 vs. 1999	
Product	1999	2000	2001	Percent increase in no. of prescriptions	Percent increase in spending at May 2002 prices*
Flixotide (fluticasone)	184,608	216,021	269,584	46%	54%
Lamisil (terbinafine)	10,161	13,415	15,661	54%	64%

Table 2.33.—Increases in Expenditure and Script Numbers From 1999–2001—Continued

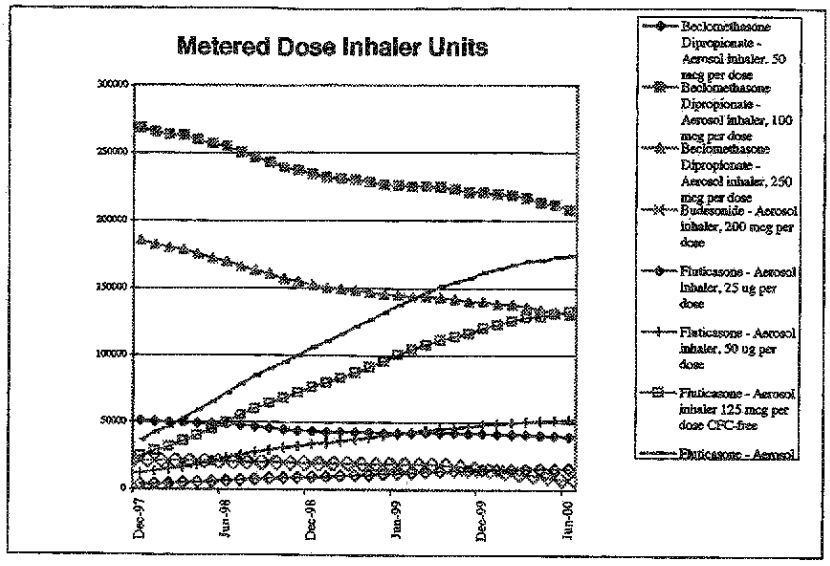
Product	No. of prescriptions/year			2001 vs. 1999	
	1999	2000	2001	Percent increase in no. of prescriptions	Percent increase in spending at May 2002 prices*
Losec (omeprazole)	294,888	337,076	327,583	11%	18%
Oxis Turbuhaler (eformoterol)	2,012	4,094	21,017	945%	704%

*May 2002 prices used as subsidy prices for some products changed during this period.

Real growth in expenditure on these four products was more than NZ$3.66 million (CDN $2.94) from 1999 to 2001. This is a lower fiscal risk than might have occurred without other policies implemented by PHARMAC, including negotiated price reductions for fluticasone (Flixotide) in mid-1999 and a manufacturer surcharge for omeprazole (Losec) in April 2001, in both cases in response to increased prescribing volumes.

PHARMAC tracked shifts in prescribing volume for metered dose corticosteroid inhalers used to treat asthma in the period from January 1998 to June 2000.[7] They documented a substitution effect from less expensive beclomethasone inhalers, which are off patent and therefore not advertised, to fluticasone (Flixotide). Television advertising campaigns had encouraged patients to switch to fluticasone if their asthma was "not controlled." This substitution effect occurred in spite of a lack of reliable evidence of greater effectiveness or safety for fluticasone versus other steroid inhalers such as beclomethasone.[8]

Figure 2.1. Numbers of Corticosteroid Metered Dose Inhalers Dispensed, 1998–2000



Source: PHARMAC, 2000. Adapted from Graph 1, page 4

These data do not allow for attribution of a causal effect between DTCA and increased prescribing volume for fluticasone, as fluticasone inhalers were most likely also promoted heavily to physicians during this time period. These are also aggregated data on population prescribing patterns, which do not allow for examination of individual switching from beclomethasone to fluticasone versus differences in product choice for initial prescriptions for a steroid inhaler for asthma. Thus the extent of substitution of fluticasone for beclomethasone among individuals who incorrectly believed that the advertised product was superior to the steroid inhaler they were already using is unknown.

WOSINSKA, 2001

In an unpublished report, Marta Wosinska has analyzed the relative contributions of DTCA and promotion aimed at physicians on shifts in prescribing of cholesterol-lowering drugs within a population insured by Blue Shield of California's PPO plan.[9] She analyzed data covering over 38,000 patients who filled a prescription for one or more cholesterol-lowering drugs between 1996 and 1999. Prescribing data were matched to monthly brand-level DTCA spending, obtained from Competitive Media Reporting, and monthly, brand-level spending on sales representatives and free sampling.

Preliminary results indicate a strong association between product choice and DTCA spending. However, the impact is diminished if physician detailing and free samples are taken into account, and the estimated impact of detailing is five times that of DTCA. She also found that although spending on DTCA strongly affects product choice, the effect for drugs that were on Blue Shield's formulary was three times that of drugs not on the formulary. Thus the effects of DTCA on product choice appeared to have been mediated by decisions related to formulary inclusion.

EICHNER AND MARONICK, 2001

Eichner and Maronick compared DTCA spending and sales data from 1996 to 1998 for products within four heavily-advertised drug classes: antihistamines, lipid-lowering drugs, antidepressants and antifungal drugs for toenail fungus.[10] This is based on annual advertising spending and sales data obtained from Competitive Media Reporting and Scott-Levin.

Between 1996 and 1998, there was a 2.5-fold increase in prescriptions for three heavily-advertised antihistamines, loratadine (Claritin), fexofenadine (Allegra), and cetirizine (Zyrtec), a much greater increase than in overall drug prescriptions within this time period. This was not accounted for by substitution of these newer products for older antihistamines; the proportion of patients prescribed an antihistamine for allergy increased. The authors were unable to examine whether patients had previously used over-the-counter medications, or whether they were treating symptoms they had previously managed without medicines. For nail fungus treatments, prescriptions within the class increased by over 50 percent between 1996 and 1998, although DTCA spending decreased within this time period. This could reflect awareness raising for the condition and/or other promotional spending. The authors also did not examine whether lagged effects occurred.

For lipid-lowering drugs, the authors found a stronger class than product-specific effect. The authors calculated the degree of correlation between product-specific DTCA spending and the product's market share within its class. Their results are generally inconclusive, especially in drug classes with several competitors. This is likely to reflect the many factors that remain unexamined, such as the date of a product's launch, product-specific characteristics (such as therapeutic advantages or disadvantages), and spending on promotion aimed at physicians.

BASARA 1996

Lisa Basara used the launch of sumatriptan (Imitrex) for migraine in February 1993 as a test case to examine the effects of a DTCA campaign.[8] She used a time series analysis to look at the volume of new prescriptions before and after a 7 month DTCA campaign. Data from four cities were used. Albany, Erie, Grand Rapids, Boise City. They were chosen because of similar demographics and physician prescribing levels. The four cities had a joint population of 1.1 million and 2,419 doctors. Physician-specific data were available for 73 percent of the doctors through IMS, which buys these data from dispensing pharmacies. All physicians in the four regions with at least one dispensed prescription were included in the study.

The sumatriptan (Imitrex) advertising campaign did not include the product name, but it mentioned a "surprisingly effective" new treatment for migraine and said to go see your doctor. As this was the only migraine therapy being actively promoted to doctors, such an approach was expected to pay off. Thus this is a study of the effectiveness of "help-seeking" DTCA in generating sales.

The interrupted time series analysis included 11 months before the launch of the DTCA campaign, 7 months during an active campaign, and 4 months afterwards. The primary hypothesis tested was whether the number of new prescriptions would increase significantly after consumers were exposed to DTCA. Basara found the DTCA campaign to be a significant predictor of new prescription volume ($p=.0006$). She estimates that 1,620 new prescriptions could be attributed to the 7-month campaign in these four cities. Extrapolating to the entire U.S. population, this campaign

would have generated about $11.5 million for the company in new prescriptions, and nearly as much again could be expected in refills.

DTCA was entered into this analysis as a binary variable representing presence or absence of consumer-directed advertising within specific months, with lagged effects also included within the model. Basara's analysis explored whether a relationship was found between DTCA presence and increased prescribing volumes; she did not include differences in the amount spent on DTCA per month in her model and was therefore unable to estimate returns on advertising investment.

This is the only published study using a time series analysis of physician-specific data to assess the effects of a DTCA campaign. Promotion of this product to physicians preceded the DTCA campaign and continued afterwards. Thus, this analysis identified increases in prescribing associated in time with the DTCA campaign and probably attributable to it.

Conclusion: Retrospective Data Analyses

The administrative data analyses described above indicate an association between heavily advertised products and increases in prescribing volume and drug costs. In other words, they strongly suggest that, as intended by manufacturers, DTCA does stimulate drug sales. The NIHCM reports have found a strong association between the most heavily advertised products and therapeutic classes, and large annual increases in retail prescription drug costs in the United States. This occurred through an increase in prescribing volume for expensive heavily advertised products.

Zachry et al. found an association between monthly spending on DTCA and increases in diagnoses for conditions treated by advertised conditions as well as for prescriptions for specific products. For lipid lowering drugs, both the drug class and individual products appeared to benefit. This is consistent with the pattern of advertising that has occurred within this class, with competing products advertised to the public. For antihistamines, increased prescribing for heavily advertised products was accompanied by a reduction for older products that are not being advertised to the public. This is similar to the pattern observed by PHARMAC in New Zealand, with a concurrent increase in prescription volume for fluticasone inhalers and a reduction in volume of beclomethasone inhalers. The experience in New Zealand suggests that some beclomethasone users (and their physicians) may have been unaware that the two products were essentially equivalent, except in price.

Wosinska found a strong association between monthly spending on DTCA and choice of lipid lowering drug within an insured population in California. However, when promotion aimed at physicians (drug detailing) was entered into the model, the association became weaker, and her results suggest that drug detailing remains a dominant means of shifting prescribing choice.

Taken together, the administrative database analyses suggest that DTCA does contribute to increased prescribing volumes for heavily advertised drugs. However, most of these analyses cannot separate out the effects of DTCA from promotion aimed at physicians, and therefore do not allow for calculation of the proportion of new prescriptions stimulated by DTCA versus those stimulated by physician-directed promotion, or of interactions between the two.

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QUESTIONS OF SENATOR MURRAY TO JOHN M. TAYLOR, J.D.

Question 1. When I joined this committee in 1997, I worked on the FDA Modernization Act. Our goal was to provide additional resources to FDA and streamline the regulatory process for drug approval.

Recently, I worked with several members of this committee to enact a Medical Device User Fee to provide additional resources to FDA to improve the approval process of medical devices.

These pieces of legislation are important in our efforts to get safe and effective life-saving drugs and devices to patients without unnecessary delay.

But, I know your agency is struggling to meet the mandates included in both of these bills, and as an Appropriator, I know we struggle to provide the resources.

- Will the new requirements included in the House-passed reimportation bill or the Senate bipartisan bill strain FDA's limited resources?
- I realize that a user fee has been proposed to offset the regulatory costs for FDA, but what happens if we are unable to collect the userfee or—if because of appropriations limits—you don't have the ability to spend the money raised through the user fee?
- Has FDA done a cost analysis on the agency if the House-passed bill or similar measures are adopted?

Question 2. Many American consumers assume that all "drugs they purchase" from Canada have been inspected and approved by Health Canada authorities.

Are products that are simply shipped through Canada for export to other countries inspected by Canadian authorities?

Drugs that are manufactured in Canada for export to other countries are subject to Health Canada inspection.

- Is this the case?
- And, if so, how can American consumers be sure that they are protected from potentially dangerous, unsafe, and counterfeit drugs passing through Canada?

Question 3. As you know, there are a number of products that could be exempt from any reimportation legislation, including infused or injected biologics and controlled substances.

While I am pleased that these products are being treated with greater caution under the proposed legislation, I am concerned that this illustrates the concerns about patient safety and abuse of prescription drugs.

- Is there a justification for excluding certain products from reimportation?
- Do you believe these exemptions are sufficient and that FDA will be able to ensure that these products are not illegally reimported?

Question 4. The growing threat of counterfeit drugs is an issue that FDA and drug manufacturers have been struggling with for a number of years.

We've heard about a number of drugs that were counterfeited and imported into the United States for patient consumption:

- drugs that had been tampered with;
- drugs that did not have the same safety and efficacy standards required by FDA; and
- drugs that had been manufactured in unsanitary conditions.

Are there adequate protections in the pending reimportation bills to prevent an explosion of counterfeit drugs in the United States.?

Could the mechanisms included in these proposals—like the full chain-of-custody—also be open to counterfeiting?

- Are there additional steps we should take to prevent an increase in counterfeit drugs?

I am concerned that many patients may never know if their drugs have been tampered with or are even the appropriate dosage.

Question 5. The Canadian drug market is significantly smaller than the U.S. market.

- Can this market sustain a huge new U.S. customer?
- How do we ensure that we have sufficient drug supplies in this country and that patients who reimport or access reimported drugs are not subject to a disruption in their supply? Many patients take medication daily or several times a day, and any disruption or delay could have serious health consequences.

Question 6. In your testimony, you endorse reimportation as a mechanism for: controlling drugs costs in the United States; introducing competition into the market; and offering patients and doctors another tool to address the increasing costs of drugs.

- What kind of pressure do you see happening on drug costs?
- What potential savings are there for all consumers or when calculating the cost of health care in this country?
- Will the savings be widespread or isolated to a few drugs?

PREPARED STATEMENT OF THE HON. JIM DOYLE, GOVERNOR, STATE OF WISCONSIN

Mr. Chairman, members of the Senate Health, Education, Labor, and Pensions Committee. I submit my testimony to this committee on behalf of the citizens of Wisconsin, so many of whom are struggling to afford the costs of basic medical care.

There is no doubt that medical science has yielded discoveries that have extended and improved the quality of our lives. But it is equally true that the skyrocketing price of prescriptions threatens to deny many of our citizens access to these lifesaving cures.

Like most Americans, I am deeply disappointed that the Federal Government has not done more to address this dramatic inflation in prices, or to provide meaningful prescription drug coverage to those who need it most.

But as I have often said, there is one thing the Federal Government could do tomorrow that would make prescription drugs more affordable for every American, and that's to allow safe reimportation of U.S. made and approved prescriptions from Canada.

Everyday, I meet people in Wisconsin who struggle with the high cost of prescription drugs—and are often forced to make inhumane and unbearable choices between food and medicine . . . or skipping a dose.

But just across the border, Canadians can walk into their corner drug store and buy prescriptions for a fraction of what we pay. These are the same medications available here, but may be two or three times as expensive for U.S. consumers.

Because the Federal Government hasn't acted effectively, States like Wisconsin have been forced to lead the way. In February, in response to overwhelming demand from the people of Wisconsin, we launched a website—*www.drugsavings.wi.gov*—that empowers our citizens to order these lower price prescription drugs from pharmacies that our State has visited and found to be safe, reputable, and reliable.

The response has been remarkable. Over the last 11 weeks we have had more than 107,000 visitors to the website, an average of more than 1,500 visitors a day trying to find help with affordable prescription drugs.

Here are some of the stories they have shared with me:

Connie sent an e-mail to tell me that the only way she and her husband can afford the drugs he depends on is to buy them from Canada—since there are no generic substitutes.

Cari is 48 years old, disabled, and has no prescription drug coverage. She hopes that my website will help her with the costs of the nine prescription drugs she takes.

Clare wrote to tell us that her husband is a transplant patient and his anti-rejection medication costs $1,000 to $1,300 per month depending on the pharmacy used. Her husband is 65 and still working, but she wonders how anyone except the wealthy can afford this medication.

Mary from Brookfield says she has been ordering drugs from Canada for over a year for herself and for her husband. They are senior citizens and take multiple medications and just could not afford the high prices.

Yvonne from Cudahy takes 20 medications daily. Some she buys from Canada, some she gets in samples from her doctor, and others she will have to drop because she simply can not find a way to afford them. Unfortunately, the drugs she will have to stop taking are the important ones—treatment for her heart and coronary artery disease, chronic pain, and depression.

Bonnie asked me if there is anything to help her pay for over $500 a month in drugs. She had to switch insurance companies and no longer has prescription drug coverage. She is 57 years old.

Bruce wrote saying:

> Thanks for your work on drugs from Canada. The only problem is that our insurance company won't cover any of the costs, because they say the drugs are not FDA approved. We need to address that issue."

I get e-mails from all over the country, because people everywhere are facing the same challenges.

Nicole from California thanked me for posting the information about Canadian pharmacies and taking the time to ensure these are reputable sources. She went on to say that her mother will have to cut back her food budget to afford Celebrex, needed after her foot surgery. The irony here is that her mother is a former employee of the Federal Government—the same government that now steadfastly refuses to take action that will make drugs more affordable.

I understand that the pharmaceutical companies don't want us buying safe prescription drugs from Canada—because it cuts into their profits. But I don't understand why the Federal Government isn't on our side, trying to get some help for our citizens.

The Bush Administration has the authority—right now—to allow the safe reimportation of U.S. made and approved prescription drugs from Canada.

The drug companies have waged an expensive, highly coordinated scare campaign to try to convince people that buying from Canada is unsafe. But do any of us really believe that the Canadian health care system is more dangerous than our own? If we were in Canada and got sick, would any of us really think twice about going to a hospital and taking the medication prescribed to us?

I know there may be a few disreputable pharmacies in Canada, just as there are here. But that's precisely why our State has checked out the pharmacies we're dealing with to ensure that they are safe.

If the FDA has concerns about the safety of these drugs, then I would encourage them to do what our State has done. Put some inspectors on a plane, send them to Canada, and check out these pharmacies for yourself.

It is time for the FDA to stop doing the bidding of the drug lobby, and start helping States like Wisconsin to implement a safe system of prescription drug reimportation. I find it amazing that the FDA has time to send out press releases attacking our website, time to send its staff to Wisconsin to hold press conferences criticizing our efforts, but not time to actually work with us to put this system into place. It is a story of missed opportunities and misplaced priorities, and it is a disservice to the American people.

One thing is clear: someone has to stand up to the big drug companies, who have proven they will do anything to protect their profits at the expense of our citizens' health.

U.S. drug manufacturers have threatened to blacklist Canadian pharmacies and cause shortages in Canada if they move ahead with reimportation. I have asked Attorney General John Ashcroft to investigate these companies for violations of antitrust laws.

Unfortunately, Attorney General Ashcroft has taken no action. And unless he does, the 25 largest online Canadian pharmacies have said they won't be able to do business with Wisconsin . . . or any other State.

Even more recently, we have heard that several merchant credit card payment processors have been scared off from providing their e-commerce credit card services to Canadian mail order pharmacies. In March, Visa and MasterCard announced that they will not service Canadian mail order pharmacies because they have been under pressure from the FDA to cease their support of payment processing. They cited pressure from the FDA and have warned their member financial institutions to avoid so-called "illegal" transactions.

The simple fact is this: people in Wisconsin—and all over America—need relief from the high price of prescription drugs. Reimportation holds the promise of lower prices, and expanded access to life saving medicines. It is time for the Federal Government to move past the scare campaign and heavy-handed tactics of the drug lobby, and start being on our side as we work to make prescription drugs affordable for all Americans.

Not only that, but Federal approval of prescription drug reimportation holds the potential for huge savings for Wisconsin taxpayers. Our State spends more than $700 million annually on prescription drugs for Medicaid recipients, employees, and inmates. If we could save just a fraction of that amount by purchasing drugs from

Canada with Federal approval, it would mean savings to taxpayers of tens of millions of dollars.

Organizations that advocate on behalf of senior citizens in Wisconsin such as the Coalition of Wisconsin Aging Groups, Wisconsin Citizen Action, and AARP-Wisconsin support our efforts to provide access to safe, low cost prescription drugs from Canada.

No matter what happens, this is an issue that won't go away. I am going to continue to fight to make lower price prescription drugs from Canada available here in the United States—and I hope that the people of Wisconsin will have your support in this effort.

PREPARED STATEMENT OF KENNETH C. CARTER, PH.D.

Mr. Chairman and members of the committee, thank you for the opportunity to submit my comments for the written record on the reimportation of prescription drugs into the United States. I commend this committee for holding this hearing and particularly for allowing American healthcare and biotechnology companies, like Avalon, to put forth our input. Please allow me to strongly encourage you to hold additional hearings on this issue that will afford companies, like my own, the opportunity to share our views directly before the committee as you consider drug reimportation. The decisions you make with respect to this issue will have profound effects on our industry which in turn will have an enormous impact on the continued development of cutting edge pharmaceuticals. The advances made by American enterprises in the area of drug development and biologicals is unsurpassed by any other nation. I ask that this committee consider how drug reimportation would impact the kind of innovation that has led to medical advances unimagined just a short time ago.

It is extraordinarily important that Congress continue to ban the reimportation of drugs from foreign countries, both for broader social reasons and because of the potential negative impact on the development of better medicines in the United States. While I am extraordinarily sensitive to the issue of healthcare costs in general, and prescription drugs in specific, having my own elderly parents and several other relatives who are struggling with this issue, passing bills which allow importation of price-controlled, potentially unsafe medications from markets that are not regulated, poses not only risks to individual patients, but undermines fundamental free trade underpinnings of the American economy.

Another important issue, which is a more critical issue for the economy, is the fact that healthcare innovation is absolutely dependent on the free trade pricing of medicines. The United States is home of the vast majority of innovative healthcare and biotech companies. Investors have risked billions of dollars on the promise that the Biotech industry will develop new and better drugs. Thousands of Biotech companies throughout the United States will be severely, negatively impacted by the passage of this bill. I am the Co-Founder and President of a company that has raised $80M to develop next-generation cancer drugs and our company is faced with the negative consequences of drug reimportation every day. Just a short time ago, when meeting with potential investors in New York, I was peppered with questions about why investors should invest in healthcare companies given the trend toward the allowance of reimportation of unregulated drugs from other countries. I fear that reimportation will simply kill innovative research in healthcare and in the end crush a vital sector of the U.S. economy.

Some ideas being considered by Congress attempt to mitigate the impact of drug reimportation by excluding biologics from the list of drugs that could be reimported. That would not help Avalon or many other biotech companies. Avalon uses cutting edge genomic techniques to develop the type of small molecule drugs that would be allowed to be reimported. Avalon and companies like it are developing hundreds of drugs in clinical trials and have thousands more in the preclincal stages. All of these companies are heavily dependent on the prospect that their drug will be approved and accepted in the marketplace, thereby generating the profits necessary to reward the investors who took the risk of backing the company and, additionally, to fund the development of additional drugs. Drug reimportation would shut off the flow of investment funds to the biotech sector and would stifle the development of new life-saving drugs that patients are waiting for.

Providing access to medical treatment for all socio-economic groups is an important issue. Please consider other options that do not risk bringing unregulated drugs into the country while damaging the economy.

I strongly encourage the committee to consider a broad view of this issue and work to find ways to address the cost of prescription drugs in a way that will not

jeopardize the availability of new cutting edge treatments at a time when medical advances show so much promise. Again, thank you for allowing me to share my views with this committee. I welcome an opportunity to continue working with this panel as you continue your examination into drug reimportation.

PREPARED STATEMENT OF J. RANDALL HOGGLE, RPH

Mr. Chairman, and members of the committee, I am pleased to share my comments with you today as you consider the very important issue of prescription drug importation. First, I would like to commend the members of this committee for your continued efforts to find ways to make prescription drugs more affordable while balancing concerns related to product safety and quality. Indeed every American wants to have affordable access to prescription pharmaceuticals and at the same time have placed a great deal of confidence in our government to ensure the safety of these medicines.

After more than 30 years of experience in the pharmaceutical industry, I know the many challenges associated with drug development and delivery. Safety and quality are two of the most important factors when it comes to placing drugs in the market. Having worked closely with the Food and Drug Administration (FDA), I know the rigorous standards in place to guard our Nation's drug supply. As CEO of Health Pathways, a privately held healthcare services and products holding company in Gaithersburg Maryland, I want to share my concerns over assuring the safety and quality of imported drugs. Further, I want to highlight for you the kinds of systems available to meet those challenges which I urge the Senate to address thoroughly as you consider prescription drug importation.

1. TAKING NECESSARY STEPS TO KEEP OUR NATION'S DRUG SUPPLY SAFE AND SECURE

The United States is one of the most tightly regulated national systems for distributing prescription drugs. As a result, we can boast that it is one of the world's safest systems as well. However the pharmaceutical supply chain in the United States is plagued with issues surrounding the potential for counterfeiting and diversion. Mark McClellan, the former Food and Drug Administration (FDA) Commissioner, recently (2004) stated "The number of discovered counterfeit drugs in the United States has increased four fold in the last decade. The counterfeiters are getting smarter and more sophisticated." The potential for counterfeiting and diversion is likely to increase when allowing drugs to enter the United States from countries that do not have the stringent standards that we have domestically.

Legislative proposals which move toward a world market in pharmaceuticals makes the regulatory mission of FDA much more challenging than ever before. Proposals allowing importation of pharmaceuticals pose issues that have never before been addressed by current U.S. regulatory or distribution schemes. There are multiple issues that need be identified to implement importation. These issues particular to the U.S. market will need to be addressed to ensure product quality and patient safety as this new market is developed. Emphasis must shift from enforcement strategies to prevention measures to keep illegal products from entering the U.S. market. Drug counterfeiters not only defraud consumers, they also deny ill patients the therapies that can alleviate suffering and save lives. Counterfeiters produce and introduce near-perfect copies of the most popular and expensive drugs through diversionary tactics employed by sophisticated schemes. Some counterfeits have passed undetected through wholesalers and/or retail chain warehouses to the shelves of retail and acute care pharmacies.

The FDA report (COMBATING COUNTERFEIT DRUGS—February 2004) describes how to achieve modern, comprehensive security protections for the U.S. drug supply so we can keep pace with the increasingly sophisticated threats we face. The FDA's comprehensive report highlights ways to assure that the Nation's drug distribution system protects Americans from counterfeit drugs. These measures address critical areas, including: (1) Securing the movement of the product as it travels into and through the U.S. drug distribution chain; (2) Enhancing regulatory oversight and enforcement; and (3) Adoption of secure business practices by all participants in the drug supply chain. In addition if importation laws are passed FDA will need new Systems to assure that any exporters into the U.S. market are inspected and continually certified for doing business with U.S. importers.

2. ABOUT HEALTH PATHWAYS AUDIT SERVICE AND PURPOSE

Health Pathways currently serves as a trusted agent by government and industry sources within the health care distribution system. Its team of management and

staff has a long track record of serving the industry in an intermediary role where they have discreetly demonstrated the use of appropriate business practices and security procedures. Health Pathways formed the Audit Services Division in October 2003 to provide a comprehensive *Inventory Management Agreement* (IMA) advisory service. Further, the division provides complete Drug Supply Audit Services to verify compliance with Federal and State regulations and the effective implementation by distributors of recently approved Guidelines for Pharmaceutical Distribution System Integrity. FDA's Counterfeit Drug Task Force Final Report (February 2004) highlights specific steps the agency is taking to keep the U.S. drug supply secure against increasingly sophisticated criminal efforts to introduce counterfeit drugs. If these measures and voluntary consensus guidelines are adopted and enforced, the U.S. pharmaceutical market will serve as a worldwide example of self regulation and will avoid further governmental intervention to insure the integrity of pharmaceutical supplies to American consumers. These systems can be expanded for use with drug exporters from foreign countries and can be the base for the development of additional systems necessary for FDA to implement new laws allowing imported drugs from outside the United States.

Health Pathways, Inc. (HPI) has met with over 25 of the major pharmaceutical and biotech companies to preview the new HPI Audit Service. Based on the knowledge and feedback gained at these meetings combined with input from the leading experts in pharmaceutical and distribution sector, Joint Council on Accreditation of Hospital Organizations (JCAHO), corporate finance, FDA inspections and materials safety audit, HPI has built a comprehensive and flexible audit service business and system that will assist all stakeholders in the distribution channel in their efforts to assure medical product distribution system integrity and product safety.

HPI audit procedures are developed by industry experts who combined standard audit practices with techniques developed from field tests. By employing these procedures, HPI auditors can support members of the distribution system to identify ways that counterfeits may be penetrating the distribution system and to close those gaps.

3. DISTRIBUTION PROCESS AND AUDIT SERVICE—A PROCESS TO PROTECT AND MAXIMIZE THE PHARMACEUTICAL DISTRIBUTION SYSTEM

Health Pathways provides a menu of five audit procedure options for manufacturers to meet individual needs and budget needs. These options allow manufacturers to select one and migrate to others based on findings and need.

In general, Audit Service options will each provide buy and sell side audit assessments and will provide a comprehensive look at wholesalers' plans for insuring integrity in workflow, documentation and IT management systems.

The five options are summarized below:

(1) *Rapid Statistical Analysis Sampling Process:* Sampling of all three-distributor categories uniformly: (a) Top 4; (b) Regionals with Multi-State Locations; and (c) Regionals with Single State Locations and Specialty Distributors. This sampling pattern will provide three sequences of statistical analysis across all three distributor categories. This approach has the value of identifying issues uniformly across the Company-authorized wholesaler community while allowing a great breadth of prevailing issues to be uncovered and addressed in unison. The other advantage is increased likelihood of finding subversive elements prior to counter maneuvers being implemented.

(2) *Detailed Analysis By Distributor Company Process:* This approach requires sequencing the Top 4 wholesalers and would allow additional time to make changes by the other companies who are audited later. The advantage of this process is that it would allow the audit teams to clearly, within each company, understand the patterns of intra-company product movement over a 2- to 3-month period, especially as it relates to interface and business relationships with its Trading Company and associated two-way tracking of Retail Chain product movement with their prime wholesalers.

(3) *Rapid Statistical Sampling followed by Detailed Analysis Process:* In this blended model, the *Rapid Statistical Analysis Sampling Process* would be completed through the First Level of three wholesalers and then converted to the *Detailed Analysis By Distributor Company Process* starting with following two groups: (a) the Company-authorized wholesalers who have Trading Company divisions; and (b) the Company-authorized wholesalers where information patterns warrant closer scrutiny.

(4) *Desktop Inventory Analysis Process:* For each distribution location, five inventory data feeds will be collected and utilized to develop an exception report for outliers on net inventory calculations. The advantage of this approach is a rapid low

cost "exception only" analysis demonstrating distribution locations with variance in net sales to purchases. If used alone, without the ability to assess physical inventory, workflow process, and potential for diversion or IT systems, there is opportunity to falsify and/or manipulate documentation.

(5) *Standard Manufacturer Audit Process:* Additionally, these four options can be converted into the Standard Manufacturer Audit Procedure Service that encompasses the additional aspects of the Distribution Guidelines. This audit provides the most comprehensive analysis and summary of how a distribution location scores against the Distribution Guidelines and the State Requirements in which the wholesaler operates. This audit process provides a supportive approach to the wholesalers by providing cure periods and re-evaluation to score improvements in workflow process, documentation and IT system capabilities. Only after the cure period is final scoring completed against a benchmark standard for distribution channel integrity. By employing this process, manufacturers can demonstrate strong leadership in the fight against counterfeits by enforcing the audit provisions of their Inventory Management Agreements with their Authorized Distributors of Record.

The HPI Audit Team performs the Audit Services consistent with the rigorous GSA contracts standard for the Department of Health & Human Services (DHHS) FDA, DEA and other government agencies. This enables manufacturers to demonstrate the rigor that has been undertaken to insure patient safety of manufacturer's product distributed in the United States by Company-authorized wholesaler customers.

4. AUDIT SERVICE SAFETY ASSURANCE FOR DRUG IMPORTS

Health Pathways has built a team of highly qualified audit experts and has developed audit processes and procedures that use a secure and sophisticated IT system to capture and analyze audit data. Collectively these capabilities enable Health Pathways Audit Services Division to identify and provide documentation for its manufacturer clients to assure compliant distribution of their products. Our copyrighted procedures have been field tested. To date the initial audits have demonstrated the ability to identify gaps in the distribution channel that allow counterfeits to enter, diversion to occur and multiple accounting entries to be recorded in legacy systems.

It is essential that any program to allow the importation of drugs into the United States adhere to strict safety standards. In this regards, a greater burden would be placed on the FDA which would have to find a way to certify the safety of pharmaceuticals coming into the country. I believe that the kind of audit system I've described today can contribute tremendously to the work of the regulatory agency. In fact, it is essential to making sure that the cross-border drug supply chain is safe and secure. I urge this committee to consider ways to adopt a system of auditing, conducted through the proper regulatory agency, if drug importation is to become a reality. It is a necessary step in assuring the safety and quality of drug imports from manufacturers through supply lines and ultimately to the American consumer.

Thank you again for accepting my written statement today. I welcome a continued dialog with the members of this committee on this crucial matter as you move forward.

McDONALD & HAYDEN,
TORONTO, ONTARIO, M5C 2Y3,
May 18, 2004.

Hon. Judd Gregg, *Chairman,*
Committee on Health, Education, Labor, and Pensions,
U.S. Senate,
Washington, DC 20510.

Hon. Edward M. Kennedy, *Ranking Minority Member,*
Committee on Health, Education, Labor, and Pensions,
U.S. Senate,
Washington, DC 20510.

Re: Full Committee Hearing on Prescription Drug Import Legislation, Thursday, May 20, 2004

DEAR CHAIRMAN GREGG AND SENATOR KENNEDY: McDonald and Hayden is a Toronto law firm that represents a number of Canadian pharmacies, some of whom sell exclusively to the domestic Canadian market and others of whom both sell in Canada and export to the United States.

Our clients have a keen interest in the legislation pending before the committee which would authorize the importation of prescription drugs into the United States from Canada. As the committee studies this matter, we believe it is very important for the committee to take note of steps which have been taken in Canada by the major branded pharmaceutical companies ("Big Pharma") to cutoff the supply of pharmaceutical products to the Canadian market. This subject appears to us to bear directly on your deliberations concerning new Federal U.S. legislation that would permit prescription drug imports into the United States from Canada.

Over the past several months, our clients have had to deal with a wide-spread and concerted effort on the part of Big Pharma to cutoff supplies to those suspected of providing pharmaceutical products to Canadian exporters.

We urge your committee to take these restrictive supply practices carefully into account in your deliberations on proposed U.S. legislation. As we understand it, the proposed legislation pending before the committee [1] is designed to permit the importation of drugs into the United States from Canada, as well as other identified countries. If appropriate preventive steps with regard to supply restrictions are not taken, it is our belief, based upon their past conduct, that Big Pharma will try to frustrate, and may well succeed in frustrating U.S. legislative reforms by continuing to limit supply in Canada, as well as elsewhere, thus drying up stocks available for export to the United States.

2003: BIG PHARMA'S EFFORTS TO LIMIT DRUG SUPPLIES IN CANADA

In early 2003, a number of pharmaceutical manufacturers, including GlaxoSmithKline Inc., Pfizer Canada Inc., AstraZeneca Pharmaceuticals LP, and Wyeth Canada Inc., took concerted steps to control the flow of pharmaceutical products from Canada to the United States.[2]

GlaxoSmithKline's actions, in particular, led one of our clients, Kohler's Drug Store Limited ("Kohler's"), which exports to the United States as well as serving Canadians, to initiate a complaint under Canada's Federal *Competition Act*, seeking relief from GlaxoSmithKline's refusal to supply products to our client under that enactment's "refusal to deal" provisions. Unfortunately, the Competition Bureau, Canada's competition watchdog, determined, on the facts before it in 2003, that GlaxoSmithKline's refusal to deal did not warrant further investigation. This determination was made because of statements issued by officials at the U.S. Food and Drug Administration ("FDA") that the importation of drugs from Canada, even by individuals for their personal use, was in "violation" of U.S. laws.

This so called "violation" is really a phantom illegality. The FDA, as is well known, in fact permits, under its enforcement discretion, repeated importation by U.S. citizens into the United States of up to 90 days supply of drugs from Canada.[3] Nevertheless, the Canadian Competition Bureau, perhaps confused by the FDA's self-imposed contradictions and verbal contortions, refused in 2003 to intervene on Kohler's behalf against GlaxoSmithKline.

2004: BIG PHARMA'S EFFORTS TO CURTAIL SUPPLY FURTHER

In 2004, as the cloud of this phantom illegality began to dissipate, and the real prospect arose of new U.S. legislation which would explicitly approve Canadian drug shipments to the United States, the response of Big Pharma, now led by Pfizer, was to redouble their efforts to curtail supply to all those whom it even suspected of providing product to Canadian exporters. The Big Pharma companies named above, and since joined by Novartis and Boehringer Ingelheim,[4] have resorted to concerted and very intense supply restriction practices, such as refusing to supply Canadian distributors with full orders for their products. Arbitrary and unilateral quotas have been, and continue to be imposed on distributors and direct pharmacy purchasers alike, with the express purpose of squeezing out the supply of drugs to Canadian exporters.

Other recent steps taken by Big Pharma in this regard have included complete refusals to supply products to any pharmacy even suspected of selling to U.S. con-

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[1] We understand that the committee has pending before it three bills: S. 2307, introduced by Senator Charles Grassley on April 8, 2004; S. 2328, introduced by Senator Byron Dorgan et al. on April 21, 2004; and, H.R. 2427, passed by the House of Representatives on July 25, 2003. We also understand that the Chairman may also introduce legislation on this issue.

[2] See copies of 2003 correspondence from these manufacturers at Tab 1.

[3] As succinctly stated by Minnesota District Court Judge Peter Albrecht, in *The Matter of GlaxoSmithKline plc*, File No. MC 03–15992 (May 7, 2004): "*not all drug importation is illegal*," Tab 2, page 11.

[4] See letters from Novartis and Boehringer Ingelheim, dated May 3, 2004 and May 12, 2004, respectively, at Tab 3.

sumers, or of selling to other pharmacies who themselves are thought to sell to U.S. customers. This practice was quite accurately described by Minnesota District Judge Albrecht as "black-balling Canadian wholesalers and pharmacies that ship to U.S. consumers."[5] This offensive, regrettably, has caused local Canadian pharmacists to reduce greatly, or curtail altogether their long-established practice of sharing surplus supply with professional colleagues who find themselves in short supply, much in the same way as individual stores of the larger drug chains in Canada (for example Shopper's Drug Mart) share product among their various outlets.

These draconian measures have even led to the complete cutoff of supplies to Canadian pharmacies that only serve their local customers, and do not export, and have never exported to the United States at all, on the slim ground that Big Pharma merely suspects them of doing so. For example, we represent Mrs. O's Pharmacy, a small pharmacy located in Fort Erie, Ontario, run by a 73-year-old pharmacist who has practised pharmacy in Ontario for over 50 years. In March, 2004, without any notice or justification, Pfizer Canada advised Mrs. O's Pharmacy that it would no longer supply any products to it, apparently because Mrs. O's Pharmacy had advertised its business on the Internet. Notwithstanding that Mrs. O's Pharmacy has never exported any drugs to the United States, Pfizer continues to refuse to supply Mrs. O's Pharmacy with any of its products. Our client estimates that Pfizer products would normally comprise at least 15 percent of its total drug sales. This loss of revenue threatens to ruin Mrs. O's business.[6]

The measures taken by Big Pharma have also forced other Canadian pharmacies to undertake not to supply drugs to anyone who may export to the United States. Another of our clients, Broadview Pharmacy, located in Toronto, Ontario, finds itself in such a predicament with respect to Wyeth Canada, whose products (now completely cutoff) comprise of a significant portion of its total sales.[7]

REACTION IN CANADA: PENDING APPLICATIONS BEFORE THE CANADIAN COMPETITION TRIBUNAL

Some of our clients have been forced to take on Big Pharma themselves, by commencing their own proceedings before Canada's Competition Tribunal (the Canadian equivalent of the U.S. Federal Trade Commission). Canada's Competition Act permits persons to seek leave from the Competition Tribunal to commence proceedings to obtain relief from a supplier's refusal to deal. Last week, Mrs. O's Pharmacy, Broadview Pharmacy and two other pharmacies based in Hamilton, Ontario all commenced leave applications for such relief before the Canadian Competition Tribunal, as against Pfizer Canada, Wyeth Canada, and Novartis, respectively.[8]

LIKELY FUTURE PROCEEDINGS BEFORE THE CANADIAN COMPETITION TRIBUNAL

We anticipate that, once suitable U.S. legislation is passed permitting the importation of drugs from Canada into the United States, other pharmacies, including our client, Kohler's, will also apply for leave to the Competition Tribunal to obtain relief from Big Pharma's refusal to deal.

Nevertheless, it must be recognized that such proceedings are time-consuming, burdensome and expensive, necessitating, as they do, individual Canadian pharmacies conducting complex litigation against Big Pharma. Such proceedings could be delayed and deliberately "strung out" by Big Pharma, which is more than capable of hiring experienced, effective counsel to represent their interests.

U.S. LEGISLATION: THE CLEAR NECESSITY FOR THE INCLUSION OF PENALTIES FOR REFUSING TO SUPPLY

The ongoing efforts of our clients to challenge Big Pharma's supply restrictions at the Canadian Competition Tribunal, while absolutely necessary for their business well-being, nevertheless do not, in our view, represent the most effective means of ensuring that Canadian exporters receive adequate supplies of drugs for their U.S. customers. A far more effective means of ensuring that Big Pharma adequately supplies Canadian exporters would be for the proposed U.S. legislation to impose severe penalties in the United States for supply restrictions sought to be imposed by Big Pharma upon exporters in Canada and elsewhere. It is apparent to us that, if such

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[5] See Tab 2, page 11.

[6] Affidavit of O. O'Charchin, paragraphs 10–12 (Mrs. O's Pharmacy and Pfizer Canada Inc.—Competition Tribunal materials, Tab 4).

[7] Affidavit of H. Cohen, paragraph 7 (Broadview Pharmacy and Wyeth Canada Inc.—Competition Tribunal materials, Tab 4).

[8] Copies of the Application materials in all three cases, which have now been filed and are a matter of public record, are attached at Tab 4. They include sworn affidavits.

penalties are not imposed by the new legislation, Big Pharma, which desperately wants to curtail Canadian pharmaceutical exports to the United States, will no doubt attempt to, and may succeed in rendering U.S. legislative reform moot, by taking some or all of the following steps:

- Continuing to cutoff the Internet pharmacies from supplies;
- Attempting to drive the Canadian Internet pharmacies out of business;
- Forcing Canadian pharmacies to engage in lengthy and expensive litigation to reinstate supplies; and
- Generally frustrating and blocking Canadian drug export activity, even after the cloud of the FDA's phantom illegality has been lifted by new U.S. legislation.

Accordingly, we respectfully urge that Big Pharma's supply restrictions be "nipped in the bud" by suitable provisions in the proposed U.S. legislation which would severely penalize Big Pharma for engaging in such practices. Of the legislation pending before the committee, bill S. 2328 would in our view be by far the most effective way to deal with this the current supply restriction problem. Such an approach would free U.S. consumers from dependence upon the outcome, which may be much delayed, of proceedings before the Canadian Competition Tribunal, where Big Pharma likely will attempt to "grind down" the Canadian pharmacies who are seeking relief from it. U.S. consumers should not have to await the favourable conclusion of Canadian Competition Tribunal proceedings in order to get the drug price relief they need and deserve now.

U.S. PATENT LAW AMENDMENTS

In addition, we also urge appropriate amendments to U.S. patent laws in order to prevent Big Pharma from taking the position that the export of drugs from Canada into the United States is an actionable patent violation. Even if Big Pharma's attempts directly to curtail supply fail, we anticipate that Big Pharma will likely launch suits against Canadian exporters alleging such patent violations.[9] Such litigation could drive Canadian drug exporters out of business, thus accomplishing Big Pharma's goals indirectly. We therefore urge that corrective U.S. legislation be passed which would prevent Big Pharma's patent rights from being abused in this manner.[10]

CONCLUSION

If the foregoing points are not taken adequately into account, and if they are not effectively dealt with in the legislative reforms which Congress is now considering, it is our fear that the resulting new U.S. laws may have little or no practical effect, because Big Pharma may still be able to cutoff the source of supply for U.S. consumers by continuing the restrictive supply practices described above, and by threatening and prosecuting patent violation suits against Canadian and other exporters. We therefore urge Congress to enact full remedial legislation accordingly.

We also respectfully urge Congress to consider the establishment, through legislation, of a statute-mandated cooperation program between U.S. and Canadian pharmaceutical regulators, such that each country may be encouraged and enabled to accept the adequacy of the pharmaceutical regulatory regimes of the other, thus enhancing the free flow of pharmaceutical products across the border, in the spirit of the free trade principles which both countries have accepted.

We very greatly appreciate the opportunity to make these submissions to your committee.

Sincerely Yours,

D.H. JACK,
MARK ADILMAN.

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[9] See Tab 1, Wyeth's letter of June 16, 2003, in which it stated to Kohler's ". . . Moreover, these exports of Wyeth Canada products from Canada into the United States may constitute infringement of intellectual property rights in the United States."

[10] InsideHealthPolicy, on March 29, 2004, and CPTech, on March 31, 2004, each identified this issue, which arises out of the Jazz Camera (or Jazz photo) case referred to in their respective publications on the subject. See Tab 5. It is urged that U.S. legislation prohibit Big Pharma from attempting to employ its patent rights to prevent Canadian and other pharmaceutical exports to the United States. One way to do this would be for the legislation to make it clear that U.S. patent rights are exhausted by the first sale of the patented product by the patent owner, or by a party authorized to use the patent, as for example on resale by a distributor.

PREPARED STATEMENT OF AARP

Mr. Chairman and members of the committee, thank you for convening this hearing and for providing AARP an opportunity to share our views on the need to address rising drug costs through the safe importation of prescription drugs.

Over 5 months ago, Congress enacted some sweeping changes to Medicare—including long-overdue prescription drug coverage. We believe that the new law, while far from perfect, lays the foundation for affordable Medicare prescription drug coverage upon which will we will build over time. AARP will continue to work with Congress to strengthen and improve the drug benefit and the Medicare program.

THE NEED FOR IMPORTATION LEGISLATION

The Medicare prescription drug benefit was an important first step. But now more needs to be done to control the rising costs of prescription drugs so that Americans of all ages can afford needed medications. Modern medicine increasingly relies on prescription drug therapies; yet the benefit of these therapies still eludes those Americans who cannot afford to pay escalating drug prices. Between 1998 and 2003, prescription drug prices rose at nearly twice the annual rate of inflation for that same period.[1]

CMS estimates that, in 2003, per capita spending on prescription drugs rose approximately 12 percent, with a similar rate of growth expected for this year.[2] Much of the increase in drug spending is due to higher utilization and the shift from older, lower cost drugs to newer, higher cost drugs. However, rapidly increasing drug prices are a critical component.

High drug prices, combined with the surging older population, are also taking a toll on State budgets and private sector health insurance costs. Medicaid spending on prescription drugs increased at an average annual rate of nearly 20 percent between 1998 and 2001. Until lower priced drugs are available, pressures will continue to squeeze public programs at both the State and Federal level. Pressure will continue on the private sector as well, possibly leading to elimination of, or reductions in, employer-provided drug benefits. Further, over 43 million Americans currently have no health insurance coverage. Without access to negotiated prices, these Americans pay among the highest prices for prescription drugs in the world or, worse yet, don't fill prescriptions because they cannot afford to pay for them.

AARP surveys demonstrate that our members consider drug prices exorbitant and the single most significant barrier to obtaining needed medications. Responses to an AARP Bulletin questionnaire last fall showed that our members split pills, skipped doses, asked doctors for free samples, and sold possessions because the costs of needed medications were too expensive. One woman poignantly noted that she begged for the unfinished prescriptions of friends who had died, hoping their leftover drugs would meet her needs.

Americans of all ages need affordable prescription drugs now. Safe importation of prescription drugs from Canada is one way to begin to secure lower priced drugs. Our members question why prices in Canada can be lower, sometimes far lower, than prices in the U.S. It is a national embarrassment that people from all over the world come to the United States to access our advanced medical systems while many of our own citizens need to look outside our borders in order to afford their prescription drugs. But with the same drugs selling, in some cases, at 30 percent and even 50 percent less in Canada and overseas, it is hardly surprising that so many make that choice.

It is no longer a question of whether we should or should not allow the importation of drugs from abroad. The simple fact is that importation is already happening. Many Americans travel to Canada for less costly prescription drugs, or purchase their drugs through the Internet without any systematic U.S. oversight process in place to assure safety. Importation of drugs is likely to continue whether or not Congress acts. The trend is growing, and we have a responsibility to ensure that Americans can access lower cost drugs without putting their health at risk. AARP therefore supports legalizing importation through a system that ensures safety and lowers drug costs.

We are very pleased that this committee—and the Senate as a whole—is moving the issue forward. We strongly urge you and your colleagues to take action that will lead to enactment of importation legislation this year. We believe we can meet the

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[1] http://data.bls.gov/servlet/SurveyOutputServlet.

[2] Data for 2003–2004 are projections from Table 11.

Prescription Drug Expenditures: Aggregate and per Capita Amounts, Percent Distribution and Average Annual Percent Change by Source of Funds: Selected Calendar Years 1990–2013, *http://cm.hhs.gov/stastics/nhe/projections-2003/t11.asp.*

challenges of designing a prescription drug importation program that will ensure the integrity of pharmaceuticals and provide a streamlined process that enables consumers to access lower cost prescription drugs.

AARP supports efforts—such as the bipartisan bill introduced by Senators Dorgan, Snowe, and Kennedy and the legislation being developed by Senator Gregg—that move to make lower priced drugs available to American consumers. We have specific recommendations for safety features that should be included in any importation legislation, and look forward to working with all of these bill sponsors on these recommendations. AARP and its members will actively support bipartisan legislation that lowers costs and ensures safety and we will aggressively work for passage this year.

SAFETY ISSUES

The health and safety of individuals is paramount in any importation system. AARP supports importation with strong safety features from licensed Canadian pharmacies and wholesalers. Regulation of the Canadian pharmacy system closely resembles its U.S. counterpart. As a result, we are confident that drugs purchased from Canada can be as safe as drugs purchased in the United States.

However, we recognize that some manufacturers are curtailing their drug supply to Canada, which could lead to supply shortages. Thus, limiting importation legislation to Canada may not be feasible. Our members do not want hollow promises of importation legislation—they want legislation passed that will allow them the opportunity to fill their prescription safely and at a lower cost. Therefore, legislation that expands importation beyond Canada should also include strong consumer safeguards to ensure that these systems closely align with the U.S. standards.

FDA CERTIFICATION

Congress has tasked the Food and Drug Administration ("FDA") with ensuring the safety and effectiveness of U.S. pharmaceuticals. Drugs manufactured for distribution in other countries may differ slightly from drugs destined for the United States. Some differences may be minimal and have little or no effect on the efficacy of the drug. Other differences may actually change the efficacy of the drug. Therefore, the FDA should determine whether imported drugs are safe for the U.S. market.

In order to accomplish this goal, FDA will need the authority and resources to inspect pharmaceutical plants in foreign countries—much as they do now—to ensure that these plants conform to rigorous U.S. safety requirements. Where appropriate, a specific manufacturing line in a plant may receive certification in lieu of undergoing the more lengthy process of certifying the entire plant. We therefore urge the committee to ensure adequate FDA resources to effectively monitor and enforce these standards.

Once the safety of pharmaceuticals from a given plant has been determined, a process should be established to guarantee the quality and efficacy of pharmaceutical distribution and dispensing. Pharmaceuticals should be dispensed and distributed according to the usual and customary pharmacy practices in the United States.

The safety and authenticity of these pharmaceuticals should be assured at each point along the stream of commerce. Regular inspection of the flow of prescription drugs from the point of manufacture to the ultimate point of dispensing is necessary. FDA should implement mechanisms by which foreign pharmacies and wholesalers can be registered with and licensed by, or on behalf of the FDA. These entities should be fully accredited and licensed by a reputable licensing board.

Consumers should be made aware of the results of FDA plant inspections and licensing activities. For example, FDA could provide electronic links from its Internet site to approved Internet pharmacies in Canada and other countries as appropriate. Having the FDA web site as the point of contact for a list of approved pharmacies would provide consumers with an official, secure source of information on safe drugs. However, not all consumers have access to the Internet; therefore, there should be mechanisms in place that will allow consumers to call a toll free number sponsored by the FDA, or other appropriate entities, in order to get information on approved foreign sources from which consumers can purchase lower cost pharmaceuticals. Consumers should also have confidence in the Internet sites they use to purchase drugs from other countries. We recommend that a system be put in place to identify and shut down unregistered Internet pharmacies.

PEDIGREE REQUIREMENTS

One way of effectively ensuring the safety of pharmaceuticals is the institution of pedigree requirements—being able to trace a drug from the point of origin to the point of dispensing. In order to accomplish this task in an expanded international arena, there should be a way to trace pharmaceuticals back to the point of manufacture and enforce pedigree requirements. Each entity that handles prescription drugs should be required to maintain records as to the drug's pedigree. Furthermore, there should be no impediments to an entity's ability to receive records regarding a drug's pedigree.

ANTI-TAMPERING/ANTI-COUNTERFEITING REQUIREMENTS

Pharmaceuticals imported from another country should be equipped with anti-tampering materials and anti-counterfeiting measures. As the technology in this area progresses, imported pharmaceuticals should be equipped with state-of-the-art devices, such as bar codes, and specialized ink, or other appropriate technology. We urge the committee to work with the FDA and others with the expertise necessary to determine appropriate anti-tampering and anti-counterfeiting requirements.

Other measures aimed at counterfeiting and tampering to be considered include the prohibition on repackaging and re-labeling of pharmaceuticals from other countries. This requirement could be enforced through the pedigree standards. Repackaging and re-labeling of pharmaceuticals creates the potential for misbranded or counterfeit drugs to enter the stream of commerce. Imported pharmaceuticals should be shipped in a manner that provides a tracking number (e.g., via international mail systems or some similar entity) to reduce the opportunity for counterfeit pharmaceuticals to enter the stream of commerce from outside the point of manufacture.

Because pharmaceuticals may be manufactured in countries where English may not be the official language, pharmaceutical labels and patient package inserts destined for the United States should be written in English as well. These labels should be applied at the point of manufacture, or prior to entry into the United States. Imported pharmaceuticals should be labeled in such a way as to indicate to the consumer that the drug has been imported under the new law.

OTHER ISSUES

We believe that features such as those previously outlined will help assure the safety of imported pharmaceuticals. Any system designed by Congress should also be realistic in terms of its safety requirements and FDA's responsibilities and capacity. This system should not be overly burdensome and costly to the point where American consumers will not be able to realize savings from imported pharmaceuticals. In addition to drug prices, shipping and handling, processing fees, licensure, and other costs should be reasonable and fully disclosed to the consumer at the time of purchase.

Consumer privacy also must be protected. As American consumers are able to purchase prescription drugs from other countries, not only should the integrity of the pharmaceuticals be ensured, but so should the privacy of the individual's protected health information. With the promulgation of the Health Insurance Portability and Accountability Act ("HIPAA") privacy standards, we have moved our Nation closer to assuring protection against misuse of an individual's medical information. Studies have shown that individuals will not take advantage of a system if they fear their protected health information may be misused. Therefore, we encourage you as you design an importation system, to ensure that an individual's private medical information is protected at least to the level currently required by HIPAA.

There are additional issues that we urge Congress to consider. There remains a strong need to examine the safety of pharmaceuticals within the United States' drug supply in order to prevent counterfeit, diluted, or ineffective drugs. As Congress examines foreign pharmaceutical supply systems, there is also an opportunity to revisit the integrity of the U.S. pharmaceutical system—from point of manufacture to the ultimate consumer.

Finally, importation legislation undoubtedly will impact the worldwide pharmaceutical market. The FDA should be required to submit reports to Congress, annually or as otherwise appropriate, to monitor the impact of regulated importation on the price, quality, and access to pharmaceuticals both in the United States and worldwide.

CONCLUSION

Our members want Congress to enact legislation this year to allow for legal, safe importation of lower priced prescription drugs. We commend this committee for its work in moving forward on the issue. We pledge to work with members on both sides of the aisle to develop a system to enable our members—and all Americans—to have secure access to lower cost imported prescription drugs.

PREPARED STATEMENT OF ALLERGAN, INC.

This testimony is submitted on behalf of Allergan, Inc., a biologics and pharmaceutical company headquartered in Irvine, California. Allergan develops innovative therapies for vision, muscular, and other disorders and conditions. We have developed a number of orphan products, including Botox, which is a biologic used to treat dystonia and related eye disorders, as well as muscular contracture in pediatric cerebral palsy patients.

We appreciate the opportunity to submit testimony on the matter of prescription drug importation legislation, and in particular, on the need for an exemption in such legislation for FDA-designated orphan drugs. Allergan believes that Congress should exclude orphan drugs from prescription drug importation legislation for two reasons: (1) permitting importation of orphan drugs would endanger patient safety; and (2) permitting importation of orphan drugs would undermine the Orphan Drug Act and thus jeopardize the future development of rare disease therapies.

I. BACKGROUND ON ORPHAN DRUGS

"Orphan" drugs are drugs (including biologicals) that are developed specifically to treat a rare disease or condition, *i.e.*, generally, a disease or condition that affects fewer than 200,000 people nationwide. According to the National Organization for Rare Disorders, more than 6,000 rare diseases have been identified. Some rare diseases are as familiar as cystic fibrosis, hemophilia, and Lou Gehrig's disease, while others—such as Hamburger disease and Job syndrome—might be known only to the relative few who are afflicted with the disease, along with their families and health care professionals. By definition, the number of people with a particular orphan disease is relatively small, but collectively, rare diseases afflict more than 25 million Americans. Rare disease patients rely on orphan drugs to treat their diseases, which often are life-threatening acute or chronic conditions.

II. IMPORTATION OF ORPHAN DRUGS WOULD ENDANGER PATIENT SAFETY

Exempting orphan drugs from prescription drug importation legislation is imperative to ensure the safety of rare disease therapies administered in the United States. Many orphan drugs are biologicals, which often require unique handling and shipping measures, such as maintaining the product at specific and often extreme temperatures, and limiting the product's exposure to light. If these handling and shipping requirements are not strictly followed, the clinical performance of a biological can be profoundly affected, resulting in an ineffective or harmful drug. Further, because many orphan drugs are infused or injected, rather than administered orally, they often are maintained in vials, syringes, or similar packaging. These types of packaging are much more vulnerable to tampering and counterfeiting than tablets or pills.

These safety concerns are not hypothetical or exaggerated. Consider the following reported examples of counterfeit or diluted orphan drugs that have entered the U.S. drug supply under current law:

• *Epogen (epoetin alfa).* Epogen is an injectable biologic used to stimulate red blood cell production. On February 21, 2001, the manufacturer of Epogen disclosed reported incidents of tampering. The flip caps from some vials had been removed and the vial contents were replaced with varying amounts of a subpotent aqueous solution. The vials bore counterfeit labels with phony lot numbers. Lab tests revealed that some vials contained active ingredient 20 times lower than expected. A 16-year-old liver transplant patient suffered severe muscle cramping after injections of the subpotent drug. His parents had purchased the drug from a national pharmacy chain store, which had in turn received it from one of three national drug distributors.

• *Neupogen (filgrastim).* Neupogen is an injectable colon-stimulating factor used mostly in cancer patients. In 2001, a distributor discovered counterfeit vials of the drug that contained fake lot numbers and incorrect expiration dates. Laboratory tests later revealed that the vials contained only saline solution.

• *Procrit (epoetin alfa).* Procrit helps anemic cancer and HIV patients increase their red blood cell counts. Counterfeit versions of the drug were first discovered in 2002 and have been found at two large wholesalers and a number of retail outlets. Counterfeit lots of the drug that purported to contain 40,000 units only had 2,000 units. Instead of active ingredients, some vials contained bacteria-tainted water that can cause blood stream infections.

• *Serostim (somatropin (rDNA origin) for injection).* There have been two counterfeit incidents associated with Serostim for injection, a growth hormone used to treat AIDS wasting. In 2001, a recall at the distributor level was prompted by consumer complaints about adverse events. A later investigation revealed the counterfeiting of two lots of Serostim. In 2002, the manufacturer of the drug became aware of another counterfeit lot. Laboratory analysis revealed that the drugs contained no active ingredients, and that the drugs did not originate from the manufacturer.

Although prescription drug importation legislation may establish safeguards to protect the Nation's drug supply, *safeguards can never be completely effective*. Even the legal safeguards currently in place have not prevented numerous cases of counterfeit and adulterated orphan drugs in the United States. Importation of orphan drugs would only increase the risk of exposing rare disease patients to an ineffective or harmful drug, because more entities that are far beyond the effective control of FDA will handle the drug before it reaches the patient. This introduces a much greater risk that a drug may be mishandled, contaminated, or counterfeited by an unscrupulous or careless person willing to exploit or ignore patient safety for economic benefit. Congress therefore should exempt orphan drugs—with their higher threat of adulteration and contamination, or compromised safety or efficacy due to mishandling—to reduce the risk of introducing unsafe products into the U.S. drug supply.

III. IMPORTATION OF ORPHAN DRUGS WOULD JEOPARDIZE FUTURE DEVELOPMENT OF RARE DISEASE THERAPIES

In enacting the Orphan Drug Act in 1983, Congress recognized the unique challenges that rare diseases pose for patients and drug manufacturers. Congress determined that there are "many diseases and conditions . . . which affect . . . small numbers of individuals," and that "because so few individuals are affected by any one rare disease or condition," companies that develop "orphan drugs" to treat these diseases may "reasonably expect . . . to incur a financial loss" in doing so. Given the inability of companies to recoup costs incurred in bringing these products to market, Congress found that "orphan drugs will not be developed" absent changes in Federal law to encourage their development.

To address this problem, Congress established certain incentives under Federal law for orphan drug development, including market exclusivity for 7 years, tax credits, assistance for clinical research, and research grants. These incentives have been essential to the development of orphan drugs. As a result of the Orphan Drug Act, more than 240 orphan drugs have been developed to treat rare diseases affecting approximately 12 million Americans.

Permitting importation of orphan drugs would thwart the goals of Orphan Drug Act, because it would introduce competition during the period in which the Orphan Drug Act promises market exclusivity. In addition to breaching the promise that Congress made in the Orphan Drug Act, this would impair manufacturers' ability to recover the costs incurred in developing rare disease therapies and discourage future research and development efforts aimed at discovering treatments for rare diseases. This result is precisely what the Orphan Drug Act sought to avoid, and could have disastrous consequences for the future development of orphan drugs—and thus for millions of Americans suffering from one of the thousands of rare diseases for which effective treatments have not yet been developed.

IV. CONCLUSION

In conclusion, we believe it is imperative that Congress exempt orphan drugs from prescription drug importation legislation to ensure the safety of rare disease therapies administered in the United States, and to maintain appropriate incentives to encourage the future development of orphan drugs. Allergan has long been supporter of the rare disease community and the Orphan Drug Program, and we remain committed to developing innovative therapies for the 25 million Americans suffering from rare diseases. We would be happy to provide the committee with any additional information that may be useful as it consider these important issues.

PREPARED STATEMENT OF THE BIOTECHNOLOGY INDUSTRY ORGANIZATION (BIO)

The Biotechnology Industry Organization (BIO) appreciates the opportunity to present the views of the industry and our members on the issue of legalizing prescription drug importation. BIO represents more than 1,000 biotechnology companies, academic institutions, State biotechnology centers and related organizations in all 50 States. BIO members are involved in the research and development of health care, agricultural, industrial, and environmental biotechnology products. BIO agrees with many in Congress and elsewhere that patients should have access to the prescription drugs they need—including the life-saving products developed by our member companies—and wants to work with Congress to find the right ways to ensure this. We do not believe legalizing importation of prescription drugs is the right solution for a number of reasons that are explained more fully below.

Legalizing prescription drug importation will put Americans at risk of obtaining products that do not meet the Food and Drug Administration's (FDA) high standards for ensuring safety and effectiveness—standards that have made the U.S. prescription drug market the safest in the world. The wholesale importation of prescription drugs across American borders will also jeopardize all U.S. consumers, not just those individuals who choose to obtain their prescription drugs from a foreign source.

Allowing the importation of prescription drugs with the intention of importing foreign government-imposed price controls will do little to curb growing drug costs while seriously threatening the continued innovation of the U.S. biotechnology industry and the patients who rely on its medical advancements to treat debilitating and often life-threatening illnesses. Further, current legislative proposals designed to establish an importation framework would erode intellectual property rights that serve as the backbone of America's biotechnology industry and would have seriously negative implications for U.S. trade policy.

PRESCRIPTION DRUG IMPORTATION IS UNSAFE

BIO strongly opposes the legalization of prescription drug importation, even though current legislative proposals exempt many biological and biotechnology products, because it would open the floodgates to a variety of unsafe prescription products.

The FDA has testified on multiple occasions that the U.S. prescription drug supply already is constantly under attack from a variety of increasingly sophisticated threats. Opening our borders, the FDA has asserted, would enable certain unscrupulous entities to circumvent the agency's standards for ensuring drug safety and effectiveness and peddle unapproved and perhaps dangerous products to U.S. consumers. Even if biologics and certain biotech products are exempt, counterfeiters and other criminals will likely find a way to shop dangerous versions of our products across the border.

Biological/Biotechnology Products Are Unique

We applaud Congress for recognizing the unique and sensitive features of products developed by the biotech industry and, therefore, exempting them from the proposed importation framework. Many biologics and other biotech medicines are particularly susceptible to adulteration, degradation and virtually undetectable counterfeiting. Moreover, many of our products cannot be safely administered by a patient and, therefore, require the intervention and/or supervision of a health care provider. As a result, our products are often not available in the United States through outpatient prescriptions, nor available at the local pharmacy.

Yet, patients and the FDA, through its sting operations, have been able to acquire biological and biotechnology products through Internet sites and through other questionable means. In many of these cases, these products were packaged improperly, maintained at temperatures that hastened their degradation or completely destroyed their effectiveness or were diluted, concentrated or otherwise dangerously adulterated. Obviously, the illegality of the transactions did not prevent them from occurring. To legalize importation for virtually all prescription drugs will do little to protect against further entry of unsafe medicines and will likely increase the availability of unsafe or, at the very least, ineffective biotechnology medicines.

Wholesale Importation Is Not Individual Importation

Questions about the safety and the integrity of the prescription drug supply are real and valid. The Congressional Budget Office recently issued a report on prescription drug importation, noting, with respect to cost savings, that although one patient filling a prescription in a foreign pharmacy may realize savings, the same would not necessarily be true for the entire health care system. This analogy can

also be extrapolated to safety concerns. If an individual chooses to travel to a foreign country to fill a prescription or to order prescription drugs from an unknown source via an Internet site, that individual is making a decision to accept the risk associated with that transaction.

Legalizing wholesale importation is not the same as personal importation. Wholesale importation will result in an intermingling of foreign drug products with those that have been approved as safe and effective through the FDA's gold-standard approval process. This means that every person filling a prescription will face the possibility of receiving a "second class" drug product. It will be irrelevant that a consumer chose to take the risk of filling a prescription from a foreign source while a different consumer has chosen not to: both will be forced to take the risk that their prescription medicine is a second-tier medicine.

Legalizing Importation Devalues the FDA Approval System

Drug importation would call into question the value and the viability of the FDA approval process. Recently introduced importation legislation, requires prescription drug manufacturers, who have non-FDA approved but foreign approved drugs, to submit an FDA application for approval. The application must state the differences between the foreign-made product and their U.S. counterpart. While this legislation technically allows the FDA to reject these applications, the legislation's clear message is an anticipation of FDA approval. Indeed, FDA will be required to make public all such notices and applications. The same public pressure that is driving this legislation will make it extremely difficult for FDA to disapprove an application. Therefore, the FDA will be required to approve drugs for distribution in the United States that have not undergone the same safety and efficacy tests as their United States counterparts. Importation legislation will allow foreign approved drugs to completely circumvent the FDA approval process.

Unrealistic Expectations for FDA Make Enforcement Impossible

Requiring the FDA to carry out numerous requirements and examine voluminous paperwork under a new importation program will not and cannot make an inherently bad system safe. It would be impossible for the FDA to register, monitor and regulate importers and exporters, ensure that all incoming drug products are in accord with proper prescriptions, and inspect parcels, products and facilities to ensure product safety with the intensity required under such a program.

Those who will recognize the infeasibility of enforcing these requirements will be those who least intend to abide by them—criminals, counterfeiters, smugglers, and others whose only goal is to make the most money in the easiest fashion without regard to whether the so-called prescription products they peddle are safe or effective. An importation program would needlessly compromise the safest drug supply in the world.

PRESCRIPTION DRUG IMPORTATION WILL HURT THE ECONOMY AND THREATENS BIOTECHNOLOGY INNOVATION

In addition to threatening the safety and integrity of the U.S. prescription drug supply, there are other valid economic reasons to oppose drug importation.

The biotechnology industry is a thriving, growing, creative force on the U.S. economic landscape. The industry provides numerous employment opportunities and a thriving tax base for many communities around the country. The biotechnology industry is a key economic component in California, Pennsylvania, Massachusetts, North Carolina, and Maryland, to name a few. National and State policies that encourage the biotech industry's innovation and foster its growth will not only provide an economic boost but will also provide fertile ground for the development of treatments and cures for patients all over the country and the world. Policies and legislation that discourage innovation will have the opposite effect—squelching a positive economic and public health force.

Importation Will Have a Negative Impact on Investment

Investment in the U.S. biotechnology industry is based on an expectation that a product's success will reap benefits not only for patients but also for future industry projects and investors. That expectation can be fulfilled if a successful product remains in a favorable competitive environment for a reasonable period of time. Investors will not look favorably on the possibility of imported products quickly becoming competitors of FDA-approved products, nor will they look favorably on what will become, essentially, a system of foreign-imposed price controls on FDA-approved products.

The vast majority of biotechnology companies across the United States are small companies with no products yet available on the market and without significant rev-

enue or profits. To fund the costly and lengthy periods of research and development, biotech companies rely heavily on three primary sources of capital: (1) private investment capital, (i.e., institutional or venture investors); (2) public investment capital (i.e., the stock markets—mutual fund investors and individual investors); and, (3) capital obtained from partnerships with other companies (e.g., pharmaceutical companies).

The capital markets are acutely sensitive to factors that threaten to limit current or future profitability for any company or industry sector. We see examples of this on a daily basis: if a public company unexpectedly announces an event that could adversely impact future earnings, the stock price plummets resulting in millions, if not billions, in lost market value. Frequently, depending on the nature of the event, an announcement by one company will also have a negative effect on other stocks in the same sector, because of the fear that something similar could happen to those companies. Broader pronouncements that threaten to limit the profitability of an entire sector have even greater significant adverse consequences.

To understand this, one need only remember the early nineties, when the suggestion of widespread healthcare reform caused a precipitous decline in healthcare stocks, in aggregate valuations, and in the subsequent flow of investment capital into the health care sector. It is worth remembering that this tide was only reversed when the specter of healthcare reform was substantially reduced. Other examples of how quickly the capital markets respond to a perceived threat to future profitability include the Clinton-Blair gene patent pronouncement, when a mis-statement by a White House press secretary caused the immediate loss of billions of dollars in market value for the biotech industry. In that situation, there was no policy change, yet the bottom literally fell out of the biotechnology market as stock prices plummeted within a matter of a few hours of the statements.

These examples illustrate the sensitivity and vulnerability of investment in the biotechnology sector. Legalizing prescription drug importation will have at least the same desultory impact and probably a greater one. The question is whether Congress and patients want to take the chance that prescription drug importation—which is arguably not even a long-term solution to the identified problem of escalating drug costs—will adversely affect biopharmaceutical innovation. BIO is certain that it will affect biotechnology innovation in a way that could slow the development of new products, or perhaps stop such development in its tracks.

It costs more than $800 million and anywhere from 5 to 10 years to develop a new pharmaceutical product; biotechnology products can require even greater costs and longer timeframes. Since many biotechnology companies are not yet profitable because they do not yet have products on the market, they must maintain a high rate of capital investment for long periods of time to stay in business. This investment is based on an expectation of return. National policy or legislative changes that affect the potential viability of the market for a new biotechnology product will affect the willingness of investors to take this risk.

Biotechnology development is an extremely high-risk venture. Of the many wonderful ideas that this creative industry generates, only a small handful result in FDA-approved new products. Our member companies are dedicated to finding the next biological-based treatment or cure. They are willing to devote enormous energy, creativity, and resources to this endeavor, even though they know success is difficult and elusive. But no treatment or cure will come without this research. And this research and development cannot be undertaken without the commitment of substantial financial resources, most of which come from the highly sensitive capital market. Some may argue that the pro forma (and we believe unenforceable) exemption of biotechnology products from importation legislative proposals will resolve these economic concerns. However, it is important to remember that many BIO member companies use the fruits of biotechnology as part of their drug discovery and development efforts, although the products themselves may not be manufactured using biotechnology processes. Such companies would be severely affected by the legalization of drug importation regardless of whether biological products are exempted.

The unrestricted importation of drugs that are sold to foreign suppliers under the foreign-government imposed (or "negotiated") price controls will reduce the profitability of the companies that developed the drugs. In fact, that is precisely the objective of the advocates of importation—to use it as a mechanism to reduce prices for consumers artificially, and thereby reduce company profits as a result. The immediate and unavoidable impact of reducing economic profitability is a reduction in investment in an industry that requires such capital to fund further innovation. Quite simply, reduced profits (via price controls or any other mechanism) mean less investment capital to support drug research and development.

De facto implementation of price controls via importation will not create a corresponding reduction in drug development costs. It will still cost the same to dis-

cover, test, validate through clinical trials, manufacture and ultimately sell a new product. The failure rates experienced during the product development process will still be the same. The costs and risks will remain the same, but the potential return will be greatly diminished. As a result, companies will have no choice but to further limit their development efforts to only those drugs that have the highest potential profitability in the face of price controls. Drug candidates that could potentially help many patients and that were once considered viable opportunities under a free-market pricing system will be abandoned because they will no longer be sufficiently profitable in a world of de facto price controls.

Importation's effects on institutional capital flow into the biotechnology sector will be even more harmful. Merrill Lynch published an industry research report in May 2004 that found that during 2001, 2002, and 2003 there was a net outflow of $500 million, $3.0 billion, and $1.0 billion in capital from biotech/healthcare investment funds for each respective year. This represents a net reduction of $4.5 billion in available investment capital for public biotechnology companies. In 2003 alone, there was an estimated $12.7 billion in financing need (i.e., amount of new investments sought by biotechnology companies), yet at the same time there was an overall net outflow of $1 billion from biotech/healthcare investment funds. In short, the amount of available investment capital diminished while the need for capital increased.

While the trend regarding the flow of investment capital out of biotechnology funds has reversed somewhat this year, the current appetite for investment capital among public biotechnology companies continues to outstrip the current supply. Currently nearly 60 percent of all biotechnology companies have less than 2 years of cash, and nearly 30 percent percent have less than 1 year of cash. In 2004, more than $4.7 billion of new financing demand has entered the market (i.e., amount of capital sought by companies in the public markets). During the same timeframe, less than $1 billion of new capital has entered the sector. The current rate of capital demand is nearly five times greater than capital supply for public biotechnology companies.

Less product innovation is the long-term effect of inadequate capital supply. If companies have fewer dollars available to invest in research, they will be unable to support the research and development required for finding and creating new medicines. Companies will scale back or eliminate research and development projects that could result in new medicines. They will also slow the growth or even reduce their research and development staff, causing the loss of many high quality, tax-paying jobs.

As the baby boom generation continues to age, the need for safer, more effective, and more cost-effective medicines is clearly increasing. Entrepreneurial innovation is the driving force that could ultimately enable us to address the growing national healthcare burden by providing more medically and economically effective ways to improve human health and treat disease. The best hope to address the growing challenge is to stimulate increased investment before the national need becomes too acute, and the only available option becomes the use of current medicines and implementation of widespread healthcare rationing. In a climate of price controls, vital investment capital will flow elsewhere, and innovation in the biotechnology sector will largely become a thing of the past.

Prescription Drug Importation Imports Foreign Government Price Controls

The importation issue is not just about the importation of drugs—it's about the importation of price controls. Importation would not even be a topic of discussion today were it not for the fact that foreign governments have arbitrarily imposed pricing restrictions on companies that develop new, safer and innovative medicines, and then elect to sell them outside the United States. That is a global trade issue that must be addressed. Why should foreign countries be allowed to force U.S. consumers and companies to subsidize their healthcare costs? Without the innovations provided by the U.S. biotechnology and pharmaceutical industry their health care costs would surely be far higher, and the quality of life experienced by many patients far less, than it is today.

Biotechnology is the future of medical innovation. The promise of the Human Genome project, huge breakthroughs in biological sciences, and the astoundingly escalating understanding of human genetics will result in products created by this industry. Policies that stymie the biotechnology industry will interfere with the fulfillment of this promise for every patient waiting for a cure.

Just recently, a study was published demonstrating that the United States is losing its technological edge in the physical sciences. The authors found that, as measured by patents issued, scientific prizes received, graduate students studying in one country versus another, and other measures, by countries such as China, Japan,

and India, are on the road to surpassing the United States. However, the United States still leads the way in biotechnology innovation. This country is without peer in terms of understanding disease and developing the most biologically and genetically appropriate ways to treat disease. The reason this country is so successful, and the reason our patients have the best chance at the latest and best medicine, is that our national policies foster innovation. We do not have prescription price controls because such controls hinder and discourage innovation. We do not have international parallel trade because those trade policies stifle innovation. We have strong protections for intellectual property because such protections foster and reward innovation. Biotechnology innovation will deliver on its promise if the country delivers on policies that allow it to thrive.

IMPORTATION PROPOSALS THREATEN PATENT LAW

Prescription drug importation legislation also erodes intellectual property rights. One bill that has been introduced would prevent U.S. manufacturers from enforcing their patents against foreign products that, if marketed in the United States under current law, would violate the patent on the U.S. product. In other words, even though the foreign product is imported into the U.S. market in direct competition with the U.S. FDA-approved drug, the manufacturer would be denied any recourse under U.S. patent laws. Again, the impact on the biotechnology industry of such a change to patent rights would be enormous. In many cases, companies in this industry own very little except their intellectual property. The entire value of the company may be attached to the existence of intellectual property rights to a material or a means to achieve specific activity from certain kinds of biological agents. The message of such legislation is loud and clear: the United States is not willing to protect patent rights associated with pharmaceutical innovation. This message alone is enough to discourage investment and smother innovation.

PRESCRIPTION DRUG IMPORTATION DOES NOT GUARANTEE COST SAVINGS

Further, although this legislation is intended to be a mechanism to provide patients with lower priced prescription drugs, the Congressional Budget Office and numerous economists have challenged the assumptions of substantial cost savings, noting both the unique features of the world pharmaceutical marketplace and the substantial costs that would be incurred by middlepersons in the import/export scheme that certainly would be passed along to patients. Recently introduced bills provide numerous requirements that were not even envisioned by the economists who looked at earlier legislation, so these transaction costs would be significantly higher. Additionally, examination by economists of European parallel imports shows that the expected significant savings for consumers have not materialized, although tidy profits have been made by the traders. Moreover, none of the bills guarantee that the cost differential obtained by the importer/exporter is actually passed along to the consumer.

CONCLUSION

BIO is strongly opposed to any attempt to legalize prescription drug legislation. We believe that any form of drug importation will harm our industry and will, more importantly, harm the patients we are dedicated to helping. No exemption is fail-safe, and the ingenuity of criminals cannot be underestimated. They will find ways around the myriad requirements proposed by these bills, and no on-paper "exemption" for biologics will stop them from dealing in whatever product they believe will be the most lucrative.

There can be no doubt that incursions into trade policy, intellectual property protection, and economic incentives for U.S. business—all of which are part of this legislation—will have unintended consequences. The benefits of a free-market economy for U.S. citizens and for this country's economic well-being are well-accepted. There will be harm when legislative policy attempts to distort the free market by imposing requirements and penalties designed to perturb what the market otherwise achieves on its own. This is particularly true when the incursions and perturbations are directed at one and only one industry and at one set of products.

BIO agrees with those who believe that patients need access to our life-saving and life-enhancing products. Health coverage helps this happen, and we encourage the Congress to take action to reduce the number of uninsured Americans and increase assistance in purchasing their prescriptions to those in need. We also support the new entitlement under Medicare, which will help all Medicare beneficiaries—most of whom are our senior citizens—with their prescription drug needs. Until that prescription benefit takes full effect, the Medicare discount card will help many. Whether one supports the new Medicare benefit or not, or believes the discount card

is sufficient or not, both of these mechanisms at least do no harm to the future of innovation and the future possibility that treatments and cures will be available for those who need them. Legalizing importation is not the answer to prescription drug access. Its promise is false and its dangers are real.

PREPARED STATEMENT OF THE NATIONAL ASSOCIATION OF CHAIN DRUG STORES (NACDS)

Mr. Chairman, and members of the committee, the National Association of Chain Drug Stores (NACDS) appreciates the opportunity to submit testimony relating to importation of prescription drugs. NACDS is a national trade association that represents more than 200 chain pharmacy companies that operate nearly 35,000 community retail pharmacies. Our members dispense more than 70 percent of all outpatient retail prescription drugs in the United States.

NACDS supports access to low cost prescription drugs. However, NACDS does not support importing drugs from Canada or other foreign sources. The safety net established to assure the integrity of the drug supply in the United States works well. We do not believe that the relative short term savings that can be realized by compromising our closed drug distribution system will be worth the longer-term costs to our patients.

There are two different methods of importation of prescription drugs that should be distinguished and evaluated separately in terms of their safety and cost effectiveness.

1. *Importation by Individuals.* NACDS is strongly opposed to proposals that would encourage or facilitate importation of prescription drugs by individuals. Simply put, there is no realistic way that consumers can know whether the imported prescription medications that they are receiving—whether through the mail or in person—are misbranded, adulterated, counterfeit, approved for use in the United States, or labeled appropriately. There are short term savings that some consumers can realize by purchasing prescription drugs from a foreign source due to the price differentials in drugs sold in other countries. However, NACDS believes that any potential savings is dwarfed by the potential dangers of purchasing drugs outside the closed system of distribution in the United States.

As is all too evident from recent Federal reports and investigations, millions of packages containing pharmaceutical products—many containing illegal, contaminated, adulterated, counterfeit or harmful controlled substances—are being shipped into the United States each year ordered by consumers through various means.[1] Many of these drugs look exactly like their authentic counterparts, making it even more difficult to determine their authenticity without some form of rigorous testing and validation.

Patients assume an incredible risk when they go shopping internationally for health care products. There is virtually no way for consumers to discern a "legitimate" source from a dangerous source. If the drug is subpotent or adulterated or otherwise ineffective, any savings realized is lost. Moreover, many of these international businesses, purportedly doing business in Canada, are not what they advertise to consumers and drug supply may be from questionable sources.[2]

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[1] *See* FDA Press Release, "Recent FDA/US Customs Import Blitz Exams Continue to Reveal Potentially Dangerous Illegally Imported Drug Shipments" (January 27, 2004) at *http://www.fda.gov/bbs/topics/NEWS/2004/NEW01011.html.*

[2] *See* Testimony of William Hubbard, Associate Commissioner of Policy and Planning and Legislation, FDA, before the Committee on Government Reform, U.S. House of Representatives (June 24, 2003) (discussing purported Canadian pharmacy service website run by three-time convicted felon which delivered drugs made in India to an American who ordered from website); *see also*, Global Options, Inc., "The Analysis of Terrorist Threats to American Medicine Supply," (2003) at 145–48.

Also, the Coalition for Manitoba Pharmacy reported on April 2, 2004 that a Vancouver Internet pharmacy company is openly selling Americans prescription medicines from Mexico, approved by neither HealthCanada nor the U.S. Food and Drug Administration. The company, *www.canadianpharmacytrust.com*, which dispenses drugs through its "affiliate" Southland Pharmacy of Vancouver, announces on its website "Generic Viagra now available at 80 percent off," and "Generic Cialis & Levitra also available from our pharmacy. Why pay more?!?"

"They are shipping Americans drugs from Mexico," said Michele Fontaine, Vice President of the Coalition for Manitoba Pharmacy. "Who knows what's in those pills? These drugs have not been validated by Health Canada or the FDA. And it seems that they're violating U.S. and Canadian patent laws, too. From our perspective it looks like Internet pharmacy companies will stop at nothing in putting profits before the interests of patients. To me, this isn't pharmacy, its piracy."

"And now they're openly selling Americans medicines not just from Canada's supply, but from any other country where they can get their hands on more drugs," said Fontaine. The trans-

Just as important, individual importation of prescription medicines usually eliminates any patient interaction with the pharmacist. This professional interaction is important to ensure that the patient understands how to take the medication appropriately and to avoid any potential interactions with other medications that the patient might be taking. With no knowledge of a patient's foreign purchases, a patient's pharmacist cannot protect the patient from a drug misadventure. Thus, a patient that receives a medication from another country is not only at risk for the potential problem with the medication, but also for potential harmful drug interactions that may occur with the other medications that the patient is taking. The coordination of care that occurs at pharmacies today cannot occur when a drug is imported by a patient from another country.[3] An incomplete health care profile is a recipe for patient harm, particularly for patients who are using multiple medications. In almost every case, the cost of hospitalization for an iatrogenic event far exceeds any savings that a patient may have realized on the purchase of a drug.

Importantly, patients in pursuit of cheaper brand-name prescription drugs from foreign sources will likely miss the fact that a cheaper generic alternative may be available in the United States. In most cases, there are safer, cheaper drugs available at the local pharmacy than in Canada—on pure price comparison, *generic* drugs are still much less expensive on this side of the border. Further, pharmacists can assist many patients in finding other savings, either through pharmaceutical manufacturer assistance programs or the new Medicare-endorsed discount cards which will be available to Medicare beneficiaries later this year. And the savings generated by these programs do not threaten the integrity of patient care and the prescription drug safety net in the United States.

Additionally, there are broader economic costs that must be considered when we send patients to foreign suppliers of prescription drugs. Drug importation schemes promote unfair competition against American pharmacies. The reason is that foreign pharmacies do not compete on a level playing field in compliance with the strict Federal and State regulatory standards to which domestic pharmacies must adhere. Instead, foreign pharmacies are given unfair advantages that make fair trade all but impossible. As examples:

- Foreign pharmacies do not have to pay U.S. taxes.
- Foreign pharmacies are not subject to Federal and State consumer protection laws.
- Foreign pharmacies do not have to comply with stringent Federal and State licensure requirements and U.S. safety standards.
- Foreign pharmacies do not face the frequent lawsuits that are an ever-growing threat in the United States; indeed they often require customers to waive all liability.
- Foreign pharmacies do not comply with the thousands of laws and regulations that apply to U.S. pharmacies, such as the stringent HIPAA privacy rules that protect patients against improper use and disclosure of their personal health information.[4]

Drug importation has another negative consequence: Job losses. Community pharmacists fill literally billions of prescriptions for Americans every year, and their work is supported by everyone from pharmacy technicians to cash register operators to truck drivers to janitors and everyone else that makes it possible to operate a community pharmacy. If prescriptions are sent through international mail order to be filled by foreign "pharmacies," some pharmacists and many other pharmacy em-

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shipment of medicines originating in distant countries has been a major concern for pharmacy and medical organizations in Canada and the United States, as well as for the FDA. Research from Prudential Financial and the FDA has indicated a major increase in drug imports to Canada from countries including Bulgaria, Pakistan, India and Argentina. If, as the Coalition believes, these drugs are being trans-shipped to the United States, the concern is that neither the FDA nor Health Canada verifies whether these medicines are safe and effective, or if they even contain the proper active ingredient."

[3] Health plans spend more money treating the adverse consequences of misuse of drugs than they do on the drugs themselves. *See* Frank R. Ernst & Amy J. Grizzle, "Drug-Related Morbidity and Mortality: Updating the Cost-of-Illness Model," Journal of the American Pharmaceutical Association, v. 41, no. 2 (March/April 2001). Patients who fail to take their drugs as directed end up costing the system much more, in terms of increased hospitalization and patient care. Separating patients from their community pharmacists will only make this problem worse.

[4] *See attached* Letter from Susan McAndrew, Senior Policy Specialist/HIPAA, HHS/OCR to S. Lawrence Kocot, Senior Vice President and General Counsel, NACDS (March 4, 2004). Specifically, HHS recently told NACDS that many Canadian storefronts facilitating importation are not even subject to the Health Insurance Portability and Accountability Act (HIPAA) which protects the confidentiality of patient information. As a result, no United States citizen should have the false expectation that their patient medical records will not be sold or traded on the international market to unscrupulous marketers.

ployees in the United States will lose their jobs. It's inescapable: When you import drugs, you export jobs.

Finally, Drug importation leads to lower tax revenues. Community pharmacies collected about $30.8 billion in State taxes nationwide. The employees of those community pharmacies also pay billions and billions of dollars in Federal, State and local taxes. Recently, we have heard some in government argue that States and cities can save money by having prescription drugs mailed into the State from distributors in other States or other countries. But will State and local governments really be better off financially if local retailers lose business and local citizens lose jobs? We believe that is a short-sighted approach. Governments should avoid importation schemes that appear to save money, but in reality hollow out their own tax bases.

2. *Importation by Pharmacists and Wholesalers.* We believe there are significant challenges and issues relating to implementing a program of importation of prescription drugs by pharmacists and wholesalers, whether limited to Canada or expanded to other countries. Moreover, we question the long term potential for savings and safety from a program of importation from Canada.

We have concerns that the testing, tracking, and paperwork requirements of a commercial importation law will outweigh any cost savings that might be realized from a program of importation. We agree that such requirements would be prudent under any program of importation that introduces foreign supplies of drugs into our closed drug distribution system. However, some of this recordkeeping information may be difficult or impossible for an importer to obtain or validate. For example, under current law, importers are required to obtain lot or control numbers, and sources of origin of prescription medications. Some of this information may not be available to the importer. Moreover, the current program assumes that manufacturers would be willing to provide information relating to assay tests and approved labeling to importers of prescription medications. These features are critical to assuring quality of the products, and limiting potential liability to importers from mislabeled medications.

Establishing the infrastructure necessary to effectively and efficiently operate an importation program—coupled with potential testing and other regulatory requirements would impose significant startup and operational costs for the entire pharmaceutical distribution system.

Additionally, pharmacies would likely have to maintain dual inventories of pharmaceutical products to assure those products that have not been imported, and those that have been imported, are tracked and billed appropriately, particularly to individuals covered under private third party contracts or Medicaid programs. However, space limitations in pharmacies, carrying costs, and other considerations make it virtually impossible to maintain separate pharmaceutical inventories.

Finally, the relatively small volume of drugs that is likely to be imported into the United States, compared to the overall market, may further create a reluctance to invest in the infrastructure needed to operate this program. The ability of the supply chain to invest in the necessary startup costs will have to be weighed against the long term viability of the program, the prices of medications from Canada, and the ability to recover costs and make a profit.

The bottom line is that once the costs of testing and validation are factored into the overall pricing equation, we cannot be certain that the price of imported medications would be significantly less expensive than the prices for prescription medications in the United States.

Even if the government limits importation of pharmaceuticals to those from a particular country or countries, it will be an ongoing challenge to assure that drugs made in those countries meet the same standards for quality that are required in this country, or if those drugs were really even manufactured in those specific countries. Also, pharmacies must be assured that products are not counterfeit or diverted. Even if products are thought to be from a particular country that has high manufacturing or quality standards, the products may in fact be diverted from a country that does not. Importation likely will generate growth in "black markets" for pharmaceuticals, raising serious questions about the quality of these drugs.[5]

In addition, many pharmaceutical products sold in other countries—albeit containing the same active pharmaceutical ingredients as those sold here—may have

[5] *See* "Importation of Drugs Into the U.S. Appears Difficult to Stop—Puts Slow Pressure on EPS," Diane Duston and Tim M. Anderson, Prudential Financial (Equity Research) (Oct. 8, 2003) (stating that the "squeeze on Canadian pharmacy supplies" has caused Canadian pharmacies to get their product from Bulgaria, Singapore, Pakistan, among others); "Cross Border web pharmacists could hurt Canada," AP, September 24, 2003, *www.ctv.ca* (reporting on rise of grey market for prescription drugs in Canada due to reduced supply).

different shapes, sizes, colors, and even trade names. Some are made with different inactive ingredients, while some are sold in different doses because the patients in other countries have different dose-response relationships. Introducing different-looking foreign pharmaceutical products into the U.S. system will only confuse patients and health professionals. This will lead to an increase in medication-related events, which already lead to deaths and injury for thousands of individuals each year, and already results in $177 billion in related health care costs.[6]

There are serious questions regarding which parties will bear the liability if the imported drugs result in harm to individuals. For example, manufacturers currently bear the potential for liability resulting from harm from prescription medications that have been sold by them through established and licensed distribution channels. It is not clear how the burden for liability might change for a manufacturer if the drug is, in fact, made by the manufacturer for use in another country, but imported here by a pharmacist or pharmacy. Pharmacists and pharmacies that import these drugs may not be willing or able to accept the liability that comes with a program of importation of drugs.

There are also questions of whether international sources of pharmaceutical supply will be adequate and consistently reliable.[7] Pharmacies may be able to obtain sufficient international drug products at one time, but inadequate product supply at another. This might lead to a higher price for consumers—or a different quality of drug—when consumers come back for their medication if the source of supply is unavailable. Pharmacies must have access to consistent, reliable, quality sources of medication supply.

3. *Market Realities and the Fallacy of Importation.* Currently, some Americans may realize a savings by individually purchasing drugs from Canada. However, that savings is only attractive to Americans who have no insurance or poor insurance coverage. This pool of "qualifying" individuals and drugs eligible for individual importation is relatively small in the United States.[8] Opening the individual importation loopholes for a relatively small number of Americans is not worth the cost to our society as a whole.

Additionally, the supply of available drugs from Canada is relatively small. IMS Health reports that dollar sales for prescription drugs in the United States totaled approximately $214 billion in 2003. According to the IMS Health Retail Drug Monitor, for the 12 months ended in December 2003, Canadian retail prescription drug sales totaled only about $9 billion (US). About 85 percent or $7.5 billion is in brand name prescription drug sales. Therefore, assuming that we would leave the Canadians with some drug supply for their population, the theoretically "available" cheaper drug supply from Canada approximates a number substantially less than $7.5 billion worth of brand name drugs. To put this in perspective, in 1 year, CVS alone could purchase *all* of the Canadian drug supply and still not satisfy its prescription drug inventory needs.[9]

Basic laws of supply and demand dictate one of two things will happen to the Canadian drug supply if the United States implements a system of drug importation by American wholesalers and pharmacists: either prices will rise dramatically in Canada[10] or Canadian suppliers will turn to alternative foreign suppliers that

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[6] See Ernst & Grizzle, footnote 3.

[7] "Ban drug exports, say regulators," Tom Blackwell, *National Post* (Canada), November 15, 2003 (referring to the "reports on drug shortages" referenced by the head of the national Canadian pharmacy regulatory); "Canadians Warn of Rx Shortage." John O'Connor, *Chicago Sun Times,* November 13, 2003 (warning that Canadian pharmacists are concerned that Canada could run out of prescription drugs if States like Illinois implement importation plans); "Net pharmacies hard to stop," *www.calgary.cdc.ca/regional*, October 14, 2003; "Pharmacist Refutes U.S. Allegations," Eliza Barlow, October 10, 2003, *www.brandonson.com* (referring to difficulty in getting some brand name drugs); Coalition for Manitoba Pharmacy Submission to Standing Committee on Health, Winnipeg, Manitoba, October 2, 2003 (reviewing negative impact of the Canadian cross-border sales on supply and price of drugs in Canada).

[8] According to IMS Health, approximately 14 percent of the 3.2 billion prescriptions dispensed in 2003 were paid in cash. With approximately 50 percent of those prescriptions already filled with generic drugs which are generally cheaper in the United States, any savings from Canadian purchasing would be realized for no more than approximately 225 million out of the 3.2 billion prescriptions dispensed in the United States. In short, by further reducing this number by the types of drugs that would be prohibited from individual international purchasing by the Secretary under Section 1121(j), we estimate that only 4–7 percent of Americans would realize any savings by assuming the risks of individually importing prescription drugs from Canada.

[9] For the fiscal year ended January 3, 2004, CVS total sales were reported to be $26.588 billion, 68.8 percent or $18.292 billion was in pharmacy sales.

[10] As the number of United States citizens purchasing drugs from Canada has grown, prices have begun to increase in Canada and shortages of drugs are being reported. This is a natural phenomenon.

would likely be unacceptable to United States purchasers. In either case, implementation of a "successful" United States importation program would likely be more costly than any theoretical savings we could derive from buying up the Canadian drug supply.

It is unrealistic for United States policymakers to expect that the Canadian marketplace would not react and adjust to a formal expansion of importation from their country. It is our guess that Canadians would, rightfully so, take steps that would further protect their drug supply to avoid shortages and excessive price increases. Meantime, Canadian pharmacies that supply the United States under any formal reimportation program might find that they are unable to obtain sufficient supply of Canadian drugs—if at all—and seek other sources of supply that would not necessarily meet U.S. standards.

CONCLUSION

NACDS does not believe that possible short term savings that may be realized through implementing a formal system of importation will outweigh the potential long term risks to patient safety or the cost of implementing such a system. However, NACDS is committed to working with Congress, the Department of Health and Human Services, and the Food and Drug Administration to fully explore the issues associated with importation of drugs and ensuring that the voice of community retail pharmacy contributes to the debate. NACDS appreciates the opportunity to submit this statement for the record.

PREPARED STATEMENT OF PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA (PHRMA)

The Pharmaceutical Research and Manufacturers of America (PhRMA) appreciates the opportunity to provide a written statement for the record regarding the importation of prescription drugs. PhRMA is the Nation's leading trade association representing research-based pharmaceutical and biotechnology companies that are devoted to inventing new, life-saving medicines.

The importation of medicines into the United States that have been outside the jurisdiction of the U.S. Food and Drug Administration (FDA) is inherently unsafe. These risky schemes are also unnecessary to ensure Americans have access to needed medicines. As we explain later in our statement, programs offered by pharmaceutical companies and others can help ensure that no American has to go out without his or her medicine. There is no assurance that such imported drugs meet the FDA's stringent requirements for quality, purity, safety, effectiveness, or proper labeling. As FDA has documented, many of these imported drugs are unapproved, contaminated, counterfeit, or have been stored, handled or shipped under substandard conditions.

While proponents of importation believe that with certain modifications, such as end product testing, chain of custody provisions and/or limiting importation to Canada, importation can be done safely—the fact is, no modification can guarantee safety. End product testing is not adequate to demonstrate that a drug was manufactured in accordance with U.S. approval standards and quality requirements. Drugs are highly sensitive and can become adulterated and even dangerous during shipment if they are not properly controlled. Some medicines require maintenance of very precise temperatures at every point in time—from production to shipment to use. So, even if a drug passes testing standards when it arrived into the United States, if it is later stored improperly it can become contaminated.

Including a chain of custody requirement also does not guarantee safety. In fact, according to testimony given by the FDA before the Senate Special Committee on Aging on July 9, 2002:

> Because we could not go certify and look in the other countries, the bill that they refuse to implement or decline to implement would have replaced the normal quality control system with a testing process with a paper or so-called pedigree process that attempted to follow the trail of the drugs, but both Secretaries found that the paper process could be forwarded by faking documents and that you really couldn't adequately test these products, either economically or feasibly.

Limiting drugs to Canada, while on its face appears safe, is not. In reality, drugs could be imported from anywhere in the world, so long as they entered the United States via Canada. There is increasing evidence this practice is happening today. In fact, the FDA has testified this to be the case. There is no effective way to prevent the transshipment of medicines from Third World countries into Canada and

then into the United States. The Canadian government is on record saying that while it regulates drugs manufactured for its citizens, it cannot vouch for the safety of medicines that are then exported to the United States. Even if the Canadian government had the authority to regulate its exports—the fact is, the Canadian prescription drug market is less than 10 percent of the U.S. market. Even creating a modest demand on the system would pose quite a challenge to the distribution and regulation of prescription drugs in the United States.

The cornerstone of our pharmaceutical distribution system in the United States is total control of the process—from selection of raw materials, design of the manufacturing process, packaging of a final product, evaluation of storage conditions and careful selection of the distribution pathway. If this system is relaxed—the chances for substandard, adulterated and counterfeit medicines to enter our system increases.

There are many unforeseen problems that may arise if pharmaceutical manufacturers lose control of the distribution system. For example, what happens in the event of a product recall for an imported drug? If a shipment of medicines is imported into the United States and later recalled, there are no requirements that a foreign government notify American consumers of the recall. The FDA would not be able to enforce a recall without receiving extensive shipping documentation *prior* to importation that identifies a lot number, the country the product came from and every wholesaler and pharmacist that imported the drug into the United States. Such an information infrastructure would cost tens of millions of dollars and still would not be complete.

Another problem relates to unknown storage conditions. Not all pharmaceuticals come in pill or tablet form—there are liquid formulations, gel capsules, freeze-dried powders, creams and lotions, drops for ocular administration, patches, etc. Every product that has been FDA approved is individually evaluated for stability and potency from the time of release from the manufacturer to the expiration date. Conditions for storage in the manufacturer's original container are specified in the new drug application (NDA) in detail so that the product the consumer receives will be safe and effective when taken as prescribed. There is no easy way for a consumer or the FDA to know whether the product that is imported into this country has been stored appropriately. Extremes in temperature, humidity or the repackaging process are likely to result in a product that deviates from the original specifications. Testing might reveal the current potency of a product, but would not be predictive of future potency if the medicine was inappropriately handled or stored. Moreover, in some cases, packaging may react with a drug over time. That may not be apparent even if the drug is tested upon entry.

Counterfeit medicines also present a very real safety issue. Counterfeit drugs are not manufactured in accordance with the original NDA. Counterfeiters may use different starting materials, additives or intermediaries that are not acceptable. The counterfeit products are not manufactured in accordance with Good Manufacturing Practices (GMPs). It is very difficult to document any of these violations. The quality of a medicine is a measure of many factors including reproducibility of the physical state in terms of particle size, crystal structure, color, density, and other characteristics.

The ability of the active ingredient to be manufactured into the final dosage form with all the other materials (usually 5 to 30 other substances called excipients) as well as the amount of impurities present is the measure of its quality. Pharmaceutical companies have many personnel and departments devoted to ensuring that necessary procedures are carried out and standards are being met. While sophisticated counterfeiters can and do manufacture pharmaceuticals that often look every bit the same as ones made by the manufacturer, there are no guarantees that there won't be dangerous impurities present, or that the medicine will have the same clinical activity. Even differences in particle size are critical to the drug's safety and effectiveness.

These examples, and countless others not mentioned here, illustrate that legalizing importation opens an avenue for unscrupulous counterfeiters. In order to continue assuring American patients that the medicines they take are safe and effective, and meet the highest standards, the current system for manufacturing and distribution of pharmaceuticals must be maintained. Only the current system, with its full battery of quality testing conducted by the manufacturer, coupled with complete knowledge of the domestic distribution process can assure the safety Americans expect.

While importation is often hailed as the only solution for individuals who lack prescription drug coverage and cannot afford their medicines, the fact is, there are better, safer ways to ensure that patients have access to affordable medicines.

Patient assistance programs sponsored by pharmaceutical companies are one option that is available to all uninsured Americans that meet income eligibility requirements. In total, 65 percent of the uninsured population have income levels of 200 percent of poverty or less and thus are eligible for many of the patient assistance programs that provide medicines free of charge. Approximately 1,400 medicines are made available through these programs. Information on these programs can be found at: *www.helpinqpatients.orq*, an interactive Web site by PhRMA and 48 of its member companies that is designed to help individuals find patient assistance programs for which they may qualify. This online service is free and completely confidential. Last year alone, PhRMA members provided 17.8 million free prescription medicines to more than 6.2 million patients in the United States at a value of $3.3 billion. According to Dr. Dexter Frederick, Tampa Community Health Center, these programs have made a positive difference to patients. Speaking of the programs, Dr. Frederick stated:

> As a family physician in Florida, I see every day how the pharmaceutical industry's Patient Assistance Programs positively help my patients. Without these programs in place, many would go without the critical medicine and health care they so desperately need. These programs offer hope and quality of life to those who have little or no means to afford medications on their own. As a doctor, it is wonderful to provide needy patients with such care.

Pharmaceutical company discount card programs are a way for seniors and the disabled to save money on prescription medicines. Seniors under 200 percent of poverty who lack prescription drug coverage can access medicines made by two PhRMA member companies at a cost of $12 per 30-day supply and $15 per prescription, respectively. Other company discount card programs exist that offer seniors and the disabled up to 300 percent of poverty discounts on prescription medicines. This June, all Medicare beneficiaries will be eligible for a Medicare-endorsed discount card that will offer discounts on prescription medicines. The lowest income seniors will be eligible for $600 (per individual, or $1,200 per couple) this year, and next year as well, to help them afford their prescription medicines until the full Medicare prescription drug benefit begins in 2006. Once individuals have exhausted the $600, three PhRMA member companies have publicly stated they will offer their medicines free of charge to these individuals.

In 2006, all people with Medicare will be able to enroll in plans that cover prescription drugs. Plans may vary somewhat, but in general, individuals can choose a prescription drug plan and pay a premium of about $35 a month. They will pay the first $250 of their prescription drug costs, and Medicare will pay 75 percent of the costs (and individuals the remaining 25 percent) between $250 and $2,250. Once an individual has reached $3,600 in out-of-pocket spending, Medicare will pay 95 percent of the costs, and individuals will be responsible for the remaining 5 percent. Individuals with low incomes and low assets will not have to pay premiums or deductibles and will only pay a small co-payment for each prescription needed. Other people with low incomes and limited assets will get help paying the premiums and deductible and the amount they pay for each prescription will be limited.

Generic drugs available in the United States are often considerably less expensive than foreign drugs, and offer a solution for many who cannot afford their medicine. In addition, many States operate prescription assistance programs for lower income Medicare beneficiaries. For instance, the State of Wisconsin offers a program for Medicare beneficiaries, which is typically a much better deal for Wisconsin seniors than any Canadian web site. According to a letter from the FDA to Wisconsin Governor Doyle, if you take the prices for five common drugs for seniors (Detrol, Lipitor, Accupril, Aricept, and Prevacid), the patient would pay only $277.50 under the Senior Care Program in Wisconsin for 112 days for all of these drugs. From the three Canadian pharmacies that the Governor of Wisconsin identified for his citizens, the patient would pay over six times that amount—a difference between $14.25 per day for Canadian drugs versus only $2.35 from the local pharmacy selling safe, FDA-regulated American drugs.[1]

Often times, shopping around to various pharmacies can yield savings for consumers. According to John Graham, the author of a study by the Fraser Institute, Canada's leading economic think tank, "We hear about Americans who claim that they save money, some say up to 60 percent, by filling their prescriptions in Canada. That is very misleading because in some cases a consumer can save as much by bargain hunting at home as he can by crossing the border."[2] Numerous surveys have

[1] Letter from FDA, Associate Commissioner for Policy and Planning, William K. Hubbard to Wisconsin Governor Doyle, March 18, 2004.

[2] Media Release, Fraser Institute, August 30, 2001, *www.fraserinstltute.ca.*

been done by States and cities across the country that show consumers can and do save money by shopping around. For example, a survey by the Maine Bureau of Elder and Adult Services of prescription drug prices within the State of Maine found that the retail price of 10 drugs commonly used by seniors varied by as much as 60 percent in the 100 stores they surveyed across the State.[3]

The solutions detailed above provide practical options for many individuals to access affordable medicines that will not risk their health and safety.

We urge this committee to keep intact the current "closed" U.S. distribution system and reject efforts that would erode the ability of the FDA to ensure the safety and effectiveness of drugs sold in the United States.

[Whereupon, at 12:28 p.m., the committee adjourned.]

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[3] "State Survey Reveals Wide Range of Prescription Drug Prices," *Maine Times*, February 8, 2001.