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DRUG IMPORTATION: WOULD THE PRICE BE RIGHT?

HEARING

BEFORE THE

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

ONE HUNDRED NINTH CONGRESS

FIRST SESSION

ON

EXAMINING THE PRICE OF DRUG REIMPORTATION, FOCUSING ON IMPLICATIONS FOR UNITED STATES CONSUMERS, PRICING, RESEARCH AND DEVELOPMENT, AND INNOVATION

FEBRUARY 17, 2005

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STATEMENTS

THURSDAY, FEBRUARY 17, 2005

ADDITIONAL MATERIAL

DRUG IMPORTATION: WOULD THE PRICE BE RIGHT?

THURSDAY, FEBRUARY 17, 2005

U.S. SENATE,
COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS,
Washington, DC.

The committee met, pursuant to notice, at 10:00 a.m., in room SD–430, Dirksen Senate Office Building, Hon. Mike Enzi (chairman of the committee) presiding.

Present: Senators Enzi, Alexander, Burr, and Isakson.

OPENING STATEMENT OF SENATOR ENZI

The CHAIRMAN. I call this hearing to order. I want to welcome everyone to the second in a series of hearings on the issue of drug importation. Today's hearing will focus on the recently released report by the Department of Commerce on pharmaceutical price controls in other countries and their implication on American consumers.

Like many Americans, I am concerned about the affordability of prescription drugs. As the new chairman of the committee charged with protecting the public health, I am looking forward to continuing our study of whether we can import lower-priced prescription drugs safely and without importing price controls that would jeopardize American pharmaceutical research and development and ultimately American consumers.

The Senate Health, Education, Labor, and Pensions Committee has jurisdiction over any legislation to amend the Food, Drug, and Cosmetic Act and remove the restrictions on importing drugs. As chairman of the HELP Committee, I am interested in developing a bill that creates an environment where consumers can trust that medications can be imported without compromising the integrity of the drug distribution system or their own personal safety.

While I am open to new and creative ideas to make importation possible, I am very concerned about placing undue restrictions on trade. Limiting the right to buy and sell freely is a bad business and it ultimately harms consumers. We should not constrain the rights of businesses and individuals to respond to the forces of supply and demand.

I am concerned that Americans are paying higher prices to fund the pharmaceutical research and development that benefits the citizens of all nations, but our response should not be restrictions that penalize rational business decisions and limit consumer access to new drugs.

We shouldn't tell companies with whom they must do business, how much they should sell for, how much they should sell, and at what price. I don't want to impose those terms on my home State industries and I doubt my colleagues on the committee would want to do that in their own States.

Importing drugs while fixing the terms of trade is equivalent to importing price controls on prescription drugs, and importing price controls could endanger the future of drug innovation by limiting the financial resources available for drug research and development.

Finally, we must not ignore some simple facts. Canada has only one-tenth of the population of the United States. Our pharmaceutical market is larger than Canada's and Europe's combined. There is simply not enough excess supply in other countries to meet our needs. Because of the size difference, other nations are preparing to take actions to ensure that drugs purchased and intended for their citizens don't flow into the United States and disrupt their supply chain.

Instead of artificially controlling drug prices or starving our neighbors and allies of life-saving medications, we ought to give the marketplace a chance to work toward equity in global pricing. That would be a true and sustainable approach that doesn't threaten the next generation of pharmaceutical breakthroughs in the process. If we can agree on this issue, I am optimistic we can move forward on a rational and reasonable drug importation plan.

I hope to find out from our witnesses today what the true cost of importation would be and if that price is right for Americans.

I do appreciate the work that has been done on this study that we will be reviewing in the next few minutes. I am always delighted to have some reports that have numbers. In fact, there are never enough numbers for me. As the accountant, I really get into that sort of thing. I notice that the crowd today isn't nearly as big as it was yesterday. It probably has to do with numbers.

I helped write the AIDS bill for the United States, and as part of the research on that we found that the average drug, or some treatments in the United States for that cost about $10,000 a year, and that is giving a reasonable return to the pharmaceutical company, of course. Now, in Africa, they are being provided at $600 a person. People over there can't afford it because they are making $50 a year, and you can't pay $600 when you are only making $50. So the pharmaceutical companies have been donating drugs over there. We don't have a supply system over there that will get those out, and so we have ones that are expiring in the warehouses.

I have always been kind of fascinated by this pricing situation and all of the sorts of things that affect it. I remember when I was growing up, my mom heard a rumor that there was going to be a shortage of toilet paper and she mentioned that to a few of her friends and they all went out and bought toilet paper, and sure enough, there was a shortage of toilet paper.

[Laughter.]

The same thing happened with sugar one Christmas. They heard that there was going to be a shortage on that, and by the time the whole community was alerted and went out and bought their sugar, there was truly a shortage.

Now, Wyoming is a little bit more isolated than a lot of places, so the supply can't recover quite as fast as it might be able to in some of the bigger markets, but I see that as a possibility with these smaller countries that we are dealing with and the sort of thing that we are doing here.

I would mention that Senator Kennedy is attending the Armed Services Committee hearing this morning, so he won't be able to be here. We will have, I am sure, other Senators as the morning progresses, but our purpose here, of course, is to build a record using the tremendous resources of a variety of witnesses that we will have this morning.

At this point, we will proceed. I want to thank Mr. Aldonas, who is the Under Secretary of the International Trade Administration with the Department of Commerce for being here today and for the outstanding work that he has done and for him to comment on that work.

Mr. Aldonas.

STATEMENT OF GRANT D. ALDONAS, UNDER SECRETARY FOR INTERNATIONAL TRADE, U.S. DEPARTMENT OF COMMERCE

Mr. ALDONAS. Thank you, Mr. Chairman, first of all for explaining a market phenomena I have never understood. Being from Minnesota, whenever there is a snowstorm in Washington, DC., and all the canned goods disappear because we are going to be home for a day or so has always surprised me, coming from a place where we figured out how to remove the snow.

[Laughter.]

But in any event, at least now I understand how that happens.

I want to thank you for holding the hearing and giving us a chance to testify about the Department of Commerce report, "Pharmaceutical Price Controls in OECD Countries: Implications for U.S. Consumers, Pricing, Research and Development, and Innovation." I welcome the opportunity to explain the findings.

If I could, Mr. Chairman, I would like to submit my written testimony for the record and summarize my findings here.

The CHAIRMAN. Certainly. Your entire statement will be included, as it will be with all witnesses today that will be testifying. We do hope that they summarize so that we can cover as many questions as possible. Of course, the report will be a part of the record, too.

Mr. ALDONAS. Thank you, sir. I want to begin by thanking the professionals at the Commerce Department, particularly John Menes, Terry Lebat, Adam O'Mallion, Mary Frances Desinsky, who were really the core of the team that produced this report. I get the benefit of standing before you and having all that intellectual firepower behind me, so I want to express my appreciation.

I also want to say that having been Under Secretary for 4 years, I have had the luxury of working with these people. It really is the finest group of analysts I have had the opportunity to work with.

A lot of hard work went into the report. That is reflected, I think, in my written testimony. We got a lot of great cooperation from the economists at HHS. At CEA, we are lucky, in a sense, to have someone at the CEA who was a health care economist who could help us in terms of developing the methodology. We spent a good

deal of time trying to solicit public comment, certainly from recognized experts in the field, reviewing their studies, getting written testimony, and then holding a public hearing, as well, and offering an opportunity for rebuttal after that public hearing. We kept the record open.

I don't mean to underestimate the challenges. I respect, Senator Enzi, from knowing you from my own experience on the Finance Committee, how much you do appreciate numbers and focus on numbers and I am very conscious that what we are working with here is, as with any study, are some significantly methodological choices, and that flows from what I was surprised by, which was a lack of data available in the public domain. We ended up, to produce this study, along with our colleagues at HHS, having to sign a contract with IMS, which is really the only holder of pricing data in this area, and that presents some unique challenges because in one sense, you are buying the data before you can fully work your way through all of the methodological challenges, and that imposes certain constraints on the study.

So I really regard the study as a very useful set of guidelines. I am always concerned as a lawyer that we not fall prey to what I call the fallacy of misplaced concreteness. The numbers are what they are. They are estimates. But they do suggest some interesting directions in terms of policy and the implications of what many of our trading partners do in the OECD.

What I want to do is really just divide my summary into three parts. The first is what we found in terms of OECD country practices. The second is the effect of those practices on prices, earnings, R&D, and the production of new and innovative medicines. And lastly, the implications of those findings, not only for American consumers and for consumers in the OECD countries, but also for the developing world, where as you rightly point out, much of what goes on in R&D, whether it is in the United States or Europe, has a cascading and potentially positive effect on the rest of the world. On the other hand, if we are shortchanging R&D, we can also have a very negative impact on the availability of drugs and new and innovative medicines in the developing world, as well.

First, with respect to the OECD country practices, each of the countries we examined relied on some form of direct price control. The methods differed. They involve reference pricing, approval delays and procedural barriers to new drug approvals, restrictions on dispensing and prescribing, volume limitations on the amount of a particular drug that can be purchased, and various reimbursement controls. The methods prevent companies from charging a market-based price for their products. They tend to be non-transparent in terms of the way the methodologies are eventually imposed.

It is generally something where a lot of data is provided to a board without a lot of impact or interchange from any companies, whether generics or the innovative companies, and a fairly arbitrary decision comes out that oftentimes rewards generics by splitting the economic rents that would otherwise be available from a patent, which interestingly enough doesn't offer much in the way of incentives for the generics to compete. There is an awful lot of money left on the table for them that wasn't due to their efforts

or their creativity or their marketing. So in one sense, they are undercutting right there the competition that might otherwise flow from generics in the market.

Needless to say, the methods prevent companies from charging not only market-based prices, but they also impose, and this is probably the most surprising thing I found in looking at the practices, a number of barriers to the flow of information. Properly understood, all markets are about information. Prices, in fact, are nothing more than distilled information about the value of products on the marketplace.

In most of the OECD countries, there were very significant barriers to generic drug manufacturers or even off-patent branded drugs to provide information to prescribers and to consumers about the efficacy of their products or about the cost. So ultimately, to the extent that individuals in the marketplace would be able to make informed judgments about the availability, that was, in fact, illegal in many of these cases.

Second, in terms of the direct effects of the OECD government practices, the direct restraints they impose on prices of innovative medicines, not surprisingly, result in prices that are significantly below market prices charged in the United States, on the order, at least under our estimates, of between 18 and 67 percent, based on 2003 pricing data.

Nor is it surprising that by limiting the profits earned by innovative drug makers on their patented products, OECD government policies have a significant impact on the earnings that are available for research and development. Our analysis suggests that price controls and other OECD government practices sharply reduce the earnings generated on patented drugs to on the order of $18 to $27 billion in 2003, and you would expect to see that same number on an annual basis. Given the roughly, say, third of earnings generated by innovative drug companies that go to R&D, we estimated that OECD price controls result in about a $5 to $8 billion reduction in R&D spending annually, which equates to roughly three or four fewer drugs per year.

OECD government practices also have a negative effect on the ability of generics to deliver cost savings through the market. We estimated that higher utilization of generics among the OECD countries might have resulted in between a $5 and $30 billion savings to their consumers in 2003 alone.

One of the points that I want to reinforce here, Mr. Chairman, is the fact that while the argument is often about the choice of social model, that wasn't really a factor in terms of these findings. The truth of the matter is you could use the power of generic competition regardless of the social model you choose, whether it was a national health care system or you allowed the market to work without government intervention. The fact of the matter is, you would want to have that competition in the marketplace regardless. So in many senses, this was inhibiting the results that you would achieve under any model of health care.

Finally, and it is probably most important than the exact figures we estimated are the implications of our findings. Perhaps most importantly, in terms of the mix of policy choices that the OECD governments confronted, they seem to have got the mix exactly

wrong. They not only provide less in the way of innovation that has driven innovative pharmaceutical companies out of Europe, certainly to the United States—we benefit from that investment, but implicitly, what they have done is short-changed the competition that would flow from further innovative medicines.

When you are talking about prescription drugs, most of the competition comes from a newer generation of drugs rather than prices at that market. The generics set an outward boundary on the substitutability of drugs. And so in this instance, what they are doing is limiting the nature of competition that flows from further R&D and new drugs that come on the market.

The second area, of course, where you have this same sort of implication is with respect to the generics. To the extent that a reference pricing system rewards the generic makers for nothing they have contributed by splitting the profits available between the patent holder and the generic company, in effect, what you are doing is reducing the incentive to compete based on price. It has a profound effect ultimately on what they provide to the market.

Over half the drugs in the United States that are consumed are generic drugs. In fact, we could do a lot better in the United States. But in most of the OECD countries, that number is far lower, and so you are not getting the pop that you would expect out of the generic industry.

The last thing I always want to underscore, because I know that the debate about drug prices tends to be about to reduce drug company profits and about lowering prices in a given market. That is really inconsistent with the nature of the global economy we are living in. To be honest, when you look at what the OECD countries have done, it is very much a "beggar thy neighbor" policy. There are distributional effects, and as far as I am concerned, moral questions that arise from the fact that they impose these sorts of drug controls.

What I mean by that is by shorting the innovation in the marketplace, they not only have an impact on competition that affects U.S. consumers, it affects the rest of the world. If we are going to lower the transactional cost related to providing pharmaceuticals worldwide, certainly, you have to be thinking about the developing world, as well. So while the reductions that price controls might impose in Germany may have an impact on their spending, overall, it is not helping the world in terms of the drugs available or the power that generics could deliver to the market.

One fact, I think, illustrates that, and that again is that we do have a debate in this country about drug reimportation, and I was surprised to find, not in our study but in the counterpart that our friends at HHS did, was that you could actually find generics available in the U.S. market at half the price you could find from an online pharmacy in Canada. So the idea that the price controls are working in a way that actually provides significant cost savings is anomalous given that what you see is generic prices in the United States that my relatives in Minnesota could take advantage of, as opposed to getting on a bus from Menomen and driving up to Winnipeg.

I don't mean to address the question of reimportation directly. Mostly what I want to reemphasize is that what Congress has done

to generate much stronger generic competition in the United States has actually had a profound effect, and that is something that would be the right mix of policies to suggest to our OECD trading partners, as well.

Let me stop there. I am happy to take any questions you have.

[The prepared statement of Mr. Aldonas follows:]

PREPARED STATEMENT OF GRANT D. ALDONAS

INTRODUCTION

Thank you, Mr. Chairman and members of this committee, for inviting me to testify today about the Department of Commerce report, *Pharmaceutical Price Controls in OECD Countries: Implications for U.S. Consumers, Pricing, Research and Development, and Innovation.* I welcome this opportunity to explain both our findings and methodological approach.

It is no secret that governments of Organization for Economic Cooperation and Development (OECD) member countries maintain a variety of practices that reduce the return on sales of innovative pharmaceuticals. To examine the effect of such practices on prices, revenues, innovation and, ultimately, on consumers, Congress directed the Secretary of Commerce to conduct a study, in consultation with the Department of Health and Human Services, the Office of the U.S. Trade Representative, and U.S. International Trade Commission, of drug price controls in OECD member countries and the implications for American consumers.[1]

Specifically, Congress requested that the study include the following:

- Identification of the countries that use price controls or other such practices, with respect to pharmaceutical trade.
- Assessment of the price controls and other such practices that the identified countries use.
- Estimates of additional costs to U.S. consumers because of such price controls, and the extent to which additional costs would be reduced for U.S. consumers if price controls and other such practices were reduced or eliminated.
- Estimates of the impact that price controls, intellectual property laws, and other such measures have on fair pricing, innovation, generic competition, and R&D in the United States and each identified country.[2]

This report we issued responds to Congress' request. It details the effect of price controls imposed by various OECD member governments on pharmaceutical prices, R&D, innovation, and American consumers. The study examined the drug price regulatory systems of 11 OECD countries[3] and involved a quantitative analysis of prices, revenues, and R&D effects, based on data available for nine OECD countries.[4]

To complete the project, we brought together a talented team of professionals including economists from the Departments of Commerce and Health and Human Services (HHS), and the United States Trade Representative (USTR) and sought input from the Council of Economic Advisers (CEA). We also consulted closely with experienced academics in the field of health economics. In the early months, interagency meetings were held with economists from HHS, USTR and CEA to share research and flesh out methodological issues. These meetings included discussions about the various methodologies used in previous academic and government studies that addressed similar, but not the same, questions posed by the Conference Report.

As those discussions on methodology proceeded, we gathered as much in the way of factual information as possible, as well as the views of outside experts. The Department of Commerce published *Federal Register* notices requesting input from industry, non-profit organizations, trade associations, and the general public. The Department received written testimony from 18 sources.[5] In addition, the Department

[1] Section 1123 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, P.L. 108–173.

[2] *See* H.R. No. 108–391.

[3] The overview of drug price regulatory systems corresponds to Australia, Canada, France, Germany, Greece, Japan, South Korea, Mexico, Poland, Switzerland, and the United Kingdom.

[4] The prices effects analysis corresponds to Australia, Canada, France, Germany, Greece, Japan, Poland, Switzerland, and the United Kingdom.

[5] Submissions were received from AdvaMed; Alberto Frati, M.D./Mexico; BIO; Consumer Project on Technology Response; GphA; AEI (Kevin A. Hassett); Aidan Hollis, University of Calgary; Industry Trade Advisory Committee (ITAC) 3; Jana Thompson/Indiana; Donald W. Light, Ph.D., University of Pennsylvania and Joel Lexchin, M.D., York University; Novartis Corp.;

Continued

held a public hearing on August 3, 2004. Three interested parties requested the opportunity to speak.[6] The Department left the record open for an additional 10 days following the hearing in order to provide an additional comment period for submission of further comments based on information provided at the hearing or in earlier submissions. Every attempt was made to ensure that all interested parties had the opportunity to provide comments and to address comments from other groups.

The information that we gathered during this development process provided us with the data and tools necessary to make well-informed decisions about the best way to approach the Conference Report questions. Our extensive efforts enabled us to develop a balanced methodology for estimating the impact of foreign drug price controls on consumers, R&D, and innovation. The report, given methodological and data challenges, provides our best approximation of the impact these pricing systems have on consumer welfare and industry innovation.

My comments today describe the study's findings, with detailed information about the methodology used to develop each result. In some cases, the findings will not be surprising. Numerous studies have shown U.S. patented drug prices to be more expensive, on an aggregated basis, than drug prices overseas. Other findings reveal that the policies OECD countries use to control pharmaceutical prices impede competition in these countries and, arguably, globally. Competition drives innovation. In attempting to reduce the burden on health care budgets, OECD countries inadvertently employ policies that dampen the incentives for innovation, thus reducing economic and health benefits for consumers. These restrictive policies deny health benefits by reducing the range of choices, and ultimately raising costs for consumers, by limiting competition from generic drugs. I will discuss this in more detail later in my remarks.

PRICE CONTROLS ARE WIDESPREAD

The study examined the drug price regulatory systems of 11 OECD countries and found that all rely on some form of price controls to limit spending on pharmaceuticals. The principal methods these governments employ are: reference pricing, approval delays and procedural barriers, restrictions on dispensing and prescribing, and reimbursement. These methods prevent companies from charging a market-based price for their products and tend to be non-transparent; the criteria and rationale for certain pharmaceutical prices or reimbursement amounts are not fully disclosed, even to the pharmaceutical companies marketing drugs.

The most direct method that relevant OECD governments use to control prices is setting sales prices and outlawing sales at any other price. Governments are often the dominant market participant and may negotiate favorable prices with manufacturers, by leveraging this monopsonistic power. Such negotiations generally result in prices that are lower than they would be in a free market. OECD governments in our study also set the reimbursement prices for new drugs at levels well below free market prices. Since any charge above the regulated price is borne by consumers, the reimbursement price often functions as the *de facto* market price, whenever such mechanisms are employed. Finally, some OECD governments regularly cut the prices of drugs already on the market.

OVERVIEW OF HOW THE DETAILED ANALYSIS OF PRICES AND REVENUES WAS CONDUCTED

In order to estimate the impact of these price controls, a detailed study of pharmaceutical prices for nine OECD countries was conducted. The nine countries represented both the largest OECD markets and a range of population wealth. To conduct the study, the Department of Commerce, in cooperation with HHS, purchased revenue and related data for all products containing the active ingredient in the 60 best-selling products in the United States from IMS Health, a leading provider of data for the pharmaceutical industry.

The analysis focused specifically on patented pharmaceuticals, which are produced by research-based pharmaceutical companies and biotechnology companies. The study assumed that, in the absence of drug price controls, average prices in the OECD countries for innovative pharmaceuticals would be equal to U.S. prices adjusted for differences in per capita income. These adjusted prices were then used to estimate revenues, in the absence of drug price controls.

Kevin Outterson, West Virginia University; Pedro Reyes Ortego/Mexico; PhRMA; U.K. Department of Health; Dan O'Day, Chairman of the Pharmaceutical Committee of the American Chamber of Commerce; The Manhattan Institute for Policy Research; and The Amyotrophic Lateral Sclerosis Association.

[6] PhRMA, AEI (Hassett), and Dr. Donald W. Light.

PATENTED DRUG PRICES IN OECD COUNTRIES ARE BELOW U.S. LEVELS

We found that patented drugs that were best sellers in the United States sold for less in other OECD countries. The study also showed that aggregate pharmaceutical prices in the analyzed markets were 18 to 67 percent less than U.S. prices, depending on the country. These results were consistent with recent academic research in this area.

Developing the appropriate data set to conduct international price comparisons presented a number of challenges. For example, since innovative drug manufacturers fund most private R&D spending, any attempt to analyze the effects of foreign drug price regulations on the development of new drugs requires understanding how price regulation affects revenue for such firms. Because their revenue depends primarily on patented drugs, the study uses a set of the best-selling drugs with patented active ingredients (molecules) from the total IMS Health data set[7] to serve as the basis for price comparisons and to clarify the implications for revenue and R&D spending.

Defining the patented data set was additionally complicated by the fact that patent expiration dates vary across nations, and the patent expiration date itself is not a reliable indicator of when generic competition begins, as those two dates don't always coincide. In the United States, by contrast, the Hatch-Waxman Act expedites generics' entry into the marketplace, so the patent expiration date is a good proxy generally for the beginning of generic competition in the United States. Other countries lack similar incentives, and generic competition may occur much later as a result. For example, in some countries, if a generic competitor does not enter the market after an innovative product's legal patent expires, the innovative product will continue to benefit from exclusivity in the marketplace, and there will be no price change. We resolved this difference by identifying and applying the effective patent expiration date—the year when a generic manufacturer enters the market—rather than the legal patent expiration date.

The second step involved classifying the information in the patented data set in a fashion that would ensure the comparison of similar products' prices. The IMS Health data set contained products that varied across countries. So, we had to determine the best way to classify products across countries. There are many ways to classify pharmaceutical products. Most studies have classified products at the molecular level, which is both the broadest and the most basic definition of any product. Other studies have used more detailed approaches, comparing products by brand name, therapeutic use, dose form (tablets, capsules, injections), strength (milligrams) and package size. We found that comparing products at more detailed levels, such as strength and package size, severely limited the data set available for analysis. Therefore, this study compared products in the United States and partner countries at the molecular level.

The on-patent drug data set includes details that are reported at the ex manufacturer levels, before hospital or pharmacy markups or dispensing fees are taken into account. This is an important condition because data at the manufacturing level offer a more reliable basis for comparison internationally than do pharmacy or hospital prices. For example, manufacturing level data does not require further adjustments for differences in tax frameworks or other markups that tend to vary across countries.

Since the IMS Health data set excluded prices, it was necessary to estimate prices based on two other variables in the data set: revenues per molecule and amount of drug consumed (volume). While revenue data were provided in U.S. dollars, the price calculation was complicated by the existence of two alternative volume indicators: standard units and kilograms of the active ingredient. While both volume measures are widely accepted in the academic literature, each generates a different price for the same product.

A standard unit is equivalent to a standard dose of medication, and it is derived from other IMS Health volume measures. Kilograms are the amount of active ingredient in a molecule. While neither measurement has proven superior to the other, each has its own drawbacks. The standard unit measurement, for example, varies across countries, as the smallest common dose in one country is not necessarily the same in another. A second difficulty is the implicit assumption that all pills have the same value to the patient, independent of dose. The drawback to using the kilogram measure is that it can vary according to the individual sample because potency in molecules varies.

[7] IMS Health is a leading provider of business intelligence services, strategic consulting services, and data for the pharmaceutical and health care industry.

Given this challenge, we decided to present a range of results based on both standard units and kilograms. Interestingly, the differences between the aggregate prices, based on the two volume measures, were moderate for all countries except Japan. The consistency between the standard unit and kilogram measures is a function of the consistency between the standard dose and the amount of active ingredient in a given medication. This discrepancy is due largely to the Japanese tendency to prescribe relatively weaker doses at higher frequencies, as documented in prior studies. That is, since the Japanese tend to prescribe a dose of medication (standard units) with smaller amounts of active ingredient (kilograms) at higher frequencies, prices vary greatly depending on the volume measure.

Despite these data quirks, we included Japan in further analysis because (1) Japan is the world's second largest pharmaceutical market and (2) Japanese prices measured in standard units or kilograms were consistently below U.S. prices. The second point was crucial to our decision to include Japan because it showed that the Japanese data were telling a consistent story about Japanese drug prices relative to U.S. prices, increasing our confidence in the Japanese data. If the two Japanese price indices revealed a divergent pattern (one index higher than U.S. prices and the other lower than U.S. prices), then the reliability of the Japanese data would have been called into question and we would have had to exclude it from further analysis.

Another important detail in our price computation methodology was the decision not to make adjustments for off-invoice manufacturer discounts related to patented drugs. This constituted a break from previous studies, which have tended to factor in such discounts, as U.S. manufacturers are known to provide discounts to managed care and government buyers. Previous studies have estimated the discounts to be between 8 and 11 percent.

The decision not to adjust U.S. prices was based on a recent Department of Health and Human Services (HHS) analysis of discounted U.S. price data from the Center of Medicare and Medicaid Services (CMS). CMS, a division of HHS, collects data from manufacturers about the prices they charge for drugs distributed to pharmacies. These prices factor in discounts and other adjustments, including those that may be excluded from invoices. HHS compared average manufacturers prices (AMP) for sales of brand-name drugs to non-Medicaid retail purchasers (CMS data) and the U.S. invoice prices collected by IMS Health. This analysis found no meaningful difference between the non-Medicaid U.S. prices reported by IMS Health and CMS.

The final step in comparing prices across countries was to produce a price index. There are three generally accepted methods of indexing prices: Laspeyres, Paasche, and Fisher. The methods vary by the quantity (volume) used to weight the prices. The Laspeyres index weights prices based on U.S. volumes, measured in kilograms (or standard units), while the Paasche index uses foreign volumes. The Fisher price index is the geometric mean of the Laspeyres and Paasche indices. We decided to present the Fisher price index, as it avoids a result that is too dependent on either domestic or foreign consumption patterns. However, we also included the results of the Laspeyres and Paasche calculations, for the sake of transparency and because both sets of results are used to calculate the Fisher price indices.

WITHOUT PRICE CONTROLS, REVENUES AVAILABLE FOR R&D COULD BE SIGNIFICANTLY HIGHER

We found that by depressing prices for patented pharmaceuticals, the price controls in OECD countries yield lower revenues for those patented products than would otherwise exist in a competitive market. Our estimates indicate that, after extrapolating to a broader set of OECD countries, the diminished returns are in the range of $18 billion to $27 billion annually. Adding them back would represent a 25 to 38 percent increase in revenues over actual 2003 revenues from sales of patented drugs in the OECD countries considered in this study.

In order to estimate revenue change in the absence of price controls, it was necessary to first estimate prices in such an environment. The market for innovative pharmaceuticals is defined by several characteristics that must be considered when estimating prices in the absence of price controls. First, the high cost of developing and testing a new drug means that no profit-maximizing firm would make the necessary investment to bring new and innovative medicines to the market, in the absence of patent protection. To overcome this obstacle, countries offer patent protection as a reward for innovation, conferring the right to use the resulting chemical compound for a specific period of time. Such patent protection affords innovative pharmaceutical manufacturers significant pricing power.

Typically, trade in pharmaceuticals cannot take place except through authorized channels. Direct manufacturing costs constitute a relatively small percentage of the

overall expense, so prices can vary considerably and still remain above the costs of production, not including R&D. As a result, pharmaceutical firms can be expected to charge different profit-maximizing prices in different markets. That is, given the low cost of production and the absence of trade, the profit-maximizing price can vary across countries because the patent holder will charge a price that reflects demand within each market.

While a variety of factors influence demand for different drugs in different countries, one consistent factor affecting demand is income. Thus, we made the assumption that U.S. pharmaceutical prices are the benchmark for unregulated prices, and relative levels of per capita income determine variances in prices, among developed countries. It is not assumed, however, that variances in prices for each molecule are determined solely by income levels, only that the aggregate prices would vary based on relative income levels.

Prices for pharmaceuticals in the absence of price controls were calculated at the individual drug level, by multiplying each price by a uniform adjustment multiplier. The uniform adjustment multiplier, designed to capture the difference in price between the free and controlled markets, is calculated by dividing the ratio of foreign per capita income to U.S. per capita income by the ratio of aggregate patented drug prices (i.e., the ratio of foreign to U.S. patented drug prices). The mechanics behind the uniform price adjustment multiplier are straightforward: a price adjustment multiplier greater than one indicates that prices are below what would be expected in an unregulated market. Our calculations uncovered only two cases in which the uniform adjustment multiplier was below one (Greece and Poland), indicating that prices are likely at, or above, reasonable levels relative to each country's income level. A further reduction in drug prices in these countries would suggest that some individual drug prices could drop below the direct cost of production—an unlikely scenario. Given these atypical specifics, and further research that indicates these markets are relatively competitive, we decided to exclude them from further analysis.

These new, market-based prices were then used to compute new revenues. It is worth noting that in conducting this calculation, we did not adjust volumes to reflect changes in consumption related to higher drug prices. It was not possible to determine a justifiable and economically sound method for making upward or downward adjustments to consumption for such a scenario. For example, we could have assumed that following the removal of price controls, volumes would rise to levels observed in the United States, adjusted for differences in population. However, prescribing practices vary significantly across countries. Therefore, we assumed the increased drug prices would not affect sales volumes.

The final step in estimating the impact of foreign drug price controls on the global revenues of innovative pharmaceutical manufacturers involved extrapolating the revenue changes from the patented data set to the total patented market in 11 OECD countries (Australia, Belgium, Canada, France, Germany, Italy, Japan, the Netherlands, Spain, Sweden, and the United Kingdom) for the year 2003. As mentioned earlier, we chose these 11 OECD countries because they collectively represented a significant share of the pharmaceutical revenues generated in developed markets for the year 2003.

HIGHER REVENUES WOULD MEAN MORE RESEARCH AND DEVELOPMENT AND NEW DRUGS

The study uses published academic research to estimate the impact of increased revenues on pharmaceutical R&D. By limiting the return that would otherwise accrue to companies that make risky investments to develop new drugs and bring them to market, the price controls that OECD countries in the study maintain also reduce pharmaceutical R&D globally; research and development spending exists at lower levels than would be the case if these countries maintained market conditions similar to those in the United States. The study estimates that this reduction falls in the range of $5 billion to $8 billion annually, once prices are fully adjusted. This represents between 11 and 16 percent of current private R&D worldwide, based on figures from the CMR International (CMRI).

Based on the estimated cost of developing a new drug, an increase in R&D spending of $5 billion to $8 billion could lead to three or four new molecular entities annually, once markets fully adjust. The U.S. Food and Drug Administration approved, on average, 30 new molecular entities between 2000 and 2003.

The long-term effects of higher revenues and prices for consumers are linked to R&D and innovation. Both economic theory and empirical evidence indicate a close correlation between revenues and profit margins on the one hand and R&D expenditures on the other. We relied heavily on the economic theory and empirical research on the relationship between revenues (cashflow) and R&D expenditures to provide

the foundation from which we then estimated the amount of R&D funding that would be available, in the absence of price controls. This included work by Henry Grabowski, John M. Vernon, and John A. Vernon, who developed the parameters for estimating how an increase in revenues following the deregulation of price controls would presumably impact R&D and the number of new drugs available in the marketplace.

We made a few key assumptions about how innovative drug manufacturers would interpret increased revenues, most critically that innovative drug manufacturers would believe that increased revenues from price deregulation were permanent. If they did not view the price changes as permanent, but rather as short-term windfall, there would be much less incentive to make long-term investments in increased R&D spending. In addition, we assumed there would be a fixed corporate tax rate of 33 percent on all additional earnings, and that pretax profits would not be consumed by additional production and distribution costs. The principle weakness in this assumption is that a portion of the increased revenues might be devoted to marketing.

The empirical work necessary to predict industry R&D investment decisions includes examining several financial factors, both separately and together, including: cashflow, profit margins, prices, and a number of other non-financial factors. Several studies that analyze the effect of changes in cashflow and profits on U.S. pharmaceutical R&D spending are most relevant to the questions posed in the Conference Report. The most recent of these studies are by: Henry Grabowski, John M. Vernon, and John A. Vernon. We used John A. Vernon's cost and profit margin parameters and his regression equation to estimate the impact a change in revenues would have on R&D spending.

The regression equation developed by John A. Vernon required data for expenditures on pharmaceutical R&D and revenues. Consistent and comprehensive data on expenditures and revenues are difficult to find. So, we consulted two independent sources for R&D expenditure data, PhRMA and CMRI. The most widely used source for R&D expenditure data is PhRMA. The association provides data regarding R&D expenditures by all PhRMA members, including non-U.S. firms within American borders. It also provides data about worldwide R&D levels, but it excludes R&D expenditures by non-U.S. PhRMA members outside the United States. PhRMA also provides pharmaceutical revenue data on the same basis. CMRI produces data on global pharmaceutical spending for R&D. This figure is based on the R&D expenditures of "traditional" global pharmaceutical companies, and as such, their contribution to biotechnology expenditures will be captured by the estimate.

The expenditures by specialized biotechnology companies, on the other hand, are not included in the data. CMRI figures differ from PhRMA figures because they include R&D performed outside the United States by non-U.S. pharmaceutical companies. However, CMRI does not provide any information regarding revenues, which means two different data sources informed our analysis: PhRMA's revenues data, combined with CMRI's R&D expenditures. In order to avoid inconsistencies, we used PhRMA data because it provided the most complete and consistent set of pharmaceutical expenditures available for R&D and revenues.

We realized that the estimated increase in R&D would not be devoted exclusively to the development of innovative drugs. Research by the Tufts Center for the Study of Drug Development suggests that only about two-thirds of total out-of-pocket R&D spending furthers the development of new medicines. The other third is spent on post-approval, long-term safety and efficacy studies in broader patient populations, or specific patient groups, and for the development of new indications and/or new formulations. For the purposes of this analysis, we assume that increased spending on R&D will be allocated for new active substances and other purposes in the same proportions as current spending on R&D, i.e., approximately two-thirds, one-third.

Various studies have been done regarding the cost of developing new drugs; the most recent and often cited study is that by DiMasi, Hansen, and Grabowski, who report that the total cost per new drug was $802 million in 2000. The estimate reflects capitalization of the out-of-pocket costs to 10 multinational pharmaceutical firms developing self-originated new molecular entities (NME) with a mean approval date of 1997, including losses on unsuccessful research. Assuming the same rate of growth in the inflation adjusted capitalized costs of drug development, between this most recent work and a comparable earlier work, the authors estimated that the capitalized cost for drugs approved in 2001 would be $1.1 billion. Applying these same assumptions would suggest that the cost of drugs approved in 2003 was about $1.3 billion in 2003 dollars.

U.S. CONSUMERS WOULD BENEFIT FROM THE ELIMINATION OF PRICE CONTROLS ABROAD

Due to time and data constraints, we could not complete a rigorous investigation of the short- and long-term effects of a price deregulation on U.S. prices and consumers. However, we were able to posit some conclusions about the impact price deregulation would have in the short- and long-term. In the short term, the deregulation of OECD prices is not likely to have any impact on U.S. drug prices. This conclusion can be explained largely by the basic characteristics of the pharmaceutical industry. Price, expected revenues and profits are all critical factors in making investment decisions to launch R&D efforts. The nature of pharmaceutical markets and economic theory suggests that the prices in one market will behave relatively independent of prices in other markets, absent more fundamental changes in the competitive forces operating in those markets.

In the long term, the "increased competition" in the U.S. market as a result of an increase in the flow of new drugs, could have some effect on U.S. prices. Relaxation of foreign price controls, if coupled with appropriate reform of foreign generic markets, could potentially bring about significant gains from the flow of new drugs leading to improved health outcomes, even without increasing foreign spending on prescription drugs. This conclusion was based on written comments and testimony submitted to the Commerce Department that suggested increased competition would lead to long-term changes in U.S. prices.

USING MORE GENERIC DRUGS AT LOWER PRICES IN OECD COUNTRIES MEANS POTENTIAL SAVINGS

Analysis by the Departments of Commerce and HHS found that higher utilization of generic drugs at lower prices could result in significant savings to OECD countries. The estimated savings, after extrapolating to a broader set of OECD countries, range from $5 billion to $30 billion annually. This range of potential savings suggests that if prices of on-patent drugs rose to competitive market levels, then a more competitive generic market could significantly, or even fully, offset any additional cost to OECD countries.

Specifically, we examined how foreign price controls impact the off-patent (generic) drug market, using a second data set from IMS Health composed of 29 of the world's top selling off-patent drugs. HHS did much of this analysis, on behalf of the Department of Commerce, because HHS had access to proprietary data from the Center for Medicare and Medicaid Services (CMS) that illuminated the analysis of generics. HHS analyzed both the prices and utilization of generic drugs across the same nine OECD countries that the Department of Commerce examined in its empirical analysis of innovative drug prices.

Generic drugs were defined within this data set as those drugs not produced by an innovator or licensed company. All drugs using the same active ingredient are treated as one product. The quantity sold is measured as the total kilograms of the active ingredient (with an adjustment for the salt factor) or number of standard units. U.S. prices in the IMS Health data set were discounted by approximately 24.2 percent. This discount is based on a comparison of U.S. prices from IMS and average manufacturer prices (AMP) collected by CMS, which include off-invoice discounts, rebates, and charge-backs. HHS found that the AMP collected by CMS were 24.2 percent lower than the invoice prices in the IMS Health data set. Finally, Fisher price indices—averaging the price indices using both U.S. and foreign weights—were constructed.

HHS went on to consider a scenario in which foreign countries would shift their usage of generic drugs to match U.S. proportions and adopt policies that foster U.S. prices for generic drugs. HHS found that such a shift in generic drug prices and utilization would yield potential savings, which varied according to the volume measure used to estimate prices. We then extrapolated the estimated potential savings from the data set of 29 molecules to the total generic market in 11 OECD countries using market share data from IMS Health.

CONCLUSION

OECD governments in various countries have relied heavily on government fiat rather than competition to set prices, thereby lowering drug spending, as price controls are applied to new and old drugs alike. Such controls, when applied to new drugs, reduce company compensation to levels closer to direct production costs, leaving less revenue available for R&D efforts. Collectively, individual nations' efforts to limit prices can diminish investments in R&D that would provide substantial health benefits to all. Improvements in health care and life sciences are important for health and longevity worldwide. The development of innovative pharmaceutical

products plays a critical role in ensuring these continued gains. To encourage the continued development of new drugs, it is essential that we preserve sound economic incentives to develop and market new health technologies.

The CHAIRMAN. If you have some more, you are certainly welcome. I have some questions here, too, but I am fascinated by what you have said, even though I can only listen about half as fast as you can talk.

Mr. ALDONAS. Sorry.

[Laughter.]

The CHAIRMAN. So I kind of need to check a couple of things——

Mr. ALDONAS. Sure. Please.

The CHAIRMAN [continuing]. That you said. I think you said that OECD restricts the ability to even advertise generics so that people can realize they are on the market.

Mr. ALDONAS. A number of countries do. In fact, it is actually illegal in places like Germany to actually provide that information to consumers and to doctors. The generic companies, indeed, all the companies, are barred, in effect, from competing on price, and competing on—what you really hope the generics would do is let the market set the outward boundary in terms of substitutability, and so, in effect, if an innovative drug company was simply changing the pill from pink to blue, the market, if there was strong generic competition, wouldn't reward that. On the other hand, if there was real innovation, it probably would reward that.

Without that level of competition in the marketplace, you are undercutting the power of the market to deliver those sorts of benefits, and again, that is regardless of the health care system that you choose. So when they interpose that barrier to the information, they are really undercutting the ability of the market to deliver any sort of cost savings and rely instead essentially on government bureaucrats to make the decision about what is substitutable in the marketplace.

The CHAIRMAN. I appreciate your comments on the fact and the fact that we could use more generics in the United States.

Mr. ALDONAS. Absolutely.

The CHAIRMAN. I am a huge believer in the local pharmacists and am glad that we have made some mechanisms for them to be able to provide advice to their customers and find that that has made a significant difference in drug savings. That local person, that hands-on, that interest, because they actually know the person, seems to make a huge difference.

Mr. ALDONAS. If I could just reinforce it, it has nothing to do with the study, Mr. Chairman, but I was out at my local CVS in Arlington and actually saw that in practice. There was a woman ahead of me. I opened up a conversation with her, just as we were waiting. She was living on a fixed income. She looked at the price of what had been prescribed by her doctor with respect to blood pressure medicine, balked, and it was really the pharmacist who said, "Well, we don't have to go that direction. Let me get the doctor on the phone and we can sort out a lower price that would be within your budget." So I have got to tell you, I have great faith in that same sort of—it is somebody who is working to provide a service to their customer and provide that kind of information. It helped, at least in that one instance.

The CHAIRMAN. Of course, I would be interested in the pharmacist being properly compensated for all the effort he has to go through.

[Laughter.]

On research and development, you had some interesting figures on what kind of a reduction there could be in the research and development, and I think you mentioned $3 to $5 billion, which would be four to five drugs on the market, which points out how expensive it is to develop drugs.

Mr. ALDONAS. That is true.

The CHAIRMAN. I was fascinated to hear you say that some of the pharmaceutical companies have been driven out of Europe by some of the restrictions they have over there and that had been a benefit to us in the United States. If research and development were to drop off significantly—I am saying this facetiously—that would solve some of our insurance increase problems, too, because a lot of the increase that we complain about on our insurance is because there are new treatments and preventions that are out there, but they cost a lot of money.

Mr. ALDONAS. Sure.

The CHAIRMAN. If we cut all those off, then that would keep it relatively at the same price that it is now, but I haven't found anybody that wanted to buy that kind of an insurance policy yet.

There are also some fallacies in what is being done out there. I have a pharmacist friend in Star Valley, Wyoming, and, of course, I am hoping that the whole world visits Star Valley. They rely on tourism a lot. It is south of Jackson Hole, which is where the Tetons are, which is just south of Yellowstone Park.

But he is a pharmacist there and he had a Canadian come in and had to refill his prescription. The Canadian was upset the whole time he was in there because he knew he was going to pay these higher United States prices, and if it hadn't been an emergency, he wouldn't be doing it. And then he got his prescription and found out that it was $3 less than he would have paid in Canada, so there is some rumor out there, just like my toilet paper and sugar example I gave earlier.

I do want to thank you, too, for flying back from Canada for this hearing. I know how difficult travel can be and appreciate that.

Mr. ALDONAS. Honestly, Mr. Chairman, it is not the travel, it is that if there is a problem that is less tractable than drug pricing, it is lumber from Canada, so I am relieved to be back.

[Laughter.]

The CHAIRMAN. Another topic I am very interested in, so I will be anxious to see your numbers on that.

[Laughter.]

It is my understanding that some countries hold down prices on the drugs in two ways. One is they make everybody that has a similar drug bid against each other. For example, if it is a heart medication, all of the heart medications that do something similar have to bid against each other and just one of them is selected. So in Canada, you would have one rather than maybe five different treatments. Is that correct?

Mr. ALDONAS. That is true, and I think what you end up with is a smaller range of choices for consumers. It is also why you see—

and this is anecdotal, not a part of our study—but having spent a lot of time in Canada over a 25-year career, it is remarkable, the number of people who, when they want the truly innovative medicine, will come to the United States ultimately for their health care, and it is because of the limits on the range of choices that they face as a result of those sorts of practices in the marketplace.

The CHAIRMAN. The second way they would hold them down, it is my understanding that if, say, the heart drugs didn't come in, one of them come in at a low enough price, then they would declare it a generic and be able to put it on the market at their own price. Is that——

Mr. ALDONAS. Yes, there are instances of that, and I have to say, the perverse nature of that is that all these governments have signed up to an agreement inside the World Trade Organization that essentially says they are going to provide 20-year patent monopolies. We have an agreement worldwide about what the nature of patent protection should be.

And what people have a tendency to forget is that when you impose these sorts of price controls, or what you essentially do is deem a product to be generic, what you are in effect doing is eroding the protection that you have guaranteed as a part of that WTO agreement. The idea that innovation is important seems to go out the window.

And again, I always want to come back to this point, is that, in effect, what they are doing is saying that the outlays they have as part of their government budget are more important than the knock-on effects in the rest of the world. I am not sure that they actually realize the extent to which they are shortchanging not just the European market in the case of the OECD countries, but the U.S. market and the developing world in terms of new and innovative medicines. That is a powerful point to be made to our friends, particularly in Europe, when they criticize the health care system here and the sorts of things they do on AIDS funding.

The CHAIRMAN. Thank you. My time in the first round is expired, but I have my patent expert here.

[Laughter.]

Senator Burr.

Senator BURR. I am just anxious to—when you said Canada, I assumed that Grant had come to tell us he had solved the lumber issue.

[Laughter.]

Mr. ALDONAS. I wish.

Senator BURR. We welcome you and I encourage you on all the endeavors that you are working on. We thank you for the work.

Yesterday, I was focused, and today, I will stay focused on what I believe is a potential huge mistake that we could make up here, and that is to ignore patent protection for a particular industry because of a quest and belief that we can do that because we want cheaper pharmaceutical products.

Let me just ask you, you are on the front line. You know the guys sitting at the table, whether they are in Beijing or wherever in the world. What do we do to their ability to negotiate for somebody to recognize the intellectual property that we protect in this country and how they infringe on that? What does that do to their

ability on everything they negotiate if we just throw U.S. Code out the window and say, "For pharmaceutical companies, we are not going to respect their patents?"

Mr. ALDONAS. Well, the fact of the matter is it undercuts our position with respect to all of the intellectual property arguments we make. Senator Burr, you and I talked about this before, about the extent to which, increasingly, the American economy depends on innovation. One of the reasons we stay so focused on intellectual property across the board is to try and make sure that other companies are living up to their obligations under the WTO. Any weakening in the United States is seized on by our counterparts as saying, you do the same sorts of things. Why are you complaining, whether it is about CDs or whether it is about drugs.

It is not something that is easy when you are trying to make the argument and insist that other countries respect these rights if, in effect, we are undermining them in any way, shape, or form, and it is not to get into a debate about some of the furthest reaches of patent policy in terms of business systems and business procedures, something like that.

We are talking about here particularly pharmaceuticals at the core of what we think of as our patent system, and so I think rather than trying to discourage the enforcement of those rights, we need to be vindicating them here as well as being able to make a clean-hands argument when we go abroad to demand patent protection and copyright protection from our trading partners.

Senator BURR. Is there any economic sector where there is not a situation where we are having to go to a country and talk to them about infringement on our patents?

Mr. ALDONAS. No. In fact, you can do it all the way from pharmaceuticals down to things that you and I have talked about before with respect to the textile industry. One of the most significant efforts we are making right now on intellectual property in China is on design patents in the textile industry. If our guys are going to compete, they are going to have to compete at that level in this new world that we are entering into textile-wise.

And so when we go to bat for companies, we are very conscious of the fact that whether it is basic manufacturing all the way to research pharmaceuticals, the IP is essentially what is going to drive our ability to compete.

Senator BURR. Let me ask whether Commerce specifically has looked at the potential economic impact on this country were we to ignore patents on pharmaceutical products, the effects that would have on the illicit products that would come in because we wouldn't be able to negotiate an agreement.

Mr. ALDONAS. We haven't. This report, Senator Burr, was focused solely on the practices in the OECD countries and the implications of their practices for this market as opposed to what would happen if you imposed price controls or allowed reimportation into the United States.

The one cautionary note to raise there, of course, as the President has said, if you could do it safely, he is a free trader.

Having said that, one of the cautionary notes you really have to raise is there is almost an expectation that if everybody else is doing price controls, that we could do it, too, and that ultimately,

you would end up with lower prices across the board. In fact, what you would do, essentially, is drive this industry out of the R&D business. You would be pushing capital into other markets rather than encouraging the same level of R&D if you imposed price controls or allowed reimportation into the United States.

That is my sense of what would happen economically, but it is not something that we have actually studied. And frankly, it would make sense as a piece of follow-on work to much of what we have done here, Senator Burr.

One of the things that I was mentioning to the chairman just at the outset was the fact that I thought this was a very good first step. I think that we faced a number of methodological challenges, which we acknowledge. We definitely have to have more in the way of both data as well as analysis to get a full picture of what is going on, both in the United States and abroad.

But most of what we see in terms of the implications for the United States would be consistent with what you are suggesting, is rather than encouraging the price effects and the consumer savings and getting the kind of innovation that we currently have, you would end up with both higher prices and less innovation if what you did was essentially drive the industry out of the market and move capital to other industries.

Senator BURR. When you have explored areas where we have not been clear in our commitment to enforce patents, how big a truck do they drive through that opening in countries where their intent is to be an expert in knock-offs?

Mr. ALDONAS. Well, a good example would be something that I know has had an impact on everybody here in the Senate, was when we had to go after drugs on anthrax or things like that and had to use the power that is available under U.S. law essentially to try and reduce the price. That argument, even though it was a unique situation, was immediately turned around by all our interlocutors on the intellectual property front to say, "You do it, too." Even though it was a very, very narrow exception, and they wanted to say, no, that exception ought to apply to every bit of what they do, and every drug, regardless of the disease.

That is the sort of advantage they try and take of those sorts of arguments, and it is hard to keep an entirely clean record. But the fact of the matter is, every time you take a step in that direction, it puts a dent in it.

And I know, based on the recent experience of going to China with then-Secretary Evans to make the political point that all the pressure we had been bringing to bear had nothing to do with elections and we weren't going to stop bringing that pressure to bear on China on a host of different issues, the most important issue was intellectual property protection, and having clean hands and being able to say what the benefits were in the U.S. market from that did have an impact in terms of Premier Wen and Vice Premier Wu Yi and President Hu when we had our discussions with them. It was important for them to know that we weren't going to let up so that they knew the pressure was going to keep coming for them to be able, frankly, to try and drive policy down to the provinces and try and encourage the enforcement of the intellectual property laws. So it goes all the way from sort of how you interact with a

country's leaders all the way down to the enforcement at the local level.

Senator BURR. Thank you. Thank you, Mr. Chairman.

The CHAIRMAN. Fascinating.

[Laughter.]

It really is. I am learning a lot here.

I need to go back to a few more basics, though, for the record. So could you describe some of the different modes of price control, including direct and indirect price caps, reference pricing, profit controls?

Mr. ALDONAS. Yes. I am going to tick through a list, Mr. Chairman, that covers most of what we saw.

The principal methods that the OECD countries use to control pharmaceutical prices and cost are referencing pricing, approval delays, procedural barriers, dispensing requirements, and prescribing restrictions and reimbursement controls.

Reference pricing and other price controls try and control the reimbursement level, not the manufacturer's price. In the process, the price is determined based on prices in other countries, an international reference price, or relative to existing therapies in the same country, what is known as a therapeutic class reference price.

With international reference pricing policies, they don't factor in differences in per capita income which influences price differentials across countries, nor do they take into account the impact on other countries of price controls that have won the final reimbursement price.

Therapeutic class reference price is more along the lines of what you described earlier, Mr. Chairman, where you take a range of different pharmaceuticals, not all of which are directly comparable in their efficacy, but group them in a therapeutic class and one which will have less efficacy will naturally command a lower price. But in effect, what you will end up doing is averaging even the true innovative medicine that has gone a step beyond in technology with the price of that generic brand or the off-patent branded product.

So in a net effect with all the reference prices system, there is sort of an averaging that goes on that knocks down the amount of economic rents that would flow from innovation or from a patent for the patent holder and takes those economic rents and implicitly, through that price device, provides it to the generic maker. That has the effect of fattening the profits for the generic company, reducing the incentive to compete on that side, as well as cutting the innovation that somebody is going to fund on the pricing side.

A second area where they impose controls is direct controls on volumes, where they control the quantity of a new drug that can be sold in a country. It is the harshest form of sort of rationing that goes on. At some point, the quota runs out and there is no more of that medicine available regardless of its efficacy in treating specific diseases.

They impose profit controls. It is a little bit like a cost-plus contract over at the Defense Department in that sense. They essentially just tell you how much you are going to be able to earn on that, regardless of what the market would allow you to command under that system.

A good example is the U.K. currently places limits on the profit a company can earn from all sales in the U.K. National Health Service. In one sense, it is the assertion of buying power, but you are really talking about a monopsony in the case of the U.K. National Health Service.

And then there is a series of things that sort of fall into the category of approval delays. I referred to the complexity and the lack of transparency in the process of marketing and price approval systems that result in major launch delays of new drugs coming on the market that would provide greater competition to other innovative medicines and potentially have a price effect.

Certainly from the point of view of our industry, one of the things you are always concerned about in dealing with governments as a trade matter is the extent to which they want to leave all regulation in the form of a black box so that our companies really don't know the basis on which they could compete. They are asked a series of questions. They provide data. A decision is made. It comes out, which may or may not be consistent with the underlying economics.

And then ultimately, approval policies employed by OECD countries delay the number of new drugs that come on the market because of the length of time it takes. That essentially gives consumers less choice, reduces the competition in the marketplace, and ironically, has a negative effect in terms of the price competition that would go on even under a national health system like the U.K.

So you have a system where, as I said earlier, they not only are jeopardizing intellectual property protection and reducing the competition that would flow from new and innovative medicines, but perversely are denying themselves the benefits of greater competition from a wider range of generic drugs, as well.

The CHAIRMAN. My experience with price controls comes from when I first went into the shoe business just after I was married and started a store in the early 1970s. When it was rumored there were going to be price controls, the price of our shoes went up about 30 percent. And then just before they went into effect, they went up another 20 percent. And then each year, they went up the maximum of 10 percent. But essentially, consumers were paying 50 percent more than they should have been because of price controls, so I am always a little bit concerned about that.

Mr. ALDONAS. I think your skepticism is well earned.

[Laughter.]

The CHAIRMAN. In the trade promotion authority that Congress gave the President, the elimination of government measures such as price controls and reference pricing, I believe are a principal negotiating objective. Is it the policy of the administration that pharmaceutical price controls are a legitimate trade issue that should be addressed through bilateral and multilateral agreements?

Mr. ALDONAS. It is, and, of course, we are working on that. Obviously, you are working in a sensitive area with health care systems that are largely beyond the scope of trade agreements. We don't use trade agreement to try and force countries to rewrite their entire health policies. But where you do have practices that undercut commitments that otherwise have already been made, for example, in the context of the TRIPS agreement or other intellectual prop-

erty arrangements, and rules that we normally ask for when we come to the table and talk to an FTA, we do want to address the economic effects of these practices on your pharmaceutical companies.

So the answer is yes. Now, the problem, of course, is that it is rare that we are negotiating a free trade agreement with an OECD country. Australia is the only example. Most of the OECD governments are either in the European Union or are already part of a free trade agreement with us, Canada and Mexico being members of both the OECD and the NAFTA. And so the availability of future free trade agreements as a tool is something which I would be surprised if we can use it effectively if we are not going to engage in a serious negotiation on a free trade agreement with Japan, Korea, or Europe. At this point, of course, the focus is largely on the WTO rather than trying to do free trade agreements with that set of countries.

What that leads us to do, Mr. Chairman, is—and it is a point I always like to emphasize, is that trade policy doesn't fall solely within the limits of negotiating in a WTO or an FTA that qualifies under the Article 24 of the GATT or something like that. Trade policy goes on every working day, and when we sit down with our friends in Europe in particular, what we try to engage them on is to understand the implications for their economies of these sorts of practices. They face the same demographic challenges we face, with fewer workers per retiree. They face the same sorts of challenges we have in terms of reducing the cost by increasing the flexibility on the macroeconomic side of the economy.

And what we point out to them is they have to compete on the basis of innovation, as well. If their economies aren't flexible enough to be able to compete with rising China and rising India, they won't succeed in the long run. We will lose export markets and we will lose the strength that that economy can provide our European allies. So we make the arguments more on the lines of saying, you have a Lisbon agenda. You are trying to reform the economy. Doing something solidly about health care that brings market forces to bear would actually be beneficial in that longer run of what they are trying to achieve economically in Europe right now.

The CHAIRMAN. I know my time has expired, but I want to do just one more question along this line. What kind of difficulties will you have in your negotiations if we have a piece of legislation that specifies that American companies have to provide to Canada so it can be reimported back into the United States all of the drugs that the United States would like to have? I am trying to fit this into a free trade thing where we are telling a company that regardless of what their margins are, their price controls are, they still have to bring it back into the country.

Mr. ALDONAS. Well, the more that we engage in that sort of direct control, issuing an edict to companies in the U.S. market about what they will do in the context of trade, the more that we provide cover for what other governments would do to intervene in the market themselves and reduce the interplay of market forces that benefit our companies and that we bargain for whenever we sit down at the negotiating table. So ultimately, it undercuts what we

would otherwise prefer to achieve, which is the full play of market forces between these economies rather than introducing further distortions.

The CHAIRMAN. Thank you.

Mr. ALDONAS. Surely.

The CHAIRMAN. Senator Burr, did you want to do some more questions?

Senator BURR. Just one additional question, if I can, stimulated by something that Grant said.

You talked about the U.K.'s policy, or when they wanted it to be a policy of limiting profit of a drug company. Is that *de facto* a nationalization of the pharmaceutical industry?

Mr. ALDONAS. Well, you know, they don't have a written constitution, so it is a little more difficult than when you have something written into American law under the Fifth Amendment that prevents expropriation directly and gives individuals rights against their government to protect their property rights.

But what you have to understand is when these rights are conveyed, they do become property rights. And when you are taking those property rights away or undercutting the utilization of it, that is, in fact, an expropriation. And ultimately, whether it is in economic or strictly legal terms, the thing to focus on is you are taking away the ability of them to exercise the rights that you otherwise have granted. You are diminishing their ability to take the full exercise of those rights.

If we thought about it in the U.S. context, it goes back to law cases I learned over 25 years ago like *Schecter Poultry*, where we flew Air Force planes over a poultry farm and we expropriated the chicken farm because we killed all the chickens. That is the level of what you are doing. You are having an impact on the ability of that individual to use their property in a way that generates a property and a return for their family.

Senator BURR. I can't remember all the specifics that led to our effort to try to harmonize our drug approval standards with the European Union, and I know you weren't involved in that process, it was an FDA function, but needless to say, we still sit here today with the inability to reach those harmonization agreements because we won't accept the approvals of some of the E.U. members and allow their approved products to come into our stream.

What effect would it have on the United States were we to just go out and say, "Okay, we agree to your harmonization and we will accept all E.U. members' approvals?"

Mr. ALDONAS. It is a delicate response, but the truth of the matter is one of the reasons I don't think we could reach an agreement on mutual recognition agreements on food and drug approvals is that I don't think there is sufficient confidence in an E.U.-wide Food and Drug Administration, the equivalent of our FDA, to actually provide the kind of intense scrutiny that our FDA provides. Now, they are coming on-stream with something that may work eventually, but at this stage, I think if you talk to the experts at FDA, I think there are still concerns.

At some point, you have got to listen to the market. The constituents in Europe are saying that it is not strong enough, and so I would be worried about us sort of buying into a system that their

own constituents feel isn't actually adequate to the task in Europe itself.

Senator BURR. Is it safe to say——

Mr. ALDONAS. That will come, but it is not there now.

Senator BURR. Is it safe to say that, potentially, were we to do that, this same hearing would turn into a drug safety hearing based upon the absolute truth that we lower the gold standard that we have at the FDA to accept theirs?

Senator BURR. You certainly would be looking at the risk associated with the approval process in individual countries. Again, I know it is sensitive diplomatically, but the fact of the matter is the E.U. combines a lot of different countries at a lot of different levels of economic development and a lot of different levels of resources they can dedicate to government functions that we take for granted in the United States.

We have a tendency—I think it is the classic thing where you need to open markets. There is no doubt about that. You also have to be realistic about what other governments can spend on enforcement that, like I say, we take for granted as a carrying cost in this country. That is not there. That level of investment hasn't been there, for example, in the 10 new entrants in the E.U.

So if you are going to sit down and talk with the E.U. about that sort of mutual recognition agreement, frankly, the addition of the 10 new countries raises the concerns that I would have and we would have to ensure that you really had a consistent and uniform approach that would achieve the same results we would and that it would be applied E.U.-wide before I would suggest that that is something you would want to buy into.

Senator BURR. Thank you, Mr. Chairman.

The CHAIRMAN. Senator Isakson.

OPENING STATEMENT OF SENATOR ISAKSON

Senator ISAKSON. Thank you, Mr. Chairman. At the risk of being very redundant, because I apologize, sir, for being late, I will really only ask one question, which hopefully won't be redundant because it is somewhat personal.

As a member of the House, when given the occasion in the end, I did not support reimportation legislation, and that is a tough vote. In the end, the reasons that compelled me were, first, what you have been discussing with Senator Burr, which is the safety factor, which is a real issue, and there are plenty of anecdotal stories to bear that out.

Secondly was I do believe the market works and I am a believer in the free market and don't think we should directly or indirectly certify price controls because it begins to mess everything up.

So the question I want to ask is on that second statement. I believe that our system encourages the development and the research that brings about the breakthroughs in health care that everybody my age is enjoying. I took two pills when I left this morning, Zocor and Nexium. They have been wonderful for me.

Mr. ALDONAS. I took five. I just want you to know I am right with you.

[Laughter.]

Senator ISAKSON. Can you elaborate on that point for a second in terms of the benefits of our system in terms of its encouragement of the development of new and meaningful breakthroughs, understanding that price is important, but it is important in the context of what you are able to buy and what you are able to buy can actually do for you?

Mr. ALDONAS. Senator Isakson, I am glad you asked that question. Let me answer it two ways, one that is with respect to the pharmaceutical industry and one that really flows from our analysis of the manufacturing sector in the United States generally.

First and most importantly, the market should tell us, because companies are moving to the United States to do their R&D, and because we innovate from that innovation and those innovative medicines make it to the market in the United States much earlier than they do anywhere else as a consequence, that consumers are benefitting from both the investment that our companies make as well as attracting investment which, I hate to say it, means disinvestment from our friends in Europe and Canada and elsewhere, but investment here, because we get the leading edge in terms of new and efficacious medicines much sooner than they do. We also get the benefit of other products becoming generics much sooner than they do. And so the system works in a way that should both drive innovation as well as set the limits on substitutability with more powerful generic competition.

So with respect to pharmaceuticals alone, you are really encouraging new products to get to the market quicker and new generics to get to the market quicker so that you are having an impact both with respect to the competition you get from new innovations and the competition you get on price from generics or from off-patent branded products.

The more powerful point, to be honest with you, is that you can't take pharmaceuticals, as far as I am concerned, out of the broader context of what we are trying to achieve in our economy. We looked at the manufacturing sector over the last couple of years because while there was a one-half a percent reduction in the last recession economy-wide, there was a 6 percent reduction in manufacturing and a lot of people wanted to know, well, why are you paying so much attention to manufacturing? You know, the old line that Michael Boskin had said that we don't care whether it is potato chips or whether it is micro chips.

Well, the fact of the matter is the reason you look at manufacturing and pharmaceuticals within that is because manufacturing produces 90 percent of the innovations that raise productivity in this country, that increases the productivity of the workforce that is on the job, and that ultimately makes our economy more flexible and able to adjust to this new competition we are going to face from a global economy.

And so the reason you want to work very, very hard at preserving the ability to provide that return to innovation is because that is what drives the economy and will continue to make us competitive, continue to give people jobs, and when you are thinking about more retirees per worker, it means that the only way we can raise our standard of living is by raising our productivity, and the key to that at the end of the day is innovation.

So pharmaceuticals, you can see the impact alone. There is a much broader impact of every time, whether it is pharmaceuticals or one of our other industries. You start to dent the incentive for innovation in this economy, because it is where we live and it is where we are going to compete.

Senator ISAKSON. Would you amplify, because I want to make sure I understood what you are talking about, you talked about bringing generics to the market faster in America. Would you amplify on that?

Mr. ALDONAS. Yes, sure. Actually, it is the result of some very valuable legislation that Congress passed that encourages the introduction of generics as soon as products go off-patent, and that is something that has led to the current statistics we see where 50 percent of the drugs in the United States that are sold are generics, whereas that percentage is far lower in every other OECD country where there is not only less of an incentive to use generic medicine because of the price controls, but there are actual barriers to the generic firms providing information about efficacy and price to doctors and consumers.

Senator ISAKSON. Is there a difference in patent protection times?

Mr. ALDONAS. No. With respect to our European counterparts, I think there is certainly comfort that the rules as written and as enforced on intellectual property live up to the WTO standards. The concern more is that when you impose something like price controls that deny a patent holder the effective use of the rights that came with the patent, that you are diminishing the incentive to investment and the power that can provide to the market.

Senator ISAKSON. Thank you, Mr. Chairman.

The CHAIRMAN. Thank you very much.

I have some other questions, but I will submit those and we will leave the record open for 10 days so that others can submit more questions.

You are a wealth of information and I appreciate the conversation we had before we ever even started, where you were outlining some of the needs for some further work in this area of the report.

Mr. ALDONAS. And we look forward to working with the committee in terms of developing that.

The CHAIRMAN. Thank you.

Mr. ALDONAS. Thank you, Mr. Chairman.

The CHAIRMAN. Thank you very much.

The CHAIRMAN. While the panel is taking its place, I will go ahead with introductions.

The next panel, we have Dr. Robert Goldberg, who is a Senior Fellow with Manhattan Institute. He is the Director for the Center for Medical Progress for that Institute in New York City, and he will comment on the impact of price controls on U.S. competitiveness in biotechnology and on investment in genomics and personalized medicine.

We have Dr. Benjamin Zycher, who is a Senior Fellow with Pacific Research Institute for Public Policy. He studies the economic and political effects of regulation. His testimony will focus on the true nature of free trade and the costs of price controls.

We have Mr. Stephen Pollard, who is a Senior Fellow with the Centre for the New Europe. It is a nonprofit, nonpartisan research

foundation headquartered in Brussels. The center is the leading forum for discussing the practical implications of European Union policies. Mr. Pollard's testimony will focus on the impacts of price controls and parallel trade on patients and on innovation.

Mr. Kevin Outterson, an Associate Professor at West Virginia University College of Law, is a member of the West Virginia Pharmaceutical Cost Management Council, which examines ways to lower drug costs for West Virginians by establishing a pricing scheduling using the Federal Supply Schedule, Canadian drug prices, and other standards. He will comment on the pharmaceutical provisions in the Free Trade Agreement with Australia and how he believes it will have a negative impact on both U.S. and Australian consumers.

I hope my summary is correct. You can correct me as you speak if not.

Dr. Goldberg.

STATEMENT OF ROBERT M. GOLDBERG, PH.D., DIRECTOR, CENTER FOR MEDICAL PROGRESS, MANHATTAN INSTITUTE FOR POLICY RESEARCH, NEW YORK, NY

Mr. GOLDBERG. Thank you very much, Mr. Chairman and members of the committee, for giving me this opportunity to testify.

The CHAIRMAN. I will mention that everybody's full statement will be a part of the record. If you can summarize, it will drive the points home more and give us more time for questions. Thank you.

Mr. GOLDBERG. I should just also add that I am also Chairman—we have a 21st Century Task Force on FDA Reform that is focused on finding better ways to usher in the next generation of medicines.

Let me start off by saying that importation is the importation of price controls and it is the appropriation of intellectual property. Many people believe that importation will give Americans access to cheaper drugs, but price controls or importation of price controlled medicines will not make medicines more affordable. It will make them unavailable and undiscoverable. It will deny millions of Americans who are dying and suffering from diseases ranging from Alzheimer's to eating disorders the targeted medicines that will save lives and our health system billions in the years to come, and they will drive up what Americans pay for health care.

Importing price controls would be the wrong policy for the following reasons. First, they delay access to the best life-saving medicines through prolonged price negotiation. Five years after its first European launch in Europe—well, obviously—the first targeted drug for breast cancer, Herceptin, is only available in 70 percent of the continent. New drugs like Avastin for cancer, Humira for rheumatoid arthritis, and Xolair for asthma, have yet to be launched in most European countries.

Second, when new drugs are finally available, they are rationed. In Australia, patients with leukemia and Alzheimer's have to sign contracts giving the government the right to take away breakthrough medicines, such as Gleevec and Aerocept, when bureaucrats think they don't need them. And contrary to what people may say on this panel, that was part of what we were trying to break in the Free Trade Act. It had nothing to do with prices. It was try-

ing to get the Australian government to explain why they would force people to sign those kind of contracts. In Great Britain and the Netherlands, drugs for cancer and asthma that are standard therapy in America are unavailable.

Referencing pricing, which is being used in West Virginia and around Europe, pegs all drugs for the same disease to the cheapest government price for medicines and assumes that all products and medicines are alike, with devastating consequences.

Now, the chairman talked about cholesterol drugs in Germany. Let me tell you, in New Zealand, Australia, and Germany, the switch to a cheaper cholesterol drug has led not only to a rise in cholesterol levels in most patients, but a significant increase in heart attacks compared to the previous 6 months of more expensive therapy. The result? Higher total treatment costs and more deaths.

Formularies that assume that one or two drugs for all patients will do, have been shown in studies to make seniors sicker and to lead to more doctor office visits, more ER visits, and more hospitalizations. In West Virginia, the formulary for managing the mental health drug budget in their Medicaid program limited the access of a drug that my daughter has used to save her life. Why? It is considered to be a "me too" drug and too expensive.

Now, reference pricing also encourages marginal or little innovation because there are few incentives to invest in different medicines for different patient populations. That is why price controls will ultimately reduce the number of new medicines for treating Alzheimer's, cancer, blindness, and other illnesses.

By contrast, as Mr. Aldonas indicated, free market policies have allowed America's biotech and drug industry to thrive compared to Europe. Last year, and this isn't a Commerce Department number, this is a scorecard that Europe itself, the European Commission keeps, American and biotech pharmaceutical firms increased their R&D investment by 16 percent compared to a 2 percent decline in Europe. America has 75 percent of all biotech revenues; worldwide, 75 percent of all R&D expenditures; and 80 percent of all key biotech patents.

We at the Manhattan Institute did a study of what would happen if we imposed either European or VA-type price controls on the future of R&D and we found that R&D spending would drop by nearly 40 percent over the next 2 decades, resulting in the loss of nearly $300 billion in R&D expenditures and 277 million life years, which means more pain and less gain.

And price controls would be particularly devastating to biotech companies who have no revenues and who will be producing most of the new breakthrough and targeted medicines in the years to come.

I would suggest to Senator Burr that he take a trip down to a company called Metabalon, which is developing that new platform for targeted medicines. I think it is down in the Research Triangle Park. They have discovered for example, that there are four different pathways for treating Lou Gehrig's disease, not the one that people assumed would be the case. So now we need four different types of drugs to treat Lou Gehrig's disease and not one.

Interestingly—I see that my time has almost expired and I will get right to the point—Dan Vasella, who is the chairman of

Novartis Pharmaceuticals, opened up a research institute with Senator Kennedy in Cambridge, and he said after the opening,

> "As a result of price controls, we were shifting our investment here. European consumers are headed toward second-class citizenship when it comes to medicine."

Now, a lot of people believe that the NIH develops a lot of new medicines. The GAO found that only six of the medicines that are saving Medicare $8 for every new dollar spent on new drugs had a patentable claim by the U.S. Government.

And I ask, if it is so easy and cheap to develop new medicines, why are generic companies generic? Why don't they just jump into the game, take the government technology, slap a label on it like bottled water, and make more money? The fact is, drugs are very difficult to discover and they are becoming even more challenging to discover in the future as medicines become more personalized.

This is the exciting part, and this is where I am going to close. We already have a test to determine which people should get what medicines at what doses. More are on the way. All of this is being done in the United States. There is and will be no such thing as "me too" medicines in the future, and the great thing about it is that targeted medicines will save billions in wasted and ineffective care, adverse drug effects, and billions more by replacing more expensive health care services. IBM had a health care consultant who did an estimate and said that we could probably save up to $100 billion a year in health care costs with this new platform of personalized drugs.

In closing, the best way to make newer medicines less expensive is to reduce the cost of developing them. Using this platform of pharmacogenomics, I believe, and our task force working on FDA reform believes, we will be able to reduce the time it takes to find a new drug, reduce it from 10 years to about 3 to 5, and slash R&D costs by 75 percent.

We should spend, Mr. Chairman, more on new medicines, not less. It is a good thing. Every time we spend a dollar on new drugs, we save $8 on other health care costs. It is a way of making health care better and making it more affordable. We won't be able to continue on that path if we embrace price controls or import them. Thank you very much.

The CHAIRMAN. Thank you very much.

[The prepared statement of Mr. Goldberg follows:]

PREPARED STATEMENT OF ROBERT M. GOLDBERG

Mr. Chairman, members of the committee, my name is Robert Goldberg. I am director of the Center for Medical Progress for the Manhattan Institute for Policy Research in New York City. Thank you for the opportunity to testify. I will focus my comments on the impact of price controls on our competitiveness in biotechnology and our ability to invest in the genomic revolution that will allow Americans to receive cost-effective and personalized medicine for a wide range of diseases.

Drug importation is the importation of price-controlled medicines. It is therefore a form of price controls. I assume we are setting aside the reality that price controls create shortages. As Americans demand more drugs and lower prices it will cause a run on Canada and our northern neighbor will not be America's drug store for long. And because Europe's inventory of medicines is tightly regulated as well, it too will not be a large and safe source of price controlled medicines. By the time any importation bill is passed, there won't be a lot of medicines to import.

Congress should oppose drug importation for several reasons.

First, it simply supports the protectionist policies of Europe. The regulation of prescription drugs in Europe and Canada are barriers that keep our innovative drugs down and out and protect less innovative companies that are not globally competitive. Europe and Canada consistently under price American medicines.

Price controls involves setting a reimbursement policy that first, delays to the market through prolonged price negotiation. For example 5 years after it's first European launch in Europe, the first targeted drug for breast cancer, Herceptin is only available in 70 percent of the continent. New drugs like Avastin for cancer, Humira for rheumatoid arthritis and Xolair for asthma have yet to be launched in most European countries.

Second, even when new drugs are made available they are priced beneath American prices and patient access is restricted.[1] In Australia, patients with leukemia and Alzeheimer's have to sign contracts giving the government the right to take away breakthrough medicines when bureaucrats think they don't need them. In Great Britain and the Netherlands, drugs for cancer and asthma that are standard therapy in America are strictly rationed. And in all cases, the reimbursement rates for the drugs are far below what the biotech companies get in America.

At the same time, these governments pay premium prices for their countries own branded generic medicines. In Germany for example, they spend more on brand name generic medicines as a percentage of drug expenditures to the exclusion of newer medicines developed by American firms for the same diseases. Instead that money is used to prop up less efficient German firms that are less innovative and unable to compete globally. The German price control system protects domestic firms at the expense of more cost-effective and globally competitive American products. Australia similarly devotes more of their pharmaceutical dollar to generic drugs that are 90 percent of the price of brand drugs through their protectionist schemes.

Thanks to America's free market pricing, U.S. biotech and pharmaceutical firms invest more relative to Europe. In 2003, American biotech and pharmaceutical firms increased their R&D investment by 16 percent compared to a 2 percent decline in Europe.[2] Today, Europe pharma companies spend less than half of their R&D in Europe, down from 73 percent in 1990. While Europe has more biotech companies than America, we have 75 percent of all biotech revenues worldwide, 75 percent of all R&D expenditures and 80 percent of all key biotech patents.[3]

Indeed, a day after Dr. Daniel Vasella the CEO of the Swiss-based Norvartis Pharmaceuticals and Senator Kennedy opened the Novartis Institute of Biomedical Research, in Cambridge, MA. Dr. Vasella said, "There's no doubt that growth and profitability in a market-place help determine where research investment goes,"[4] In a separate interview Dr. Vasella went on to say,

> "Any government under pressure could do things that are shortsighted. We've seen the effect in Europe—less investment in R&D and less progress in treating diseases like cancer. Many Europe-based companies are focusing increasingly on the U.S. market. As a result of price controls, European consumers are heading toward second-class citizenship when it comes to access to medicine."[5]

While Europe's price controlled pain may be our gain, ultimately I believe the continent and the entire world can benefit from our commitment to medical innovation and should embrace our market-based approach to improve their economic and physical well-being. Indeed, it is part and parcel of our entrepreneurial and innovative character as a Nation that Americans have avoided price controls as a cost-saving measure. Instead, we have shown that we can save money by investing health care dollars by improving quality, and investing more money on the most valuable and cost-effective medical technologies available. Time and again, that has meant spending more on prescription drugs, which at 11 percent is still the smallest part of our health care budget.

Since the advent of penicillin, new medicines have produced the biggest gains in well-being and life expectancy compared to most other medical goods and services. The more we spend on new medicines, the more we save in money and in lives. As Columbia University economist Frank Lichtenberg has shown, over the past 30

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[1] Pricing and Reimbursement Review 2003, Cambridge Pharma Consultancy, London, England 2004.

[2] PARAXEL's Pharmaceutical R&D Statistical Sourcebook 2004/2005.

[3] The EU Industrial R&D Scorecard, 2004, European Commission 2004, http://eu-iriscoreboard.jrc.es/docs/2004—Scoreboard—%20VOL%20II.pdf.

[4] *Novartis to Move Global Lab to U.S. The Wall Street Journal, A3* – 17. May 2002—Vanessa Fuhrmans and Rachel Zimmerman.

[5] Novartis Reaps Benefits From CEO's Changes By GAUTAM NAIK. Staff Reporter of THE WALL STREET JOURNAL, *October 13, 2003.*

years, each generation of new medicines reduces what it costs to treat disease, increases productivity and lengthens our lives. For every dollar Medicare will spend on new medicines in the future, it will save $8 on hospitals, physicians and home health care.[6]

Let me digress for a second to discuss the claim that me-too medicines exist and that we can save research and health care dollars by eliminating what we spend on them. The majority of follow-on drugs were in clinical development before the breakthrough drug for that disease was approved. In addition, one-third of follow-on drugs for a disease receive FDA's priority rating.[7] Most follow-on drugs have different mechanisms of actions, side effect profiles. Finally, as a number of studies have shown, formulary limitations on the elderly, based on the assumption that all medicines are alike make seniors sicker and to lead more doctor office visits, more emergency room visits and more hospitalizations per year. In Australia and Germany, patients are routinely denied access to the newest medicines, even those such as Gleevec or Herceptin that have known disease targets and genetic tests that can identify for whom the medicines work. Hence, common cost-containment strategies based on the me-too medicine myth are associated with higher health care costs and poorer health.[8]

This me-too medicine myth flows from the belief that most drug development is imitative or merely the easy part of bringing medicines to market. As a result, price control supporters claim—without evidence—that it is cheap to develop new medicines or that government does all the research and that drug companies simply market what government labs invent. That begs the question that if drug development is more like opening up a Dunkin Donuts franchise, why aren't more generic firms jumping into the game? Why do biotech venture capital firms demand such a high rate of return?

Indeed, critics claim that companies don't need high profits to be innovative. That's ironic since under price controls in Europe, innovative drug development has been on the decline.

Using Dr. Lichtenberg's analysis as a starting point, the Manhattan Institute commissioned economists from the University of Connecticut to do a study to uncover the impact of European and VA type price controls on medical innovation and access to new medicines in the United States over the next 25 years. A copy of the full report is available here today and on the Manhattan Institute Web site. The researchers found that R&D spending will drop by nearly 40 percent over the next 2 decades, resulting in a loss of nearly $300 billion in R&D and 277 million life years.[9]

Given the negative impact on future investment, the decision to impose or import price controls comes at a critical time in the course of medical progress. I believe that the impact of price controls on our well being would be greater than can be imagined because the scientific opportunities that await are so exciting and so significant. Further, they often originate in small companies with no revenues. Taking medicine to the next level of targeted drug development will require a complete transformation of the discovery and development platform and billions in new investment each year.

Smaller biotechnology firms—many of which have pharmaceutical firms as venture partners—will lead the way in developing the next generation of targeted medicines. Thirty of the 34 drugs approved by the FDA last year came from such companies and fit the targeted medicine profile. Indeed, the era of the blockbuster drug is over. All companies are investing in the development of medicines targeted to specific molecules that control how we respond to drugs and to the different ways diseases are triggered.[10] In this fundamental respect, all companies large and small are starting from scratch.

This will lead to more cost-effective medicine and better health in two ways. First, gene-based diagnostics will be able to determine what drugs that are on the market

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[6] "Pharmaceutical Innovation, Mortality Reduction, and Economic Growth," in *Measuring the Gains from Medical Research: An Economic Approach,* ed. by Kevin M. Murphy and Robert H. Topel (Chicago: University of Chicago Press, 2003), pp. 74–109.

[7] DiMasi, J. The economics of follow-on drug research and development: trends in entry rates and the timing of development, Pharmacoeconomics, Feb. 2004.

[8] Horn SD, Sharkey PD, Tracy DM, Horn CE, James B, Goodwin F. *Intended and Unintended Consequences of HMO Cost-Containment Strategies: Results from the Managed Care Outcomes Project,* The American Journal of Managed Care 2:3 (March 1996): 253–264.

[9] Are Drug Price Controls Good For Your Health? Authors: John A. Vernon, Rexford E. Santerre, and Carmelo Giaccotto Source: Center for Medical Progress at the Manhattan Institute, December 2004.

[10] Pharma 2010: The threshold of innovation IBM Institute for Business Value study by: Steve Arlington, Sam Barnett, Simon Hughes and Joe Palo, 29 Apr 2004.

now work best for which patients. Contrary to the popular belief that there are me-too medicines, most people respond differently to the same medicine or need different drugs to obtain the same outcomes. My daughter, whose life was saved by the last of five drugs given to her for an eating disorder is a case in point. We will have an array of genetic tests to guide such decisions.

Second, new drugs will be tailored to smaller groups of patients—or even a single person—based on their genetic response or adverse reaction to drugs as well as to differences in how diseases unfold. We have seen that with cancer drugs but the same will apply to drugs for diabetes, arthritis and heart disease.

Here too, American companies have been leading the world in this next medical revolution investing nearly $4 billion in gene-based tools for researching and developing treatments. Price controls and importing price controls will only discourage the personalized medicine revolution. This revolution will save more money and lives than any across the board price cut might generate. That's because the cost of poorly caring for patients with Alzheimer's, cancer, Parkinson's, blindness, stroke and others is much more expensive than the personalized and targeted medicines that will treat. Put another way, treating or curing a disease with a new medicine is always cheaper than the disease itself.

In the final analysis, the best way to make new medicines less expensive is to reduce the cost of developing them. As more companies move toward targeted medicines and as the FDA embraces scientific reforms that encourage their development, companies will be able to reduce the time it takes from target identification to launch from more than 10 years to between 3 and 5 and slash research and development costs by 75 percent.[11] That will save companies and consumers billions of dollars a year in drug costs without undermining incentives for investment or access to new medicines. The Manhattan Institute has established a 21st Century FDA Task Force that seeks to create a path toward personalized medicine. We welcome the opportunity to assist the committee in reducing the cost of drug development.

Price controls will not make medicines more affordable, they will make them unavailable and undiscoverable. We can pay for new medicines as we always have, by taking the money we used to spend on intensive care units, polio wards, on TB hospitals, on HIV hospice, on body bruising chemotherapy, on nursing homes and spending it to cover more people with miracle cures. And we can pay for them by transforming the way we discover and develop new medicines by sustaining our investment in genetic science. Let's embrace the future and avoid the mistakes of the past.

The CHAIRMAN. Dr. Zycher.

STATEMENT OF BENJAMIN ZYCHER, SENIOR FELLOW IN ECONOMICS, PACIFIC RESEARCH INSTITUTE FOR PUBLIC POLICY, SAN FRANCISCO, CA

Mr. ZYCHER. Thank you, Mr. Chairman and distinguished members of this committee. I will summarize briefly the four central points covered in my written testimony, which has been submitted.

First, pharmaceuticals subject to price controls overseas are not cheap and I urge this committee to reject efforts to impose price controls on U.S. medicines, whether directly or indirectly. Any such policies incontrovertibly would mortgage the future in favor of the present by reducing the market research and development incentives yielding more improved medicines, alleviating future human suffering.

Second, foreign price controls enable overseas consumers to obtain a free ride on the prices the American consumers pay for research and development. U.S. trade and other policies that raise foreign prices toward competitive levels unambiguously would benefit U.S. consumers regardless of the assumption one makes about the competitiveness of the U.S. pharmaceutical sector.

Third, the recent free market argument favoring the importation of price controlled medicines from overseas is fundamentally flawed

[11] Ibid.

because compulsory licensing processes combined with ambiguities and the failure to work the patent framework mean that negotiations would be highly vulnerable to implicit or explicit threats of patent theft. At a more general level, free markets domestically, even in principle, cannot be reconciled with the enforcement of price controls overseas.

Fourth, Federal price negotiations over the long term would harm consumers. The Federal Government is not like a very large pharmacy chain. It is instead so big that it has monopoly pricing power as a buyer that large private sector buyers engaged in competitive negotiations do not have. At a more subtle level, private sector buyers must compete for customers and so must balance the conflicting objectives of low prices and broad formulary availabilities. The Federal Government, on the other hand, does not have customers as such so that short-term budget pressures inexorably will tend to crowd out consumer choice over time. That is the deeper implication of the evidence-based medicine approaches now being considered and adopted by some States. The non-interference provisions of the 2003 Medicare Act truly were far-sighted and I urge this committee to continue that approach.

In conclusion, we want our medicines to be affordable and we want them also to be available over the long term. That is why price controls must be rejected. Thank you very much.

The CHAIRMAN. Thank you very much, and thanks for the conciseness of your statement. I will repeat that the full statement will be in the record and we appreciate that.

[The prepared statement of Mr. Zycher follows:]

PREPARED STATEMENT OF DR. BENJAMIN ZYCHER*

Thank you, Mr. Chairman and distinguished members of this committee, for this opportunity to offer my perspective on the now-prominent issues of pharmaceutical importation, domestic/foreign pricing differentials, and the long-term economic effects of pharmaceutical price controls and Federal price negotiations, particularly in the context of consumer well-being.

Well-known principles of economic analysis and existing bodies of data not subject to serious challenge yield several conclusions on the prospective adverse effects of the importation of price-controlled pharmaceuticals into the U.S. Moreover, the recent "free-market" argument favoring the importation of price-controlled pharmaceuticals is deeply flawed, as discussed below. Similarly, the perverse market effects of a possible imposition of Federal negotiating power—Federal "interference"—in the context of the Medicare program are not difficult to predict. Alternatively, U.S. consumers would benefit from efforts to end the free ride that foreign consumers are able to obtain on U.S. research and development investments, financed largely by U.S. consumers. These central observations and some other ancillary arguments form the basis of my testimony today.

I. PHARMACEUTICALS SUBJECT TO PRICE CONTROLS OVERSEAS ARE NOT "CHEAP"

The true economic cost of pharmaceuticals—that is, the real resource cost to the economy of developing and producing them—cannot be reduced without improvements in the economic and regulatory environment, a broad set of issues outside the scope of today's hearing. The importation of drugs subject to foreign price controls, far from reducing real economic costs, by necessity would import those price controls into the U.S. in terms of prices received by manufacturers. To the extent that lower prices for consumers result, that would not represent a true reduction in "costs"; instead it would be a wealth transfer from pharmaceutical producers and possibly

*The views expressed are those of Benjamin Zycher, and do not purport to represent the views of the Pacific Research Institute for Public Policy or of any of its officers or contributors. Benjamin Zycher can be reached at 818-706-1028 or at *benzycher@bzecon.com.* A short biographical summary is appended to this testimony.

from foreign consumers to U.S. consumers in the short run, with adverse consequences for U.S. consumers in the long run, as discussed below. The more likely short run outcome for U.S. consumers, depending on market conditions, would be little or no price reductions but instead price increases for various market participants (intermediaries) in the supply chain, since the importation of price-controlled pharmaceuticals would not affect either market demand conditions or market supply conditions on the margin.[1]

In the long run—which is not necessarily a long period of time—it is incontrovertible that lower prices will reduce the marginal efficiency of investment, that is, the incentive to invest in the research and development of new pharmaceuticals.[2] Since ultimately it is anticipated consumer demands—for cures, for disease alleviation, for better health, and for reduced suffering—that drive the research and development choices of profit-seeking firms, lower anticipated prices will reduce research and development investment and thus the future flow of new drugs. The adverse future effects in terms of fewer cures and greater suffering will be real economic costs attendant upon the importation of foreign price controls; but such costs will not appear directly in government budgets or private balance sheets, except to the (significant) extent that more-costly hospitalizations and other substitute medical procedures will be used in place of the drugs that will have failed to have been developed due to the long term effects of price controls.[3] Thus will the adoption of price controls through the vehicle of the importation of price-controlled drugs mortgage the future in favor of the present by weakening incentives for research and development investment and other activities yielding streams of new and improved medicines.

Based upon the recent experience in the non-U.S. OECD and upon simulation exercises and other analyses, the magnitude of this projected adverse research and development effect varies somewhat, although it is never predicted to be small.[4] My view is that all of these estimates are biased downward because they fail to take into account the fact that the imposition of price controls, whether direct or indirect, introduces an asymmetry into the statistical distribution of future returns to research and development, in that the price controls have the effect of limiting (truncating) upside potential while leaving downside risk unaffected. This is an effect separate from the price reduction itself, the implication of which is that the long term effects of price controls in terms of a reduced flow of new and improved drugs is likely to prove larger rather than smaller.[5]

Some observers have argued that there can be an inefficiently large amount of pharmaceutical research and development investment, so that a reduced amount still may be efficient. High purported "profits" (either undefined or defined poorly) then are used to infer that current investment is too high.[6] But if "profits" are (uncompetitively) high—adjusting for investment risk—we would expect to see significant entry into the market by new firms. We do not.

More generally, the current emphasis by some commentators on total revenues or total profits as predictors of research and development incentives is incorrect. It is the marginal efficiency of investment for a particular research and development effort that is relevant. Consider, for example, a firm earning enormous profits, however defined; would it sink dollars into a project that it knows will not yield adequate returns (however broadly defined)? Regardless of overall revenues or profitability, firms have powerful incentives to make only efficient investments, that is, investments expected to yield at least normal rates of return with some allowance for risk. Price controls cannot further that outcome; and competitive capital markets will enforce such discipline.

Finally, an accounting of the true cost of imported drugs subject to price controls must include some consideration of the safety problem, important socially in particular in the context of contagious diseases. That solutions to the safety problem are likely to prove highly elusive is evidenced by the fact that current legislation

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[1] See, e.g., U.S. Department of Health and Human Services, *Report on Prescription Drug Importation,* December 2004, pp. 65–67.

[2] See *Ibid.*, chapters 7 and 8. See also U.S. Department of Commerce, International Trade Administration, *Pharmaceutical Price Controls in OECD Countries: Implications for U.S. Consumers, Pricing, Research and Development and Innovation*, December 2004, chapters 2–4.

[3] See, e.g., Frank R. Lichtenberg, "Are the Benefits of Newer Drugs Worth Their Cost? Evidence From the 1996 MEPS," *Health Affairs* 20(5), September/October 2001, pp. 241–51.

[4] See U.S. Department of Commerce, *op.cit.,* chapter 8.

[5] In order to see this, suppose that market conditions shifted for some reason, yielding a reduction in future pharmaceutical demand and prices. That would shift the entire distribution of investment returns, but would not *bias* future returns in favor of losses.

[6] This seems to be the argument of Professor Kevin Outterson in his "Statement" to the Committee on Ways and Means, U.S. House of Representatives (undated), on the U.S.-Australia Free Trade Agreement.

under discussion either shunts the issue aside completely, or apparently bestows an "FDA-approved" imprimatur upon foreign plants not actually approved by the FDA.[7] The safety problem is discussed in detail in the Department of Health and Human Services study noted above; I will not repeat its findings here.[8]

In short: As much as we want our medicines to be affordable, we also want them to be available when needed.

II. U.S. CONSUMERS WOULD BENEFIT FROM POLICIES REDUCING THE FOREIGN FREE RIDE

The basic cost economics of pharmaceuticals are somewhat unique, in that large fixed costs (for research, development, and production facilities) are accompanied by small marginal production costs.[9] The large fixed costs—over $800 million per drug[10]—yield a body of knowledge, which itself is a classic collective (or "public") good in that those who can find ways to avoid paying their "fair" share thus obtain a free ride on the efforts of others to finance the research and development investment. Foreign price controls on drugs have the effect of yielding for foreign consumers just such a free ride at the expense of U.S. consumers.

Some have argued that policies designed to increase foreign prices would not yield benefits for U.S. consumers because "drug companies are under no obligation to lower U.S. prices as [foreign] prices increase."[11]

That argument is incorrect, regardless of the assumption one makes about the competitiveness of the U.S. pharmaceutical market. From the viewpoint of U.S. pharmaceutical producers, an increase in foreign prices analytically is equivalent to an increase in foreign demand; total perceived worldwide demand would increase, yielding an increase in the marginal efficiency of research and development investment, and so a long run increase in that investment and in the flow of new drugs. But, *ceteris paribus*, U.S. demand would not change, so that the increased long run supply of drugs would induce profit-seeking U.S. firms to reduce their U.S. prices, that is, would put downward pressure on U.S. prices.[12] Again: This is true whether the U.S. market is viewed as perfectly competitive or as a perfectly discriminating monopoly.[13] In the short run, it is unclear whether U.S. prices would fall; demand and cost conditions would not change, but producers might have incentives to cut prices in the expectation of increased competition over the longer term.

III. THE "FREE-MARKET ARGUMENT" FAVORING DRUG IMPORTATION IS FUNDAMENTALLY FLAWED

Some prominent supporters of free markets have argued recently in favor of the importation of price-controlled drugs. The argument in summary is that an end to the import ban would force pharmaceutical producers to negotiate more stringently with foreign governments over the prices for drugs, because the prospect of "cheap" foreign drugs flooding the U.S. market would make it difficult to preserve U.S. prices sufficient to cover high R&D costs. The producers also could insist upon "no foreign resale" provisions in contracts, which could be enforced by limiting sales to the foreign governments.

This argument is fundamentally flawed. Most foreign governments under their patent laws reserve the right to engage in compulsory licensing under various conditions, one of which is a "failure to work the patent." The precise meaning of that phrase is unclear, but to foreign officials it might mean a failure to sell all that is demanded at the controlled price. What is clear is that foreigners will not be happy to pay more for medicine. And so it is unlikely that foreigners faced with substantial increases in their drug costs would be fastidious in their adherence to the rule of patent or international trade law, as interpreted by U.S. drug producers and some

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[7] See S. 334, the "Pharmaceutical Market Access and Drug Safety Act of 2005"; and S. 109, the "Pharmaceutical Market Access Act of 2005."

[8] See fn. 1, *supra.*

[9] An exception is marginal production cost for biologics, a topic outside the scope of this testimony.

[10] See, e.g., J. Dimasi, R. Hansen, and H. Grabowski, "The Price on Innovation: New Estimates of Drug Development Costs," *Journal of Health Economics,* 22 (2003), pp. 151–185. See also Christopher P. Adams and Van V. Branner, "Estimating the Costs of New Drug Development: Is It Really $802M?" December 2004.

[11] See Professor Kevin Outterson, *op.cit.*, at p. 2.

[12] Whether U.S. producers face competitive or monopolistic market conditions, the increased prices from overseas would increase long run incentives to produce new drugs. Because demand is an inverse function of price—it is "downward sloping"—the greater flow of drugs would put downward pressure on prices.

[13] The latter assumption would be highly questionable and inconsistent with the evidence, but that is an issue outside the scope of this testimony.

U.S. officials. Indeed, compulsory licensing already has been used, so that price negotiations and trade environments are highly vulnerable even to implicit threats of patent theft.

Moreover, under some prominent interpretations of patent law, producers control their patents but not the resale of their patented products. Would contracts to limit resale of price-controlled drugs, even if they could be negotiated and enforced, survive challenge under this interpretation? Such uncertainties inevitably will force the producers to sign agreements eroding their ability to recover R&D costs or to protect their intellectual property.

The basic problem with the "free market" position in support of drug importation is that it tries to reconcile free markets domestically with price controls overseas. That is a circle that cannot be squared as long as foreign governments can steal patents; and in the final analysis, it is likely to be difficult and time-consuming to stop a government intent on doing so. What is needed instead are U.S. Government efforts, perhaps in the context of trade policy, designed to end the free ride that many foreigners now obtain at the expense of U.S. consumers. That many U.S. officials now attack drug producers—whose investments have saved millions of lives—rather than the foreign theft of U.S. intellectual property is unlikely to prove salutary.

IV. FEDERAL PRICE NEGOTIATION WOULD NOT SERVE THE INTERESTS OF CONSUMERS

Consider a large pharmacy chain or other sizable intermediary between pharmaceutical producers and consumers. That intermediary must balance two competing objectives, which actually are the objectives of its customers. It seeks to reduce costs, and thus prices for its customers; and it seeks to preserve a formulary broader rather than narrower, so that it can serve as broad a market as possible, that is, preserve more rather than less consumer choice. Both objectives are driven by competition among pharmacies and other intermediaries; that these objectives conflict is obvious, so that private sector intermediaries, reflecting the preferences of their customers, must find ways to balance them.

The more obvious difference between such private sector intermediaries and the Federal Government is the sheer size of the latter as a purchaser; it is almost axiomatic that the Federal Government has more monopsony power[14] than private sector intermediaries. At a more subtle level, the Federal Government has incentives in terms of the cost/formulary tradeoff incentives that differ substantially from those constraining private sector intermediaries. Budget pressures are strong at all times, so that incentives to negotiate substantial price reductions are powerful. But the Federal Government is not a profit-seeking firm, so that its incentives to satisfy its "customers" in terms of broad formularies must be attenuated through political processes; voting is simply a weaker constraint than the ability of customers to take their business elsewhere. This is a common problem with public sector services: The tradeoff incentives between cost (budget) reduction and preservation of service quality systematically are different from those constraining private sector choices. This bias in favor of price reductions as opposed to formulary availability is obvious overseas,[15] and arguably has affected U.S. consumers in the vaccine market.[16]

V. CONCLUSIONS

The interests of consumers are served by a pharmaceutical sector offering medicines both affordable and available. More generally, consumers are served by economic efficiency, that is, policies yielding an aggregate output basket as valuable as possible. Policies that bestow benefits upon one set of consumers at the expense of others, perhaps in the future, are inconsistent with that goal; in particular, price controls are fundamentally incompatible with the operation of free or competitive markets, with the institutions of free trade, and with the interests of consumers. It is incontrovertible that the importation of pharmaceuticals subject to foreign price controls will have the effect of importing the price controls themselves, with clear and substantial adverse effects over the long term in terms of research and development incentives and the flow of new and improved medicines. Other analyses suggest that such policies will not save much even in the narrow dimension of budget

[14] This essentially is monopoly power on the part of a buyer to force prices down.

[15] See, e.g., Sally C. Pipes, *Miracle Cure: How To Solve America's Health Care Crisis and Why Canada Isn't the Answer*, San Francisco: Pacific Research Institute, 2004, pp. 171–179. See also, Cambridge Pharma Consultancy, "Delays In Market Access," December 2002.

[16] See Institute of Medicine, *Financing Vaccines in the 21st Century*, Washington, DC.: National Academies Press, 2004, ch. 5. See also, *The Global Vaccine Shortage: The Threat To Children And What To Do About It*, Proceedings of the Albert B. Sabin Vaccine Institute Ninth Annual Vaccine Colloquium, 2003, pp. 25–33.

dollars and drug spending; and the longer term costs in terms of substitution of costly substitute medical procedures and reduced human health outcomes are obvious. This committee would be wise to reject efforts to allow the importation of pharmaceuticals subject to foreign price controls.

Instead, the pursuit of consumer well-being would be served by policies—perhaps in the context of trade negotiations—ending the free ride that foreign governments have garnered for themselves, through the imposition of price controls, at the expense of the U.S. market. Noninterference—a farsighted policy incorporated into the 2003 Medicare legislation—with competitive private sector negotiations will further those consumer interests as well.

The CHAIRMAN. Mr. Pollard.

STEPHEN POLLARD, SENIOR FELLOW AND DIRECTOR, HEALTH POLICY, CENTRE FOR THE NEW EUROPE, BRUSSELS, BELGIUM

Mr. POLLARD. Mr. Chairman, members of the committee, it is a great honor for me to be here as a foreigner to testify before you this morning and give you a European perspective on this, the most critical of health care issues.

For your information, my background is in policy making for the Labor Party in Great Britain. My time as Research Director of the Fabian Society, the oldest think tank in the world, and the Labor Party's in-house policy proposing vehicle, coincided with Tony Blair's election as party leader and I remain proud today to describe myself as a Blairite.

In my current role as Director of the Health Unit at the Centre for the New Europe, a free market think tank in Brussels, I study health care systems across the European Union and beyond. In my view, there is only one thing which really matters when examining health policy: The patient.

In that context, it is clear to me, the evidence is unarguable, that European patients suffer directly and avoidably as a result of two interrelated problems, price controls and parallel trade. There may well be ideas which the U.S. could consider importing from Europe. What puzzles me is why, despite the experience of European patients, the U.S. should be considering importing one of the most damaging and dangerous aspects of our health arrangements.

Importation will weaken, if not destroy, the United States's global dominance in developing new drugs. It will do that because, as well as importing foreign drugs, importation will also import the consequences of foreign price controls, which falsely lower prices and in so doing deny patients access both to new medicines and drive away research. This is not theory. It is the current experience of European patients.

In every member state of the European Union, the state imposes, as we have heard, price controls on pharmaceuticals. Prices are lower in countries such as Spain and Greece than in Britain, not because costs are lower or competition is greater, but simply because the government has decreed them to be lower. And so what happens is arbitrageurs import drugs from Greece and Spain, making easy profits which contribute nothing to research and development and nothing to the broader health care economy.

By the end of 2001, the parallel trade in pharmaceutical products in Europe reached $3.3 billion and is set to reach $7.4 billion by 2006. In Germany, for instance, from an almost standing start, the largest pharmaceutical company is now Kohlpharma, which does

no research of any kind and exists purely to import drugs from foreign countries. Indeed, it is now the fourth-largest company in Germany as a whole.

Price controls and parallel trade have crippled the development of new products in Europe. In 1990, major European research-based companies spent 73 percent of their global research expenditure within the E.U. By 1999, that had fallen to 59 percent. Between 1993 and 1997, 81 unique new drugs were launched in Europe, compared to 48 in the United States. But from 1998 to 2002, the European number had declined to 44, while the U.S. number had risen to 85. During 1990, Europe's share of the world pharmaceutical research has fallen from 32 percent to 22 percent.

This is not supposition, it is not academic economic theory, it is fact. This is what happens to research when importation is allowed. Those who favor importation into the U.S. are arguing quite straightforwardly for the importation of all these problems.

An array of cost-containment measures are limiting pharmaceutical spending within E.U. member States. As a result, for example, in cardiovascular medicine, so high are the hurdles for reimbursement that the most innovative and effective lipid-lowering therapy is only available usually to heart attack sufferers. And with cardiovascular disease, 83 percent of Italians, 77 percent of Brits, and 74 percent of Germans receive what is medically described as suboptimal treatment, compared to only 44 percent of Americans. This is, again, not by accident. It is the inevitable consequence of the price controls which come alongside parallel trade.

American concern with European free riding on investment and research is understandable and wholly justified. European governments are, in effect, shifting the cost burden of research from Europe to the United States, but the correct response is for Europe to get its act together, not for the U.S. to adopt the same mistaken policies which have caused the problem in the first place. Importation might look like a panacea, but it is no such thing. It involves the importation of the price controls which have wreaked havoc with European patients' health care and the European pharmaceutical industry.

The argument is made that this is an issue of free trade. It is not. Allowing such imports will not, as one proponent put it, allow American consumers, particularly seniors, to benefit from worldwide price competition. Far from inserting competition and the free market into the price of medication, as another advocate has put it, there is no competition. There is simply pricing by governmental dictate with all the deleterious consequences I have outlined.

It is precisely because the patient should come first that the sophistic and superficially appealing arguments in favor of importation should be resisted. Thank you.

The CHAIRMAN. Thank you.

[The prepared statement of Mr. Pollard follows:]

PREPARED STATEMENT OF STEPHEN POLLARD

Executive Summary:

There is only one thing which really matters when examining health policy: the patient. Whatever reforms might be proposed, the deciding factor must be the impact on the patient.

European patients suffer directly (and avoidably) as a result of two inter-related problems: price controls and parallel trade. Importation will weaken, if not destroy, the US's global dominance in developing new biotech drugs because, as well as importing foreign drugs, importation will also import the foreign price controls which falsely lower prices and, in so doing, deny patients access to new medicines and drive away R&D.

Because each of the 25 Member States has its own regulatory framework and approach to pharmaceutical pricing, what emerges is a price competition not between pharmaceutical manufacturers but between state-determined price controls. And so arbitrageurs import drugs from and make easy profits. Those profits do not contribute to R&D or to the broader health care economy. They do not widen access. They simply make profits on the back of foreign governments' price controls.

In 1990, major European research-based companies spent 73% of their global R&D expenditure in the EU, but only 59% in 1999. Between 1993 and 1997, 81 unique new drugs were launched in Europe, compared to 48 in the U.S.; but from 1998 to 2002, the European number had declined to 44 while the U.S. number rose to 85. Europe's share of world pharmaceutical research had fallen from 32 per cent to 22 per cent.

Price control has limited the profitability of European pharmaceutical companies in their home markets, and has crippled their willingness and ability to spend on development of new products.

Those who favour importation into the US are arguing for the importation of all these problems.

An array of cost containment measures are limiting pharmaceutical spending within EU Member States. Only 5 percent of UK patients with a prostate cancer are treated by an oncologist. 40 percent of all breast-cancer patients die in Germany - compared to 26 percent in the United States - due partly to a lack of use of innovative medicines. And with cardio-vascular disease, 83 percent of Italians, 77 percent of Brits and 74 percent of Germans receive suboptimal treatment, compared to only 44 percent of Americans.

This is not by accident. It is by design, and is the inevitable consequences of the price controls which come alongside parallel trade. American concern with European "free riding" on investment in R&D is understandable, and justified. But the correct response is for Europe to get its act together, not for the US to adopt the same mistaken policies which have caused the problem in the first place.
Mr. Chairman, and Members of the Committee:

Testimony:

I am honoured to be invited to testify before you this morning to give you a European perspective on this most critical of healthcare issues.

For your information, my background is in policy making for the Labour Party in Great Britain. After a spell working for a senior Labour Member of Parliament in the late 1980s, I then became Research Director of the Fabian Society, the oldest think tank in the world and the Labour Party's 'in house' policy proposing vehicle. My time there coincided with Tony Blair's election as party leader, and I remain proud today to describe myself as a 'Blairite'.

After leaving the Fabian Society I became Head of Research at an independent think tank, the Social Market Foundation. I then switched to journalism, writing on public policy issues. Today, I combine think tank work with journalism.

My brief at the Fabian Society was to examine how Labour, then a party which had lost four general elections in a row, could transform itself into a modern party of government. It soon became clear to me that the issue of healthcare was emblematic both of the party's failure to adapt to the modern world and how it could indeed transform itself. Our attitude to the structure and funding of health care was fundamental. So over time, through force of circumstance, I came to specialise in health care policy. Now my work brings that specialisation to a European audience.

In my role as Director of the Health Unit at the Centre for the New Europe, a free market think tank in Brussels, I study health systems across the European Union (and beyond). All have their own problems; some are unique, most are shared.

When I analyse these problems, I come at the issues from a left-of-centre (or, in US parlance, liberal) perspective. That means that in my view there is only one thing which really matters when examining health policy: the patient. Whatever reforms might be proposed, the deciding factor must be the impact on the patient. Anything which gives the patient better access to good healthcare should be considered; anything which detracts from that should be resisted. I thus have an open mind about mechanisms and machinery.

In that context, it is clear to me – the evidence is unarguable – that European patients suffer directly (and avoidably) as a result of two inter-related problems: price controls and parallel trade. There are, I venture to suggest, many ideas which the US might consider importing from Europe. What puzzles me is why, despite the experience of European patients, the US should be considering importing one of the most damaging and dangerous aspects of our health care arrangements.

On one level it is obvious. The response to relatively high drug prices in the US has been to look at importation from Canada and Europe. Why pay more, after all, when something is available cheaper elsewhere? But the European experience shows that the logic is deeply flawed, and the consequences deeply damaging.

First, price discrimination (when a good is sold at different non-marginal cost related prices) has a rational economic purpose which can be entirely justified on welfare

grounds. It enables companies to offer products which would otherwise be unavailable. If price discrimination is not possible then, by definition, only one price can be set. That price will almost always be higher than many consumers can or will pay. When the good in question is a medicine, and the aim is to widen access, that matters.

As Julian Morris puts it (ADPIC et Services Médicaux : Repenser le Débat, Centre for the New Europe, 2001): "Price discrimination thus benefits all. Poorer people less able or unable to pay the normal, uniform profit maximising price gain access they otherwise would not. Today's medicines, for example, can be made available more cheaply. Producers reap greater profits, increasing incentives for research to develop tomorrow's medicines more quickly. And a portion of these additional profits comes from the better off who have the most obvious revealed desire to purchase innovations (as indicated by their willingness to pay) and who tend (sometimes, but not always), to have altruistic feelings towards the poor and less privileged... The ability to practice discriminatory pricing also depends on lack of arbitrage or leakage between segments. The firm can only charge the different prices in the segments if it is not possible for a third party to come along and buy cheap in the one segment, and sell dear in another ('sell dear' certainly, but at a lower price than the existing firm is currently charging)."

That is undermined by parallel trade. Importation will weaken, if not destroy, the US's global dominance in developing new biotech drugs. It will do that because, as well as importing foreign drugs, importation will also import the foreign price controls which falsely lower prices and, in so doing, deny patients access to new medicines and drive away R&D.

This is not just theory; it is the current experience of European patients.

Article 28 of the Treaty of Rome, as strengthened by the Single European Act, creates a single market within the European Union. With a few restrictions in the interests of public health and public morals, whatever may be freely bought in any one member state must be freely allowed into any other.

Because each of the 25 Member States has its own regulatory framework and approach to pharmaceutical pricing, what emerges is a price competition not between pharmaceutical manufacturers but between state-determined price controls. Thus in a country such as Greece, which imposes severe restrictions, drugs can cost less than in, for example, the UK. And so arbitrageurs import drugs from Greece and make easy profits. Those profits remain in their pockets. They do not contribute to R&D. They do not contribute to the broader health care economy. They do not widen access. They simply make profits on the back of foreign governments' price controls. And, as a result, the EU-based pharmaceutical industry and R&D research capacity is fast disappearing. Incentives are significantly reduced for large biotech and pharmaceutical companies to engage in research, just as they are for venture capitalists to invest their funds in startup biotech firms. Healthcare as a whole suffers because the overall cost of care rises when the introduction of innovative treatments for illnesses is slowed. The quality of care decreases as the supply of innovative medicines falls short of demand.

By the end of 2001, the parallel trade in pharmaceutical products reached $3.3 billion in Europe, and is set to reach $7.4 billion by 2006. In Germany, the biggest pharmaceutical market in the European Union by volume and value (and the third largest market worldwide) – and thus a key target for parallel traders - parallel trade has grown exponentially since 2000 following the enactment of a law requiring pharmacists to replace brand names with imported drugs when the latter are at least 10% cheaper. Between 1998 and 2001, parallel trade more than trebled, from 260 to more than 800 million euros. The market share of imported drugs increased from 1.8% in 1998 to 5.8% in January 2002.

As in all other countries, the National Health Service in the UK is under severe cost constraints. While there is no control of prices in Britain, purchasers do of course take advantage of the immediate cost savings from importing pharmaceutical products from parts of the European Union where price control makes them substantially cheaper.

Licences granted for parallel imports went from 426 in 1995 to 1,363 in 2000 and applications have continued growing since then. By 2002, Britain had the third highest penetration of imports (11 per cent) after the Netherlands and Denmark. Parallel trade volume increased by 38 per cent in 2001 and a further 20 per cent to the end of 2002. The Association of British Pharmaceutical Industries puts the loss of income at £1 billion per year. As Britain remains outside of the Euro, there are substantial profits to be made from exchange rate differentials. Other factors include the volume of and ease of becoming an importer to the UK; the lack of patient push-back and their compliance with the system. The lack of appropriate regulatory involvement in the monitoring of imports and importers is a factor. So is the vertical integration of wholesalers and pharmacists in the UK.

According to the Consumers' Association, 90 per cent of British pharmacists source products through parallel trade. This saves the National Health Service approximately £60 million a year or some 0.5 per cent of the country's medicines budget. Today, however, Britain is a major destination for imports in Europe with an estimated drug expenditure of £5 billion in 2000. Nevertheless, the traders involved cream off £350 million a year.

According to Pfizer, 60 per cent of British sales of Lipitor – which is used for the treatment of high cholesterol – are supplied by parallel importation. By 2001, up to one eighth of all National Health Service medicines were already dispensed using parallel imports. And today, according to the Association of British Pharmaceutical Industries, one in five branded prescriptions are now filled by a parallel traded product. One source indicates that by late 2004, 20 per cent of all British prescriptions would be imports.

In this way, the adverse effects of price control are spread by free trade from one market to another. If this were the case with textiles or home electronics equipment, there would be no reasonable grounds for worry. Here, trade enhances social welfare through superior efficiency of lower real costs. In the case of pharmaceuticals, however, lower prices in the exporting countries simply reflect greater regulatory leverage. Prices are lower in countries like Spain than in Britain not because costs are

lower or competition is greater, but simply because the Spanish Government has decreed them to be lower.

In May 2004, ten new member states joined the European Union. Those from the former Soviet bloc – for example, the Czech Republic, Slovakia and Poland – have significant pharmaceutical sectors and significantly lower prices of imported products. The accession treaties specify that for the new member states, and in particular the Czech Republic, Estonia, Latvia, Lithuania, Hungary, Poland, Slovenia and Slovakia, that parallel imports shall be prevented until the patent or supplementary protection of the medicinal product concerned expires in these member states. But this is a temporary restriction. Given the combination of a single market and national price regulation, the only direction for the parallel trade is upwards.

So far, pharmaceutical companies have continued to invest in research and development of new products despite price regulation in even the majority of their markets. It has only been necessary for them to be able to set prices in some markets for them to be able to recover their whole costs of production. We are now entering a world in which whatever country has the most restricting price control scheme will become the largest exporter of pharmaceutical products; and the pharmaceutical companies will find themselves pressured into marginal pricing in all their markets.

From 1992 to 2001 over 400,000 new jobs were created in the US in the biotech and related industries. These have been made possible by investment in R&D from pharmaceutical companies and new biotech start-ups. A mere 0.0002 percent of potential new drugs make it to the market; most such biotech firms fail. But the investment is made because the patent system allows the eventual price to cover this research. Importing price controls from the EU and Canada threatens all this by reducing the returns on investment to a level set by foreign drugs regulators with no concern for the complex R&D economy. Investors will simply go elsewhere, and the research will not happen.

Look at Europe. Total pharmaceutical production in Europe in 2001 amounted to €130 billion ($140 billion) and € 138 billion ($150 billion) in 2002. The industry employed approximately 560,000 people in 2002 of which 82,500 were in research and development. The European share of the world pharmaceutical market has declined from 32% to 22% over the past decade; the US share increased from 31 to 43%. Similarly, in 1990 major European research-based companies spent 73% of their global R&D expenditure in the EU, but only 59% in 1999. On average, European countries spend 8% of GDP on healthcare compared to about 14% in the USA. According to Gilbert & Rosenberg (In Vivo, March 2004), between 1993 and 1997, 81 unique new drugs were launched in Europe, compared to 48 in the U.S.; but from 1998 to 2002, the European number had declined to 44 while the U.S. number rose to 85.

This has caused job losses. The large Swiss company, Novartis, recently moved its research facilities to the United States. From 1990 to 2001 the number of high value-added employees in Germany's drug industry fell by 36 percent (while those in the United States increased by 52 percent).

This matters not just because of its impact on the European Union economy, but because of a direct effect on the quality of care available to European patients.

Every member state of the EU has some kind of welfare safety net for its citizens. In all member states, perhaps the most important part of this safety net is the health care system, in which medical treatment is made available to citizens without regard to ability to pay. The financing of health care differs across the member states. In Britain, the National Health Service aims to provide a universal system of care free at the point of use. In most other member states, it is provided more or less by the independent sector, with means tested subsidies or reimbursements given to individual patients by the State.

However financed, the burden of public health care has pressed increasingly heavy on European tax payers for at least the past generation. Because people are living longer, they are dying of illnesses for which there is no cure, and for which palliative treatments are complex and expensive. Even otherwise, people are now expecting more of health services than ever before. Unlike their ancestors, people now are less willing to live with chronic pain and disability.

Because it is the largest and most elaborate scheme of provision in Europe, these effects can be seen most clearly in the budgets of the National Health Service. Government spending on the system has increased by 50 per cent in money terms since 1997. The 2002 budget outlined plan to increase spending by a further £18 billion over the next three years. Despite this, complaints continue of under-funding. Almost as clearly, these effects can be seen in every European health service. In France, for example, the health service is calculated to have been €14 billion per year in deficit by the end of 2004. As of April 2004, the Slovak health service was running a deficit of 9 billion Crowns – or €200 million.

There are numerous ways of dealing with this inflation of health care costs. One of the easiest and most obvious is to cut the cost of the drugs bill. This is not the most important single cost, but it is a large cost. Pharmaceutical products, for example, account for 12 per cent of the National Health Service budget, and the proportion is somewhat higher in most of continental Europe. Any reduction is likely to be welcomed by the politicians and managers who are trying hard to squeeze as much as they can out of increasingly inelastic budgets.

For this reason, every member state of the European Union has in place some scheme to regulate the price of pharmaceutical products. In every member state, the state is the largest singly buyer – directly or indirectly – of pharmaceutical products; and so the health authorities can use their monopsonistic power to negotiate lower prices than would otherwise obtain. These prices are then enforced generally through laws that prohibit the charging of different prices for the same product. To give a detailed review of these schemes across each Member State is not possible in so short a paper as this. Indeed, as the schemes generally lack transparency, even an overview would require a book in itself. In brief, however, the regulatory schemes can be set within two categories.

First, there are those countries where prices are set largely by reference to marginal cost of production. These countries are: Austria, Belgium, Denmark, Finland, France,

Luxemburg, Spain, Sweden, and – in part – Germany. Here, prices are supposed to reflect production costs and allow for a certain margin of profit. However, negotiations between pharmaceutical companies and the health authorities often lead to prices based on criteria hard for outsiders to comprehend.

Second, there are those countries where prices are set largely by reference to the price of the same product in neighbouring countries. These countries are: Greece, Holland, Ireland, Portugal, and – in part – Italy. In most cases, average prices are based on controlled prices, and so there may be a further downward pressure.

The exception to this rule is Britain, where the National Health Service uses its immense buying power to get lower prices, but allows an average profit of 21 per cent to its pharmaceutical suppliers, and is willing to allow the margins of specific products to vary significantly.

In most of its forms, price control leads to consequences that can be reasonably comprehended – and are immediately bad. If, for example, a government wants to fix the price of some product below its immediate costs of production, there will be an increase in demand and a fall in supply, leading to shortages in the market. The effects of price control are different where pharmaceutical products are concerned. In no European country are prices set below marginal cost of production – and it would be hard for this to happen, bearing in mind in most cases the very low marginal costs of production. Instead, profit margins are squeezed.

But there are (following the idea of the great French economist Frédéric Bastiat's essay of 1850, "What is Seen and What is not Seen"), two consequences of pharmaceutical price controls; one 'seen', the other 'unseen' or unintended. It is the latter which should cause concern.

The 'seen consequence' is to hold down medical costs, allowing wider access at any one time to treatment than would otherwise be the case.

Its 'unseen consequences' however are to diminish the range of treatments available in the long term, and to increase medical costs. Price control will in the long term reduce the number of new products introduced to the market. And it may actually increase pressure on health budgets. Money spent on pharmaceutical products is, of course, a cost. But it is also a cost saving, taking into account often larger amounts of money that would otherwise need to be spent on less effective forms of treatments. In this respect, any budget savings that damage the ability of the pharmaceutical companies to continue developing new products are not savings at all, given any other view than that of short run neoclassical market analysis.

And we can see clear evidence from Europe that price control is reducing the rate of innovation. Until the 1980s, continental Europe had a dynamic and innovative pharmaceutical sector. Germany, in particular, had long had a distinguished record in pharmaceutical innovation – from morphine and heroin and aspirin in the 19th century, to Cipro and Baycol in the 20th. With the exception of Britain, all these sectors are in decline. In 1990, pharmaceutical companies spent $7.2 billion on research in Europe, and $4.9 billion in the United States. By 2000, spending in Europe had risen to $16.9 billion, but in the United States to $23.7 billion.

Granted, this does mean an increase in European budgets. But these are exceptional times for pharmaceutical research. During the past generation, research and development budgets in the pharmaceutical sector have been rising at 7.1 per cent a year. Between 1996 and 2001, the pharmaceutical industry as a whole spent $130 billion on research and development – more than in the whole of the previous 25 years. Yet while the pharmaceutical companies in Europe doubled research during the 1990s, they quintupled it in America. Put another way, Europe's share of world pharmaceutical research had fallen from 32 per cent to 22 per cent.

The results are easy to see. In 1988, three of the best selling new pharmaceutical products in the world had been developed in Britain. By 2000, there were none from Britain – and Britain still has a viable pharmaceutical sector. In Germany, investment in pharmaceutical research has been declining. Germany had 16 per cent of the world's new drug patents in the years 1980 to 1985, but that share dropped to 8 per cent in the years 1986 to 1990. In France, there is almost no innovation – yet France in 1970 was third in the world in terms of new patents for pharmaceutical products.

Price control has limited the profitability of European pharmaceutical companies in their home markets, and has crippled their willingness and ability to spend on development of new products.

Of course, it may be argued, the effect of price control need not be so great. So long as other markets in the world remain uncontrolled, research and development will continue there.

Perhaps the continental Europeans are enjoying continued medical progress at the expense of British and America health care schemes. Perhaps this is unfair. But unfairness is no argument in itself against continuing with a policy that reduces medical costs in one country at the expense of another. Complaints are only to be taken seriously when it can be shown that control has put brakes on the rate of pharmaceutical innovation.

There are two replies to this argument.

First, price control does apply such brakes. Medicine is not like mathematics or pure physics, where speculation is wholly abstract, and separate from any cultural bias. Medical research may be a science, but the objects of research are determined by cultural bias. For example, it was found in the 1960s that the same constellation of symptoms were routinely diagnosed in America as emphysema and in Britain as chronic bronchitis. In Britain and France, there were apparent differences in the incidence of schizophrenia. On examination, it was found that French doctors were much less willing to make the diagnosis.

According to this view, every developed nation has something unique and important to add in the field of medical research. If Germany and France now count for little in this field, the whole world is poorer for the decline. Perhaps only in Germany could aspirin have been developed, just as only in Britain could Penicillin. Perhaps the decline of the German pharmaceutical sector is robbing humanity of something equally important.

Second, the more often countries able to bear the full cost price of pharmaceutical products push prices towards marginal cost, the less able the pharmaceutical companies are to supply products at slightly above marginal cost to poorer countries. Every time a European government forces down the price of some pharmaceutical product, it is to some degree making that product less available to patients in the third world.

The pharmaceutical industry has come under considerable fire in recent years regarding the supply of medicines to lesser-developed countries. However, by imposing price controls, it is the European governments who are imposing costs on the developing world. This policy is most probably counter-productive, since the costs to European governments in terms of aid and trade with developing countries are likely to be much higher than the short-term savings from price controls. This is clearly a complex and controversial debate, which lies outside the remit of this paper, but perhaps needs to be explored further elsewhere.

In a world of increasingly open trade, the effects of price control are no longer confined to the market where they are applied. They now extend via parallel trade into markets where no price control exists. Those who favour importation into the US are arguing for the importation of all these problems.

(Given the focus of today's session, I have ignored the patient safety issue, which is no less worrying.)

To start at the beginning: governments which pay for pharmaceuticals involve themselves, as night follows day, in both pricing and availability. Although the EU-wide drug approval process is capable of speedy decision making, at Member State level speed disappears as individual health and finance ministries create a series of differing barriers against the introduction of new drugs. In countries such as Belgium France and Greece, for example, with heavy regulation, new drugs take an average of nine months after EU approval to reach patients.

That is the average. Taxol, a medication to treat advanced breast cancer and refractory ovarian cancer, was approved in 1995, but did not reach British cancer patients until 2000. It is no surprise that the UK has lower breast cancer survival rates than the US and much of Europe.

In 1995, new EU-wide procedures were introduced to do two things: to strengthen the role of 'mutual recognition', by which companies with permission to market their drug in one country could apply for this to be acknowledged across the EU; and to introduce a complementary, formal structure under which a drug could be approved centrally with so-called 'Community Marketing Authorisation' for use across the EU by the European Medicines Evaluation Agency. According to the EU directives, granting of mutual recognition status should take no longer than 90 days beyond the date of application, and pricing and re-imbursement no longer than a further 180 days.

In a report published in 2000, the consultancy Europe Economics examined the three methods – one national and two EU-wide - of approval. It found astonishing variations within an overall picture of heavy delays. Among those drugs sent for

approval at national level, patients in the countries with the longest delays finally got access to new drugs four years after patients in the quickest countries. The worst countries were France, Greece and Portugal (an average delay of over two and a half years), with Belgium, Germany and Austria not far behind.

Europe Economics then looked at all 24 of the medicines sent for the new system of central approval between 1995 and 1997. Delays between approval being granted and their appearance at pharmacies were longest in Portugal, Italy and Spain, with bad delays also in Greece, Belgium, France and Ireland. 20 of the 24 drugs were not on the market in Portugal by the time the survey stopped at the end of 1998. Even in Germany, with a relatively good record, 6 of the 24 were still unavailable. Belgium, Greece and Portugal were the countries with the worst delays in patient access for those medicines approved under the new mutual recognition procedure. Europe Economics only examined seven countries' records here, but in every one of them the delay far outstripped the 90 days permitted in the regulation.

Overall, the report found that EU patients faced an average delay of over two years before gaining access to a new drug after licensing by their own Member State, whilst patients in the most dilatory Member State had to wait four years.

The leading cause of this crisis is hardly a revelation: cost containment and price controls. An array of highly pointed and increasingly effective cost containment measures are becoming increasingly successful at limiting pharmaceutical spending within EU Member States. Take cardiovascular medicine, where so high are the hurdles for reimbursement (in Italy and Belgium the threshold is a cholesteral level of about 290, plus proof of family history, even though established medical opinion holds that 190 is the appropriate level) that the most innovative and effective lipid-lowering therapy is only available to heart attack sufferers. Even in countries which once had a relatively good story to tell, cost-containment is now beginning to undermine patient access, as the British government's establishment of the National Institute for Clinical Excellence shows.

The most extensive study of these delays has been undertaken by Prof Oliver Schoffski, at the University of Erlangen-Nuremberg. In a report published in January 2003 ("Diffusion of Medicines in Europe", which can be downloaded from his website at the University of Erlangen-Nuremberg: http://www.gm.wiso.uni-erlangen.de) he examined the treatment of 20 illnesses across Europe, incorporating nearly 200 studies of how people were treated. He concludes that although effective medicines exist and are available in principle for all eligible patients throughout Europe, not everyone receives adequate treatment; in some cases patients are not treated at all; in other cases they only receive outdated medicines (with lower effectiveness or with more severe side-effects), while prescribed dosages can also be too low to have an effect.

Data collected by Prof. Schoffski show, for example, that in Germany one million people suffer from migraine unnecessarily. In France, 9 in 10 patients with acute asthma do not receive adequate care.

Take diabetes. Diabetes is one of the most common diseases of western civilisation; it affects more than 18 million people in the EU. If diabetes is treated in the proper way,

other serious and expensive illnesses like strokes, heart attacks, blindness or amputations can be avoided, or at least delayed for a long time. There is a fundamental problem of lack of proper diagnosis: in France about 60% of patients are not monitored satisfactorily. But even when patients are diagnosed, they do not receive proper medication. In Germany 30% of at least four million diabetes patients receive no medicine at all as a result of cost cutting. Yet with proper treatment a huge amount of unnecessary costs could be avoided: the 6000 annual German cases of blindness, the 8000 new dialysis patients, the 27,000 heart attacks, the 28,000 amputations and 44,000 strokes, all of which are the result of inadequate diabetes treatment.

Only 5 percent of UK patients with prostate cancer are treated by an oncologist. 40 percent of all breast-cancer patients die in Germany - compared to 26 percent in the United States - due partly to a lack of use of innovative medicines. And with cardio-vascular disease, 83 percent of Italians, 77 percent of Brits and 74 percent of Germans receive suboptimal treatment, compared to only 44 percent of Americans.

This is not by accident. It is by design, and is the inevitable consequences of the price controls which come alongside parallel trade. The UK's National Institute of Clinical Excellence, for example, exists specifically to reduce choice. NICE was set up in April 1999 with one of the most misleading launch promises in history: spreading excellence throughout the National Health Service and ensuring that all patients received access to the 'best' treatments available.

But there is a golden rule in public policy: the name of a body is, almost always, the exact opposite of its real effect on the world. Its real effect – one might say its real purpose - has been rather different: to restrict the variety of treatments available to patients. In reality, NICE was set up to provide an independent, expert justification for the rationing which has always been a fundamental and necessary part of the NHS' modus operandi. Rather than NICE, it might best be described as NASTY: Not Available, So Treat Yourself.

The German Centre for Quality Medicine, similarly, is supposed be able to issue guidance to doctors across all of Germany, ensuring up to date knowledge of the latest research and that the most effective medicines are used on patients. It sounds wonderful in theory. But the practice, as NICE shows, is rather different. In reality these decisions are about not widening the range of treatments but narrowing them; not increasing the options but restricting them. They are, in short, designed to ration health care, and to do so in the most misleading manner possible – on the pretext of rationality.

The rationale behind such a policy is clear. The healthier we get, the more we spend on healthcare. Demand for healthcare seems to rise inexorably, driven by a cocktail of demographics, new technologies and expectations. Across the globe, those responsible for the delivery of healthcare strive to find ways to limit the rate of growth in spending. These have taken a variety of forms, from HMOs in the US to restructuring of some social insurance models in Europe. Whatever other merits they have, they all have this same overriding concern as a driving force.

As one of its main decision-making tools, NICE employs economic evaluation, a method which is becoming increasingly required by healthcare decision-makers. Economic evaluation involves the comparison of the costs and consequences of alternative treatments for a given condition. It is promoted as a rational, scientific means of allocating resources and containing costs. In reality, it is a spurious justification for rationing drugs which would have a significant impact on spending.

The crucial words are 'clinical excellence', and how they are defined. The unavoidable truth is that such decisions cannot be value-free. The decision making process – which drugs to allow, and which to bar - represent a set of value judgements which are hidden from view and may not reflect the values that the general public would like to use in the allocation of healthcare resources. Such decisions go to the heart of economics – and of politics. Indeed, the cynic's view of NICE is the only plausible view: the very purpose of basing rationing decisions on the outcomes of such evaluation is to provide a supposedly objective alibi behind which intensely unpopular political decisions –rationing healthcare – can be hidden. Subjective choices about which treatments to deny, and to which groups of patients, are thus disguised as objective decision-making, and given entirely spurious credibility, when in reality they are no more objective than any other political decision.

Even the most cursory look at NICE's methodology and purpose shows precisely how it ends up denying treatments to patients which they would otherwise have had. The list of drugs which NICE now refuses to sanctions is almost endless:

In 2002, NICE said that irinotecan and oxaliplatin should not be used as first line treatment for advanced colorectal cancer, even though they are licensed for this in the UK with an established drug 5FU. They added that a third drug, raltitrexed, should only be used in clinical trials. The real reason? The newer drugs cost £1,200 per patient a year, compared to the £70 of more traditional treatments.

In the same year, 2002, NICE said that there was 'insufficient evidence' to recommend the use of a new cancer medicine which has clearly proved its efficacy in the treatment of patients in two of the three phases of chronic myeloid leukaemia. The medicine has been licensed for all three phases in 65 countries around the world – but not, thanks to NICE, in the UK.

Relenza for influenza, beta interferon for multiple sclerosis, herceptin for breast cancer: on and on the list goes, all on the basis of supposed 'clinical excellence' – and all, in reality, based on a desire to save money.

Prof Schoffski describes "a huge difference between a possible optimal treatment and the treatment delivered to the patient". Current drug budget management in many EU countries (i.e. drug pricing policy, inadequate government planning and cost-containment measures) leads to sub-optimal medical treatment of the European population for many pathologies.

There were, he found, five strongly interrelated factors influencing the diffusion of effective medicines in national health care systems: patient related, health care professionals related, industry related, system related (long term) and policy related (short term) factors – which he concluded are the most important.

American concern with European "free riding" on investment in R&D is understandable, and justified. European governments are, in effect, shifting the cost burden of research from Europe to the US. But the correct response is for Europe to get its act together, not for the US to adopt the same mistaken policies which have caused the problem in the first place. By adopting drug-importation measures, the US will simply be importing the same problems arising out of price controls and leading to diminished incentives for innovation. The price differences might fall, but so too will everything else – critically, health care.

There is, unfortunately, no such thing as a free lunch. You cannot get something for nothing. Importation might look like a panacea but it is no such thing. It involves the importation of the price controls which have wreaked havoc with European patients' health care and the European pharmaceutical industry. The argument is made that this is an issue of free trade. It is not. Allowing such imports will not, as one proponent put it, "allow American consumers, particularly seniors, to benefit from worldwide price competition". Far from "inserting competition and the free market into the pricing of medication.", as another advocate put it, there is no competition. There is simply pricing by governmental diktat, with all the deleterious consequences outlined above.

One congressman - a free market conservative – argued that importation would force drug makers "to present the price-setting countries with an ultimatum: Either liberalize your market or we will leave. It's hard to imagine that countries in this situation will deny their citizens access to life-saving drugs.". Clearly, he has never studied healthcare in Europe, where denying access to life-saving drugs is almost a matter of policy.

The fate of the pharmaceutical industry would be irrelevant to my concerns but for one thing. It is R&D which saves lives, and innovation which transforms the quality of life of patients across the globe. If the pharmaceutical industry is unable to undertake such research, we all suffer. It is precisely because the patient should come first that the sophistic and superficially appealing arguments in favour of importation should be resisted. Unless, that is, the US wishes to turn itself into Europe, and deny its patients.

The CHAIRMAN. Mr. Outterson.

KEVIN OUTTERSON, ASSOCIATE PROFESSOR, WEST VIRGINIA UNIVERSITY COLLEGE OF LAW, MORGANTOWN, WV

Mr. OUTTERSON. Good morning, chairman and distinguished members of the committee. My name is Kevin Outterson. I am a Professor of Law at West Virginia University, a purple State. I am here today to talk about the Commerce Department study.

I would have to say that about 80 percent of what Mr. Aldonas said, I agree with. I am not a fan of price controls, but given the 5 minutes, I am going to focus on the things we disagree on on the report. But if you understand it broadly, much of what he says, I agree with.

I offer three conclusions to the report. First of all, the strategy to raise foreign drug prices through free trade agreements is not only unnecessary, but it is dangerous, and I think he supported the

fact that he doesn't think free trade agreements are the way to do that.

Secondly, the report grossly overestimates the likely impact of free riding by rich countries and ignores the tremendous human cost of higher prices.

Third, the drug industry suffers from too little transparency. We need independent research on these questions, not PhRMA-funded studies cloaked as an academic exercise.

So, first of all, let us look at free riding. The USTR strategy depends upon raising patented drug prices abroad, but it will only succeed in doing that in the poorer countries of the world and it will fail to do that in the richer countries, like Europe, Japan, and the other OECD nations in the report. What PhRMA calls price controls, if you listen carefully, are actually governments deciding what they will pay, what they will reimburse for a drug. The mechanisms that they use are very similar to American managed care mechanisms, but the goal is to control government reimbursement.

The United States employs very similar mechanisms. The Veterans' Administration's Federal Supply Schedule, the 340(b) Public Health Service program, the Medicaid Federal mandatory rebate and supplemental rebates, all of these things are very similar mechanisms, and through the studies we have done in West Virginia, the prices out of these programs are, in many cases, lower than Canadian and European prices.

For us to say that this is a bad idea, we are being hypocrites. We are throwing stones. We are living in a glass house. We should not be attacking European core domestic policies when we use the exact same techniques both in our commercial sector in managed care as well as in our government.

These powerful OECD countries will resist an American attempt to increase their drug prices. The Australian FTA was hailed as a model, but the actual text of the Australian FTA is exceedingly modest on this particular issue and it has failed. It is counterproductive. John Howard, his government has announced in the past few weeks that they are going to cut drug prices by 12.5 percent across the board in Australia in response, partially, to the Free Trade Agreement. It is counterproductive.

Is it going to increase drug prices in Australia? No. They are actually going to go down. It is far more likely that the U.S. will succeed in raising drug prices only in smaller and more vulnerable countries who need a free trade agreement with the United States for other reasons, places like the CAFTA agreement. The terrible human cost of these price increases will be many times greater than the R&D benefit, according to PhRMA-supported studies which link how prices affect utilization of necessary drugs.

Now, my second topic, is the relationship between drug company revenues, R&D, and innovation. To the extent that the HHS, Health and Human Services report touches on this topic, my comments apply there, as well.

Now, the Commerce Department report relies on a series of highly contestable estimates, primarily the work of Vernon, Grabowski, and DiMasi, to conclude that free riding by rich OECD countries will destroy three to four innovative new drugs per year. The re-

port grossly overestimates the benefits and ignores the cost of this free rider strategy.

First of all, given what I have said about Australia, a more realistic revenue target for the USTR strategy is many times smaller. Mr. Aldonas said, $15 to $27 billion needs to be increased in the rich OECD countries. How will they achieve that? In Australia, we tried—the report says $400 million is needed out of Australia. In fact, their prices are going to decline over the next 4 years by 850 million Australian dollars.

How will we achieve it? It is more likely, and this is laid out in more detail in my written report, that we will achieve increases only in the low- and middle-income countries of the world. We are talking about a very small amount of money, which reduces the impact of the report. We are taking the widow's mite and we are using that to fund PhRMA innovation, which I suggest we may want to think about.

Secondly, why assume that the drug companies will use incremental revenues for U.S. R&D? It is an assumption here that if U.S. prices are high, they will do the research here. They do their research here because we have the NIH here and they want to be close to our scientists. We have the great human capital of our research engine and they want to be close to those people. It makes no difference what our price system is. These are global companies.

In a recent Tax Court filing, GlaxoSmithKline told the Tax Court that the vast majority of their profits on research and development are in Ireland, not the United States. So I would like some consideration of that issue.

If we use more realistic estimates on pharmaceutical research and development, such as the estimates by the National Science Foundation, then this report is inflated by an additional factor of four to five times. He assumed this morning that one-third of the incremental revenue would go into R&D. PhRMA's data on their Web site says 17 percent, if you believe that. The National Science Foundation says it is more like 8 percent. You change that number from 33 to 8, you have just cut by 400 percent the impact of innovation of this report.

The final conjectural step in this report assumes that these funds will be turned into drugs. The report promises three to four new drugs per year. The evidence is based on DiMasi's analysis of confidential data provided by the pharmaceutical companies themselves, knowing what it would be used for. This data cannot be verified for accuracy. This isn't a scientific study in the normal sense of the word and it is the source for all the estimates of what drug spending actually costs, research and development.

Now, seeing the time, I just want to conclude by saying the analysis suggests that—my analysis suggests that the USTR's strategy might buy one innovative new drug every 12 to 13 years, which is hardly a price worth paying in order to offend our best trading partners and to damage the health of millions, not only abroad but also in the United States. A 1 percent change in the NIH budget has a much more significant impact than everything this report talks about.

In conclusion, I also think we should approach these topics with some humility. I am not suggesting that my estimates are anything

near the last word on these topics. What we need here is transparency on the data. Grant Aldonas said they had to buy the IMS data, and that is pricing data. We don't have access to the R&D data. Congress is making major public policy decisions without the necessary facts. Every time someone proposes something about PhRMA, the response is innovation, but we do not have the data. They don't give transparency on these relationships. It is shocking that we don't have the access to this data on a transparency basis in order to make good public policy.

Mr. Chairman, I want to thank you for allowing me to speak today. If I can, you left out one Wyoming site. I spent 3 weeks in the Wind River Mountains, which is a wonderful place to visit and would encourage tourists to head that direction, as well.

The CHAIRMAN. I thank you for that comment. We usually don't tell people about that until they have been to Yellowstone and Jackson. We leave out some of the really beautiful places that are kind of saved for those who have been to some of the other spots.

Mr. OUTTERSON. I am willing to remove those comments from the record.

[Laughter.]

[The prepared statement of Mr. Outterson follows:]

PREPARED STATEMENT OF KEVIN OUTTERSON

Good morning Chairman Enzi, and the Members of the Committee. My name is Kevin Outterson,[1] and I will testify today about the Commerce Department Study on Pharmaceutical Price Controls in OECD Countries.[2]

The Study is a flawed discussion of the issues regarding global pharmaceutical pricing, including the strategy of the Department of Commerce and the USTR to utilize trade agreements and trade leverage to increase foreign drug prices. I will discuss 2 issues: (1) free riding by foreign countries; and (2) the linkage between pharmaceutical innovation and drug prices. In my written testimony I also discuss related issues in the HHS Task Force Report on Prescription Drug Importation, and conclude that importation would be safe and save several billion dollars, with no net effect on pharmaceutical innovation.[3]

I offer 3 conclusions on the Department of Commerce Report:

- The strategy to raise foreign drug prices through free trade agreements is not only unnecessary, but dangerous. It will not succeed in rich OECD countries, but will offend our best trading partners. In low income countries it may succeed in raising prices, but with a minimal impact on innovation and a devastating impact on global public health. The strategy will also open important US domestic programs to criticism.

- The Department of Commerce Report grossly overstates the likely impact of free riding by rich OECD countries, probably by a factor of 8 to 16 times or more. The strategy may yield only $355 million per year after years of effort, enough R&D to buy just one innovative drug every decade. The cost to global health will be 10 to 100 times greater. A 1% change in the NIH budget would have a larger effect on drug innovation.

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[2] US Dept. of Commerce, International Trade Administration, Pharmaceutical Price Controls in OECD Countries: Implications for U.S. Consumers, Pricing, Research and Development, and Innovation (Dec. 2004) [hereinafter, the Commerce Department Study].

[3] US Dept. of Health and Human Services, HHS Task Force on Drug Importation, Report on Prescription Drug Importation (Dec. 2004) [hereinafter, the HHS Task Force Report]. For my conclusions on the HHS Task Force Report, *see* Appendix B below.

- Public data is not available to properly answer these questions. Congress needs transparent access to verifiable data. Any studies interpreting such data must be independent. The National Academies of Science, the Institute of Medicine or the GAO are possible sponsors.

1. Free riding

First, let's discuss the charge that other OECD countries are 'free riding' on American innovation.

Undersecretary Aldonas, CMS Administrator McClellan, former USTR Zoellick, and several Members of Congress have publicly articulated the strategy of using free trade agreements to address free riding.[4]

The strategy depends upon raising patented drug prices abroad, but it will succeed only in poor countries which will suffer under higher prices and will fail in rich countries where it is needed most. According to the Report, the greatest free riders are the UK ($1.0 to 1.6 billion), France ($1.0 to 1.5 billion), Japan ($200 million to 1.4 billion), Germany ($700 million to 1.2 billion), Canada ($600 million to 700 million), Switzerland ($400 million), and Australia ($400 to 700 million).[5]

In each of these countries, what PhRMA calls 'price controls' is actually a limit on what the government will pay for drugs under national health plans.

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[4] Peter Drahos & David Henry, The Free Trade Agreement Between Australia and the United States: Undermines Australian Public Health and Protects U.S. Interests in Pharmaceuticals, 328 Brit. Med. J. 1271-72 (2004); Elizabeth Becker, Drug Industry Seeks To Sway Prices Overseas, N.Y. Times, Nov. 27, 2003, at A5; Elizabeth Becker & Robert Pear, Trade Pact May Undercut Importing of Inexpensive Drugs, N.Y. Times, July 12, 2004, at A1; Marilyn Werber Serafini, Drug Prices: A New Tack, Nat'l J., Apr. 17, 2004, at 1177 ("So [House Speaker] Hastert and [Senator] Kyl championed the novel idea that the key to lowering U.S. prescription drug prices is to persuade foreign governments to raise their prices. . . .The idea of trying to level the international playing field on prescription drug pricing originated with the U.S. pharmaceutical industry. But Hastert and Kyl played significant roles last fall in persuading the Bush administration to embrace this strategy. . . .The result was the United States' first free-trade agreement that included modest concessions on pharmaceutical price controls."); Marilyn Werber Serafini, The Other Drug War, Nat'l J., Mar. 20, 2004, at 871-72; Mark B. McClellan, Speech Before the First International Colloquium on Generic Medicine (Sept. 25, 2003), http://www.fda.gov/ow/speeches/2003/genericdrug0925.html. McClellan's speech was widely reported. See, e.g., Christopher Bowe & Geoff Dyer, Americans Lured by Lower Prices, Fin. Times, May 5, 2004, at 17 ("The rhetoric intensified in September when Mark McClellan, then head of the FDA, attacked European drug price controls and said other rich nations should pay more of the development cost for drugs.").

[5] Department of Commerce Report, at 18-19, figs. 5 & 6.

The US employs very similar rules in the VA federal supply schedule (FSS), the Public Health Service's 340B program, and mandatory and supplemental rebates under Medicaid. Data clearly demonstrate that our government's prices for these programs are lower than Canadian and European prices.[6] If Patricia Danzon's pricing studies[7] used FSS, 340B and Medicaid prices as the US price, most or all of the international price differentials would disappear.

Consider the negotiations between USTR and the EU: we demand that they modify an important social policy, universal access to care, and raise their drug prices to match our own. If they respond at all, it will be to call us hypocrites, and to demand that we sacrifice our veterans, public health clinic patients, and Medicaid recipients in the bargain.

Powerful OECD countries are likely to resist an American attempt to increase domestic drug prices. Even Australia stood up to most of the US drug price demands during the free trade negotiations. While the USTR and some Members of Congress suggest that the AUSFTA will raise prices in Australia, the actual language of the Agreement is quite modest. The Australian government insists that the AUSFTA won't raise Australian prices at all.[8] In fact, just as the AUSFTA became effective, Australia announced a plan to cut drug reimbursement prices by an additional 12.5% when the first generic in a therapeutic group is approved. The net price reductions are estimated to exceed AU$830 million over four years.[9] A strategy which relies upon attacking a core domestic policy of our most important trading partners seems an unlikely path to success.

It is far more likely that the US will 'succeed' in raising drug prices in smaller and more vulnerable countries. In the face of the humanitarian crisis of access to drugs in low and medium income countries, do we really want

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[6] See the 2004 Annual Report of the West Virginia Pharmaceutical Cost Management Council, available at http://www.wvs.state.wv.us/gol/pharmacycouncil/.

[7] *See, e.g.*, Patricia Danzon & Michael Furukawa, Prices and Availability of Pharmaceuticals: Evidence from Nine Countries exhibit 8 (undated presentation), *at* http://hc.wharton.upenn.edu/danzon/index.htm (now a Health Affairs web exclusive, W3-521, 2004).

[8] Vaile, M. (2004), 'Free Trade Agreement with the United States', Media Release, 8 Feb. 2004 (MVT08/2004) (available at http://www.trademinister.gov.au/releases/2004/mv008_04.html). See also Abbott, T. (2004) 'Australia-United States Free Trade Agreement (AUSFTA), Implementation of the Obligations to Improve Transparency of the Pharmaceutical Benefits Scheme (PBS) through An Independent Review Mechanism, Hearings before the Pharmaceutical Benefits Advisory Committee (PBAC) (25 July 2004) (statement of The Hon. Tony Abbott, MP, Minister for Health and Ageing).

[9] The Australian plan has been proposed by the Government, but not yet implemented. Pharma in Focus (Australia), 12 Feb. 2005, 7 Feb. 2005, 20 Dec. 2004 available at www.pharmainfocus.com.au.

to raise drug prices in Central America and the Dominican Republic through DR-CAFTA? In Morocco or Jordan? In sub-Saharan Africa? Can anyone imagine a *worse* idea for global drug pricing?[10]

When it comes to the world's poorest countries, the *free rider* label is especially inapposite. Low income countries cannot contribute much global drug R&D cost recovery in any case, and should be considered *fair followers* rather than free riders. The economist F.M. Scherer described this policy in a recent article,[11] giving economic language to the human rights appeals by essential medicines advocates like Médecins Sans Frontières.[12] Scherer's point is that any pharmaceutical patent rent extraction[13] from low income countries is likely to be very damaging to people and not very helpful to R&D.

In the wake of the Indian Ocean tsunami, we've seen the WTO and rich countries suggest trade concessions[14] and debt forgiveness[15] to help this region rebuild. While the tsunami was a terrible tragedy, the ravages of AIDS and other diseases inflict a larger toll every month in much poorer countries. The US and the WTO should offer new flexibilities to these countries, permitting them to be fair followers in pharmaceutical innovation. Millions of people would benefit from enhanced access to patented medicines, without harming innovation.

2. Revenues, R&D and Innovation

My second topic is the relationship between drug company revenues, R&D and innovation. To the extent the HHS Task Force Report is concerned about R&D, then these comments apply to that study as well.

The Commerce Report relies on a series of highly contestable estimates, primarily relying on the work of an economist, John Vernon. It begins with

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[10] For an argument for generally lower drug prices in low income countries, without harming pharmaceutical innovation, *see* Kevin Outterson, Nonrival Access to Patented Pharmaceuticals (Submission to the WHO Commission on Intellectual Property Rights, Innovation & Public Health) (3 Jan. 2005) *available at* www.ssrn.com (search Author=Outterson).

[11] F.M. Scherer, A Note on Global Welfare in Pharmaceutical Patenting, 27 World Econ. 1127, 1141 (2004).

[12] http://www.accessmed-msf.org/.

[13] An economic term meaning the additional profits captured due to patent laws and other laws designed to support the brand name drug company.

[14] WTO (2005).

[15] G. Brown (2005).

the calculation that foreign prices should be raised by $17.6 to $26.7 billion per year.[16]

The report then calculates, based upon industry-provided data, that an increase of $17.6 to $26.7 billion in sales will result in $5.3 to $8 billion in additional R&D.[17]

Finally, it concludes that $5.3 to $8 billion in additional R&D will translate into 3-4 new drugs per year.[18] In short, that free riding by rich OECD countries destroys 3-4 innovative new drugs per year.

Let's take these points one at a time. I will perform a sensitivity analysis to some of the assumptions.

First, as I stated moments ago, it will be impossible to raise drug prices abroad by billions of dollars, except in the poorest of countries where it will do the greatest damage. When we tried in Australia, drug prices look like they will actually decline. The strategy is counterproductive. Rather than assuming that the global increase will be $17.6 to $26.7 billion per year, it would be much more realistic, given the experience with Australia, to assume that the price increases will come largely in low and medium income countries. The total prescription drug market size of these countries is approximately $25 billion. A 20% price rise in all non-OECD countries might yield approximately $5 billion per year in additional revenues.

Second, why assume that drug companies will use the additional sales to increase R&D in the US? In recent tax court filings, GlaxoSmithKline claims that most of its R&D profits are in Ireland, not the US.[19] (GSK is trying to avoid a multibillion dollar IRS assessment.) The Report assumes that about a third of the additional revenues will be spent on R&D, but this is based on data provided by the companies themselves, and the company data are highly suspect. PhRMA self-reports that about 15.6% of its revenues are

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[16] Department of Commerce Report, at 11-19. The Report also suggests that a more robust generic market in the 11 OECD countries studied would result in a savings of $5.2 to $29.6 billion per year. Id. at 24. At these levels, generic savings will swamp much of the additional R&D effect of higher prices.
[17] Department of Commerce Report, at 29.
[18] Department of Commerce Report, at 25.
[19] 2004 Tax Notes 388 - ECONOMIC ANALYSIS: WITH BILLIONS AT STAKE, GLAXO PUTS APA PROGRAM ON TRIAL. (Section 482 -- Transfer Pricing) (Release Date: APRIL 22, 2004

currently spent on global R&D.[20] If we use PhRMA's number, the estimates in the Department of Commerce Report must be cut in half.

But there is every reason to assume that even PhRMA's R&D figures are inflated. Some funds which are characterized as R&D are actually marketing tools.[21] The revelations of rampant consulting arrangements at NIH[22] and off-label marketing which relied on sponsored studies are other possible examples. While the NSF has estimated that PhRMA's 'real' R&D figures are much lower, around 7.1%[23] we have no way of knowing what the truth is. If 7.1% is the correct number, the Department of Commerce report is inflated by 465%. Raising drug prices by $5 billion per year might result in a net gain of $355 million in global R&D. The terrible human cost of a 20% price rise in patented drugs in non-OECD countries would be many billions of dollars, relying on PhRMA-supported studies on the value of medicines and consumer sensitivity to price increases.

The third and final step in the calculation assumes that $5.3 to $8 billion in additional R&D will yield 3-4 new molecular entities. (The actual R&D increment is likely to be only $355 million, with offsetting costs in poor countries in the tens of billions). The translation of R&D money into actual drugs is based on DiMasi, Hansen and Grabowski's analysis of confidential data provided by PhRMA companies. It cannot be verified for accuracy and has many critics. Even if one accepts these numbers, it represents an average cost. We should expect that the project PhRMA companies trimmed from the R&D budget were less likely to succeed, that they were being intelligent in managing the R&D budget. If so, the effective yield from this incremental R&D will be less, perhaps much less. Nor does this mean that the supposed new drugs will be actually a major improvement. Most new drugs are modestly incremental, or actually no better than existing drugs in class. If one estimates 75%[24] of new FDA approvals to be in this category, then the Department of Commerce estimates must be reduced by another factor of 4.

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[20] Pharmaceutical Industry Profile 2004, at table 2, *available at* www.phrma.org.

[21] *See, e.g.* Barry Meier & Stephanie Saul, Marketing of Vioxx: How Merck Played Game of Catch-Up, N.Y. Times Feb. 11, 2005.

[22] NIH Blue Ribbon Committee (2004/2005).

[23] Quoted in Light (2004). The gross NSF figure is 11.8%; net of taxpayer contributions, US pharmaceutical R&D is estimated at 7.1% of revenues. National Science Foundation, Division of Science Resources Statistics, Research and Development in Industry: 2000 (2003) at table A-20 (non-federal pharmaceutical R&D was 9.8% of net sales in 2000).

[24] Light (2004) estimates 85% have modest incremental value, based upon FDA data.

My cumulative analysis suggests that $355 million per year will buy one innovative drug every 12 or 13 years, which is hardly a price worth paying for the likely impact on the world's population of a 20% increase in non-OECD drug prices. A 1% change in the NIH budget would have a larger effect on R&D.

3. Transparency

I am not suggesting that my rough estimates be relied upon as the last word on these subjects. What is needed is transparency. The US Congress is making major public policy decisions without the necessary facts. Every time someone proposes to improve drug access, PhRMA retorts with "protect innovation," but never discusses questions of financial access to drugs or the optimal level of R&D. It is shocking that Congress does not have access to reliable data with independent analysis on pharmaceutical innovation and pricing.

APPENDIX A: *What is the optimal level of pharmaceutical innovation?*[25]

For the pharmaceutical industry, the optimal level of appropriation through rents[26] must be sufficient to fund the socially optimal level of R&D. Optimization must balance concerns of cost, quality, and access, looking for the greatest net gain to global public welfare. Excessive rents harm human health without advancing socially optimal R&D. Society adjusts incentives

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[25] A fuller account of this next section may be found in Kevin Outterson, Pharmaceutical Arbitrage: Balancing Access and Innovation in International Prescription Drug Markets, 5 Yale Journal of Health Policy, Law & Ethics (2005) (pending) available at www.ssrn.com (search for author=Outterson).

[26] The economic analysis of socially optimal patents has been undertaken by Nordhaus and Scherer. See William D. Nordhaus, Invention, Growth, and Welfare: A Theoretical Treatment of Technological Change 70-90 (1969); William D. Nordhaus, The Optimum Life of a Patent: Reply, 62 Am. Econ. Rev. 428 (1972); F.M. Scherer, Nordhaus' Theory of Optimal Patent Life: A Geometric Reinterpretation, 62 Am. Econ. Rev. 422-27 (1972). Scherer argues that shortening patent life will reduce R&D only for the most marginal inventions, particularly in industries with non patent barriers to entry and post innovation pricing discipline. Scherer, Optimal Patent Life, at 426. The pharmaceutical research industry contains both conditions. Nordhaus concluded that a fixed patent life was not optimal, but given that requirement, the length of the life should err to a longer rather than a shorter period. Nordhaus, The Optimum Life of a Patent, at 428. Philipson and Mechoulan cover the same territory when they argue that "[a]ppropriate policy must simultaneously solve the externality problem ex-post and the R&D problem ex-ante." Tomas J. Philipson & Stéphane Mechoulan, Intellectual Property & External Consumption Effects: Generalizations from Pharmaceutical Markets 3 (Nat'l Bureau of Econ. Research, Working Paper No. 9598, 2003) at 12, 12-15.

such as patent law, grants, and tax incentives to achieve the best level of appropriation.[27]

Maximizing R&D at all costs should not be our objective. Resources devoted to R&D are not available for other uses.[28] Uwe Reinhardt puts it this way: "Year after year, the last dollar spent on drug research and development (R&D) should yield society as much benefit as it would have yielded if it had been spent to produce other goods or services."[29]

We should also avoid the assumption that all R&D targets are equally valuable. Some innovations are more valuable than others. Companies allocate research funds in response to price signals from commercial pharmaceutical markets. As a result, Americans now have a third drug for erectile dysfunction,[30] and funds for neglected disease innovation are literally going to the dogs,[31] but malaria and AIDS vaccines are not available.[32]

You get the sense that ships are passing in the night on this issue. James Love estimates the static global deadweight loss on pharmaceutical patents at over $400 billion per year,[33] and Larry Lessig implores us not to allow IP law to be perverted while a holocaust devastates millions in the developing

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[27] Philipson and Mechoulan make a similar point in the language of economics: "Under external effects in consumption, rewards to innovation should not be guided by potential consumer surplus, as under private goods, but the entire social surplus that includes benefits to non-consumers as well as consumers . . . ." Tomas J. Philipson & Stéphane Mechoulan, Intellectual Property & External Consumption Effects: Generalizations from Pharmaceutical Markets 3 (Nat'l Bureau of Econ. Research, Working Paper No. 9598, 2003).

[28] Currently the United States spends more than fifteen percent of its GDP on health care. Robert Pear, Health Spending Rises to Record 15% of Economy, N.Y. Times, Jan. 9, 2004, at A16. Perhaps we can agree that increasing pharmaceutical R&D to twenty percent or fifty percent of GDP would be excessive.

[29] Uwe E. Reinhardt, An Information Infrastructure for the Pharmaceutical Market, 23 Health Aff. 107 (2004).

[30] Viagra (sildenafil) was approved by the FDA in 1998. First Oral Therapy for Erectile Dysfunction, 28 FDA Medical Bull. 1 (1998), http://www.fda.gov/medbull/summer98/erectile.html. Levitra (vardenafil) was approved in August 2003. FDA, Talk Paper, FDA Approves New Drug for Treatment of Erectile Dysfunction in Men (Aug. 19, 2003), http://www.fda.gov/bbs/topics/ANSWERS/2003/ANS01249.html. Cialis (tadalafil) was approved in November 2003. FDA, Talk Paper, FDA Approves Third Drug To Treat Erectile Dysfunction (Nov. 21, 2003), http://www.fda.gov/bbs/topics/ANSWERS/2003/ANS01265.html.

[31] In 1999, the FDA approved two drugs to treat canine Cognitive Dysfunction Syndrome, also known as separation anxiety in dogs. FDA, Talk Paper, FDA Approves First Behavioral Drugs for Dogs (Jan. 5, 1999), http://www.fda.gov/bbs/topics/answers/ans00934.html. Perhaps soon a drug will be developed for erectile dysfunction in dogs.

[32] For an introduction to donor efforts led by the Bill & Melinda Gates Foundation to stimulate development of a malaria vaccine, see Malaria Vaccine Initiative, at http://www.malariavaccine.org.

[33] James Love, Statement of Essential Inventions, Inc. to the Commission on Intellectual Property Rights, Innovation and Public Health (Apr. 5, 2004).

world.[34] Meanwhile Joseph DiMasi and Henry Grabowski suggest that the "dynamic benefits created by patents on pharmaceuticals can, and almost surely do, swamp in significance their short-run inefficiencies."[35] Yet, in a major study, the Congressional Budget Office conceded that no one knows whether current levels of pharmaceutical R&D are optimal.[36] This is the pressing question.

Some empirical evidence suggests that PhRMA companies earn well above market rates of return, one possible indicator of supra-optimal pharmaceutical rents.[37] Until recently, the industry's long-term profits were four times the rate of the Fortune 500.[38] IRS data from 1990 to 1996 demonstrate that the drug industry's after-tax profits are more than triple the rate for all industries.[39] The industry is not doing as well in the recent past.[40]

Calculating optimal pharmaceutical rents must account for other sources of public funding for R&D, such as government grants, direct government expenditures, foundation donors, and tax incentives. The industry receives

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[34] Lawrence Lessig, The International Information Society, 24 Loy. L.A. Ent. L. Rev. 33, 36-37 (2004).

[35] Joseph A. DiMasi & Henry G. Grabowski, Patents and R&D Incentives: Comments on the Hubbard and Love Trade Framework for Financing Pharmaceutical R&D 2 (2004) (citation omitted), http://www.who.int/intellectualproperty/news/en/Submission3.pdf. DiMasi and Grabowski cite the 2003 study by Philipson and Mechoulan, but that study assumes sub-optimality rather than proves it. See Tomas J. Philipson & Stéphane Mechoulan, Intellectual Property & External Consumption Effects: Generalizations from Pharmaceutical Markets 3 (Nat'l Bureau of Econ. Research, Working Paper No. 9598, 2003).

[36] The 1998 study by the Congressional Budget Office states: "No one knows whether that amount of investment in R&D is over or under the optimal level." Cong. Budget Office, How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry, at 48 (1998).

[37] The barriers to this calculation are both empirical and theoretical. On the empirical front, internal company data are not generally available to researchers. Studies by DiMasi, Hansen, and Grabowski rely on self-reported PhRMA company data rather than a truly objective data set. Joseph A. DiMasi et al., The Price of Innovation: New Estimates of Drug Development Costs, 22 J. Health Econ. 151 (2003). IRS data show extraordinary profits and low taxation but is protected against public disclosure by the Internal Revenue Code. See Gary Guenther, Cong. Research Serv., Federal Taxation of the Drug Industry from 1990 to 1996 (1999); but see Gary Guenther, Cong. Research Serv., Federal Taxation of the Pharmaceutical Industry and New Drug Development (Updated Dec. 27, 2004) (tax rates rising with the phase-out of the possessions tax credit). Accurate pricing data is unavailable outside of the companies. Cong. Budget Office, How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry, at 20 (1998). On the theoretical front, useful questions are posed by Reinhardt, Uwe E. Reinhardt, An Information Infrastructure for the Pharmaceutical Market, 23 Health Aff. 107 (2004); and William S. Comanor, Political Economy of the Pharmaceutical Industry, 24 J. Econ. Lit. 1178, 1182-86 (1986).

[38] David H. Kreling et al., The Kaiser Family Found., Prescription Drug Trends: A Chartbook Update exhibit 32 (2001). The judgment of the equity markets is significant, even under a weak form of the efficient capital markets hypothesis.

[39] Gary Guenther, Cong. Research Serv., Federal Taxation of the Drug Industry from 1990 to 1996 (1999).

[40] Gary Guenther, Cong. Research Serv., Federal Taxation of the Pharmaceutical Industry and New Drug Development (Updated Dec. 27, 2004).

substantial tax incentives, resulting in an effective U.S. federal income tax rate in the late 1990s of 16.2%, compared with 27.3% generally.[41] Again, this tax rate advantage has recently moderated, but other tax advantages remain which are not captured by rate comparisons.[42]

The ways in which PhRMA companies currently opt to expend their cash flows may also indicate supra-optimality. The pharmaceutical industry currently spends more on sales and marketing than on R&D.[43] Large marketing expenses are not proof that pharmaceutical rents are supra-optimal, but merely indicate that the industry believes the return on investment in marketing is greater than alternative investments such as R&D. If the industry holds a relatively low view of the value of an additional dollar of R&D investment, then perhaps society would be better served with that additional dollar being used to provide life-saving access to medicines.

Some scholars, including proponents of the anti-commons movement,[44] suggest that the neo-classical link between patents and innovation is overstated, particularly for industries marked by cumulative innovation[45] such as genetics.[46] If so, optimal rents may be lower than previously expected.

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[41] Gary Guenther, Cong. Research Serv., Federal Taxation of the Drug Industry from 1990 to 1996 (1999).
[42] Gary Guenther, Cong. Research Serv., Federal Taxation of the Pharmaceutical Industry and New Drug Development (Updated Dec. 27, 2004).
[43] David H. Kreling et al., The Kaiser Family Found., Prescription Drug Trends: A Chartbook Update exhibit 32 (2001). exhibit 30 (noting that the top ten major pharmaceutical manufactures in 2000 spent 34.4% of their revenues on "marketing, general and administrative" expenses and 13.7% on "research and development."). But see Uwe E. Reinhardt, Perspectives on the Pharmaceutical Industry, 20 Health Aff. 136 (2001) (suggesting that not all SG&A expenses are truly marketing). With deference to Reinhardt, the differential is large enough to suggest that R&D receives less than marketing, absent more specific and verifiable data.
[44] The leading article is Michael A. Heller & Rebecca S. Eisenberg, Can Patents Deter Innovation? The Anticommons in Biomedical Research, 280 Science 698 (1998). For a recent study on the importance of maintaining a scientific commons, see J.H. Reichman & Paul F. Uhlir, A Contractually Reconstructed Research Commons for Scientific Data in a Highly Protectionist Intellectual Property Environment, 66 Law & Contemp. Probs. 315 (2003).
[45] Oren Bar-Gill & Gideon Parchomovsky, The Value of Giving Away Secrets, 89 Va. L. Rev. 1857 (2003). While Bar-Gill and Parchomovsky list "pharmacology" as one such industry, they do not make that case convincingly in the article. If PhRMA companies are eager to publish and forego patents, it is a nascent trend.
[46] The work of Tim Hubbard and James Love is particularly interesting in this regard. The open source movement in science is built upon such factors, as articulated by several leading scientists. Tim Hubbard & James Love, Medicines Without Barriers: From the Human Genome Project to Open Development Models for Medical R&D, New Scientist, June 14, 2003, at 29; Stephen M. Maurer et al., Finding Cures for Tropical Diseases: Is Open Source an Answer?, in Biotechnology: Essays from Its Heartland 33-37 (Lynn Yarris ed., 2004), http://www.sulilab.org/publications; Sir John Sulston, Open and Collaborative

The most important data required to resolve this question are in the hands of the pharmaceutical industry and are not available in a reliable form to independent researchers.[47] This fact alone is a compelling reason to demand transparency. It certainly seems plausible to presume that supra-optimal rents are currently being collected. The burden of coming forward with contrary evidence should be placed on the parties controlling the relevant information: the PhRMA companies.

Appendix B: *A Brief Note On the HHS Study*

1. Safety

While in the abstract, safety is a possible issue with drug importation proposals, in the real world any supervised importation program is preferable to today's unregulated Internet importation markets. Programs like I-SaveRx (Illinois and other States) or the Dorgan-Snowe Bill (S.334) are much safer than anything that is happening today, and more closely supervised than present domestic mail order pharmacies serving millions of Americans.

2. Impact on US Sales[48]

As for the likely volume of drugs which would be imported from abroad, some highly speculative estimates can be made. Current volume of Internet purchases from Canada are on the order of $600 million per year.[49] Opening the US market to drugs from Canada and Europe will have an appreciable

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Movements in Science, Presentation at the Trans-Atlantic Consumer Dialogue Future of WIPO Workshop, Geneva (Sept. 13, 2004).

[47] See supra notes 28-30. Pharmaceutical pricing and profitability data are notoriously opaque and misleading. Gardiner Harris, Drug Companies Settle 7 Suits for $1.6 Billion, N.Y. Times, Nov. 6, 2003, at 8 ("Drug companies have paid a total of $1.6 billion since 2001 to settle seven suits brought by whistle-blowers that accused them of marketing fraud and overbilling Medicare and Medicaid . . . ."). Some researchers suggest that increased pricing opacity is necessary to sustain differential pricing for low income countries. Patricia M. Danzon & Adrian Towse, Differential Pricing for Pharmaceuticals: Reconciling Access, R&D and Patents 16-20 (AEI-Brookings Joint Ctr. for Regulatory Studies, Working Paper No. 03-7, 2003). I suggest that transparency will better serve global public health.

[48] In general, this section follows the analysis in Kevin Outterson, *Pharmaceutical Arbitrage: Balancing Access and Innovation in International Prescription Drug Markets*, 5 Yale Journal of Health Policy, Law & Ethics (2005) (pending) *available at* www.ssrn.com (search author=Outterson).

[49] IMS (2004). When foot traffic to Canada is included, the number reaches $1 billion.

impact on US prices, but not perhaps as much as some claim.[50] Recently created importation programs (such as Illinois and Minnesota) have seen modest growth, demonstrating the effectiveness of the FDA campaign as well as drug company practices to restrict importation.

Recently, two competing studies on the European experience with parallel trade have been issued, one for the name brand companies,[51] and another for the parallel importers.[52] As is common, these studies come to opposite conclusions, favorable to the firms which funded the study. But they do agree that within Europe, parallel trade comprises about 10 to 20% of the market share by value in higher priced European markets.

If we make similar assumptions in the US, adjusting for the existing price discrimination within the US market, one could expect parallel trade to stabilize after a few years at $12 to 24 billion per year.[53]

Savings to US health plans are more difficult to estimate. The drug industry funded study reported meager savings. But this is primarily because the industry has made life so difficult for parallel traders. Today, the savings from Canada are less than a year ago because the drug companies are choking off the supply to Internet pharmacies. If one assumes a more transparent market, and forbids companies from manipulating downstream markets (as in S.334), then one could expect significant savings after expenses, in the range of 20% to 30% of the sales. Net savings to US health plans and consumers can thus be estimated in the range of $2.4 billion to $7.2 billion per year. It is a modest sum compared to total US health expenditures, and yet the savings are significant for the individuals who

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[50] For a discussion of the mechanisms drug companies use to support price discrimination, many of which will remain after legalized importation, *see* Kevin Outterson, *Pharmaceutical Arbitrage: Balancing Access and Innovation in International Prescription Drug Markets*, 5 Yale Journal of Health Policy, Law & Ethics (2005) (pending) *available at* www.ssrn.com (search author=Outterson).

[51] A recent study from the London School of Economics does not find any evidence of the predicted price convergence in pharmaceutical parallel trading markets in Europe. PANOS KANAVOS ET AL., THE ECONOMIC IMPACT OF PHARMACEUTICAL PARALLEL TRADE IN EUROPEAN UNION MEMBER STATES: A STAKEHOLDER ANALYSIS 15-16 (London Sch. of Econ. & Political Sci., Special Research Paper, 2004), http://www.lse.ac.uk/collections/LSEHealthAndSocialCare/Documents/otherreports/ia.htm.

[52] Peter West & James Mahon, Benefits to Payers and Patients from Parallel Trade (York Health Econ. Consortium, Working Paper, 2003) (estimating direct savings of € 631 million in 2002 from legal pharmaceutical arbitrage (parallel trade) within the EU) (funded by a grant from European parallel traders).

[53] IMS Health estimates the US retail prescription drug market at $235.4 billion in 2004. A significant percentage of the US market is currently enjoying prices at or below EU norms, and would not be affected by the arbitrage opportunity. Therefore, this estimate assume that about half of the US market ($120 billion in 2004) would be exposed to possible importation, and that parallel trade would capture 10-20% of that market.

resort to Internet purchases. Most importantly, PhRMA supported researchers (such as Frank Lichtenberg) suggest that increased access to drugs will save lives. We must assume that $2.4 billion to $7.2 billion per year in lowered consumer prices will save hundreds or thousands of American lives, based on these PhRMA estimates.

3. Impact on R&D

Assume reduced sales on the order of $2.4 to $7.2 billion per year. To calculate the amount of R&D affected, and then the number of drugs affected, requires us to face the same issues described in the Department of Commerce report above. If the R&D response is 33%, the range is $800 million to $2.4 billion per year. If the percentage is 7.1%, the range is $170 million to $511 million per year. With savings of $7.2 billion, the upper-end R&D deficit of $511 million could be addressed with increased NIH grants, leaving taxpayers with a dynamic gain of $6.689 billion dollars due to importation, together with the associated health impacts of enhanced financial access.

The CHAIRMAN. I appreciate the testimony of everyone this morning. This is an educational process that we are going through. I am a firm believer that we need to find out as much about a problem from as many sources as we possibly can before we do the legislation. It is a trend I am trying to reverse, but hopefully, we can get there.

We have had some good testimony here and need to follow up on that a little bit. I will start with Dr. Zycher.

While many economists believe as you do that importing medicines from abroad is nothing more than importing foreign government price controls, there are others who disagree, such as Mr. Outterson. They argue that importation is the epitome of the free market at work. How do you answer your critics who believe that legalizing importation is about opening markets? Do you believe that opening U.S. borders to prescription medicines from all over the world advances the cause of free trade?

Mr. ZYCHER. Well, no. I don't think the importation of price controlled products from overseas is any more free trade than the purchase of stolen merchandise from a fence is free enterprise.

At the same time, I think it is important to avoid quibbles over terminology, what is and what is not free trade, and focus on the issues that you, Mr. Chairman, have raised, the analytic issues. What would be the effect on patients, on the pharmaceutical sector, on the U.S. economy generally of a regime in which price controlled drugs from overseas are imported?

There are safety issues, which I think the Health and Human Services Department report explores in good detail. I did not discuss them in my testimony.

More generally, I think it is incontrovertible that the long-term effect on patients in the U.S. would be negative and large, and so

that is the context in which I think we ought to focus attention in this area.

The CHAIRMAN. Thank you. Mr. Pollard, I share your appreciation of Tony Blair. I have gotten to visit with him a few times and listened to him speak and even appeared before the House of Commons. He is a very knowledgeable person. You share an accent with him, too.

[Laughter.]

It is a little different than Wyoming, but I think that adds to your credibility.

Mr. POLLARD. It is spurious British credibility. We play on it a lot.

[Laughter.]

The CHAIRMAN. I want to ask, why is it that European countries tend to devalue the new innovative medicines by restricting access and attaching price controls to those products while overpaying for the generic versions of the medicines? Doesn't this policy seem out of line with what you want in a functioning marketplace, to reward innovation?

Mr. POLLARD. Absolutely. Europe is caught in a sort of a dilemma as a result of the single market. On the one hand, there is free trade within that single market. Anything that is allowable—that is bought and sold has to be moved about without restriction. What that means, though, is that because of the obsession with price controls, which is a result of the fact that the state in Europe plays so much of a role in the purchase of pharmaceuticals, what that means is that the market is, right from the very beginning, distorted and is not a free market.

You see with generics the role of the state, again, is not about—let me rephrase that. In Britain, we have the perfect example of this. We have a body called the National Institute for Clinical Excellence, which is known by its acronym of NICE. It was introduced in 1999, ostensibly to assess all kinds of different medicines, innovative new medicines, generics, whatever, basically to decide whether a particular treatment could be made available throughout the NHS for a particular illness and so on.

Like all these things, what it was sold as is almost always the exact opposite of what its actual effect has been. Its actual effect is one of pure rationing. I prefer to think of it not as NICE but as NASTY, "Not Available So Treat Yourself."

[Laughter.]

And what it does is it includes all the different medicines and it examines them purely on the basis, supposedly, of what they call economic efficiency and so on. But what that means, we heard from Dr. Goldberg about Herceptin. It is not available in the U.K. Relenza for flu, not available in the U.K. Beta interferon for multiple sclerosis, not available in the U.K. as a result of the state determining what should and shouldn't be available rather than allowing it to the market, leaving it to the market.

The CHAIRMAN. Thank you. I will try and quickly cover one more.

Mr. Outterson, again, I am just relying on my shoe business background, which is not very good on economics—profitable, but not very good on economics. We made investment decisions all the time about building our business, and your conclusion that drug

importation is safe, saves billions of dollars with no net effect on pharmaceutical innovation strikes me as a little counterintuitive. Could you explain to me how R&D expenditures can be delinked from innovation and the return on investment?

Mr. OUTTERSON. My written testimony goes into this in more detail and that, in turn, is based on a much longer study which is being studied this week, in fact, at Yale.

But to put it briefly, I believe in intellectual property and in the story about innovation, but the question that is never asked, really, is when do we have too much innovation and when are we getting the wrong types of innovation?

So we have 20 years of patent term. Maybe 20 years is the right amount. Maybe it should be 25. Maybe it should be 15. It is an open question. When society is developing and giving funds to research and development, what is the socially optimal amount through the marketplace?

That question, we can't answer, ultimately, because we do not have access in the pharmaceutical industry to the data, the transparent data on pricing and research and development to know whether we are wasting money and it should be going to something else or whether we are not investing enough money. So that is really my core conclusion of the study, is that we don't know the answer.

Now, for importation, I do come out on the free trade side and say that within the rich countries of the world, we probably should have pricing that is roughly equivalent between the rich countries of the world and that we should forbid the type of arbitrage or importation that would take a cheap drug from Africa that is being provided really on a charitable basis and bring that into the United States. That should be absolutely illegal and a criminal act. But within the rich countries of the world, all the other goods that we deal with, we want to see free trade and price equalization to some degree.

So the question is, why don't we have that in PhRMA, and, of course, it is because governments try to set the prices on which they are going to buy these drugs and that is at the nub, the problem.

Mr. Aldonas and the Commerce Department are trying to address that through free trade agreements, forcing these other countries to increase their prices, and he acknowledged that that is not going to happen with Europe and with Japan and even with Canada and Mexico because we don't have new agreements coming up and it is going to be difficult to convince them. So how do we get that equilibrium?

Another way to get that equilibrium is for the United States to upset the apple cart, in a sense. If the United States allowed safe importation from countries with equivalent drug regulatory systems, it will force the pharmaceutical companies, in a sense, to go back to Europe and to make the case, this time with transparent data, publicly available data, of, look, innovation is really being hurt, and not just stuff on their Web site that is not verifiable, but actual data that independent researchers can look at.

At that point, all of these arguments that are being made are essentially saying Europe is being foolish, and I think the Europeans

are a little more sophisticated than that. They are resisting because they don't have the data to make that judgment. If we allowed importation on a safe basis, I think we would, in a sense, create a revolution for markets in the European Union on drug pricing.

Mr. GOLDBERG. Mr. Chairman, may I respond?

The CHAIRMAN. I have run out of time. I have been a bit too liberal there, but perhaps someone else. I will be submitting some follow-up on that because I am not sure what over-innovative is, so I want to follow up on some of that.

Senator Burr.

Senator BURR. Thank you, Mr. Chairman, and I thank this panel. Your testimonies really have been enlightening.

Mr. Pollard, we can't thank you enough for being here. There are Blairites here, and those are great looking cufflinks, I will tell you.

Mr. POLLARD. Thank you.

[Laughter.]

Senator BURR. Mr. Outterson, you are a law professor.

Mr. OUTTERSON. Yes, sir.

Senator BURR. Let me say one thing about patents. A patent in the pharmaceutical world is triggered when an application to the FDA is submitted. There is no manufacturer outside of those that participate in the Orphan Drug Act that can, with some predictability, tell you how long their patent is going to be because it is dictated by how long the approval process is. So one drug may have 7 years left by the time it is approved, another one may have 11 years, another one may have three. That patent life is what dictates the price that they set for the recovery of their research and development.

As a law professor, I know that you have got a basis in U.S. Code, and U.S. Code specifically protects patents and intellectual property. And as it relates to drugs specifically, the TRIPS agreement, the Trade Related Aspects of Intellectual Property Rights, is in effect. U.S. patent law is in effect. The Food, Drug, and Cosmetic Act is very specific as it relates to intellectual property protection. The Prescription Drug Marketing Act of 1987 is very specific.

If we pass reimportation, we basically step on four pieces of legislation—five, excuse me—that clearly state U.S. law, and I think as Grant Aldonas alluded to and I agree with, it inherently comes out of the U.S. Constitution.

Are you willing, as a law professor, just to step all over that to achieve reimportation of drugs?

Mr. OUTTERSON. One word, no.

Senator BURR. Well, that is a relief to me from the standpoint of the law students that are coming out.

Mr. OUTTERSON. I could give a slightly longer answer if you want.

[Laughter.]

Senator BURR. Let me go to Canada, because you made a statement and I just want to try to clarify the truth. When Canada negotiates drug pricing, it is my understanding that Canadians say, "Here is the price we will pay. Your option is to sell to us at this price or we will take your patent and we will have a company somewhere else in the world make this compound and we will buy

it from them and, in fact, bypass your patent." I am not sure that that is how you portrayed it, that there is a negotiation that takes place.

In the United States, when you go into the VA, the VA does have a price target. But a company has another option. They can choose not to sell to them. They can choose not to sell them and know that their patents are still protected in this country because we do it across the board.

If you understand Canada to be different, please share that with me.

Mr. OUTTERSON. Canada formerly had a broad compulsory licensure statute which was really done away with in the process of them joining NAFTA. Canada, to my knowledge, is not exercising compulsory licensure with the exception that they have passed the Jean Chretien bill to permit it under the WTO Doha process only for utilization in the poorest countries of the world, which is something the U.S. agreed to.

You are right to say that when a government says, here is the price, take it or leave it, that it really is kind of the immovable force—the unstoppable force hitting the immovable object. You have a monopsonistic buyer, the government, and a monopolistic seller, the person with the patent, and what do you do in that situation?

I am not a fan within developed nations of rampant compulsory licensure. I think it is a mistake and I think you are right, that it does endanger unnecessarily patent rights. If we did it in the United States, it has to be done under the Fifth Amendment and 14th Amendment. Just compensation has to be given.

Senator BURR. I think if you ask Germans today whether, in fact, the German price policies on drugs have cost in innovation, they would tell you, yes, and it has also cost them jobs, because most of them have moved those research facilities here. I think Mr. Pollard is very wise at recommending to us that we not look at what they have done and make similar mistakes.

Mr. Chairman, I will ask one additional question to anybody on the panel. If we approve reimportation, what effect would that have on the products that are currently developed in this country under the Orphan Drug Act? Given that the Orphan Drug Act extends, for a predictable period of time, exclusivity because we ask innovators to create things for very small populations of Americans who need that drug, and on the economics of the amount of research and development it would cost, those drugs would not be created. We provide them with additional exclusivity to get those drugs made and those Americans to have products. What would happen if——

Mr. GOLDBERG. I can address that, Senator, because we have been talking about that on our task force. We talked to venture capitalists and here is an area where, despite Mr. Outterson's derision of peer-reviewed economic literature by people of Peter Price's economics, there is extreme transparency since you are supposed to, as he knows, his colleague, James Love, has looked at the orphan drug R&D, venture capitalists would pull out of the orphan drug market. Why? Because they have actually said so on the record, that if there was a hint of importation, it was a signal that

the government would be endorsing price controls and they would terminate their investment in the orphan drug market, even with the exclusivity, because the returns on the small market would be tenuous and insubstantial. That is the long and short of it. It is a high risk, unpredictable market even with the orphan drug incentives.

Mr. OUTTERSON. Very briefly, because I know we are restricted on time, many of these other nations have analogs to the Orphan Drug Act, and if Europe has the same link to protection on an orphan drug as we do, then the importation issue becomes—doesn't affect orphan drugs.

Secondly, orphan drugs really deserves its own hearing, I think, because the number of things that are getting orphan drug designation right now is tremendous. In June of 2004, the FDA gave orphan drug designation to Vioxx for juvenile rheumatoid arthritis. Vioxx, a drug, one of the best-selling drugs in the world.

Senator BURR. Well, you are right. That is for another hearing and I think we all would agree that the attractiveness in the Orphan Drug Act is the exclusivity, and I would only challenge you that if we say we are not going to protect patents or intellectual property on everything else and we turned around and said, "but we are going to on orphan drugs," why would they believe us? Why would Microsoft believe us if we ignored it on prescription drugs? Why would any company out there that looks at the safety and predictability of this country for their intellectual property protection believe us if every time we are forced to address something that is expensive, we choose to find a way to make it cheaper just by ignoring our own laws.

Mr. Chairman, I thank you.

The CHAIRMAN. Senator Isakson.

Senator ISAKSON. Thank you, Mr. Chairman. I will yield 1 minute to Dr. Goldberg, who had something to say a minute ago and got cut off, so Dr. Goldberg.

Mr. GOLDBERG. I just wanted to address this issue of transparency. First of all, the issue of transparency is important, and one of the principles—the fact of the matter is, there is ample public data on the cost in development of R&D. Our Federal Trade Commission just released a study saying that the estimate that it costs, with the opportunity cost built in of $182 million to bring a new drug to market, not just adding another coat of paint to it, was wrong. It is probably more. It is probably $865 million.

But there is another element to transparency, Mr. Chairman and members of the committee, and that is why European governments restrict access to new medicines. The principal driving element of our negotiations with Australia and the other European countries is they won't tell us, they won't tell us why they won't give people access to breakthrough drugs.

As Mr. Pollard says, with the NICE Commission, it is a black box. Again, my daughter has an eating disorder. I looked at the NICE guidelines for treatment of bulimia. They are the dark ages. It is nasty. If you have an eating disorder, you are given a pamphlet and then you are—the only drugs that they use to treat eating disorders is an SSRI. Now, I know that the standard of care for eating disorders is three different types of drugs, two of which

are not on the formularies in West Virginia, which is part and parcel of their way of using the VA pricing and drug pricing and Canada.

Why is that happening? There is an ample amount of literature, the clinical literature, which is peer reviewed, not paid for by drug companies, and to suggest that somehow, that the Commerce Department study is a rigged study because it is just paid for by the drug industry is disrespectful to the fine work of the Commerce study, the fine work of many clinical researchers, and it denies, ultimately denies patients the best care possible now and in the future.

Senator ISAKSON. Thank you. I will reclaim my time. I wanted to ask Mr. Outterson to make sure I understood something correctly, because I was listening and writing and I didn't have a chance to read.

I thought I heard you say it makes no difference what our price system is. Ultimately, the Europeans will bring the drug to the United States because of NIH, or something to that effect. Would you tell me what you meant by that?

Mr. OUTTERSON. I was probably speaking a little fast at that moment, seeing the clock tick on me. But what I meant to say, if I did indeed misspeak, was that these companies do the research and development on a global basis. These are global companies. And they market in the markets that give them the highest prices first, and then they market more slowly into places like Greece and Italy, who have lower prices. So that is why drug introductions are slower in those countries, because the price isn't quite as good, so they don't get around to introducing them right away. They wait a couple of years.

But the decision about where the research happens is not based on how valuable the market is because these pills are made in Ireland and Puerto Rico and shipped globally. The decision on where the research lab is is based largely on the fact that we have the NIH and we have a great human capital invested in the United States and the research institutions, the biotech companies, the universities, and they want to be near those people.

So if you want to increase more PhRMA research in our country, boost the NIH budget a little bit and they will put another research facility right next door. That was my——

Senator BURR. Thank you, but I just have to ask you, though, isn't your statement a ratification for a market-based system, because you just got through saying that most innovative drugs are going to go first to the markets where they can recover and last to those where they are so repressive. I think you used Greece as an example. And ultimately—price is a tremendously important factor for the constituents I represent, but so is life and health. And so how do you—I just wanted to—in that answer, it made a pretty good statement for market forces to work.

Mr. OUTTERSON. And I am in favor of market forces. The thing about slow introductions into Greece and New Zealand and places like that is that that is a company decision. It is not something given by chemistry. The company decides to introduce later in Greece because the process may be slower there, their version of the FDA, or they may not want those drugs to get on a truck and

come to England. So that is a company decision. If we had more rationalized pricing, market pricing, across the rich countries of the world, you would eliminate that incentive to slow down and introduce drugs more slowly in certain countries of the world. We should all be introducing these innovative, safe, effective drugs at the same time throughout the world. That would be best for the patients.

Senator BURR. My time has expired.

The CHAIRMAN. Thank you.

Senator Alexander.

Senator ALEXANDER. No questions, Mr. Chairman. I have been at the Budget hearing on Medicaid and Medicare and I just came to listen. I want to thank the witnesses for their appearance.

The CHAIRMAN. Thank you. I didn't get a chance to let Dr. Goldberg speak earlier, and I noticed you just had some reaction to what had just been said. Would you care to comment on that?

Mr. GOLDBERG. Maybe I have said enough, Mr. Chairman. I don't know.

The CHAIRMAN. Well, I——

Mr. POLLARD. If Dr. Goldberg doesn't, I would quite like to.

The CHAIRMAN. Okay.

[Laughter.]

Mr. POLLARD. I have to say that sort of flies in the face of the evidence of what has actually happened in Europe. Professor Outterson is quite right to say that these are complicated issues and that these are global drug companies and so on, but what matters is the general economic climate in which a company is operating.

In the European Union, for instance, we have seen a direct brain drain. I mean, there was a front cover of Newsweek, I think it was, 18 months or so ago on the brain drain in Europe, and it is a direct flight of some of Europe's most able scientists from Europe to the United States, and they are doing that not simply because they fancy the lifestyle here in the United States. They are doing it because companies, pharmaceutical companies, are leaving Europe and headquartering themselves in the United States.

Novartis, for instance, recently upped stakes from Europe and moved to the United States. The clear lesson—I mean, in Germany, employees who were working on high-level research in the last 11 years, from 1990 to 2001, fell by 36 percent, just at the same time as in the United States another 400,000 jobs were created, an increase of 52 percent, and that is a direct result of the flight from Europe to the United States.

If the United States wants to see a flight in reverse, as it were, from its own research base back to Europe or to elsewhere on the continent, then really, all it needs to do is copy what we have done in Europe. That seems to be what the professor is recommending.

The CHAIRMAN. Dr. Zycher.

Mr. ZYCHER. Thank you very much. Just a couple of very brief comments on my colleague, Professor Outterson's, presentation.

First, his argument that somehow if the Europeans had better data, they might be willing to pay more, is an argument that to me is a little difficult to take seriously, to put it mildly.

Second, implicit within the professor's argument is the premise that there are no complementarities economically between research and development activities, marketing activities, et cetera. I think that is wrong simply as a matter of the industrial organization of the sector.

And third, his argument that we really don't know whether there is too much or too little research and development going on similarly is a rather unappealing argument. If, in fact, there is too much R&D going on, that presumably would be because profits were so high that it would be attracting all of this capital in the industry. But we don't see that kind of massive entry into the sector. So I think, again, Professor Outterson's argument that there might be too much research and development going on, therefore, price controls might actually be efficient, again, is an argument that really is quite difficult to take seriously.

The CHAIRMAN. I suspect the brevity of a hearing like this, though, impedes all of you in your explanations, and in particular, Mr. Outterson, we will hope that you will provide us with a copy of the paper that you have done so that we can have the additional detail and benefit of that, as well.

We will leave the record open for another 10 days so that any of you can expand on your remarks and also so that we can submit some more questions. I have got at least four or five more questions for each of you, not counting follow-up that I might have. They are fairly technical in nature and I would prefer perhaps a more thoughtful answer to them than you might be able to give in the few seconds that we can do during a hearing, and I suspect that other members of the panel might have questions, as well.

I want to thank you all for the time and effort that you went to to provide us with this additional information and we look forward to yet more information that we can hopefully base some good decisions on that will help the American people. Thank you.

The hearing is adjourned.

[Additional material follows.]

ADDITIONAL MATERIAL

RESPONSE TO QUESTIONS OF SENATOR ENZI BY GRANT D. ALDONAS

Question 1. The Commerce Departments study concludes that price restrictions tend to have the most significant impact on the newest and most innovative medicines. Since the U.S. market does not impose price controls, consumers here pay higher prices than in the rest of the world. This results in U.S. consumers absorbing over 80 percent of R&D costs.

What can the Department of Commerce do to convince OECD members to contribute their fair share to R&D costs?

Answer 1. Our objective is to encourage these governments to create a transparent environment where they work with industry, through formal dialogue, to reach mutual objectives on appropriate levels of care for their citizens at a price that the government and patients can afford.

Our approach has been to ask host governments to hold meetings with innovative producers. We urge that meetings include representatives of all ministries whose responsibilities are affected by drug pricing decisions. I have often found that ministries with healthcare expertise, like Health Ministries, are not aware of the impact their decisions have on trade, the economy, and innovation. As a result, we always ask that the Ministries of Finance, Economics, Trade, and Health, as well as the Prime Ministers' offices, participate.

We have had some positive results using this approach. We successfully addressed concerns in Austria by calling together such a group. We have also raised pricing, reimbursement, access, transparency, and intellectual property issues in Germany, Denmark, Italy, Poland, and Portugal in interagency meetings.

Question 2. Various studies comparing drugs show that Americans appear to pay higher prices for some drugs than consumers in other parts of the world. The U.S. International Trade Commission 2001 report highlights many of the reasons U.S. prices differ from those of other countries. Differences in wealth, purchasing power, insurance coverage, product liability coverage, exchange rates and drug coverage policies all can have an impact on pricing in various countries. Price controls prevent the market from reflecting the true value of drugs.

If foreign prices were allowed to reflect the true value of drugs, would a free and open market adjust accordingly?

Answer 2. If price controls were eliminated, a price adjustment would take place. This study assumed that relative levels of per capita income determine variances in prices among developed countries. Further research would be required to determine the likely impact of other factors, such as product liability coverage, insurance coverage and exchange rates, on prices.

Question 3. The Administration has addressed market access and price control issues in the pharmaceutical sector, especially in the U.S.-Australia Free Trade Agreement. Your report demonstrates that price controls in developed countries impede access to state-of-the-art medicines, undermine global research in life-saving drugs, and unfairly shift the burden of developing new drugs to American citizens. The Medicare Modernization Act calls for the Administration to develop a strategy to address these price control practices in OECD countries. What do you see as the elements of an effective strategy, and what is the Administration doing to implement such a strategy?

Answer 3. With other agencies in the Administration, we are looking at the details of the Commerce study and the follow-up public debate in order to develop a coordinated strategy. We intend to strike a balance between supporting continued R&D and innovation in the pharmaceutical sector and ensuring access to innovative pharmaceuticals. In addition to any new actions we may decide to take, we will continue to encourage governments to consider the benefit to the health of their citizens and their economies that result from creating and preserving sound economic incentives and a competitive environment in which to develop and market new health technologies.

RESPONSES TO QUESTIONS OF SENATOR KENNEDY BY GRANT D. ALDONAS

Question 1. Given Professor Outterson's testimony, did the Free Trade Agreement with Australia succeed in raising drug prices in Australia?

Answer 1. The Free Trade Agreement (FTA) does not require Australia to increase pharmaceutical prices. Instead, the pharmaceutical provisions of the FTA set forth shared principles, like the importance of research and development; of recognizing

and appropriately valuing the therapeutic benefit of innovative drugs; and of transparent, expeditious, and accountable procedures. Australia agreed to make improvements in its Pharmaceuticals Benefits Scheme (PBS) to enhance transparency and accountability in the operation of the PBS. The FTA establishes a Medicines Working Group to further promote the agreement's public health principles through an ongoing dialogue between the United States and Australia. No data are yet available on whether the FTA has had an impact on prices in Australia, and evaluating the potential impact may be difficult because drug prices are affected by factors not directly related to the FTA.

Question 2. The Commerce Department Report states that price controls in OECD countries lead to decreased revenues to the pharmaceutical industry, which in turn leads to a decrease in R&D expenditures and a subsequent loss of new molecular entities available to the U.S. market. The Report also states that the loss of revenues also decreases competition in the drug market, which could indirectly raise U.S. prices.

On page 24, the report suggests that OECD countries should adopt policies similar to the U.S. to increase the availability and decrease the cost of generic drugs, stating, that this study estimates that total savings for these 11 OECD countries would have ranged between $5.2 billion and $29.6 billion in 2003, depending on the volume measure. This range of potential savings suggests that if prices of on-patent drugs were to rise to competitive market levels, then the additional cost to OECD countries could be significantly or fully offset by a more competitive generic market.

Would the decreased revenues to the drug industry from the switch to generics lead to the same untoward effects on R&D and competition that the Report attributes to price controls, or would it at least offset the gains in R&D that the report identifies?

Answer 2. The report studied the impact drug price controls have on the patented and generic drug markets separately, allowing no interplay between the two markets. It would be reasonable to conclude that increased spending on generic drugs would reduce revenues from innovator drugs (after such drugs lose their patent protection), and that the increased generic competition could offset some gains in R&D spending estimated in this report, at least in the short-term. However, the deregulated market would likely result in increased expectations of returns on newly developed drugs, and greater R&D investment based on those expected revenues. In considering whether to research and develop new products, drug company executives compare the expected present value of net revenues from such investments with their expected costs. Greater use of generics may adversely affect the expected value of net revenues but this effect would likely be modest because it appears far in the future and because those future revenues are much more uncertain than revenue changes during the patent term.

Overall, it is likely that increased R&D spending associated with the increased revenues from new drugs while they are patent-protected would be offset somewhat by the short-run reduction in revenues from generic competition (and any concomitant effect on R&D spending).

The study estimated that the potential savings from greater generic drug utilization was in the range of $5 billion to $30 billion dollars. This estimate is based on a shift in usage of off-patent branded and unbranded drugs. The study found that off-patent unbranded[1] drugs in the United States are used more frequently and have lower prices than in comparison countries. Therefore, using the off-patent unbranded generic drug market in the United States as a benchmark, the report estimated a counterfactual situation where comparison OECD countries allow greater generic drug competition that would lead to an increase in the utilization of off-patent unbranded generic drugs at lower prices.[2] This resulted in an estimate of potential savings from shifting within the off-patent drug market.

Question 3. The Report uses U.S. prices as the benchmark for deregulated competitive market levels. Can you explain how the U.S. prices were calculated? Is that the price charged to the uninsured in the U.S. or the average price paid in the U.S.—taking into account prices paid by people with insurance, drug cards, or coverage through government programs? Is it the policy of the Administration to encourage all people, in America and abroad, to pay the price paid by the uninsured

[1] Off-patent unbranded generic drugs are drugs that are marketed under a molecular name rather than a brand name.

[2] U.S. off-patent unbranded generic drugs were used as a benchmark for the new off-patent unbranded generic drug prices in comparison to OECD countries.

person in America who has no one—whether a benefit manager or a government official—to negotiate a lower price for them?

Answer 3. U.S. drug prices were estimated by dividing total manufacturing sales for each active ingredient or molecule by total volume sold for that active ingredient or molecule. The result of this calculation is an estimate of the U.S. manufacturers selling price to wholesalers. The price paid by the uninsured is the public or retail price, which would include mark-ups on the manufacturers selling price to wholesalers and mark-ups on the wholesaler selling price to pharmacies. Manufacturers selling prices rather than wholesalers or pharmacies selling prices were used to make the price comparisons because they offered a more reliable basis for comparing drug prices internationally. If wholesaler or pharmacy selling prices were used, the study would have had to adjust them for differences across countries.

RESPONSE TO QUESTIONS OF SENATOR ENZI BY ROBERT M. GOLDBERG

Question 1. Many innovative drugs are not available in Australia because of PBS pricing policies. Most innovative drugs are not available in Australia for several years following their launch in the U.S. The process for getting a drug on the PBS is onerous, time consuming and bureaucratic.

Pricing is only part of the Australian PBS schedule. The schedule also includes strictly enforced prescribing restrictions that cover most innovative products. For example:

• Merck's osteoporosis drug Fosamax is only available to women who have suffered a fracture. The fracture must be proven to be a result of low bone mineral density.

• The Novartis drug Gleevec, which treats Chronic Myeloid Leukemia, is restricted by an enforced "stopping rule." The stopping rule requires a patient to sign a legally binding agreement that allows the Government to discontinue their access to Gleevec after 6 months if they do not "respond" to the drug. The patient's response is measured by a technical test. The patient can fail the test even if they no longer show symptoms, have returned to work or enjoy an overall better quality of life.

Is this really the sort of system Americans would be satisfied with?

Answer 1. Americans now receive widest access to the newest and best medicines faster than any other group of people on the planet. They would revolt against such rationing. Further, rationing of such products overseas translates into limited quantities for importation should it come to pass.

Question 2. As you are aware from Mr. Aldonas's testimony, price controls reduce company compensation to levels closer to direct production costs, leaving less revenue for R&D. According to the Department of Commerce report, "As OECD countries individually seek to reduce spending on drugs through price controls, their collective actions reduce R&D that would provide substantial health benefits."

Considering these statements, how do you suppose importation may affect patients' "health benefits" in the United States?

Answer 2. Given that EU is seeking to eliminate wide price variations among member states to do away with parallel trade because of the impact it has on R&D—in an effort to boost over all prices—we can only assume that the importation of European prices controls will hurt R&D here.

Question 3. The vast majority of biotechnology companies do not have products on the market; rather, they have patents on what may eventually become a commercially viable product or technology. The capital generated as a result of this intellectual property supports companies as they invest hundreds of millions of dollars over decades to develop a commercial biotechnology product.

Government instituted price controls essentially remove a fundamental tenet of patent law, the right of the innovator—not the government—to determine price of the product.

How might a system of importation be implemented while still protecting the rights of patent holders?

Answer 3. Importation violates patent rights two ways . . . it tells the owner of the patent it can't determine who it can sell it's products to and it can't set the terms of the sale. Rather, it allows the government to hand those rights over to distributors and wholesalers and foreign ministries without due process or compensation.

Question 4. New medicines have produced the biggest gains in well-being and life expectancy compared to most other medical goods and services. It was for this very

reason that we passed the MMA last Congress and added prescription drug coverage to Medicare. You reference in your testimony a report the Manhattan Institute commissioned regarding the impact of European and VA price controls on medical innovation and access to new medicines in the United States over the next 25 years. The researchers found that R&D spending will drop by nearly 40 percent over the next 2 decades, resulting in a loss of nearly $300 billion in R&D and 277 million life years.

Based on the findings of the study you reference in your testimony, what are the possible long-term impacts of legalizing commercial importation in the United States?

Answer 4. Legalizing commercial importation is the quickest way to ship our biomedical industry overseas to places like India which just reaffirmed its commitment to international patent treaties and is increasing investment in pharmaceutical R&D by 400 percent over the past 4 years. The idea that prices have no effect on R&D is now being floated as an excuse for removing the non-interference clause and imposing importation. Why then is Europe stating that it is seeking to do away with price controls and importation to boost R&D?

RESPONSE TO QUESTIONS OF SENATOR HATCH BY ROBERT M. GOLDBERG

Question 1. Without a doubt, medical innovation thrives because of America's free market pricing. As you noted, it is our entrepreneurial character as a Nation that Americans have avoided price controls as a cost-saving measure.

How might we encourage price-controlled countries to embrace our country's market-based approach, rather than focusing on short-term fixes?

Answer 1. As noted above, the European Commission is seeking to roll back price controls and improve access to new medicines in part because of the success of our free market approach to innovation and the growing competitiveness of countries like India, Singapore and Korea in attracting and retaining scientific minds in developing their biotechnology industries. Individual countries in Europe need to understand that access to new medicines actually reduce total health care spending and promote better health. Our USTR, in coordination with Medicare's Mark McClellan and the Department of Commerce should produce studies demonstrating how many countries in Europe, by restricting access to American products are costing European countries money and lives.

RESPONSE TO QUESTIONS OF SENATOR KENNEDY BY ROBERT M. GOLDBERG

Question 1a. The Department of Commerce Report suggests that the increased prices of name-brand drugs in Europe could be offset by reduced prices (and increased utilization) of generic drugs.

Do you agree with that assessment?

Answer 1a. Yes . . . appropriate generic use, particularly in the treatment of cholesterol, hypertension and depression could reduce total health care costs in Europe as it has in the United States.

Question 1b. How much could Europe save with increased generic use?

Answer 1b. Currently a country like Germany spends up to 20 percent more on generic drugs than they would if it introduced generic drug competition. At the same time, it limits access to newer medicines for similar disease, restricting a broader range of treatments that are necessary to treat individual differences in illnesses and in recognition of the fact that not every one responds the same way to the same medicine. Suboptimal therapy and side effects cost every health system billions.

Question 1c. Would increased generic savings impact innovation?

Answer 1c. Increased generic savings can provide an additional and cost-effective addition to the range of treatments doctors can offer patients.

Question 2. Would you agree that increased utilization of pharmaceuticals is beneficial to health status?

If so, should the Health and Human Services and Department of Commerce Reports have estimated the positive health impacts of increased consumer access to drugs due to lower prices? Should comparative effectiveness play a role in approval or R&D or marketing incentives?

Answer 2. The Commerce Report could have demonstrated, based on a large body of evidence that increased use of new medicines allows people to live longer,

healthier, more productive lives, with reducing the total cost of treating disease. Comparative effectiveness is not the best way to evaluate medicines post market. Rather companies should, perhaps as a precondition for remaining for Medicare reimbursement, provide data of its value as part of a total approach to therapy for a specific patient population. To this end, companies would have a strong incentive to provide patient level data, including outcomes and pharmacogenomic data that could be used to determine a drug's safety and effectiveness in new uses and in future clinical trials.

QUESTION OF SENATOR HATCH TO RICHARD CARMONA

Question 1. You mentioned that there are significant safety concerns regarding drug importation, but if Congress wants to legislate a system, it should be closed, well-defined, and capable of ensuring the pedigree of the drugs.

While these seem to be valid principles if there were to be an import regime, I am concerned about the practicality of designing a system to meet those requirements. Could you elaborate on what you meant by a closed system? For example, would other countries have to participate? If so, how would the U.S. negotiate the agreement with those other countries? How would this be enforced? Similarly, what are the ways in which the U.S. would go about ensuring that pedigree?

The enforcement mechanism is also of great interest to me, especially in reference to Internet pharmacies. Could you please advise the committee as to how the Internet marketplace could be policed so that American consumers could be assured about the safety, efficacy and pedigree of the consumers they are receiving? In the United States, for example, pharmaceutical manufacturing plants are registered and regularly inspected, pharmacies are licensed, etc. Would those same regulatory safeguards exist with respect to products distributed through Internet pharmacies.

Answer 1. Response unavailable.

QUESTION OF SENATOR HATCH TO TIM PAWLENTY

Question 1. I understand from your testimony that Canadian pharmacies on the Internet require customers to sign a waiver absolving the pharmacies of any liability. These waiver forms routinely make U.S. customers waive many other rights, such as the right to privacy, the right to consult a qualified pharmacist, the right to child-proof packaging, and any warranties that the drugs are safe and effective.

Many of these requirements are well-established tenets of U.S. practice and law. For example, the right to privacy of medical information was established by HIPAA, an act passed overwhelmingly by the Congress. The U.S. standard of safety and efficacy for pharmaceuticals is the hallmark of our country's drug approval system, and a requirement that has led many to call our system the "gold standard" of the world.

My questions are this: Why should Minnesota consumers be required to waive these important requirements, requirements that largely apply to the purchase of pharmaceuticals in other states? Have you developed any information, such as public education or surveys, to gauge the measure to which your residents are aware of these important rights and the fact that they are entering into legal agreements to waive them, agreements that would in effect make the consumers responsible for the potentially hazardous results of safety problems?

Answer 1. Response unavailable.

QUESTION OF SENATOR HATCH TO ROBERT GOLDBERG

Question 1. Without a doubt, medical innovation thrives because of America's free market pricing. As you noted, it is our entrepreneurial character as a Nation that Americans have avoided price controls as a cost-saving measure.

How might we encourage price-controlled countries to embrace our country's market-based approach, rather than focusing on short-term fixes?

Answer. Response unavailable.

QUESTION OF SENATOR HATCH TO STEPHEN POLLARD

I appreciated your insights on European healthcare issues as they relate to prescription price controls and parallel trade. I agree that every developed Nation has something unique and important to add in the field of medical research. Your com-

ments about price controls and how the European governments are imposing costs on the developing world were particularly interesting.

Could you explain how the supply of medicines to lesser-developed countries is affected by price controls on prescription drugs?

Answer. Response unavailable.

RESPONSE TO QUESTIONS OF SENATOR ENZI BY KEVIN OUTTERSON

March 18, 2005.

U.S. Senate,
Committee on Health, Education, Labor, & Pensions.

DEAR CHAIRMAN ENZI: Thank you for the opportunity to testify before the Committee, and for your written questions.

Drug importation should not be opposed on innovation grounds. The OECD Drug Pricing Report [1] grossly overstates the negative impact that lower prices would have on innovation, and dramatically misses the main point: that lower prices would help U.S. consumers by improving access to needed therapies. Where is the estimate of the number of Americans who would benefit from being able to afford their medications?

I also continue to challenge the USTR strategy to raise drug prices abroad, particularly with regard to developing countries. This is a terrible idea for global health, and unnecessary on innovation grounds. As for raising prices in the OECD, perhaps the USTR can articulate its strategy, given my written testimony previously offered to the committee. The experience with the Australian free trade agreement appears to have been counterproductive on this score.

These are complex issues with important consequences for health and trade. I would be willing to explore them in more depth, at your convenience.

Please let me know if you require anything further.

Best wishes,

KEVIN OUTTERSON,
Associate Professor of Law,
West Virginia University.

Question 1. Germany employs reference pricing for statins, cholesterol-lowering drugs taken by millions of Germans. Due to cost pressures on the system, and the expiration of the patent of one drug in the statin class, reimbursement for Lipitor is now so low that the manufacturer cannot have the drug participate in the national health system. In theory, patients can pay the full cost of the drug, but in practice only reimbursed products are prescribed by doctors and sought by patients. Unless these state-insured patients can pay for the full cost of the drug out of pocket, 1.5 million Germans will lose access to Lipitor.

Do you think we will see more of this, as price controls get tighter and tighter? Do you believe Americans would accept a system whereby they could lose access to a drug they have come to depend on?

Answer 1. The statin class includes several drugs with similar modes of action and FDA approved uses. The fact that we have choices among statins is exactly the reason Pfizer faces competition and must negotiate for price.

Germany's position is no different in principle from the U.S. Medicare Part D plans which will negotiate to include only 2 or 3 statin drugs in their formularies. U.S. commercial managed care plans and PBMs also routinely exclude some drugs from formularies, or subject them to prior approval or tiered co-pays. This is a normal part of the price negotiation between the drug companies and the payors. I suspect that Pfizer and Germany will negotiate a mutually agreeable price.

Question 2. The Australian Pharmaceutical Benefits Scheme (PBS) is subject to significant public criticism because patients are often denied access to modern and innovative therapies. Many innovative products for the treatment of chronic and debilitating conditions are either not available, or their availability is restricted and many patients that would benefit are denied access. In addition, prices for generic medicines in Australia are high—approximately 70–90 percent of the brand price. You advocate U.S. states adopting the Australian pricing scheme. Will States really

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[1] Pharmaceutical Price Controls in OECD Countries: Implications for U.S. Consumers, Pricing, Research and Development, and Innovation (U.S. Department of Commerce, International Trade Administration, Dec. 2004).

want to adopt the Australian pricing schedule, including increased prices for generics?

Answer 2. I have divided the question up into parts in order to respond fully:

Question 2a. The Australian Pharmaceutical Benefits Scheme (PBS) is subject to significant public criticism because patients are often denied access to modern and innovative therapies.

Answer. 2a. The PBS has not been subject to significant public criticism in Australia. The pharmaceutical companies certainly are critical, but the PBS enjoys remarkable public, political and professional support within Australia.

I queried an email list of leading Australian pharmaceutical specialists, and they were unaware of any evidence of significant criticism by the public. The PBS enjoys remarkable support from all major political parties in Australia, as was demonstrated in the last election.

Legislation creating the PBS arose from a constitutional referendum in which a majority of Australian citizens in all States voted for its protection of their access to affordable, essential medicines. That legislation was eventually ruled constitutionally valid by the High Court, the Australian equivalent of the U.S. Supreme Court.

Support for the PBS is also very strong within the medical profession. The following is a quote from the Royal Australasian College of Physicians, *Response to a Public Consultation Document (25 July 2004) Australia-United States Free Trade Agreement, Implementation of the Obligations to Improve the Transparency of the Pharmaceutical Benefits Scheme* (16 August 2004):

> It is the concerted view of the College that all Australians should continue to have affordable and timely access to essential medicines. This reflects the College's broader commitment to the principle of equity in the financing and delivery of health care services in Australia . . .
>
> The PBS is a scheme that is much admired worldwide: both for its equitable delivery of medicines to all Australians, and (despite current concerns) for its proven record of containing costs relative to the drug expenditures of other highly developed countries . . .
>
> The College rejects the proposition that the PBS restricts pharmaceutical industry innovation and profit through the undervaluing of research and development and market distortion. (at 2)
>
> It is the College's view that all information submitted to PBAC by a drug sponsor be placed in the public domain. This would facilitate clinical decisions by physicians that are based on the best available evidence. (at 4)

Question 2b. Many innovative products for the treatment of chronic and debilitating conditions are either not available, or their availability is restricted and many patients that would benefit are denied access.

Answer 2b. I queried leading Australian specialists in pharmacy and public health, including government officials, and they were unable to provide a list of any such medications. If PhRMA or Medicines Australia were willing to provide a list, then I could respond directly.

As one Australian expert put it:

> I would feel confident to say that there are no drugs that are more effective than an alternative AND are cost-effective at the requested price AND have been submitted to PBAC that are not available to Australians at a subsidized price. There are drugs that are approved by the TGA for a given condition but are not subsidized by the PBS because they are not cost effective for that condition (compared to the therapy that would otherwise be used). But again there are very few of these. And I would like to see the list!!! So in summary—show me the list . . . and I will eat my proverbial hat.

A second Australian expert offered the following explanation:

In general, if a drug company is unhappy with the price or other terms offered by Australia for any drug, they are free to renegotiate, particularly if new evidence of the cost-effectiveness of the drug is available. The AUSFTA also provides an independent review process for these decisions. If drug companies have a specific complaint about a particular drug, they should exhaust their available processes and remedies under Australian law rather than make general, unsubstantiated complaints to the U.S. Senate.

Also many medications that are very specific and expensive are either available through public hospitals (such as antiretrovirals) or under a special access S100 scheme and are thus still paid for out of the public pocket (a bit more complicated as the public hospitals are funded by State level governments and not the Federal

Government). An example I used recently was accessing sufentanil for a palliative care patient at home, this was obtained by the local public hospital pharmacy and presented to him at no cost even though it is not available on the PBS. An example of a medication available in Australia but not subsidized by the PBS would be the Anti-Alzheimer's medication Ebixa (Memantine), if the doctor is willing to prescribe it and the patient is willing to pay the $150–180/month then it is freely available (mostly because Lundbeck has applied in the last 2 rounds for the medication to be listed on the PBS but been rejected for what I understand to be "insufficient cost benefit ratio").

A third Australian expert has provided some additional information about access under the PBS follows, which may further answer the question:

This frequently cited criticism of the PBS from the pharmaceutical industry arises from a selective analysis of the Australian pharmaceutical market. In fact, applying the economic definition of access, one can show that access to modern innovative medicines in Australia is far greater than that in the U.S. For a product to be accessible to consumers it needs to be:

1. Available for sale on the market, AND
2. Available at a price that all consumers who may gain a benefit from it, can afford.

Criterion 1. All products passing TGA safety and efficacy approval (equivalent to the FDA process), are available for purchase by consumers in the Australian market, at the price set by producers free of any price controls. This is comparable to the U.S. Virtually all products available on the U.S. market are also available for sale in Australia. The 2001 study by Australia's Productivity Commission also found that the PBS process does not delay the launch dates of new innovative medicines in comparison to the U.S. and other OECD countries:

For most countries, there is no significant difference in the delay between the global launch and the local launch. For example, the delay between the global and Australian launch dates is an average of 2.6 years for all categories. This is similar to the results for France, the U.S., Spain, Canada and NZ. (PC 2001, p. 85)

Therefore access to modern innovative medicines in Australia is at least equivalent to that in the U.S.

Criterion 2. Pharmaceutical access in Australia is further expanded by addressing financial impediments to products deemed essential and cost effective. PBS listing subsidizes the cost of medicines to ensure universal access to modern innovative medicines deemed essential and value for money by a panel of experts. All U.S. citizens without access to a drug insurance benefits plan therefore have less access to modern innovative medicines, than do Australian consumers. If a product is determined to be uneconomical relative to cost, by a panel of experts and fails PBS listing, Australian consumers can still access the product by purchasing it on the private market. Consumers who have private health insurance may have part of the cost of these medicines refunded by their insurer; other consumers will pay the full market cost of the product. The lack of PBS listing is not a denial of access but a restriction on the availability of taxpayer subsidies for medicines deemed by experts to be uneconomic.

Additionally, the PBS Schedule is extensive with all available modern innovative and essential drugs listed for subsidy. If a product is not listed it is because a therapeutically equivalent product is listed for subsidy at a cheaper price.

Question 2c. In addition, prices for generic medicines in Australia are high—approximately 70–90 percent of the brand price.

Answer. 2c. The reason that generic medicines are close in price to brand name medicines is not that the generics are expensive in absolute terms, but that the brand name medicines are relatively cheap. They are cheap mainly because the Pharmaceutical Benefit Advisory Committee employs stringent cost-effectiveness criteria to get the best value for their money. Please see *http://www1.health.gov.au/pbs/* for an online list of current medication prices in Australia. Generics may be priced at 70–90 percent of the cost of brand name drugs, but both prices are really cheap in absolute terms.

A number of institutional factors influence generic drug prices in Australia. Generic manufacturers in Australia face limited economies of scale due to the small size of the Australian market and intellectual property law that limits Australia's ability to export to developing countries in the region while a patent is in force in Australia, but not in the destination country. One measure which has been recently put forward would encourage competitive prices in the open international tendering for PBS generic medicines.

The narrow gap between PBS brand name and generic prices mainly relates to me-too drugs rather than truly innovative therapies. Reference pricing in the PBS

narrows the price differential between therapeutically equivalent generics and patented me-too compounds. Rather then being a weakness, this pricing approach should result in a more efficient outcome in the allocation of R&D resources by rewarding product innovation above product differentiation.

For example, the Productivity Commission's study in 2001 found price differentials between Australia and the U.S. were large for me-too drugs, and smaller for innovative medicines (PC 2001).

Question 2d. You advocate U.S. States adopting the Australian pricing scheme. Will States really want to adopt the Australian pricing schedule, including increased prices for generics?

Answer. 2d. I do not advocate the wholesale adoption of the Australian PBS by the United States, or by particular U.S. States.[2]

I have argued on several occasions, however, that the Australian PBS is an excellent model, because it pays for value.[3] If a drug company demonstrates that the drug is highly cost-effective over existing therapies, the PBS pays more for it. If the drug is a relatively modest addition to an existing class of medications, the PBS will reimburse at the same level of other drugs in the class. The PBS pricing system rewards product innovation above product differentiation. If the U.S. adopted a similar system we would have more innovative drugs and fewer me-too drugs.

PBS pricing also reduces the rewards for strategic patent games designed to evergreening existing blockbusters beyond 20 year patent terms. If a generic in a therapeutically equivalent class exists all products within that class are priced at comparable levels regardless of patent status.

Paying for value is an excellent idea for U.S. health care markets. The Centers for Medicare & Medicaid Services (CMS) are experimenting with paying for value and quality in several areas, as are many private payors.

If U.S. payors adopted an economic evaluation system, it is beyond doubt that significant savings would ensue, even if generic prices rose. An even more favorable pricing result would be to adopt economic evaluation for patented products, but retain current U.S. pricing for generics.

Question 3. Implementation of price controls will not create a corresponding reduction in drug development costs. It will still cost the same to discover, test, validate through clinical trials, manufacture and ultimately market a new product. The costs will remain the same, but the potential return will be greatly diminished if there are price controls.

Do you believe that in the face of price controls, companies will limit their development efforts to those drugs that have the highest potential profitability? And that this limitation could have the greatest negative impact on drug candidates—such as orphan drugs—that, while they have the potential to help many patients, are not market "blockbusters?" Is a free-market pricing system more favorable to smaller market products?

Answer 3. I will divide this question up into two parts:

Question 3a. Do you believe that in the face of price controls, companies will limit their development efforts to those drugs that have the highest potential profitability? And that this limitation could have the greatest negative impact on drug candidates—such as orphan drugs—that, while they have the potential to help many patients, are not market "blockbusters?"

Answer. 3a. We do not have the data to adequately answer this question. All major studies on pharmaceutical company response to modest changes in revenue are based ultimately upon data provided by the companies themselves. I have suggested in my testimony before this committee and in other articles[4] that we should not rely on this data, but should have access to transparent, audited data for this important public policy.

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[2] For my published comments on price controls and the Australian PBS, *see* Kevin Outterson, *Pharmaceutical Arbitrage: Balancing Access and Innovation in International Prescription Drug Markets,* 5 Yale J. Health Policy, Law & Ethics 193, 238–241 (2005).

[3] *See. e.g.,* Kevin Outterson, *Agony in the Antipodes: The Generic Drug Provisions in the Australia—U.S. Free Trade Agreement,* 2 Journal of Generic Medicines (pending, Spring 2005); and Kevin Outterson, *Free Trade in Pharmaceuticals,* 181 Medical Journal of Australia (Sept. 6, 2004, pp. 260–261).

[4] Kevin Outterson, *The Transparency Revolution in PhRMA Pricing,* 10 PhRMA Pricing and Reimbursement 4–9 (IMS Health, Cambridge, Jan. 2005); Kevin Outterson, *Pharmaceutical Arbitrage: Balancing Access and Innovation in International Prescription Drug Markets,* 5 Yale J. Health Policy, Law & Ethics 193, 217–222 (2005).

However, common sense would suggest that drug companies would cut their least valuable projects first. Innovative, blockbuster drugs would continue to be developed; marginal me-too drugs might get less funding.

As for orphan drugs, the Internal Revenue Code and FDA law provide many direct and indirect incentives for the development of orphan drugs. (Orphan drugs are an increasingly disparate category. In June 2004, the FDA approved Vioxx as an orphan drug for certain juvenile conditions). These incentives are expected to continue in any event.

Question 3b. Is a free-market pricing system more favorable to smaller market products?

Answer 3b. It is a mistake to characterize our present pharmaceutical system in the U.S. as "free market." Tens of billions of dollars in government grants flow into the system to stimulate basic research through the NIH and other sources. The patent system itself is a severe distortion of the market, designed to address the appropriation problem with investments in knowledge. Billions of dollars in tax credits and incentives are offered in the Internal Revenue Code. Additional market exclusivities are offered under the Orphan Drug Act and for pediatric testing, among others. Yet more incentives are proposed under BioShield II. FDA marketing approval rules delay market entry pending review of safety and efficacy.

On the pricing side, mandatory rebates in Medicaid, FSS pricing in the VA, 340B pricing in the Public Health Service, and many other special programs demand and receive concessionary pricing. Pricing transparency in PBMs and private insurance plans is quite limited (free markets typically imply transparent prices). Information disparities are rampant. Intellectual property rules prohibit parallel trade. FDA rules block global pharmaceutical competition through pricing arbitrage. Other examples could be given.

I don't know any responsible economist who would describe the U.S. pharmaceutical system as a "free market."

Question 4. In your written testimony you state some countries should be characterized as "fair followers" and not "free riders." If it is fair for developing countries to not pay for the development costs of pharmaceuticals generally, what incentive would exist to develop pharmaceuticals that are needed to treat diseases that are endemic in developing countries?

Answer. 4. It is clear that the present patent system offers very little incentive to research and develop drugs for conditions which are endemic only in developing countries. (Usually called "neglected diseases").[5] The poverty of the potential customers blocks a normal commercial market for these drugs. Almost everyone, including the major drug companies, would agree with this statement. The question is what we should do about it.

In response to the failure of the commercial patent system for neglected diseases, many public-private cooperative ventures have been established to focus R&D dollars on neglected diseases. Donors include governments, multilateral agencies, and private sources such as the Bill and Melinda Gates Foundation. Michael Kremer's group at Harvard has suggested offering global prizes and purchase commitments for successful R&D into neglected diseases.[6] Other researchers, such as Jean Lanjouw at Brookings and Alan Sykes at the University of Chicago suggest modifications to the patent systems of developing countries to encourage neglected disease innovation.[7] The eminent economist F.M. Scherer has stated that developing countries should be allowed to be "fair followers" on pharmaceutical innovation.[8] My own views on these subjects were published in February 2005 in the Yale Journal

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[5] *See* Global Forum for Health Research, "The 10/90 Report on Health Research 2003–2004" ("health research has suffered from an overall lack of funding and from a huge discrepancy between the allocation of research funding and the diseases or conditions that account for the highest global disease burden . . . less than 10 percent is devoted to research into the health problems that account for 90 percent of the global disease burden . . .").

[6] Michael Kremer & Rachel Glennerster, "Strong Medicine: Creating Incentives for Pharmaceutical Research on Neglected Diseases (2004); Michael Kremer, *Creating Markets for New Vaccines: Part I: Rationale & Part II: Design Issues, in* 1 "Innovation Policy and the Economy" 35–109 (Adam B. Jaffe et al. eds., 2001).

[7] Jean O. Lanjouw, "A Patent Policy Proposal for Global Diseases" 4 (The Brookings Institution, Working paper No. 84, 2001); Alan O. Sykes, *TRIPS, Pharmaceuticals, Developing Countries, and the Doha "Solution,"* 3 Chi. J. Int'l L. 47, 56–62 (2002).

[8] F.M. Scherer, *A Note on Global Welfare in Pharmaceutical Patenting,* 27 World Econ. 1127, 1141 (2004).

of Health Policy, Law & Ethics [9] and in September 2004 in Pharma Pricing & Reimbursement, published by IMS Health.[10]

In addition to neglected diseases, many "Western" conditions such as heart disease, AIDS, diabetes and cancer are increasingly common in the developing world. The markets of the OECD members are sufficient to sustain robust innovation in these conditions. Extending the pharmaceutical patent system to low-income populations for these "global diseases" will be both cruel and unnecessary: cruel because we know the higher prices under a patent system will discourage medically necessary use and encourage counterfeiting; unnecessary because OECD markets alone are sufficient to stimulate innovation and very little additional R&D will be stimulated by these low income markets. For a longer description of this particular issue, please see my submission to the WHO in January 2005.[11]

The USTR pursues many strategies which limits the sale of drugs at marginal cost of production for global disease conditions in low income settings worldwide. These policies damage static human health, but are allegedly supported on innovation grounds. The basic "fair followers" argument is that the USTR strategy is not important to global pharmaceutical innovation, and so it should yield to the pressing needs of global human health.

RESPONSE TO QUESTIONS OF SENATOR ENZI BY BENJAMIN ZYCHER

Question 1. As I am sure you are aware, every free trade agreement that the United States has signed recognizes the importance of allowing legitimate domestic regulation. Both WTO agreements as well as NAFTA explicitly permit governments to restrict imports for a number of important purposes, like protecting public health and safety, and national security. Do you believe that permitting importation of pharmaceuticals from foreign nations works against such trade agreements?

Answer 1. Throughout the postwar GATT and more recent WTO negotiating rounds and through the NAFTA process, the central purpose of liberalized trade has been the improvement of economic productivity and thus the long-term well-being of consumers. That improvement is achieved through the reduction of artificial barriers to efficient resource allocation, so that individuals, firms, and economies can exploit both their own comparative advantages and those of others as well. In short: The central goal of free trade agreements is an expansion in the value of overall economic output, and so a reduction in the aggregate level of real prices. International trade in pharmaceuticals is fully consistent with that goal, subject to safety and other public health considerations,[1] and subject to the absence of other policies that might obviate the gains that trade otherwise would yield. In the context of the international pharmaceutical market, foreign price controls are foremost among such perverse policies. Because of the basic economic conditions of pharmaceutical development and production—for the most part fixed costs are high while marginal production costs are low—foreign governments have strong incentives to obtain a "free ride" on (a substantial part of) the fixed costs financed by U.S. consumers, by imposing price controls on retail transactions. These foreign price controls impose several types of inefficiency costs, foremost among them an inefficient reduction in incentives for the development of new pharmaceuticals. Accordingly, the importation of pharmaceuticals subject to foreign price controls necessarily would introduce those controls into the U.S., either at wholesale or at retail depending upon market conditions; such pricing distortions and the perverse long term effects attendant upon them are inconsistent with the efficiency goals of free trade agreements, and so indeed would "work against such trade agreements." This inconsistency would take the form of reduced and distorted pharmaceutical investment over the long term, thus increasing real prices by reducing the future availability of new and im-

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[9] Kevin Outterson, *Pharmaceutical Arbitrage: Balancing Access and Innovation in International Prescription Drug Markets*, 5 Yale J. Health Policy, Law & Ethics 193, 244–250 (2005) (concluding that neglected disease innovation does not require appropriation of pharmaceutical rents from low income populations via the patent system).

[10] Kevin Outterson, *Free Trade Against Free Riders?*, 9 Pharma Pricing & Reimbursement 254 (IMS Health, Sept. 2004).

[11] Kevin Outterson, Nonrival Access to Pharmaceutical Knowledge, Submitted to the World Health Organization Commission in Intellectual Property Rights, Innovation & Public Health, Jan. 3, 2005, *available at www.who.int and www.ssrn.com* (author = Outterson).

[1] Note that profit-seeking firms generally have efficient and powerful incentives to preserve the economic value of their brand names and thus the safety and effectiveness of their products. In the context of the pharmaceutical market, the problem of contagion may introduce a distortion, and the cost of policing counterfeit drugs may yield an efficient role for government activity. See, e.g., Benjamin Klein and Keith B. Leffler, "The Role of Market Forces in Assuring Contractual Performance," *Journal of Political Economy* 89(4), 1981, pp. 615–641.

proved medicines. That outcome obviously is at odds with the central goal of efficient investment in the context of free trade agreements, thus reducing rather than expanding the value of aggregate output and consumer well-being.

Question 2. Trade agreements such as the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and NAFTA require governments to protect intellectual property rights. These agreements are designed to ensure the continuing viability of industries involved in the research and development of innovative products, and to prevent unfair competition from companies who would otherwise free-ride on the technology developed by others.

Do you think that unauthorized importation of prescription pharmaceuticals would undermine the value and purpose of U.S. patent rights?

Answer 2. The central economic purpose of patent rights is the creation of a temporary stream of "monopoly" returns to investment in pursuit of efficient investment incentives for innovation and research and development.[2] These returns are engendered by a (marginal) revenue stream temporarily higher than otherwise would be the case; accordingly, any policies that reduce such revenue streams artificially indeed "would undermine the value and purpose of U.S. patent rights." The importation of pharmaceuticals subject to price controls obviously would reduce the (expected) revenue stream for the given drugs (or drug class), and so would have the effect of undermining the goals of the patent system. Indeed, even without importation of pharmaceuticals, and even without compulsory licensing or other such policies, the imposition of price controls overseas interferes with patent rights by reducing the marginal revenues yielded by introduction of a new or improved medicine. (Merely consider the extreme case of a drug the price of which is controlled at zero; the patent value would be zero as well.)[3] Note also that neither overall firm "revenues" nor "profits" is the correct criterion for determining whether investment incentives will be efficient; instead we must ask whether a policy affects the marginal expected returns attendant upon investment in a given drug.[4]

Question 3. You indicate that the magnitude of the projected adverse effect of importation on research and development varies somewhat, "although it is never predicted to be small." You also mention that all of the estimates are biased downward.

What do you see as the realistic potential effect on research and development? Do you feel that even if importation leads to price reductions, U.S. consumers would end up sacrificing choice in favor of cost?

Answer 3. The importation of pharmaceuticals subject to price controls would yield both reduced consumer choice and higher overall health care costs. The reduced consumer choice would be one central adverse effect of the lessened research, development, and innovation that inexorably will be engendered over the long run by price controls. The higher overall health care costs will be caused by the substitution of hospital and other types of medical services in place of the pharmaceuticals that will have failed to have been developed over time.[5] In the narrow context of the pharmaceutical market, any short term reduction in drug costs (prices) will be offset partially, fully, or more than fully by the higher real costs of reduced drug availability over the long term.[6] The potential effect on research and development

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[2] The issue of the efficient structure and length of patent rights in the pharmaceutical context is not addressed here.

[3] The imposition of price controls is very different from differential pricing. Such "price discrimination" is efficient, fully consistent with competitive market behavior, and makes consumers better off by allocating fixed costs in accordance with differing valuations placed upon the knowledge capital yielded by pharmaceutical innovation, thus moving the production of pharmaceuticals closer to the efficient level.

[4] In order to see this, consider the case of a highly profitable pharmaceutical producer; would it invest in a drug subject to severe (future) price controls merely because overall profits are high? It will do that no more readily than bury a $100 bill in the hope that a money tree will sprout.

[5] See, e.g., Frank R. Lichtenberg, "Are the Benefits of Newer Drugs Worth Their Cost? Evidence From the 1996 MEPS," *Health Affairs* 20(5), September/October 2001, pp. 241–51. See also Kevin M. Murphy and Robert H. Topel, eds., *Measuring the Gains From Medical Research: An Economic Approach,* Chicago: University of Chicago Press, 2003. Even with an adjustment for the costs of substitute medical procedures, such measured "costs" underestimate the adverse effects of pharmaceuticals made unavailable by the prior direct or indirect imposition of price controls because they exclude the real but difficult-to-measure costs of increased mortality, morbidity, and suffering.

[6] Note that because pharmaceutical producers have incentives to invest only in drugs the development and production costs of which consumers are willing to bear, the reduced prices in the short run are likely to be offset at least fully by the longer term higher costs of reduced drug availability, as a first-order approximation. Moreover, the imposition of price controls might not yield price reductions at retail even in the short run, as the difference between con-

is difficult to measure, although a crude but unbiased approximation can be obtained by estimating the reduction in the present value of the expected future revenue stream for a prospective drug, and then comparing that reduced revenue base with the cost of developing new drugs, estimated at over $800 million in peer-reviewed journals, or perhaps with the present value of the expected costs of developing that prospective drug.[7] Such analyses are reasonable as initial starting points for analysis, but they are likely to underestimate the adverse effect of price controls on research and development because they are static rather than dynamic; they fail to take into account the fact that the imposition of price controls, whether direct or indirect, introduces an asymmetry into the statistical (stochastic) distribution of future returns to research and development. This is an effect distinct from the price reduction itself: *Ex ante*, any given potential investment offers upside potential that is limited (truncated) by the price controls, while downside risks remain unaffected. The dynamic effect, therefore, is to shift the entire statistical distribution of possible returns downward (or to the left); this means that the standard static measurements of the adverse research and development effects attendant upon the imposition of price controls are biased downward.

Question 4. The Department of Commerce study acknowledged that improvements to health care and life sciences are an important global source of gains in health and longevity. According to the study, "The development of innovative pharmaceutical products plays a critical role in ensuring these continued gains." The report states that "economic incentives are essential" in order to encourage the continued development of new medicines.

Do you think legalized importation would reduce the "economic incentives" that are critical to the development of new medicines?

Answer 4. It is incontrovertible that the imposition of price controls on pharmaceuticals, whether directly or indirectly in the form of competition from drugs subjected to price controls overseas, would weaken incentives to invest in pharmaceutical research and development. This is true under any set of assumptions about the competitiveness of the industry, about its maximand, or other parameters; the market for investment capital will recognize immediately the attendant reduction in expected returns to investment in this sector, and will reallocate some capital elsewhere. As discussed in footnote 4 above, such parameters as the overall profitability of the industry (or given firms) or overall industry (or firm) revenues are not relevant. For any given prospective investment in a new chemical entity or other developmental product, the capital market will ask whether expected returns (on the margin) justify the expected development costs. Price controls cannot improve the marginal efficiency of any such investment.

RESPONSE TO QUESTIONS OF SENATOR KENNEDY BY BENJAMIN ZYCHER

Question 1a. The Department of Commerce Report suggests that the increased prices of name-brand drugs in Europe could be offset by reduced prices (and increased utilization) of generic drugs.

Do you agree with that assessment?

Answer 1a. It certainly is true that name-brand and generic drugs in the short run are substitutes to some substantial degree. In the long run, they are more complementary, in that generic drugs over time cannot become generic drugs unless they are developed first as name-brand drugs. In the short run, an increase in the prices of name-brand drugs would increase the demand for generics; depending on supply conditions for the latter, increased utilization of generics would be expected to yield some savings that might be substantial.[8] In the long run, increased prices for name-brand drugs would reduce the prices of generics by increasing competition among them. The reasons that generic prices seem to be higher in Europe than in the U.S. (abstracting from exchange rate issues and the like) are unclear; some attribute that condition to anticompetitive policies in Europe, but in my view a careful analysis of this question is yet to be done. As an aside, the elimination of European price controls unambiguously would make U.S. consumers better off, in the long run

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trolled prices and market value might be captured in whole or in part by various transaction agents ("middlemen") under a broad range of market conditions.

[7] See U.S. Department of Commerce, International Trade Administration, *Pharmaceutical Price Controls in OECD Countries: Implications for U.S. Consumers, Pricing, Research and Development and Innovation,* December 2004, chapter 8.

[8] For most drugs marginal production costs are low and short run scale economies seem not to be particularly important; accordingly, supply conditions as a first approximation suggest that the increased demand for generics would not increase the prices of generic drugs substantially.

and possibly the short run, by inducing profit-seeking producers to reduce their U.S. prices.

Question 1b. How much could Europe save with increased generic use?

Answer 1b. The best evidence that I have seen on this issue is presented in a 2004 study by the Boston Consulting Group, which concludes in summary that an increase in European generic use to levels proportionate to those in the U.S. would reduce drug spending by 20 percent.[9]

Question 1c. Would increased generic savings impact innovation?

Answer 1c. Certainly there would be more innovation investment if competition from generics were reduced, that is, if name-brand drugs enjoyed more or longer "monopoly" positions. The presence of generics yields competition, as does the presence of name-brand competitors, sometimes called "me-too" drugs quite incorrectly. But the possible reduction in innovation yielded by competition from generics is not necessarily inefficient if we assume that patent periods are optimal and that other government policies are efficient also. In the context of Europe, if increased generic savings were caused by a loosening or removal of price controls, then such a shift would enhance innovation because the removal of the price control policies would improve the investment climate. In short, in the European context, the removal of price controls might induce a shift toward generics, which might increase the savings yielded by the use of generics, but that would be salutary for long run innovation because the removal of the price controls would improve investment incentives.

Question 2a. Would you agree that increased utilization of pharmaceuticals is beneficial to health status?

Answer 2a. Yes; see footnote 5.

Question 2b. If so, should the Health and Human Services and Department of Commerce Reports have estimated the positive health impacts of increased consumer access to drugs due to lower prices?

Answer 2b. In the narrowest sense, the issue of what the HHS/DOC studies should have examined is a question for Congress. More broadly, the purported price and attendant health effects of "increased consumer access to drugs due to lower prices" in a real sense answers the question (qualitatively) before it has been asked: Price controls increase "access" in the short run but not the long run, so that the improved health outcomes yielded by drug utilization in the short run must be weighed against the adverse long term health effects of reduced pharmaceutical research and development. Is it worth mortgaging the future in favor of the present? I believe not; but that is one crux of the debate over the importation of pharmaceuticals subject to foreign price controls. And so any such study must examine not only the short term effects of prospective policy shifts, but the long term effects as well.

Question 2c. Should comparative effectiveness play a role in approval or R&D or marketing incentives?

Answer 2c. If "R&D or marketing incentives" are the products of market forces, then comparative effectiveness is a crucial parameter that should influence investment choices by producers, and market forces yield precisely that outcome. If, on the other hand, such incentives are imposed by regulators and other public officials—if "evidence-based medicine" is used to allocate resources in a top-down decision process—then they would be highly inappropriate. Patients respond differently to given medicines; what is "effective" in the aggregate may not be "effective" for specific patients, who in consultation with their physicians should choose among alternatives for the best solutions to their respective conditions. Moreover, the differences in "effectiveness" can manifest themselves in ways essentially unobservable to analysts; consider a generic diuretic equal in "effectiveness" with some name-brand hypertension drug, but which causes the patient to visit the bathroom multiple times during the night, before work the next day. Only patients in consultation with their physicians can evaluate all the relevant tradeoffs in pursuit of "effectiveness;" government policy is too blunt an instrument to do so without the creation of important adverse effects in terms of patient well-being.

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[9] See Charles-Andre Brouwers, Martin B. Silverstein, and Tory Wolff, *Adverse Consequences of OECD Government Interventions in Pharmaceutical Markets on the U.S. Economy and Consumer,* Boston Consulting Group, July 1, 2004, esp. exhibit 14.

QUESTIONS OF SENATOR ENZI TO STEPHEN POLLARD

Question 1. There are several studies that compare the cost of some of the most widely prescribed drugs in the U.S. to the cost of those same drugs in Canada, the UK, Germany, France, and other countries where there are price controls.

What impact have price controls had on drug discovery and development in Europe? It is my understanding that there has been a notable decline in R&D in Europe in particular over the past 10 years. Have price controls contributed to this decline? Do you know how pharmaceutical inventions in Canada, Germany, and the UK, based on NMEs, compare to those in the U.S.?

Answer 1. Response unavailable.

Question 2. Many compare importation of drugs into the U.S. to parallel trade in Europe—are there important differences that make these two practices different—if so, what are they? What impacts will EU expansion have on parallel trade in pharmaceuticals?

Answer 2. Response unavailable.

Question 3. According to a recent study by the London School of Economics, profits from parallel imports accrue mostly to the benefit of the third party companies that buy and resell the medicines, not to patients. Specifically, the LSE study found that savings to insurance organizations ranged from .3 percent to 2 percent, while parallel trader mark-ups ranged from 12 percent to 54 percent. Does the European experience truly demonstrate that this practice benefits intermediaries rather than consumers? If commercial importation were to become legal in the United States, do you think we would have a similar experience in terms of savings or lack of savings?

Answer 3. Response unavailable.

Question 4. According to the Irish Medicines Board's 2005 annual report, the unauthorized importation of medicinal products, which it investigates, includes those originating from outside the EU. The report also states that number of investigations it is carrying out into the illegal mail order/Internet supply of drugs is steadily increasing. How can parallel trade in Europe be safe for patients if—according to the report—there are a growing number of unregulated prescription drugs coming into the EU from foreign nations?

Answer 4. Response unavailable.

QUESTION OF SENATOR HATCH TO STEPHEN POLLARD

Question 1. I appreciated your insights on European healthcare issues as they relate to prescription price controls and parallel trade. I agree that every developed Nation has something unique and important to add in the field of medical research. Your comments about price controls and how the European governments are imposing costs on the developing world were particularly interesting.

Could you explain how the supply of medicines to lesser-developed countries is affected by price-controls on prescription drugs?

Answer 1. Response unavailable.

QUESTIONS OF SENATOR KENNEDY TO STEPHEN POLLARD

Question 1. The Department of Commerce Report suggests that the increased prices of name-brand drugs in Europe could be offset by reduced prices (and increased utilization) of generic drugs. (a) Do you agree with that assessment? (b) How much could Europe save with increased generic use? (c) Would increased generic savings impact innovation?

Answer 1. Response unavailable.

Question 2. Would you agree that increased utilization of pharmaceuticals is beneficial to health status?

If so, should the Health and Human Services and Department of Commerce Reports have estimated the positive health impacts of increased consumer access to drugs due to lower prices? Should comparative effectiveness play a role in approval or R&D or marketing incentives?

Answer 2. Response unavailable.

PREPARED STATEMENT OF ELLEN R. SHAFFER AND JOSEPH E. BRENNER, CPATH

RAISING OECD DRUG PRICES WOULD NOT SOLVE THE U.S. CRISIS IN AFFORDABILITY

CPATH conducts research, policy analysis and advocacy to bring the voice of public health to the trade debate. We appreciate the work of Chairman Enzi and the committee to explore the issues raised by the U.S. Department of Commerce report, *Pharmaceutical Price Controls in OECD Countries: Implications for U.S. Consumers, Pricing, Research and Development and Innovation.* An objective review of OECD country policies could provide guidance as the U.S. seeks policies to assure that prescription drugs are more affordable. However, the present report and much of the testimony presented at the committee's hearing on February 17, 2005, are deeply flawed. We concur with others who have criticized the dearth of substantiated evidence, and the choice of sources and terminology that are known to be biased in favor of the pharmaceutical industry. It draws upon unfounded assumptions to conclude any association between affordable prices for prescription drugs abroad and ongoing innovation in research.

Nevertheless, even this flawed report reaches the unassailable conclusion that in the short term, "the deregulation of OECD prices is not likely to have any impact on U.S. drug prices." In the undefined long term, the report speculates that certain changes in OECD prices might, under particular and questionable circumstances, lead to "improved health outcomes" there, and eventually "could have some effect on U.S. prices." One must question, then, why current U.S. policy seeks aggressively to achieve higher drug prices abroad through trade negotiations.

A central concern regarding this report is not that supporting statements lack intellectual rigor, or even that the report supports bad trade policy. Rather, the report is bad health policy: it asks the wrong question. The American public is actively looking to Congress for relief from the high price of prescription drugs. To their credit, most Members of Congress have voted more than once for the most viable short-term solutions available, the drug reimportation proposals. The report, however, dodges Americans' most critical concerns.

To our elderly traveling to Canada to buy the drugs they depend upon, to our Governors struggling with Medicaid budgets, to our African-American communities and others battling the scourge of AIDS, this report suggests: the pharmaceutical industry doesn't have enough money yet to take care of you. If we are able to raise prices in Germany, perhaps we'll get back to you.

NEGOTIATING HIGHER DRUG PRICES: BAD TRADE POLICY, BAD HEALTH POLICY

Reasonable regimes for assuring access to affordable life-saving medicines throughout the developed world do not account for unsustainably high prescription drug prices in the U.S., or for the pharmaceutical industry's dwindling development of innovative products. U.S. proposals to our trading partners to dismantle their own drug pricing and distribution systems are already creating serious diversions from our ability to successfully negotiate agreements with middle and low-income countries, and would certainly cause an uproar in wealthy nations. The U.S.-Australia Free Trade Agreement offers a case in point.

Trade language on drug pricing can have consequences for domestic U.S. programs that provide affordable drugs for vulnerable populations. These include veterans eligible for Veterans Administration benefits, Medicaid and Medicare beneficiaries, and community clinic patients who benefit from 340B programs. There are three reasons these complications could arise:

- These U.S. programs engage in complex negotiations for drug pricing and listing that are in some cases similar to the OECD country programs erroneously described in the report as "government fiat."
- Trade agreements apply to all signatory nations. Trade agreement language can be imprecise, and subject to retroactive interpretation by non-U.S. trade tribunals.
- There are no public health representatives engaged in trade negotiations. Such representatives could advise trade representatives of potential unintended pitfalls.

The pharmaceutical industry is among the most profitable in the world. It is not necessary, nor is it sufficient, to raise more money from higher prices abroad if the goal is to increase funding for research and development. The industry's reliance on ever-lengthening terms of protection for monopoly pricing and barriers to competition, and production of marginally useful but highly profitable copycat blockbuster drugs, must be addressed through policy. This includes reinvigorating market competition among pharmaceutical manufacturers.

Much of the testimony at the February 17 hearing suggested that the U.S. would do poorly to import drugs from OECD countries. Doing so would amount to importing those countries' pricing systems, and exposing Americans to fewer appropriate

treatments, according to an example offered by one witness, by oncologists. These remarks suggest the actual interest behind the veneer of concern for the health of our European counterparts. The attempt to discredit pricing systems abroad may delay reforms needed to achieve affordable drug prices in the U.S. It is unlikely to convince Americans that the high prices we pay are worth it.

(According to Alan Sager and Deborah Socolar, among others, reducing prices in the U.S. would not necessarily decrease pharmaceutical revenues, as the resulting increased volume could hold revenues constant, or increase them.)

Surely international cooperation would be a valuable element of the realignment that must take place to assure affordable drugs in the U.S. Lower prices in the U.S. could reduce the already limited funds devoted to truly innovative research and development, and a better framework to assure sufficient investment may be required. Limited patent protections can help to protect and encourage genuine innovation in pharmaceuticals as in other endeavors that depend on up-front investments. Different pricing structures for regions of the world at different income levels can be part of the solution. But pursuing wrongheaded, unpopular and ineffective trade proposals with our trading partners will not lead to meaningful progress. We encourage Congress to help engender the political will to seriously entertain thoughtful policy solutions to the present crisis in the cost and accessibility of prescription drugs.

SPECIFIC COMMENTS ON THE DOC REPORT: ADDITIONAL REVENUES WOULD NOT IMPROVE INNOVATION

The report contends that higher drug prices in OECD countries might increase drug company revenues abroad, but then again perhaps not, if spending shifts to less expensive generics.

In the somewhat unlikely event that Europe, Canada and Japan agree to raise their drug prices, and that more revenues become available to the pharmaceutical industry, the question then becomes whether additional revenues, if generated, would in fact lead to the development of any new drugs.

No one knows with certainty what the pharmaceutical industry spends on research, development, or marketing, because they will not reveal the data. Nevertheless, figures favorable to and in some cases directly sponsored by the industry are roundly questioned by independent researchers. Independent reports contend:

1. The industry has sufficient funds to sponsor research and development, if it chose to so allocate those funds. While earning profits of about 19 percent on average, it spends less than 15 percent of revenues on research and development (including government subsidies), and 37 percent on marketing and administration.

2. Many newly marketed drugs are of scant if any additional therapeutic value.

Professor Joel Lexchin, Associate Professor at the School of Health Policy and Management, York University, offers the following estimate:

Category	Number of New Drugs	Percent of New Drugs
Major therapeutic innovation in an area where previously no treatment was available	7	0.3
Important therapeutic innovation but has limitations	73	2.7
Some value but does not fundamentally change the present therapeutic practice	212	7.9
Minimal additional value and should not change prescribing habits except in rare circumstances	432	16.0
May be new molecule but is superfluous because does not add to clinical possibilities offered by previously available products	1780	66.1
Without evident benefit but with potential or real disadvantages	73	2.7
Decision postponed until better data and more thorough evaluation	116	4.3
Total	2693	100.0

(Value of new drugs introduced into France 1981–2002—Prescrire International 2002;11:58–60).

3. The actual cost of bringing a new drug to market, including research and development, is probably around $100 million, rather than the industry's claim of $800 million. (Light, D. W., and J. Lexchin. 2004. Will Lower Drug Prices Jeopardize Drug Research? A Policy Fact Sheet. *The American Journal of Bioethics* 4(1):W1-W4.)

4. "The amount that the industry spends on research and development depends on many factors aside from revenue generated through sales. A more important stimulus to industry R&D is the level of public funded basic research.

Dr. Lexchin notes that between 1980 and 2002:

• Every $1 billion increase in NIH spending was associated with $1.316 billion more in domestic R&D.

• Every $1 billion increase in retail spending was associated with $172 million more in domestic R&D.

OECD NATIONS ARE HEALTHY

The report acknowledges that U.S. drug prices are higher than in other OECD countries. Testimony suggested that Europeans receive worse health care and are in worse health compared with Americans, suggesting that we buy better health with our drug spending. These assertions are not documented. As with any such broad topic, the choice of indicators determines the conclusion. Dr. Lexchin has compiled a table on the most significant indicators, based on OECD data, demonstrating that U.S. residents lag behind Canadians and Europeans:

Country	Infant mortality (2002)	Life expectancy at birth (males) (2002)	Life expectancy at birth (females) (2002)
United States	6.8 (2001)	74.4 (2001)	79.8 (2001)
Canada	5.2 (2001)	77.1 (2001)	82.4 (2001)
Australia	5.0	77.4	82.6
France	4.2	75.4	82.9
Germany	4.3	75.6 (2001)	81.3 (2001)
Sweden	2.8	77.7	82.1
United Kingdom	5.3	75.7 (2001)	80.4 (2001)

OECD, 2004.

CONCLUSION

Widespread importation of prescription drugs could improve rather than undermine market competition, lower prices, and increase access and the volume of sales. It might or might not lower total drug expenditures in the U.S. There is no reason to project a decline in innovation or health status as a result. Congressional leadership is badly needed to guide the Nation toward sensible policies that assure development and distribution of effective, affordable prescription drugs.

PREPARED STATEMENT OF JOEL LEXCHIN

The following comments respond to the Department of Commerce report, *Pharmaceutical Price Controls in OECD Countries: Implications for U.S. Consumers, Pricing, Research and Development and Innovation,* published in December, 2004.

1. One of the most serious flaws in the Department of Commerce report is the data on the division of market share between brand-name and generic drugs. For instance for Canada the DOC report says that 54.9 percent of market share (dollar sales) comes from off-patent and 41.1 percent comes from on-patent drugs. The real figures from the 2003 report of the Patented Medicine Prices Review Board is: total sales of $15 billion of which $10.1 billion from patented medications (i.e., about 66 percent), $3.2 billion from off-patent brand name and $1.7 billion from generics. Therefore, 66 percent from on-patent medication (>50 percent higher than figure in DOC report) and 33 percent from off-patent medications or about 66 percent lower than DOC report figure. This type of gross mistake completely throws off all of the calculations about changes in overall expenditures if Canada adopted U.S. prices and lowered generic prices.

2. The assumption that pharmaceutical prices in U.S. are market-oriented ignores the effects of intellectual property laws in the U.S., and company actions that create restrictive monopoly conditions. These include, e.g., evergreening tactics, deals with generic companies to delay marketing of generic products, and patent extensions for pediatric studies even when drugs are unlikely to be used in children.

3. The report ignores multiple factors that might lead to differences in drug prices in other industrialized countries—e.g., production costs, costs of other forms of health care. Absent consideration of these other factors, the conclusions from this study are seriously weakened.

4. GDP includes many things that do not improve standard of life, e.g., clean-up costs from pollution spills, military expenditures, etc.

5. The report assumes that movements in the ratio of drug prices in the U.S. relative to other countries are linked to movements in the ratio of GDP per capita. No empirical data is presented to support this contention. Data comparing Canada and the U.S. seem to indicate that even when the GDP per capita ratio remains the same, the ratio of drug prices drops as the table below shows:

Year	Drug price ratio (Canada/ United States)	Gross domestic product per capita ratio (Canada/ United States)
1999	0.62	0.63
2000	0.63	0.63
2001	0.59	0.64
2002	0.60	0.65
2003	0.57	0.64

6. The increased use of generics in OECD countries, as suggested by the report, might require restrictions imposed by government, e.g., setting maximum reimbursement prices and the DOC Report argues against government interference in the pharmaceutical marketplace.

7. Other studies, e.g., even the one that the DOC Report cites from Danzon, put Canadian generic prices below those in the U.S.

8. Generic prices in the U.S. are heavily dependent on competition between generic companies, and one of the most important factors in generating competition is market size; the larger the market the more the number of companies willing to enter the market. Market size in the U.S. is much larger than in any other country. Therefore, other countries may not match the level of competition and therefore the prices found in the U.S.

9. The report assumes that price levels are the only thing that determine R&D spending. This ignores multiple other factors, e.g., level of public spending on basic research (much higher in U.S. relative to other countries), number of trained researchers and sophistication of health care system, and the home country of multinationals. R&D spending by the pharmaceutical industry in the U.S. also tracks very closely with NIH spending.

10. Many of the sources cited, and particularly Grabowski, J.M. Vernon and J.A.Vernon, produce work favorable to the brand-name industry.

11. For the U.S., R&D data by PhRMA are much higher than the figure reported by the National Science Foundation. For example, in 2000, the NSF reported that the pharmaceutical industry spent $15,451 billion on R&D; that same year, PhRMA's figure was $21,364 billion.

12. Launch delays are also due to internal company marketing decisions—which country to first file for approval in, size of estimated market, cost of getting a drug approved.

13. Does drug availability correlate with improved health outcomes in U.S. relative to other countries? Data on accepted indicators such as life expectancy and infant mortality would suggest not.

Country	Infant mortality (2002)	Life expectancy at birth (males) (2002)	Life expectancy at birth (females) (2002)
United States	6.8 (2001)	74.4 (2001)	79.8 (2001)
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Canada	5.2 (2001)	77.1 (2001)	82.4 (2001)
France	4.2	75.4	82.9
Germany	4.3	75.6 (2001)	81.3 (2001)
Sweden	2.8	77.7	82.1
United Kingdom	6.8 (2001)	74.4 (2001)	79.8 (2001)

14. On p. 32, the DOC Report says that there is "research that suggests that there are benefits as well from 'follow-on' drugs in terms of increasing competition and

reducing prices." The study that this conclusion comes from is unpublished and therefore not peer reviewed.

16. The study by Garattini (BMJ 2002;325:269–71) that examined new cancer medications introduced into the European market from 1995–2000 found that they offered few or no substantial advantages over existing medications, yet cost several times more.

PREPARED STATEMENT OF DONALD W. LIGHT

Summary Points:

1. Blocking free trade makes American businesses less competitive, less productive and less profitable. Current proposals should be rejected as bad for U.S. business.
2. Foreign free-riding is a myth, contradicted by industry and government data.
3. Drug companies earn back all R&D expenses each year at European prices, with profits. Thus, Americans pay super-prices for super-profits.
4. So-called "price controls" are negotiated wholesale contracts between large buyers and large sellers. The "controls" are largely terms found in other serious contracts.
5. So-called "reference pricing" is value pricing, a refusal to pay more for new drugs that offer little advantage over existing cheaper ones.
6. Pharmaceutical investments in Europe have been rising, not declining. European teams have been discovering proportionately more new molecules than American teams. Europeans are healthier. "Poor Europe" does not need to be rescued from a made-up crisis.
7. The Department of Commerce report is not based on solid data, is biased, and is misleading. An independent study should be commissioned.
8. The U.S. pharmaceutical market is far from "free." Prices are secret. Companies use corporate price controls to set prices very high and then raise them, seemingly at will. Resulting profits are three times the average—all signs of monopolistic behavior, not open market competition.
9. Corporate investment in research to discover breakthrough drugs is far lower than the pharmaceutical industry claims. R&D costs are also far lower.
10. Current protections from price competition reward derivative "me-too" research, not basic research, and that's what we get: 85–90 percent of all new drugs are little better than existing ones.

DRUG IMPORTATION BENEFITS AMERICAN BUSINESS AND ECONOMIC GROWTH

Congress is being asked, and the Bush Administration is already implementing, policies to lock in world-high prices for prescription drugs in the U.S. and raise prices in other affluent countries.

These policies are anti-business. *If you believe in free markets, in competition and in promoting the growth of American business you will oppose these policies.*

Locking in high U.S. prices and raising prices abroad reinforces a major driver of rising health care and labor costs. What employers and employees have in the United States is *corporate price controls*. Pharmaceutical companies routinely set prices in secret at 5,000 percent to 10,000 percent more than ex-factory costs. The mark-ups are much greater than those documented by Senator Estes Kefauver in the late 1950's, and American business knows it.

These corporate price controls make patented drugs unaffordable to many workers who do not have good insurance for drugs, and when they get sick, a number of them will not buy the drugs their physician thinks they need. This reduces productivity, increases sick days, increases disability days, and raises production costs. It makes American businesses less able to compete in world markets.

In sum, when Congress approves an (un)free trade agreement that prohibits the export of patented drugs and delays generic price competition, it is harming every American business sector except the pharmaceutical industry. You could call this The Great Profit Robbery—big pharma taking millions out from the bottom lines of every other business and putting into theirs. No wonder their profit margins are 3 times greater than the rest of the Fortune 500, year after year.

THE BIG LIE ABOUT FOREIGN COUNTRIES FREE-RIDING

Both industry and government reports show that countries charging European prices earn back all their R&D investments within each year, just from their sales in that country, with profits to spare. Why should prices, then, be any higher?

This is the bottom line nobody tells Congress—there is no hard evidence of the free-riding myth. Americans are simply paying super-prices to give big pharma super-profits. These too are well documented, and they harm American businesses by raising their labor costs.

EXCESSIVE PROTECTIONS FROM PRICE COMPETITION

It does not take big pharma 10 or 20 or 25 years to earn back their R&D costs. Their own records show they earn them back in the year they are spent, even at Canadian and European prices, with substantial profits left over. Further, an investigative financial reporter, James Edwards, has finally figured out a way to separate the marketing from administrative costs that the pharmaceutical companies intentionally blur and document from company records that major firms spend 25 percent of revenues on marketing alone, far more than any other industry, and twice as much as independent data show they spend on R&D.

If pharmaceutical companies want to increase R&D, they already have the billions to do it in-house. All they need to do is spend more on R&D, less on marketing, and let superior drugs sell themselves, rather than be marketing companies that also do some research. Big pharma does not need high prices or more money to be productive. It needs to be more dedicated to research than to marketing.

Competition has been the greatest engine for innovation since capitalism began, with *patents as a temporary stay from the pressures of price competition to spur still more innovation*. If patents are too long, or if they have fuzzy endings that can be manipulated and extended, then patent-dependent companies turn from focusing on innovation to focusing on crafty ways to extend their corporate price controls by keeping normal price competition from happening.

"PRICE CONTROLS" ARE NEGOTIATED DISCOUNTS

The "price controls" that advocates like Robert Goldberg and Grant Aldonis talk about are volume discounts negotiated between giant pharmaceutical companies and a given nation's pricing board. No one ever describes in detail the negotiations when these boards set prices. It's like Medco or Express Scripts negotiating discount prices with big pharma. It's normal, wholesale, free-market horse-trading.

Most of the time, nations are negotiating for fewer patients than are Medco, Express Scripts and other large PBMs. Mr. Aldonis says these countries are monopsonies, but so are the large PBMs, only larger. What we have here is the bilateral horse-trading of titans on the wholesale market: the company can demand a higher price or else a whole Nation won't get its drug, and the price board can demand a lower price or else the company will not get to sell its drug to a population. Of course, the drug companies spend millions of dollars to get advocates to give a distorted picture of this process.

I guess I'm one of the people Goldberg calls "price control supporters." Not at all. *I support free trade and competitive wholesale markets, as the best way to reward innovation and good value.*

"REFERENCE PRICING" IS VALUE PRICING

Every American shopper worth her salt compares new products with existing ones to decide if they offer any advantage. It they don't, no one will pay more for them. If they do, they decide how much more they are willing to pay for them. This is the beauty of the new Consumers Union web service that compares the benefits of different drugs doing the same job and recommends which is the "Best Buy." This revolution in truly free markets can be found at *http://www.crbestbuydrugs.org/*.

Finally, America has what many other nations have had for years, professional side-by-side comparisons of new drugs with old and the ability to pay what new drugs are worth. That's so-called reference pricing. Drug companies hate it and do all they can to keep people from being able to compare the value of different drugs.

Just like good American bargain shoppers, countries like Germany compare new drugs with older ones and conclude (as do therapeutic committees in many places), that 80–85 percent of them offer little or no advantage over older ones. Drug companies are furious, because in the fixed "free market" in the U.S., they can use millions of free samples and spend billions in inducements to get physicians to prescribe the new drugs over the old ones. Because of corporate price control, the companies charge substantially more for the "new" drug that is no better and thus carry out another Great Profit Robbery on the bottom lines of American employers. This shows that drug companies do not believe in classic price competition for value. They love using their corporate price controls to charge much more than a drug is worth, and they love the help that Congress has provided to perpetuate this process.

POOR EUROPE

A striking part of the testimony is how concerned people like Robert Goldberg and Grant Aldonis are about how much Europeans are suffering from their lower prices. Big pharma is pulling its research out of Europe and moving it to the U.S. because of its low (negotiated wholesale) prices. Europeans suffer from substantial delays in getting new drugs, or don't get them at all. As a result, their health is worse than Americans, who benefit from discovering most new molecules and getting them to market as soon as they are approved.

Before we impose monopoly corporate price controls on Europe as an act of kindness so that they can bask in the sunshine of an American "free market" (which means free to price where you like without price competition), let's look at some facts.

First, in proportion to size, *Europe has been more innovative and discovered far more new molecules than the U.S. going back at least to the 1980's.* The U.S. is catching up, but the annual reports of the European Federation of Pharmaceutical Industries show that the U.S. is just now about to finally match the record of European research teams.

Those annual reports also show that *pharmaceutical firms have kept investing more and more R&D funds in Europe, not less*. They are not pulling out; they are not stupid. Investments in the U.S. have increased still faster, but European research is not going down the tubes. Broader reports about scientific research in general document the opposite to Goldberg myth: Europeans pulled ahead of Americans in basic science about 1995, and gap has been widening. The spoilers, however, are India and China. The head of global research for Roche recently pointed out that most U.S. labs are run by Chinese and Indians; so Roche is going to invest in the source.

Second, I asked Mr. Goldberg for evidence on the alleged delays to market in Europe, and he sent me a report containing a table that "proved" this was so. But the numbers were odd and inconsistent. For example, why would the table show delays to market for the U.S. after FDA approval, when drug companies can go to market after approval? Besides oddly suspicious numbers, the measures used were also unclear, and they fused delays due to decisions by the companies with regulatory delays. I asked Mr. Goldberg to explain how "delay" was actually being measured and what data was actually being used? He shot back that I was "nit-picking." In other words, solid facts and good measures don't matter. What matters is asserting the big pharma line, evidence be damned. But one thing is clear: Mr. Goldberg's alleged facts are not to be believed until solid, independent data are presented to back them up. There appear to be no good independent studies and measures of "delay", especially that separate out delays due to corporate decisions from delays due to regulatory foot-dragging, so I don't know whether there are unwarranted "delays" and neither does Mr. Goldberg or any other advocate for big pharma.

Third, international data show that if you compare demographically similar Europeans with Americans, it is the Europeans who are healthier and live longer. Poor Europe is doing rather well. But industry-sponsored reports try to tell Europeans that they are worse off. For example, the Bain report on poor Germany is based on the premise that *the more drugs you take, the healthier you will be, and the more nations pay for them, the better off they will be*. Does that sound absurd? Not to leaders of the pharmaceutical industry who finance these campaigns.

THE DEPARTMENT OF COMMERCE REPORT IS BIASED AND MISLEADING

Grant Aldonas devoted considerable time to explaining the supposedly authoritative study recently done by the Department of Commerce, which in the past few years has become the most powerful lobbyist for the pharmaceutical industry in slowing down economic growth and making American businesses less competitive by locking in high U.S. prices and raising prices abroad. No Congressman should be so naive as to assume that this report is independent or authoritative.

For example, Mr. Aldonas explains that the data set they used "excluded prices"! Imagine! A major report on prices that lacks data on prices! Why? Because the prices of drugs in our so-called free market are secret. They are "proprietary." Adam Smith would roll over in his grave. So, "it was necessary to estimate prices" and then use econometric models that turn suppositions into "facts." After that, as Aldonas explains on page 6 of his testimony, the models and indexes and "factors" get us farther and farther away from reality and toward a made-up story constructed for big pharma. For these reasons alone, no Member of Congress should give any credibility to the conclusions of this study, but it gets worse.

The models, equations and parameters come from Grabowski and Vernon, two of the most prominent industry-supported researchers who have been supplying the in-

dustry with justifications for more protections from normal capitalist competition for over 20 years. Using these "authorities" and studies from the Tufts Center, one of the industry's leading policy research centers for over 25 years, is another sure sign that this report is not independent or credible. Why didn't Aldonas commission any independent economists or researchers from the U.S. or Europe if the goal was too authoritative? And why does Aldonas call the PhRMA data they used an "independent source?" No source could be more biased and inflationary.

Then we learn that the study used the old pharma trick that dates back to studies done in the 1980's to mislead Congress into extending patents from 17 to 20 years—the trick of taking the expiration date of the first patent on a drug as "the beginning of generic competition," when everyone knows drug companies pay patent lawyers millions to add one patent after as a way to obstruct or delay generic competition. This old trick greatly reduces the resulting artificial estimates of how much the sponsoring company makes per new drug.

Finally, this report on prices not only has no data on prices but then reports "we could not complete a rigorous investigation of the short- and long-term effects of price deregulation on U.S. prices and consumers." But wasn't that the whole point of doing the study, the effect on U.S. consumers? The headline in Aldonas's testimony reads "U.S. Consumers Would Benefit From The Elimination Of Price Controls Abroad," but the text provides no evidence! And indeed there is no evidence. This is yet another myth aggressively promoted by the pharmaceutical industry, together with the Department of Commerce, a new story made up about 4 years ago to add a new twist to the old myth that prices had to be high in order to pay for their very costly R&D.

Let's look at some pharma doublespeak:

- "free market": free to set prices where you want, free of price competition;
- "market price": the price a drug company can set in a market protected from price competition;
- "price controls": negotiated wholesale contracts by national buyers seeking good value;
- "reference pricing": paying no more for a new drug that is little better, but paying more for ones that are better;
- "innovative drug": any new drug, even though 80–90 percent of them are no better; and
- "R&D": characterized as devoted to discovering breakthrough drugs but largely devoted to derivative research for new variations.

THE MYTH OF THE U.S. "FREE MARKET"

Grant Aldonas and all the other advocates of big pharma refer to the "free market" in the United States and claim that other countries pay less than "market price." But what is "market price" in a oligopolistic market, where competitors hold off from competing on price and practice forms of *de facto* collusion that are legal, because true price competition would seriously damage all of them? *"Market prices" are essentially monopoly prices that other large firms do not challenge very much.*

This leads to a second myth implied by pharma advocates, that patents give one the right to 20 years of monopoly pricing. Both of these claims are untrue. No expert in patent law who is not retained by the pharmaceutical industry would agree they are. Patents give one 20 years to try to find a market application and to see what buyers will pay for their unique advantages, without competitors copying one's invention. Most patents never find a market, and when they do, their price varies from little more than cost to bonanza profits.

Most patents on "new" drugs are for innovations little better than much cheaper drugs already discovered before: so why should anyone pay more for them? Because the advocates for big pharma say their clients have a "right" to a monopolistic "market price"? That's a contradiction in terms and just not true. The whole argument is trumped up.

Further, it is well documented that pharmaceutical companies unilaterally raise their world-high prices still higher. This is the only industry where prices are raised on last year's model, and the model from the year before that costs even more!

Corporate price controls, the ability to raise prices on last year's model at will, and consistently much greater profits than other industries are three clear signs that drug companies are monopolies, created by anti-free trade government laws. This hearing is on a proposal to eliminate wholesale competitive markets and impose corporate price controls on other nations. What big pharma loves so much here is a monopoly friendly market and government, not "market prices" or "free trade." *What the drug companies are advocating is imposing corporate price controls on the rest of the free world.*

Secret prices are a major feature of the so-called free market in drugs in the United States. Have you ever heard of a "free market" that features secret pricing? It's as if you go into a restaurant for a fine meal and the menu has no prices. You tell the waiter what you'd like and ask how much it will cost? The waiter says, "Come back to the manager's office and we'll set a price for you." The manager closes the door and assesses how much you want that meal, how much money you have, and how much money he'd like to make. Then he gives you a secret price. Next customer. That is roughly how the pharmaceutical firms have arranged for the "free market" to work.

A far more accurate way to think about pharmaceutical markets is that they are competitive wholesale markets throughout most of the world, where large volume buyers negotiate with large, powerful sellers who hold patents on unique products. Then other countries, like Canada, set their prices on these wholesale negotiated prices.

LITTLE SPENT TO SEEK BREAKTHROUGH DRUGS

The advocates for the industry misled Congress and the public into believing that they spend 16–18 percent of sales on research for breakthrough drugs. As one company puts it, "Today's medicines pay for tomorrow's miracles."

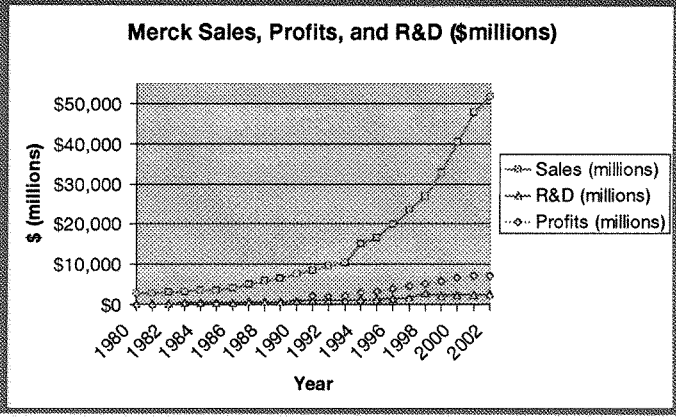
But objective data from the National Science Foundation (NSF) document that all R&D investments are closer to 11 percent of sales, and that only 18 percent of that goes to basic research to find the next miracle. Then taxpayers subsidize pharmaceutical R&D to the tune of 40 percent; so *the net investment of pharmaceutical companies in research for breakthrough drugs is 1 percent, 1 cent on the dollar, not 18 percent*. (.11 x .18 x .60)

Raymond Gilmartin goes around the country presenting Merck as the premier research drug company, old and far more dedicated to discovering breakthrough drugs than many other, more market-oriented drug companies. But an analysis of Merck's 10-K financial reports to the Securities and Exchange Commission documents that Merck has been putting far less of its soaring revenues (before the Vioxx crash) into research than the industry average. It peaked at 12 percent for R&D in 1985 and has declined steadily through the 1990's to only 5.2 percent in 2002. As the graph below shows, Merck has been pocketing more and more of its profits too, rather than plowing them back into research. If you assume that 18 percent of total reported R&D goes to basic research and subtract out 40 percent of subsidies from other taxpayers, that means Merck spent only 0.37 of a penny on every dollar of revenue it took in 2002.

Merck's R&D as Percent of Sales and Profits

Year	Sales	R&D	Profits	R&D as % of Sales	R&D as % of Profits
	($millions)				
1980	$2,734	$234	$418	8.6%	56.0%
1985	$5,847	$826	$840	14.1%	98.3%
1990	$7,672	$854	$1,581	11.1%	54.0%
1995	$16,681	$1,331	$3,335	8.0%	39.9%
2000	$40,363	$2,315	$6,822	5.7%	33.9%
2002	$51,790	$2,677	$5,149	5.2%	52.0%

Merck: Soaring Sales Did Not Go to R&D



The cost of R&D for new drugs is also far lower than $800 million or $1.6 billion. First, those estimates are based on secret, unverifiable "costs" submitted by drug companies to research teams they sponsor to produce big estimates. Second, the best of the estimates is based on the most costly 20 percent of new drugs and then generalized to the average new drug, a large distortion. Third, the estimates leave out substantial taxpayer contributions. Fourth, half or more of the estimates consist of building large estimated profits into the econometric model and then calling them a "cost." One bottom line is that the actual costs reported in secret, unverified numbers by drug companies were $60 million average for the most costly 20 percent of new drugs. Then the industry-sponsored team built a model to multiply those real costs 14-fold, to $802 million. Independent analyses, which Congress and employers never see, estimate that the R&D for new drugs averages less than $100 million.

Current laws and regulations do not reward true innovation but derivative innovation. They reward both equally, and derivative innovations involve much less risk and costs; so we get what we pay for. This is an important reason why pharmaceutical companies are becoming less innovative, because current incentives reward low-level innovation. That's why pharmaceutical companies hire twice as many lobbyists as Congressmen and spread around hundreds of millions, so that corporate welfare replaces success in open markets. That's why they want you to use legal powers and threats to substitute for true innovation.

In sum, government laws and regulations reward derivative research rather than research for breakthrough drugs, and blocking free trade will further reward the signs of monopolies: manipulating governments and politicians rather than producing good value, setting high protected prices and raising them, and raking in monopoly profits far higher than other healthy industries. Congress can choose to help the industry become more innovative and productive, or condone the increasingly unsustainable present course.

CONCLUSION

If Congress wants to know how credible its witnesses are, it should require witnesses under oath to state how much money or other benefits they have received in the past 3 and 6 years, directly and indirectly, from the industry with a stake in the issues being discussed. The pharmaceutical industry has never provided audited figures showing how long it takes them to recover R&D costs, but now we know they recover them every year at European prices, with profits to spare, not counting the huge U.S. market. If Congress wants to get an honest picture of how European prices affect American prices and whether Europeans are "free riding" on Americans, why don't they commission an independent study? Meantime, the limited research by my colleagues and me have documented that these claims are myths and that current policy is harming American business and economic growth.

DEMYTHOLOGIZING FOREIGN FREE RIDERS AND OTHER POLICY MYTHS

OVERVIEW

An international campaign by the United States Government aims to use the threat of trade sanctions to persuade other industrialized countries to sign bilateral Free Trade Agreements that would lock in U.S. high prices by prohibiting the export of lower-priced patented drugs and raise prices in other countries by making them agree to postpone generic price competition by extending the exclusive control of patent-holding companies for 5 more years over the data from clinical trails that generic companies need for approval to market their drugs. Other clauses weaken a country's pricing scheme to further increase prices on patented drugs.[1 2]

This campaign is based on the argument that lower prices in the UK, Canada, Australia and European countries do not pay for research and development (R&D) costs. Thus the UK and these other countries are widely characterized as "free riders" on high U.S. prices and innovation, where most of the world's pharmaceutical research is now said to be taking place. Lower foreign prices are said to impede innovation, which now occurs predominantly in the United States, and the price gap between the USA and other affluent countries is widening. Lower foreign prices are said to be a cause of high prices in the United States.

We have examined each of these widely believed "facts" and found no evidence to support any of them. In fact, we have found that industry data supports the opposite of these facts, namely:

(1) prices in the UK, Canada and other affluent countries pay for all R&D costs every year just out of their domestic sales;

(2) prices in the UK and other affluent countries have nothing to do with high U.S. prices, which the industry raises frequently after setting them at the highest levels;
(3) research and research funds for new drugs is growing briskly, not declining, even in Europe and the UK;
(4) Europe and the UK are more innovative than the U.S. in proportion to their size;
(5) this whole argument makes no sense in terms of the global nature of pharmaceutical markets or in terms of basic economic theory;
(6) not much research effort goes toward finding new drugs that are superior to existing drugs because incentives reward derivative and me-too research more than long-shot breakthrough research; and
(7) drug companies devote only 1.3 percent of gross revenues to breakthrough research, net of taxpayers' contributions.

The references enable any journalist or policymaker to verify the basis for our statements, and further detail is available upon request.

The "free rider" argument is a story told tirelessly to policymakers and journalists with no foundation in fact. The pharmaceutical industry's own data and reports document that U.S. prices are well above levels needed to pay for R&D, manufacturing, marketing and administration, with profits to spare. The British approach, despite its flaws, rewards the discovery of new molecules over variations of existing ones. It guarantees profits and supports small, young biotech companies. It promotes the growth of its pharmaceutical industry, while it holds down prices for its own health service.

In response to a revolt among American patients to the high prices charged for their drugs, and to widespread pressure from almost every State legislature to lower the prices of drugs for their employees and for Medicaid,[3] the pharmaceutical industry and high government officials have claimed that U.S. prices are so high because other industrialized nations' low prices do not pay for research and development. The price gap, they claim, is widening as foreign countries lower their prices. Thus, they are "free-riders" on Americans, who have to pay for the bulk of the R&D and who make most of the important new discoveries.

Americans have taken this argument to heart and are angry about what the nationally syndicated columnist, William Safire, called the "foreign rip-off."[4] Acting on these claims, the Bush administration is threatening trade sanctions and using other forms of economic pressure to get these other countries to raise their prices, limit price competition and block export of their cheaper drugs to the United States.[5][6] The goal is to make other countries pay as much as Americans do. The implicit promise is that if other countries pay more, American patients or their payers can get relief and pay less.[7]

Some Congressmen, however, have been concerned from the start that this global campaign to erect a new set of legal barriers to free trade and price competition will harm American payers and patients by locking in high prices.[6][8][9][10] These concerns have merit, because the Free Trade Agreements raise costs for businesses and make them less competitive in world markets. They are likely to reduce productivity and increase sick days for workers who get ill but feel they cannot afford prescribed medicines to get better. The concerns of these Congressmen also have merit because we can find no evidence for the reasons given for pressuring other countries to raise their prices and block free trade.

NO EVIDENCE OF FREE RIDING

All the evidence we can find indicates that corporate R&D costs for new drugs are fully paid for in each country as an annual corporate expense. For example, 70 pharmaceutical companies report that domestic sales in Canada are about 9 times greater than R&D costs; so they are easily paid for each year. Audited reports in the UK show that domestic sales just to the National Health Service are about 6 times R&D costs, with substantial profits after all costs each year.[11][12]Huge export sales (largely to the U.S. at prices much higher than in the UK) are extra. William Safire's claim of a "foreign rip-off" with Americans paying for the world's R&D is contradicted by these facts.[4]

PRICE GAP DUE TO COMPANIES RAISING U.S. PRICES

Studies confirm that the gap between U.S. and foreign drug prices has been widening, but the growing difference is due to pharmaceutical firms raising their U.S. prices, not to European countries lowering theirs.[13][14][15][16] As audited figures from the UK show, drug prices could be substantially lower and still cover research costs, with healthy profits as well. Specifically, although prices in the U.K. are substan-

tially lower than in the U.S., pharmaceutical firms in that country devote a greater percentage of domestic National Health Service sales to R&D than do companies in the U.S. At the same time, these companies still report profits of 15 percent on those sales before taxes.[14]

NO EVIDENCE OF RESEARCH DECLINE

There is also no verifiable evidence for the claim that the prices in other affluent countries are "slowing the process of drug development worldwide." For example, according to Organization for Economic Cooperation and Development figures, between 1995 and 1999 R&D grew in Germany, the United Kingdom and Canada by 85 percent, 51 percent and 46 percent respectively, compared to 30 percent in the U.S.[17] Investments in R&D have continued to rise steadily since then as well.[18] Since 1990, pharmaceutical companies have increased their European research budgets by more than 160 percent, and in Belgium, Sweden and Spain by much more than that.[19] Nor can we find any evidence that these foreign prices "discourage the R&D needed to develop new products," as the Commissioner of the FDA put it.[1]

U.S. LESS INNOVATIVE THAN THE UK OR EUROPE

Contrary to claims of American dominance, the latest data from the pharmaceutical industry itself show that European research teams have been discovering more major new drugs (new molecular entities) than their proportional share of global sales, while U.S. teams have discovered less.[19] Specifically, in 2002 the U.S. accounted for just over 49 percent of world sales, but it took 50 percent of global R&D expenditures invested in the U.S. to discover 45 percent of the new molecular entities that were launched on the world market.[19] In previous years, Europe was still further ahead of the United States. The U.S. is gaining ground, but corporate R&D investment in Europe has continued to grow. In 2000, four other industrialized countries devoted more of their GDP to R&D for new drugs than the U.S.[17]

LIMITED BASIC RESEARCH BY INDUSTRY

The long-standing survey of basic and applied research by the National Science Foundation (NSF) last calculated that 18 percent of the total domestic research and development (R&D) budget for the pharmaceutical industry went to basic research, to discover breakthough new molecular entities.[20] Industry-sponsored figures based on proprietary data are much higher but cannot be independently verified.[21] Given that the NSF survey found that pharmaceutical firms spend only 11.8 percent of revenue on R&D, this means only 2.1 percent of revenue goes to discovering new drugs. The net percent after taxpayer subsidies is even lower. The after-tax cost of $1 of R&D expenditures in the U.S. for large companies appears to be in the range of $0.53 to $0.61.[22]

The end result is that, net of taxpayers' contributions, drug companies invest net about 1.3 cents of every dollar from sales in basic research for "tomorrow's miracles." This investment pattern makes good economic sense, as senior financial writer, Merrill Goozner, describes in detail.[23] Basic research takes so long and has so many twists and frustrations that no company can reasonably invest much in it year after year. Quite sensibly, the industry monitors the hundreds of basic science teams around the world and waits until one of them comes up with a promising breakthrough. It would help if industry claims and rhetoric more accurately reflected the facts. "Today's medicines pay for tomorrow's miracles" only a little bit.

U.S. taxpayers also paid for the National Institute of Health budget as well as medically oriented R&D funds in the Department of Defense and other departments. Most of that money went for basic research, and public money also supports more than 5000 clinical trials.[24] [25] These figures do not support the industry's claim that they spend huge sums at high risk to discover the next generation of breakthrough drugs.

Companies are investing most of their money into the less risky task of developing variations on existing drugs, where the mechanism of action, general effectiveness and safety profile are already known. Independent review panels plus a major industry review have concluded that only 10–15 percent of "new" drugs provide a significant therapeutic breakthrough over existing drugs.[26] [27] [28]

To summarize, basic R&D into drugs that provide significant therapeutic advantages is only a fraction of overall R&D expenditures and does not require the high prices currently seen in the United States to support it.

THE BAIN REPORT—PERPETUATING THE MYTH OF LOW PRICES AS A BAD BARGAIN

A recent report supported by the pharmaceutical industry (the Bain Report) and reported to millions of Americans by AARP[29] claims to document the "high cost of Europe's free ride."[30] Yet the report contains almost no verifiable facts. It portrays Europe as a "free rider" that will suffer from less drug innovation and "higher morbidity and mortality from diseases that could be treated with innovative drugs—if they were more readily available in Europe.[30] No evidence is provided for this unlikely prediction. Morbidity or mortality are lower in Western Europe than in the United States. No evidence is provided that therapeutically beneficial drugs are less available in Europe. The few facts in the report are contradicted by reputable published reports, including a publication from the European Federation of Pharmaceutical Industries and Associations.[19]

The Bain report does not mention that proportionately more new major drugs are being discovered in Europe, nor that pharmaceutical companies have continued to invest more and more research money in Europe, nor that most new drugs have few additional benefits to patients. The Bain report's model claims to show a negative economic and social impact in Germany as a result of "free riding," but it presents no data or facts and hides many unlikely assumptions inside its general graphs. The fact that the countries in which substantial drug research takes place pay for the cost of that research through domestic sales alone is ignored.[12 17] Rather, readers will find that the "free rider model" and the report are based on a new premise of industry-sponsored reports: *the more drugs people take, the healthier they will be, and the more they pay for them, the better off a country will be.* The increased prices and profits from the U.S. market are presented as the ideal. What may be unsustainable are the rising prices in the United States.

ECONOMIC THEORY AND THE PHARMACEUTICAL INDUSTRY

Beyond not being substantiated by the facts, the free-rider story that the pharmaceutical industry promotes in Europe to pressure the UK and the EU to liberalize market makes no economic sense. First, the entire argument that prices are high because there are high fixed costs for research contradicts basic economic theory that price has nothing to do with past fixed costs but is set by the market. The argument for high prices to cover fixed costs only makes sense if companies are asking governments to make sure that prices cover the high fixed costs as a social good. This line of reasoning is basis for utilities: high fixed costs and low running costs for a valued social good like clean water or electricity. Society sets up a system for accounting and review so that charges are aligned with those costs. But the pharmaceutical industry makes a utilities argument in order to gain the power to charge what it wants, without having to report cost data or be subject to a utilities board that would review the relations between charges and costs.

Second, which country discovers more drugs is largely irrelevant to how the global pharmaceutical markets work. It is effective political rhetoric that arouses nationalistic feelings but has little to do with the economics of the global drug market. The industry quickly capitalizes on new discoveries from any country, tests them in countries where it is most advantageous and then markets the resultant products everywhere where it is profitable. If research and discovery really worked by national markets, the industry would shut down its operations in small countries like Switzerland, when in fact it is delighted by exploit Swiss innovations worldwide. It is both remarkable and disturbing when leading health economists promote either of these arguments that contradict basic economic theory and the economics of the pharmaceutical industry.[1]

Third, the claim that prices in most affluent countries do not pay for research can only be made through unorthodox accounting methods in which all research costs are written off each year as they occur. Further, R&D is the heart of the industry, and R&D costs are reduced by tax deductions and credits; so if anything, they are deducted before marketing and other costs. If revenues were inadequate, it would make more sense to conclude they do not cover all marketing costs rather than research costs. Global pharmaceutical companies report that they invest 2.5–3.0 times more in the combination of marketing, advertising and administration than in research costs.[31]

A fourth common assertion is buried inside the term "free rider." This term conveys the image of someone jumping on for a free ride; but the formal economic definition is something referred to as the "proportional allocation of fixed costs." For example, if some buyers (Group A) pay $1 per pill and others (Group B) pay $2 a pill, and if they each buy a million pills, then a conventional rule in financing allocates any large fixed cost proportionately, so that Group A is said to be paying half as much of the fixed cost as Group B. Group A (e.g., Europe) is then said to be "free

riding," though the term is both inaccurate and moralistic. If, however, the fixed costs are only $300,000–$600,000 or ½10th to ⅕th" of the $3 million total revenues for the 2 million pills, then one could just as easily say that Group A is more than paying for the fixed costs, while Group B is paying much more than it has to. This is the flat allocation of fixed costs, and it highlights how much more Group B (American patients and payers) are paying than is necessary to cover the fixed costs of corporate research. So-called free riding can be eliminated by cutting the price of Group B in half as easily as doubling the price of Group A.

The core argument by the Bush administration and the drug industry is that nations in Group A are "free riders" and should be coerced into paying $2 a pill like Group B. But there would also not be any "free riding" if Group B's prices were cut in half to $1 a pill. Solving the so-called free rider problem this way would make drugs more affordable and lowers the ceiling of global prices, while still paying for the fixed costs of research. The U.S. campaign to raise foreign prices to American levels simply makes them less affordable and raises profits even higher for what is already one of the world's most profitable industries.

A final charge is that efforts to lower prices for patented drugs by other countries, and by major employers, unions and Governors within the United States, are "no different than violating the patent directly" to make cheap copies.[32] This is a remarkable statement by a major health economist, because it means that normal competition, in which large buyers use their buying power to seek better value, is a criminal act and morally offensive. In a similar vein, the Under Secretary of Commerce told Congress that lower prices abroad were a "negative tax" on the American people. Yet most countries pay by value, little or no more for new drugs no better than existing ones, and considerably more for superior new drugs. The UK, of course, does not set prices at all but rather uses a system to reward serious research and support the pharmaceutical industry.

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[Whereupon, at 11:50 a.m., the committee was adjourned.]

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