

**POLICY IMPLICATIONS OF PHARMACEUTICAL
IMPORTATION FOR U.S. CONSUMERS**

HEARING

BEFORE THE

SUBCOMMITTEE ON INTERSTATE COMMERCE,
TRADE, AND TOURISM

OF THE

COMMITTEE ON COMMERCE,
SCIENCE, AND TRANSPORTATION

UNITED STATES SENATE

ONE HUNDRED TENTH CONGRESS

FIRST SESSION

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MARCH 7, 2007
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ONE HUNDRED TENTH CONGRESS

FIRST SESSION

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POLICY IMPLICATIONS OF PHARMACEUTICAL IMPORTATION FOR U.S. CONSUMERS

WEDNESDAY, MARCH 7, 2007

U.S. SENATE,
SUBCOMMITTEE ON INTERSTATE COMMERCE, TRADE, AND
TOURISM,
COMMITTEE ON COMMERCE, SCIENCE, AND TRANSPORTATION,
Washington, DC.

The Subcommittee met, pursuant to notice, at 9:30 a.m. in room SR-253, Russell Senate Office Building, Hon. Byron L. Dorgan, Chairman of the Subcommittee, presiding.

OPENING STATEMENT OF HON. BYRON L. DORGAN, U.S. SENATOR FROM NORTH DAKOTA

Senator DORGAN. We'll call the hearing to order.

This is a hearing of the Subcommittee of the Commerce Committee. The Subcommittee on Interstate Commerce, Trade, and Tourism is here today to consider an issue of importation of prescription drugs, FDA-approved prescription drugs.

I'm joined by the Ranking Member on the Subcommittee, Senator DeMint. Senator DeMint, welcome. And we will have some others join us momentarily.

There had previously been two votes scheduled for 10 o'clock this morning. They have just been postponed until this afternoon. So, we will not now be interrupted by votes.

Let me ask that the door be closed, please.

We're here today to consider a matter that literally can mean the difference between life and death for many Americans, and that is the cost of prescription medicines. Clearly, there are some miracle drugs that are available in this country, thanks to substantial research by the National Institutes of Health, by the pharmaceutical industry and others. But miracle drugs offer no miracles to those who can't afford them. And the question we're going to ask today is whether we believe that American consumers ought to pay the highest prices in the world for prescription medicines. My answer to that is, of course, no. I don't believe they should be paying the highest prices in the world. I think the American taxpayers already heavily subsidize research, through the tax code, and we pay for basic research at the NIH that's led to many breakthroughs for wonder drugs currently marketed by prescription drug manufacturers.

Today, we're considering whether we should continue to allow the prescription drug companies, or the pharmaceutical industries, to dictate the prices that U.S. consumers pay for prescription

drugs, or whether we ought to allow a little price competition into the marketplace for prescription drugs.

Today, we will talk about prescription drugs, and we will only refer to, and mean, FDA-approved prescription drugs.

Should we allow the safe importation of FDA-approved medicines from Canada and other Western industrialized nations? This routinely has happened for a couple of decades in Europe, through parallel trading. If you're in France and want to buy a prescription drug from Italy; or in Spain and want to buy one from Germany, the parallel trading system has worked well for European consumers, with no safety issues at all.

Given the substantial price differences between products sold in the U.S. and abroad, it will come as no surprise that the American people feel strongly about this and already do import some prescription drugs. Let me use a chart to show the difference in pricing. And I'll show two bottles of Lipitor. Lipitor is a fairly common prescription drug in this country for lowering cholesterol levels. These two bottles contain exactly the same pill, produced in exactly the same FDA-approved plant in Ireland. The only difference is, one is shipped to Canada, one is shipped to the United States, one is \$1.83 per tablet, the other is \$3.57 per tablet. Same bottle, same pill, produced in the same place, different prices. The American taxpayer is charged just about double, and I think that's unfair. The same is true with a good many other drugs—Prevacid, Zocor, Nexium, Zoloft, and so on.

[The information referred to follows:]

Drug Companies Take Advantage of U.S. Consumers				
Drug	Use	U.S.	Canada	Markup to U.S. Consumers
Lipitor	Cholesterol	\$321.30	\$164.34	96%
Plavix	Cardiovascular Disease	\$370.41	\$252.90	46%
Prevacid	Ulcers	\$419.96	\$213.36	97%
Zocor	Cholesterol	\$178.87	\$136.98	31%
Nexium	Acid Reflux	\$417.48	\$269.10	55%
Zoloft	Depression	\$248.81	\$163.83	52%
Zyprexa	Depression	\$556.54	\$244.56	128%
Neurontin	Seizures	\$147.65	\$102.60	44%
Effexor XR	Depression	\$302.18	\$169.20	79%
Advair Diskus	Asthma	\$157.37	\$85.02	85%

Source: U.S. and Canadian Websites
All prices are based on 90 doses except for Advair Diskus which is based on 60 doses.

Senator DORGAN. The question before the Congress has been now, for some long while: Can we allow for the safe import of pre-

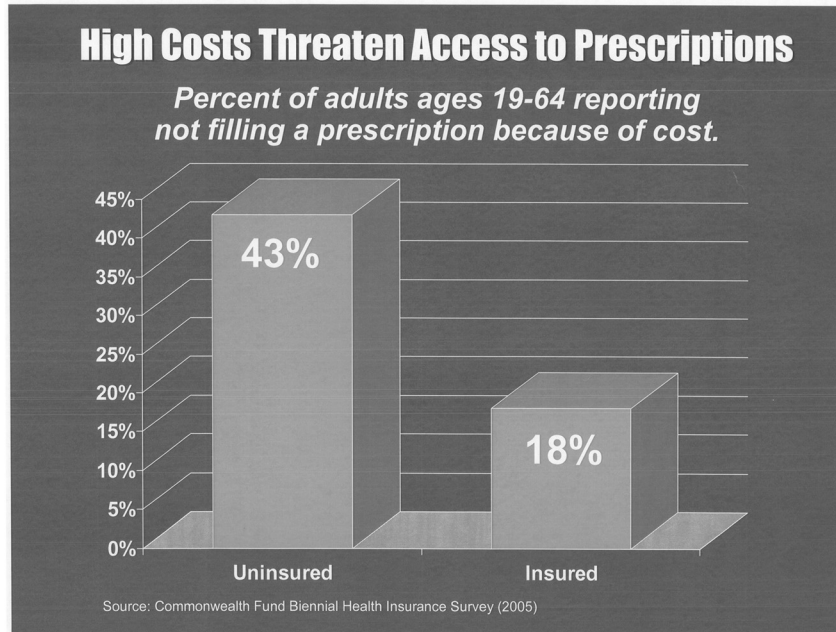
scription drugs from FDA-approved plants in other countries? My answer to that is yes. I believe that we have produced a bipartisan piece of legislation—cosponsored by many Members of Congress. The Pharmaceutical Market Access and Drug Safety Act of 2007—Senator Snowe, Senator Grassley, Senator Kennedy, Senator McCain, Senator Stabenow, and many, many others have cosponsored this legislation. We believe it puts in place an effective regulatory framework to make the importation of FDA-approved drugs safe for consumers, and gives consumers the opportunity to use the market system for FDA-approved drugs, to avoid having to pay the highest prices in the world.

We have witnesses today with a wide variety of views on this subject. It will be interesting to hear them. Some are among the most vigorous defenders of the pricing strategy by the prescription drug companies, others say we ought to put market-price competition to work for consumers.

Let me be clear that my goal is not to force Americans to go to Canada to purchase prescription drugs, but, rather, to create a little competition in the marketplace so that we can put real downward pressure on domestic drug prices. I believe that what is happening currently is wrong. I think it's unfair. Some say that, "Well, it doesn't matter. We now have prescription drug coverage for senior citizens."

There are tens of millions of citizens—in fact, 43 percent of the uninsured American adults, aged 19 to 64—I have a chart to show on that—18 percent of insured adults did not fill prescriptions because of cost. The result is that paying the highest price in the world is diminishing opportunities for healthcare for a good many Americans, and we believe the marketplace ought to be used to provide a fair break for American consumers. When I say "we," I'm speaking the royal "We," of course. I'm sure there are—well, I know there are some in Congress that would disagree with that.

[The information referred to follows:]



Senator DORGAN, Let me call on the Ranking Member, Senator DeMint.

**STATEMENT OF HON. JIM DEMINT,
U.S. SENATOR FROM SOUTH CAROLINA**

Senator DEMINT. Thank you, Mr. Chairman. Appreciate you holding these hearings. And I do take Lipitor, and if there are any in there you'd let me have, I'd really appreciate that.

[Laughter.]

Senator DEMINT. Could save me \$300.

But I appreciate everyone being here, particularly the ones who are going to be on the panel. And what I hope we can have today, maybe, is a little intellectual honesty. There are so many of us who are supportive of free trade and the value of that and how that keeps prices down, how that keeps competition in this country and outside of this country. It needs to apply to prescription drugs. It doesn't make sense for the Food and Drug Administration to say it's OK to import all kinds of food products from all over the world that are much more difficult to put in tamper-proof containers than pharmaceuticals, and then say that it's not safe to import pharmaceuticals, particularly reimport the drugs that have been made here in blister packs that are tamperproof. It doesn't make sense to take that tack. It doesn't make sense to say it's dangerous to import drugs that were made in America, when a lot of the ingredients for all the drugs in this country are imported in bulk, which are much easier to contaminate than finished drugs that are in tamperproof containers. It's very obvious to me that safety is not

an issue. It's just a distraction. And I want to hear that explained, particularly from Dr. Lutter today.

We know the issue is with other countries and trade agreements. We're afraid, the pharmaceutical companies are, that if they don't honor the fixed prices in Canada and other parts of the world, that these countries will simply take their patents and produce their drugs. This is a trade issue which the Administration needs to address. I hear folks say that, by us reimporting from Canada, that we're importing socialism. In fact, what we're doing now is, we are propping up socialism in Canada and other parts of the world. We charge American consumers a higher price, and then allow other countries to dictate a lower price for their citizens, allowing Americans to subsidize and pay for our own drug products in other parts of the world. It's difficult for me to find any intellectual honesty in the arguments against allowing Americans to buy drugs from any part of the world that are FDA-approved from FDA-approved or certified facilities.

So, I'm very interested in the discussion today. And, again, all I ask for is some intellectual honesty and consistency.

Thank you, Mr. Chairman.

Senator DORGAN. Senator Vitter?

**STATEMENT OF HON. DAVID VITTER,
U.S. SENATOR FROM LOUISIANA**

Senator VITTER. Thank you, Mr. Chairman. And thank you for convening this important hearing.

I guess I round out the spectrum of opinion on the panel by saying amen to everything that was said before me, because I also am an ardent supporter of reimportation, which I know can be done safely, completely protecting American consumers. And I say that about those of us up here, because I think it makes an important point. We obviously represent different points on the political spectrum. Maybe we define the political spectrum, I don't know. But we all agree on this issue, and I think we all share the clear majority consensus opinion of the American people.

I've been working on this issue since I was in the House. It's been a top priority of mine, including as I came to the Senate. I want to thank and salute the Chairman for his leadership on this. He and Senator Snowe have one of the leading bills, and I appreciate all of their leadership on it.

I have a separate bill that's very similar in many ways, and certainly has exactly the same goal, which is supported by Senator DeMint and others. And I completely agree with the previous comments, that this is a matter of political will—not technology, not what is possible, but what is the—when will we have the political will to get this done for the good of the American people? Besides my broadbased reimportation bill and my work with Senator Dorgan and others on their measures, I've also been involved in a couple of amendments that have passed. In particular, I teamed up with Senator Stabenow to pass language prohibiting trade agreement barriers to reimportation. Up until that point, there was a very, very onerous practice which was becoming established of the Administration using bilateral trade agreements to insert anti-reimportation language through those trade agreements. And the

threat was being posed that even if we were to be able to pass significant reimportation legislation, if you had all these trade agreements out there, with many, many countries, reimportation would still be blocked through that route. I'm happy to say we put an end to that practice—first, with this amendment on an appropriations bill, and that led to the current USTR abandoning, and stating very clearly to me and others that she would abandon this practice of trying to negotiate those provisions in trade deals.

Also, more recently, we were able to pass a significant amendment, again, on an appropriations bill, to prevent the enforcement of the law against United States consumers who are coming home from Canada with amounts of prescription drugs from Canadian pharmacies that were simply for personal use. That passed the Congress overwhelmingly. It has now gone into law. And I would also note that, after dire predictions about what that would cause, the safety concerns and everything else that would cause, I don't know of any documented cases of problems that that has, in fact, caused.

But we do need to go further. We do need a full-blown reimportation bill to establish all of the safety procedures that we need to ensure the American people safe drugs in a true free-market environment.

And I would certainly echo Senator DeMint's comments. I believe in free trade. I believe in global commerce. I don't understand why all of that stops, and all of those rules go out the window completely when we get to prescription drugs. It doesn't occur when we talk about food and other products that clearly have safety implications. We do things to guard against safety violations in those areas. It doesn't when we talk about products which may be subsidized in other countries. We certainly try to fight that subsidization. But, you know, free trade doesn't come to a grinding halt with regard to those other products because of those concerns. So, I would echo Senator DeMint's call for intellectual honesty and consistency on this topic.

Thank you.

Senator DORGAN. Senator Snowe is the principal cosponsor of the Pharmaceutical Market Access and Drug Safety Act of 2007. We have 31 cosponsors in the United States Senate, spanning the ideological spectrum. My expectation is that the Congress will have to address, and the Senate will address, this legislation, at long, long last, this year. Senator Snowe, thank you.

**STATEMENT OF HON. OLYMPIA J. SNOWE,
U.S. SENATOR FROM MAINE**

Senator SNOWE. Yes, thank you, Mr. Chairman. And I thank you very much for holding this hearing, once again, on a critical issue facing so many American consumers. And I want to applaud you for the leadership that you provided in shaping the legislation that we are considering here in the Senate, and hopefully in the overall Congress, and before this Committee.

It's unfortunate that we're at a point that we have not been able to enact this legislation. This is about the tenth Senate hearing that's been held on the subject since 2004. It's been repeatedly studied. One-third of the Senate, as the Chairman indicated, is co-

sponsoring this legislation. In fact, 2 years ago, the Commerce Committee adopted an amendment to the FCC reauthorization based on our legislation. But, despite that, we've obviously faced considerable resistance and barriers to enacting this legislation.

And what is tragic in all of this is that 70 percent of the American people support drug importation. And for a very good reason, because of the skyrocketing increases in the cost of medications, exceeding two and even three times the rate of inflation. And I think that the penalties that ultimately are imposed by cutting off supplies to pharmacies in Canada, for example, is another way of placing tremendous burdens on the American consumer, and forcing them to ultimately look to sources that might end up being counterfeit drugs. And so, we set up a system in this legislation that I think undeniably provides for the security of the medications coming across the border from Canada or from the European Union and other countries, that have demonstrated, over decades, that parallel trading can work, and can work safely. And that's what our legislation is designed to do. With FDA-approved, registered, and inspected, facilities—and, the fact is, many more inspections than is required now currently under law for those FDA-approved facilities, and then, second, setting up a pedigree, being able to track the medication. We also provide for the financing for the administration of this program, as well.

So, I think that we have identified every conceivable and legitimate concerns about how we're going to import these medications, and we will do so on a safe basis. We've addressed all of those initiatives in this legislation. Furthermore, it provides savings to the consumer, according to Congressional Budget Office.

In addition to all of that, I think the American consumer deserves to have a break when it comes to prescription drug prices in this country. We pay the highest prices of any consumers in the world. And I think that is inappropriate, given the investments the America taxpayer makes in research and development, without question. And the industry has not had to operate under the competition which would ultimately benefit the American consumer. And so the American consumer has paid a price in more ways than one.

And so, in drafting this legislation, we designed a safe system, above and beyond everything else. It is possible to implement. It is doable, it is reasonable. And I think that, frankly, the time has come—hopefully it's going to be this year. We can assure safety. That's what it's all about. It's not simply certifying safety, our legislation assures safety through a systematic process that requires every facet to be determined and certified and monitored by the FDA. And with the requirements that are necessary in dispensing prescriptions and certifying people's histories and verifying their prescriptions, and also tracking drug shipments, and the entire history and chain of custody.

So, with that, Mr. Chairman, I appreciate your leadership on this matter. Hopefully, we can get above and beyond and address the questions here today, and hopefully we can pass this legislation.

Senator DORGAN. Senator Snowe, thank you very much.

I don't think there's much question but that there is a majority on the Commerce Committee now in support of reimportation legis-

lation. It's my intention to work very hard to move it out of the Commerce Committee and get a vote on it, on the floor of the Senate. Identical legislation has been introduced in the U.S. House, and my hope is that, at long, long last, perhaps the America consumers will be treated fairly.

We are, first, joined by Dr. Randall Lutter, who's the Acting Deputy Commissioner for Policy at the Food and Drug Administration.

Dr. Lutter, we appreciate your being here, and you may summarize your testimony. We have added a copy of your full testimony, which I read last evening. And we appreciate your being here.

**STATEMENT OF RANDALL W. LUTTER, Ph.D.,
ACTING DEPUTY COMMISSIONER FOR POLICY,
FOOD AND DRUG ADMINISTRATION, HHS**

Dr. LUTTER. Thank you very much, Mr. Chairman and members of the Committee—Subcommittee. I'm Randall Lutter, Acting Deputy Commissioner for Policy at the U.S. Food and Drug Administration, and I very much appreciate the opportunity to discuss the important issues relating to importation of prescription drugs.

At FDA, our statutory responsibility is to assure the American public that the drug supply is safe, secure, and reliable. FDA remains deeply concerned about unapproved imported pharmaceuticals whose safety and effectiveness cannot be assured because they originate outside the closed system we're fortunate to have in the United States.

In 1987, due to widespread distribution of imported counterfeit drugs, including antibiotics and birth control pills, Congress passed a law that strengthened the oversight of domestic wholesalers and only allows a drug manufacturer to import a drug originally made in the U.S. and then sent abroad. The conclusion of Congress reflected, in current law, is that the safety and effectiveness of imported drugs is best assured by carefully limiting how prescription drugs can be imported into the U.S. as part of a closed drug distribution system.

The Department of Health and Human Services convened a task force in 2004 to examine issues related to drug importation as it was directed to study by Congress as part of the Medicare Modernization Act. We have copies of the report available to anyone here. The report drafted by this task force clearly outlined significant safety and economic issues that must be addressed before the widespread importation of unapproved prescription drugs can be permitted. The report is still, we believe, the most comprehensive examination of the issue, and we continue to find evidence supporting some of its findings.

Key findings identified in the task force report include the following. There are significant risks associated with the way individuals are currently importing drugs that violate the Food, Drug, and Cosmetics Act. It would be extraordinarily difficult and costly for personal importation to be implemented in a way that ensures the safety and effectiveness of imported drugs. Overall savings from legalized commercial importation will likely be a small percentage of total drug spending, and developing and implementing such a program would incur significant costs and require significant additional authority.

The public expectation that most imported drugs are less expensive than American drugs is not generally true, especially in the case of generic drugs marketed in the U.S. And legalized importation may raise liability concerns for consumers, manufacturers, distributors, pharmacies, and other entities.

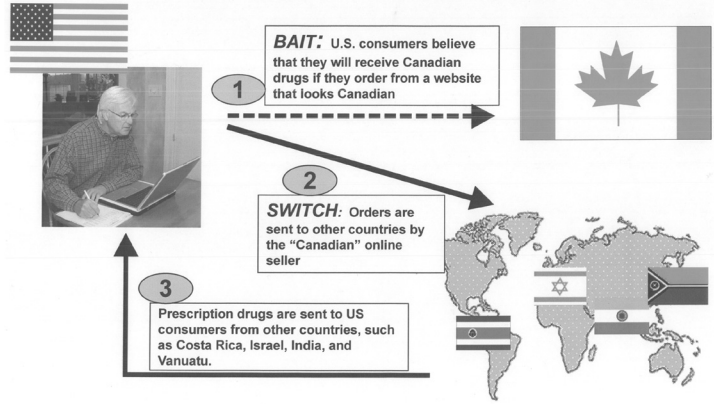
The Internet today has created an extraordinary unregulated marketplace for the sale of unapproved drugs, prescription drugs dispensed without a valid prescription, and products marketed with fraudulent health claims. Patients who buy prescription drugs from a rogue website are at risk of suffering adverse events, and some of them can be life-threatening. These risks include, most importantly, therapeutic failure due to lack of effect because the drug doesn't contain the correct dose prescribed by a physician or active ingredients, and potential side effects from inappropriately dispensed medications, dangerous drug interactions, or drug contamination.

Patients are also at risk because they often don't know what they're getting when they purchase some of these drugs from websites. Although some patients may receive the genuine product, others may unknowingly receive counterfeit copies that contain inert or harmful ingredients, drugs that are expired and have been diverted to illegitimate resalers, or dangerous subpotent or superpotent products that are improperly manufactured.

I'd like to show you a couple of slides to illustrate just a few examples highlighting our concerns with imported drugs, and my written statement further describes these concerns and illustrates some cases.

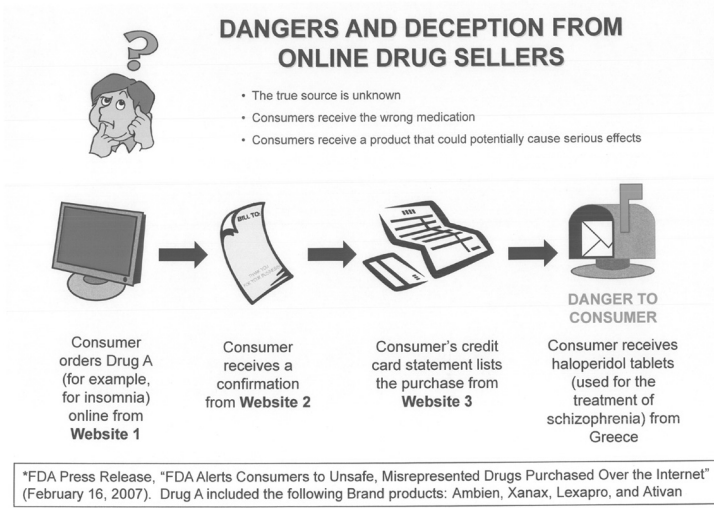
The first slide—I don't know if you can see it from there, but the first slide identifies a phenomenon that we first reported in December of 2005 in a press release called "Bait and Switch." Consumers had placed orders on Internet websites that appeared to be Canadian, and we intercepted, at international mail facilities, parcels which were coming into the country from other countries—in particular, India, Israel, Costa Rica, and Vanuatu. And about—nearly half of the parcels coming in from those countries had documentation indicating that they had been shipped in response to orders on apparently Canadian websites, and almost 85 percent of those parcels, in fact, originated from 27 countries all over the globe. Consumers were not getting what they thought they were buying.

American consumers are misled by buying drugs from alleged "Canadian" Websites - "BAIT and SWITCH"



* In FDA's 2005 Operation "Bait & Switch" nearly half of the imported drugs FDA intercepted from four selected countries were shipped to fill orders that consumers believed they were placing with "Canadian" pharmacies. Eight-five percent of those drugs actually came from 27 countries around the globe.

The second slide shows a scheme where consumers are sent drugs containing the wrong active ingredient, which is potentially a very harmful practice. This was reported only recently, in, actually, February, last month, of 2007. Consumers ordered drug A, for example, for insomnia, they received a confirmation from a second website, the credit card's statement lists purchase from a third website, and then they received Haloperidol tablets, which are used for the treatment of schizophrenia. Some people sought emergency medical care because they received the wrong active ingredient in these instances.

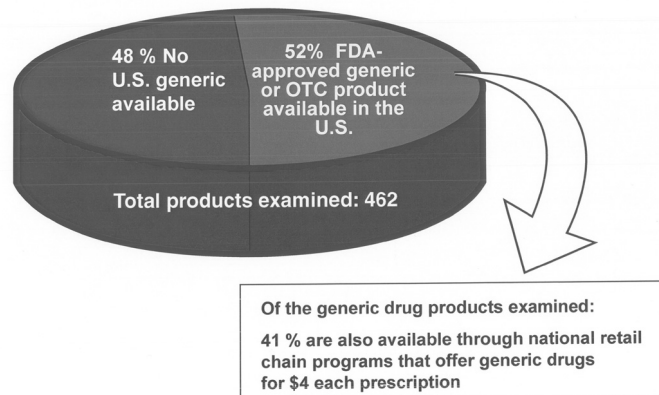


FDA understands that Congress and the public are concerned about the high price of some prescription drugs. FDA currently has a very successful generic drug approval program that brings lower-cost versions of brand name drugs to U.S. consumers. In general, FDA-approved generic drugs are less expensive, not only compared with the brand name innovator product that are sold in the United States, but also generally less expensive than generic drugs available abroad that would appear to be comparable.

And you may be surprised to learn—and this is slide 3—that a survey conducted—also in January of 2007—revealed that approximately half of the drugs intercepted at one international mail facility are available as FDA-approved generics in the United States. And, even more surprising, of those generic equivalents, over 40 percent are available at some national retail pharmacy chains for about \$5 each. That's less than the shipping price for most Internet sellers.

Many purchases of foreign drug products appear to offer little or no savings to U.S. consumers

SURVEY OF PACKAGES FROM AN INTERNATIONAL MAIL FACILITY (IMF)
January 2007

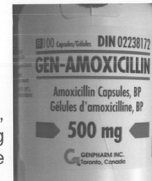


Next slide. In this survey, we also saw examples of products that U.S. consumers ordered from foreign sources that cause us grave concern. Warfarin is a blood-thinner that requires routine and very careful blood monitoring by physicians. Another drug that was intercepted is Amoxicillin. These could—if misused, may contribute to antibiotic resistance. Antibiotics should only be used if a bacterial infection, as opposed to a viral infection, occurs. Another drug that we intercepted is Dipyrrone, an analgesic which was removed from the U.S. market in 1977, due to serious adverse health concerns. Methotrexate, a cancer drug, requires careful monitoring for potential serious toxicities. These are examples of some of the drugs that we've found in this survey that cause us to think very carefully about safety concerns of Internet purchasing.

**Special Cases:
Examples of drugs found in January 2007 survey
at an International Mail Facility**



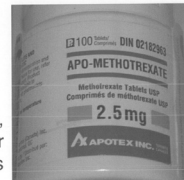
Warfarin - blood thinner,
requires careful blood
monitoring



Amoxicillin - antibiotic,
misuse can cause drug
resistance



Dipyron - analgesic,
removed from US market
in 1977 due to serious
adverse effects

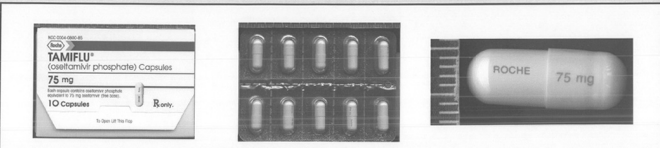


Methotrexate - cancer drug,
requires careful monitoring for
potential serious toxicities


Consumers may be obtaining these types of products without valid prescriptions, and without the appropriate supervision of a physician.

Slide 5, the final one, deals with a drug of special importance these days. We've uncovered counterfeit Tamiflu. This concerns us greatly, given the implications not only for seasonal flu, which is associated with deaths of more than 20,000 Americans annually, but also the Tamiflu may be useful in the event of a pandemic flu.

Authentic Tamiflu



Counterfeit Tamiflu



As a public-health agency, we understand very much the importance of protecting public health, not only through regulation and enforcement, but also through education and collaboration. FDA's

website contains extensive information for consumers about drug importation, buying drugs online, counterfeit drugs, our enforcement activities, and potential public-health threats. Our website also provides resources to report problems with FDA-regulated products or websites that could be selling fake or harmful products.

The standards for drug review and approval in the U.S. are unsurpassed in the world, and the safety of our drug supply mirrors those high standards. However, despite these very real risks, a substantial number of Americans are obtaining prescription medications from foreign sources. Many drugs purported to be from Canada are actually from other countries that lack regulatory oversight. And FDA cannot assure the safety or effectiveness of these drugs.

Thank you very much for the opportunity to testify, and I look forward to responding to questions that you may have.

[The prepared statement of Dr. Lutter follows:]

PREPARED STATEMENT OF RANDALL W. LUTTER, PH.D., ACTING DEPUTY
COMMISSIONER FOR POLICY, FOOD AND DRUG ADMINISTRATION, HHS

Introduction

Mr. Chairman and Members of the Subcommittee, I am Randall W. Lutter, Ph.D., Acting Deputy Commissioner for Policy at the U.S. Food and Drug Administration (FDA or the Agency). Thank you for the opportunity to discuss with you the important issues relating to the importation of prescription drugs.

At FDA, our statutory responsibility is to assure the American public that the drug supply is safe, secure, and reliable. For more than 60 years, the Federal Food, Drug, and Cosmetic (FD&C) Act has helped to ensure that Americans can be confident that when they use an FDA-approved drug, the medicine will be safe and effective and will work as intended in treating their illness and in preventing complications. In carrying out this responsibility, we work, through a variety of steps, to do all we can under the law to make medicines accessible to patients and help doctors and patients use them as effectively as possible. These include: expanding access to essential unapproved treatments that are being studied under FDA investigational new drug applications; approving generic medicines; reducing the time and cost of showing that new medicines are safe and effective; and providing up-to-date information for health professionals and patients to allow them to obtain the benefits and avoid the risks associated with medicines. That is the primary mission of the thousands of dedicated staff, including leading health care experts, doctors, and scientists who work tirelessly at FDA in public service for the American people. FDA remains immensely concerned about unapproved, imported pharmaceuticals whose safety and effectiveness cannot be assured because they originate outside the closed legal structure and regulatory system we are fortunate to have in the United States.

The FD&C Act requires that FDA approve each new drug as safe and effective before marketing. It also authorizes FDA to oversee the production of drugs that are the subject of approved applications, whether manufactured in a facility in the U.S. or a foreign country and imported into the U.S. by the manufacturer. By the 1980s, Congress recognized that some foreign entities were importing counterfeit drugs as well as improperly handled and stored drugs into the U.S. For example, at that time, millions of counterfeit birth control pills from Panama found their way into the U.S. drug distribution system. In another case, a counterfeit version of a widely used antibiotic entered the U.S. drug distribution system from a foreign source. These types of activities posed significant risks to American consumers. In 1987, Congress passed the Prescription Drug Marketing Act (PDMA), which strengthened oversight of domestic wholesalers and added the provision to the FD&C Act—801(d)(1)—that generally prohibits anyone except a drug's manufacturer from re-importing into the U.S. a drug originally manufactured in the U.S. and then sent abroad.

The conclusion of Congress, reflected in current law, is that the safety and effectiveness of imported drugs is best assured by carefully limiting how prescription drugs can be imported into the U.S. as part of a closed drug distribution system. In the case of legally imported drugs, the chain of custody is known for an FDA-

approved drug manufactured in an FDA-inspected facility using FDA-approved methods before it is introduced into the U.S. distribution system.

In 2003, Congress tasked the Department of Health and Human Services to examine issues related to drug importation. A task force, chaired by then U.S. Surgeon General Carmona, examined the relevant data, considered testimony from the public and health experts, and then issued the "Report on Prescription Drug Importation" (Task Force Report). This Task Force Report clearly outlines significant safety and economic issues that must be addressed before the widespread importation of unapproved prescription drugs can be permitted. Even though 2 years have passed since the Task Force Report was issued, it is still the most comprehensive examination of the issue and we continue to find evidence confirming its findings.

Some of the key findings identified in the Task Force Report include the following:

- There are significant risks associated with the way individuals are currently importing drugs that violate the FD&C Act.
- The integrity of the distribution system must be ensured.
- It would be extraordinarily difficult and costly for "personal" importation to be implemented in a way that ensures the safety and effectiveness of the imported drugs. Regulating personal importation could be extraordinarily costly, on the order of \$3 billion a year based on 2003 estimates of the volume of packages entering the U.S.
- Overall national savings from legalized commercial importation will likely be a small percentage of total drug spending, and developing and implementing such a program would incur significant costs and require significant additional authority.
- The public expectation that most imported drugs are less expensive than American drugs is not generally true, especially in the case of generic drugs marketed in the U.S.
- Legalized importation of now-unapproved drugs will likely adversely affect the future development of new drugs for American consumers.
- The effects of legalized importation on intellectual property rights are uncertain but likely to be significant.
- Legalized importation raises liability concerns for consumers, manufacturers, distributors, pharmacies, and other entities.

Keeping unsafe drugs away from American consumers is an enormous task, as we are faced with a deluge of drugs at points of entry into the U.S. originating from all over the world. We are continually assessing this issue to determine how FDA can best protect American consumers from this threat.

The Internet has created an extraordinary, unregulated marketplace for the sale of unapproved drugs, prescription drugs dispensed without a valid prescription, and products marketed with fraudulent health claims. Patients who buy prescription drugs from a rogue website are at risk of suffering adverse events, some of which can be life threatening. These risks include therapeutic failure due to lack of effect because the drug does not contain the correct dose or active ingredient and potential side effects from inappropriately-prescribed medications, dangerous drug interactions or drug contamination. Patients are also at risk because they often don't know what they are getting when they purchase some of these drugs. Although some patients may receive genuine product, others may unknowingly receive counterfeit copies that contain inert or harmful ingredients, drugs that are expired and have been diverted to illegitimate resellers, or dangerous sub-potent or super-potent products that were improperly manufactured.

Efforts of Federal and state authorities have kept infiltration of counterfeit drugs in the U.S. drug supply chain to a minimum. Our success is a result of the extensive system of laws and our enforcement efforts. In recent years, however, FDA is challenged by efforts of increasingly well-organized counterfeiters who are often located overseas, backed by sophisticated technologies and criminal operations, intent on profiting from drug counterfeiting at the expense of American patients. To respond to this domestic emerging threat, FDA has been working with manufacturers, wholesalers, retailers, other Federal and state government entities, standards bodies, and others to implement measures to further secure our Nation's drug supply.

When FDA learns of schemes intended to use the drug supply to harm U.S. consumers, we actively work to prevent them to the fullest extent of the law. A recent case illustrates why American consumers ordering prescription drugs from Canadian sources cause FDA great concern. In August 2006, FDA advised consumers not to purchase prescription drugs from various websites, including *www.RxNorth.com*, that have orders filled by a firm in Manitoba, Canada, following reports of counter-

feit versions of prescription drug products being sold by these companies to U.S. consumers. FDA is investigating these reports and is coordinating with international law enforcement authorities on this matter. Laboratory results to date have found counterfeits from these websites, destined for the U.S. market, of the following drug products: Lipitor, Diovan, Actonel, Nexium, Hyzaar, Ezetrol (known as Zetia in the United States), Crestor, Celebrex, Arimidex, and Propecia.

In addition, just last month, FDA issued an alert to consumers who placed orders for specific drug products over the Internet (Ambien, Xanax, Lexapro, and Ativan), but instead received a product that, according to preliminary analysis, contains haloperidol, a powerful anti-psychotic drug. Reports show that several consumers in the U.S. have sought emergency medical treatment, after ingesting the suspect product, for symptoms such as difficulty in breathing, muscle spasms, and muscle stiffness. Haloperidol can cause muscle stiffness and spasms, agitation, and sedation. Identifying the actual sellers or websites has been challenging because of the deceptive practices of many commercial outlets on the Internet. Currently, the origin of these tablets is unknown but the packages were postmarked in Greece. Preliminary investigation has identified some of the responsible websites and we are currently pursuing both domestic and foreign leads. Details of additional cases are included in an appendix to this testimony.

In an effort to gauge the volume and scope of drugs coming into the U.S., we routinely survey international mail facilities. A recent finding confirms our concern that buying drugs from foreign sources pose specific risks to U.S. citizens. An FDA operation in 2005, called "Bait and Switch," found that nearly half of the imported drugs that FDA intercepted from four selected countries (India, Israel, Costa Rica, and Vanuatu) were shipped to fill orders that consumers believed were placed with "Canadian" pharmacies. Of the drugs being promoted as "Canadian," 85 percent appeared to come from 27 countries around the globe. Many of these drugs were not adequately labeled to help assure safe and effective use and some were found to be counterfeit.

FDA also works with U.S. Customs and Border Protection on their surveys at international mail facilities. In the last 6 months, FDA has assisted in two such operations. These operations revealed that we are still fighting the same issues we have seen in the past:

- Almost all of the pharmaceuticals found in mail parcels continue to be subject to refusal of admission because they violate the FD&C Act.
- We continue to see evidence of websites employing tactics such as those revealed by FDA's "Bait and Switch" operation. These suppliers appear to be Canadian sources, but send U.S. consumers drugs from countries other than Canada.
- A survey conducted in January 2007 revealed that of the 462 drug products intercepted and examined at one international mail facility, over half were drugs that are available as FDA-approved generic drug products in the U.S. and are most likely cheaper in the U.S. than abroad. Of those products examined, with generic equivalents, over 40 percent are available at national retail chains that offer certain generic drugs for \$4 each. This is less than the shipping price of most Internet sellers.

Last year, an FDA investigation found that many foreign medications, although marketed under the same or similar-sounding brand names as those in the U.S., contain different active ingredients than the U.S. products. For example, in the U.S., "Flomax" is a brand name for tamsulosin, a treatment for an enlarged prostate, while in Italy, the active ingredient in the product called "Flomax" is morniflumate, an anti-inflammatory drug.

FDA also has found 105 U.S. drug brand names that are so similar to drugs marketed in foreign countries that consumers who fill such prescriptions abroad may receive a drug with the wrong active ingredient. For example, in the United Kingdom, "Ambyen," a brand name for a drug product containing amiodarone, used to treat life-threatening abnormal heart rhythms, could be mistaken for "Ambien," a U.S. brand name for a sleeping pill. Consumers taking medications containing active ingredients not prescribed by their physician increase their risks of unnecessary side effects and possibly serious adverse outcomes.

FDA also publishes Import Alerts to field personnel about potentially dangerous drugs being offered for import into the U.S. Field personnel use this information to halt shipments of potentially dangerous products at the borders. For example, last month FDA added 39 known foreign suppliers of unapproved isotretinoin (known by the brand name Accutane) to an existing Import Alert, "Unapproved New Drugs Promoted in the U.S." The unsupervised use of isotretinoin carries significant poten-

tial risks, including birth defects and even fetal death, and may cause serious mental health problems. For this reason, the approved medication should only be taken by persons taking part in a specific risk management program closely monitored by their personal physician. Consumers receiving isotretinoin from these foreign sources are not likely taking part in the risk management program.

As a public health agency, we understand the importance of protecting the public health not only through regulation and enforcement, but also through education and collaboration. FDA's website (www.fda.gov) contains extensive information for consumers about drug importation, buying drugs online; counterfeit drugs, enforcement activities, potential public health threats, as well as resources to report problems with FDA regulated products or websites that could be selling fake or harmful products.

FDA coordinates with other governmental bodies and meets regularly with other Federal agencies and state officials to share information and identify opportunities for partnering in enforcement actions. Some of the Federal agencies that are FDA partners include U.S. Customs and Border Protection, U.S. Drug Enforcement Administration, U.S. Immigration and Customs Enforcement, U.S. Postal Service, and the Federal Bureau of Investigation, just to name a few. We also work with organizations representing consumers, health care practitioners, industry, and others. These relationships are essential to keep the Agency abreast of emerging issues, to leverage resources, and to best protect American consumers.

FDA understands that Congress and the public are concerned about the high cost of prescription drugs. FDA currently has an efficient generic drug approval program that brings lower cost versions of brand name drugs to U.S. consumers. In most instances, FDA-approved generic drugs are less expensive than generics sold abroad.

Prompt approval of generic drug product applications is a priority for FDA. Resources for generic drug approvals have consistently increased. Moreover, both the number of generic drug applications FDA receives and the number of applications FDA's Office of Generic Drugs (OGD) approves continue to increase each year as well. OGD recently instituted many new practices and procedures to help expedite the generic drug application review process. Because of these efforts, on the very day that the last controlling patents or exclusivities expired on an innovator product, OGD has approved at least one generic drug application in most cases. Recent examples of approvals when the exclusivities expired include pravastatin (Pravachol); sertraline (Zoloft); simvastatin (Zocor); and ondansetron (Zofran). Multiple versions of these products from various manufacturers are currently on the market.

Last year, 21 applications for meloxicam (Mobic), a product with no patent or exclusivity protection blocking approval, were approved. (This product is used to relieve the signs and symptoms of osteoarthritis and rheumatoid arthritis.) The cost to consumers of this product dropped dramatically after these generic approvals. Using OGD's "cluster" team approach, many of these applications were approved in just over 9 months. These approvals will result in many generic alternatives available for patients potentially saving millions of dollars in medication costs for consumers and the Federal Government.

The standards for drug review and approval in the U.S. are the best in the world, and the safety of our drug supply mirrors these high standards. However, despite the very real risks, a substantial number of Americans are obtaining prescription medications from foreign sources. U.S. consumers often seek out Canadian suppliers, sources that purport to be Canadian, or other foreign sources that they believe to be reliable. Many drugs purported to be from Canada are actually from other foreign countries that lack regulatory oversight and FDA cannot assure the safety or effectiveness of these drugs.

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

APPENDIX

Drug Importation Cases

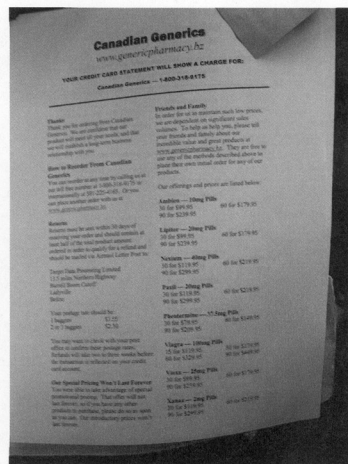
Provided below are summaries of selected cases FDA investigated that pertain to drug importation.

Counterfeit Percocet®, Viagra® and Cialis® Tablets: In January 2007, an individual in Philadelphia who purchased thousands of counterfeit drugs over the Internet from China, including Percocet, Viagra and Cialis, was sentenced in the Eastern District of Pennsylvania on charges related to trafficking in counterfeit goods and other counterfeit prescription drug related charges. The defendant sent samples of various medications to a counterfeit pharmaceutical manufacturer in China to be copied and manufactured. After the counterfeits were made in China, the medica-

tion was then shipped to the defendant in Philadelphia for eventual sale on the Internet and other venues. The United States Attorney said of this case: "When you go around government safeguards to either the Internet or the street to purchase prescription medication, you have no idea what you're getting. The reality is that you might wind up taking something that is ineffective, as we saw in this case, or downright dangerous."

This Office of Criminal Investigations (OCI) case, worked jointly with U.S. Immigration and Customs Enforcement (ICE), U.S. Drug Enforcement Administration (DEA), U.S. Postal Inspection Service and the Philadelphia Police Department, was part of a much larger OCI-ICE counterfeit drug investigation.

Clandestine Drug Manufacturing of Internet Drugs: In 2006, eleven individuals and an Atlanta, Georgia-based company were indicted by a Federal grand jury on multiple felony charges relating to a scheme to sell adulterated and unapproved new drugs over the Internet. The defendants in this case opened up a pharmaceutical manufacturing facility in Belize where they made over 24 different prescription medications. The defendants marketed the drugs through "spam" e-mail advertisements where they claimed the drugs were Canadian generic versions of brand name drugs. Some of the drugs the defendants made were unapproved versions of Ambien®, Valium®, Xanax®, Cialis®, Lipitor®, Vioxx® and others. These drugs were then purchased by and shipped to U.S. consumers and to various drug wholesalers.

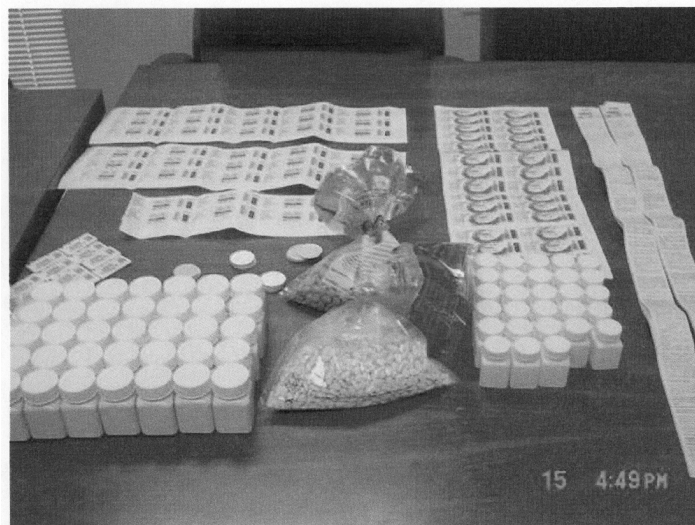


Dextromethorphan deaths: On April 12, 2006, two men were sentenced in the Southern District of Indiana Federal Court to 77 months incarceration after pleading guilty to introducing a misbranded drug into interstate commerce; specifically, dextromethorphan (DXM), a cough suppressant, which they sold over the Internet through their website.

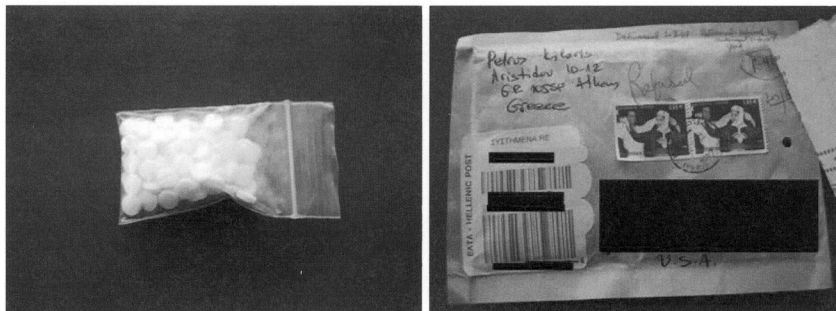
This case started in 2005 after five young people died after ordering and consuming DXM from the defendant's website. DXM is an anti-tussive (cough suppressant), which is approved for over-the-counter cough medications. The defendants purchased the raw ingredients from a firm in India, manufactured the finished product, and sold the DXM through their website. The defendants marketed the DXM by falsely claiming that DXM was a chemical used for research and development rather than a drug for human consumption. DXM is often abused by some in order to experience a "high."



Counterfeit Viagra®, Cialis®, and Lipitor®: In January 2006, an individual from the state of Washington was convicted for his involvement in the importation of counterfeit drugs from China including Viagra, Cialis and Lipitor and the subsequent distribution of those counterfeit drugs. In this joint OCI-ICE investigation, cooperation was sought and received from the Chinese government. As a result of this cooperation, the Chinese authorities arrested eleven individuals in China and recovered significant amounts of counterfeit drugs and counterfeit drug packaging. The defendant was sentenced in October 2006 to 10 month's incarceration.



Consumers Warned of Receiving Incorrect Medication in the Mail: In February 2007, FDA issued an alert to consumers who placed orders for various medications such as Xanax®, Ativan®, Lexapro®, and Ambien®, over the Internet. Instead of receiving the products they ordered, these consumers instead received a product containing haloperidol, a powerful anti-psychotic. Some of these consumers sought emergency medical treatments for a variety of symptoms after ingesting the suspect product. In all instances, consumers received the suspect medication in packaging, which was postmarked from Greece. FDA is attempting to identify the actual vendors and source of the suspect medication, but the illusive nature of the Internet and the deceptive practices of many Internet pharmaceutical businesses are making identification of the actual supplier of these medications problematic. This investigation is ongoing.



Counterfeit Drug Arrest in Hong Kong: In September 2006, an individual from China was arrested by officers of the Hong Kong Customs and Excise Department based on a Federal arrest warrant issued by the U.S. District Court for the District of Colorado. The defendant was arrested in Hong Kong after meeting with an undercover OCI agent who posed as a buyer of over 400,000 counterfeit Cialis and Viagra tablets. This investigation also involved the sale of several thousand counterfeit Tamiflu® capsules that were manufactured in China and shipped to the U.S. Information developed by OCI and ICE was shared with Chinese authorities, which led to the August 2006 arrests of four individuals in China. Furthermore, information developed during this joint OCI-ICE counterfeit drug investigation was the basis for the previously mentioned counterfeit Percocet investigation in Philadelphia, PA. In addition to the arrest in Hong Kong, three other defendants in the U.S. have pled guilty to counterfeit drug charges. This case is ongoing.

Counterfeit Viagra® and Cialis®: In July 2006, a man was arrested by OCI and ICE agents after several transactions in the Houston, Texas area where significant quantities of counterfeit Viagra were sold to an undercover ICE agent. Subsequent to the arrest, counterfeit Viagra and Cialis valued at approximately \$600,000 were seized. The drugs were manufactured in China and sent to the suspect in Houston for distribution. The suspect was charged with trafficking in counterfeit goods and other related counterfeit drug charges and remains incarcerated as a potential flight risk. The defendant pled guilty in this case in October 2006 but has not yet been sentenced. Other defendants have been arrested and are awaiting judicial action. This joint OCI-ICE investigation is ongoing.

FDA Warns Consumers of Canadian Website Shipping Counterfeit Medications: In August 2006, FDA published a warning to consumers about counterfeit medications shipped from RxNorth, a company based in Manitoba, Canada, which operates several websites. RxNorth, which operates as Mediplan Prescription Plus Pharmacy and Mediplan Global Health, were shipping counterfeit medications from various countries to American consumers who were ordering a variety of medications through the RxNorth and affiliated websites. Although this is an ongoing investigation, FDA issued a press release alerting consumers about these websites because of the potential dangers of counterfeit medications.

Counterfeit Lipitor® Tablets: In August 2005 in the Western District of Missouri, three businesses and eleven individuals were indicted for their involvement in a \$42 million conspiracy to sell counterfeit, smuggled and misbranded Lipitor and other drugs and for participating in a conspiracy to sell stolen drugs. These indictments are the result of an ongoing OCI investigation that was begun by OCI in April 2003 involving the manufacturing, smuggling, and the interstate distribution of counterfeit pharmaceuticals. To date, twelve defendants have been convicted; one received a nine-year term of imprisonment. Additional defendants are awaiting trial.

Senator DORGAN. Dr. Lutter, thank you for being here.

It's hard for me to know where to start with respect to your testimony.

The task force you referred to in the first paragraph was largely a joke. Creating a task force with Dr. McClellan, Dr. Crawford, and so on, to tell us what they think about drug importation? Creating a task force of people who largely oppose drug importation to tell us that they largely oppose it? That was a joke, in my judgment. So, I place little credibility in that.

Let me just say to you, as well, when Tommy Thompson left government, the Secretary of HHS, we met at the elevator on the second floor of the Capitol one day after he had retired and left government, and as we greeted each other, he said, "By the way"—to me—"By the way, keep on that prescription drug issue, the importation issue. You're right about that." So—that's after he left the government.

But let me ask you, did you study the piece of legislation that Senator Snowe and I have introduced, with respect to the safety considerations in that legislation?

Dr. LUTTER. I have been briefed on it, and I've discussed it with staff. I have not read it in detail.

Senator DORGAN. But most of your testimony had nothing to do with that, isn't that correct? Your testimony is about the seizure of counterfeit medicine or importation from unapproved venues and so on? So, your testimony had little to do with the legislation that Senator Snowe and I and 31 Senators have introduced. Why is that the case?

Dr. LUTTER. The concerns that we have with importation currently are related, Senator, to the risks that we see currently, and that is that people are now buying unapproved products over the Internet in a manner that we think is unsafe. And we think we have a key responsibility to communicate that to the public so that they understand the safety risks that they face when buying unregulated, unapproved products from foreign sources.

Senator DORGAN. You'll find no objection from the four of us on this panel at all about that. That's not the point of this hearing. No one, that I'm aware of, has suggested that we allow unauthorized drugs, drugs not approved by the FDA, drugs coming in from Internet sites that have not been approved—I don't think anyone is suggesting that. So, I guess you have won—won a debate we're not having. Congratulations.

But the fact is, we've introduced a piece of legislation, with nearly one-third of the Senate, that has very specific—very specific safety issues. Would you testify about your evaluation of those safety issues?

Dr. LUTTER. I'm sorry, the safety issues pertaining to?

Senator DORGAN. In the—well, we have introduced legislation that has nearly a third of the Senate as cosponsors of the legislation. We have included issues dealing with safety in that legislation, because much of your testimony dealt with safety. We've included provisions, that are very significant provisions, that address, for example, the first time we went through this, where Donna Shalala refused to certify, and set out four conditions that needed to be met. We meet all these four conditions in this legislation that responds to the Executive Branch issues. My question for you is, how do you respond to those, or do you believe there is not the capability to provide for safe reimportation of FDA-approved drugs from FDA-approved plants or FDA-approved sites? Do you believe that is impossible?

Dr. LUTTER. My understanding, Senator, from the invitation was that you wanted me to talk about the policy implications of importation broadly. And if you wish, we will be very happy to offer tech-

nical assistance on the legislation, in particular, if you request us to do so.

Senator DORGAN. Let me ask it a different way, then. As I indicated in my opening statement, Europe has a system of parallel trading. They've had it for a couple of decades. German can buy from Spain; an Italian can buy from France, under parallel trading, a prescription drug that is an approved drug. Let me ask you whether you think we are as capable as the Europeans in establishing—providing you the resources, and then establishing a system by which, with FDA approval and FDA certification, that a U.S. consumer can safely reimport an FDA-approved drug that has never left the chain of custody, an FDA-approved chain of custody? Do you—

Dr. LUTTER. I think, surely, Senator, the Americans are as capable as Europeans in that regard, but there's a key distinction with respect to that model, and that is that Brussels, as the capital of the European Union, can establish regulations which apply to all countries. And I believe, Senator, that the form of importation that we're talking about in the United States lacks a clear parallel, in the sense that the foreign countries from which we would be importing are ones that are not governed by any "international government," if you will, in the way that Brussels governs countries that are members of the European Union.

Senator DORGAN. Well, that's a novel answer, because the proposal in our legislation deals with plants in foreign countries that the FDA has already approved. It deals with an Internet seller that the FDA would have approved and certified. So, we're not talking about a regime outside of the FDA's approval process. My question is—the FDA—the FDA approved the plant that this Lipitor was produced in, in Ireland. I assume the FDA actually sends people to this plant and says, "Yes, you can produce this medicine in this plant, and you can ship this medicine to the U.S. consumer, and we believe that is safe." Is that correct?

Dr. LUTTER. Yes, sir.

Senator DORGAN. All right. And if the FDA approves a foreign plant that is a production facility for this medicine, and a foreign—a distribution system to move that, in a closed system, to a U.S. consumer, tell me where the safety implications are.

Dr. LUTTER. Well, I think the issue, Senator, is that, when we inspect a foreign facility that is manufacturing an FDA-approved product, that this is very necessary and essential to ensure that that product meets FDA standards. But there may be another facility, even another line, even another building within that same manufacturing facility, which isn't inspected by us. And the question is, if that product is not inspected by us, what is our ability to ensure that it meets our standards? And that's, I think, a key distinction to follow.

Senator DORGAN. What about the case today? How do you assure this comes from the line that you've inspected, and not the line that you didn't inspect?

Dr. LUTTER. Well, I have trouble recognizing the bottle from its distance.

Senator DORGAN. It's Lipitor.

Dr. LUTTER. If that's the Lipitor which is manufactured in Ireland, then that's inspected by an FDA inspector at the plant in Ireland, and it is shipped from Ireland to the United States.

Senator DORGAN. Well, let me—my colleagues wish to ask questions. Let me ask you a simpler question, if I might. In Emerson, Canada, there's a one-room drugstore. And I went there one day with a group of senior citizens from Fargo, North Dakota. And just miles across the border, in this little one-room drugstore, they purchased their prescription drugs that, 10 miles on the other—on the U.S. side of the border, they would have had to pay substantially more money for. These were citizens who didn't have a lot of money. And they made their purchases in this drugstore, and showed me their savings, and were excited about it. And my understanding of the chain of custody in Canada is such that you would not be concerned about someone buying a prescription drug in a Canadian drugstore. Would you agree with that? Do you believe the chain of custody of drugs in Canada, with respect to the drugs that go from the producer to the wholesaler to the drugstore, is essentially as safe as the chain of custody in the U.S.?

Dr. LUTTER. FDA has no particular expertise in the regulatory system of Canada.

Senator DORGAN. The FDA has already answered that question affirmatively previously.

Dr. LUTTER. But, in general, it is very, very well respected as being safe and adequate for Canadians.

Senator DORGAN. Essentially has the same type of chain of custody with the same safety circumstances as the U.S.?

Dr. LUTTER. It's widely seen that way.

Senator DORGAN. And that's what the FDA has previously said. If that's the case, then at least you and I can probably agree that the importation of that drug purchased in the one-room pharmacy in Emerson, Canada, brought back across the border, is not a safety issue. Is that correct?

Dr. LUTTER. There are a collection of safety issues that people need to be concerned about. In January of last year, we issued a report on our website dealing with confusing brand names. And it illustrates an example that many people don't—aren't aware of, of a regulatory function performed by FDA in the United States that many people recognize is valid, which isn't often appreciated, and that is that in the United States when a new product comes to market, we ascertain whether or not the proposed brand name for that product is one that is similar to existing brand names, or so close that it could be confused by pharmacists dispensing medications. In the case of Americans taking prescriptions and filling them abroad, there's no such function provided by FDA or any other regulatory body. So, Americans taking prescriptions, even crossing the border, if you will, to a pharmacist that they think is entirely reliable in other circumstances, should be aware that the name of the product does not necessarily translate across the border to one that is otherwise equivalent.

Senator DORGAN. Yes. Well, that's the—a new defense, the confused-pharmacist defense, I guess. I don't understand. I don't understand, at all, why the FDA, given the resources—and our legislation gives them the substantial resources they need—cannot do

what others in the world are able to do, and that is stand up for the consumers of this country, give them a safe supply of drugs, allow a little market—a little bit of the market system to play a role in putting downward pressure on market prices. What you are supporting, Dr. Lutter, is a circumstance in which we do have price controls in this country. The price controls are imposed by the pharmaceutical industry. They're the ones that impose the price controls. And, by the way, they say, "Well, we really can't make any money, except in the U.S. That's why we have to charge the U.S. consumer the highest prices." Well, why did they repatriate 60-plus-billion dollars when this Congress, regrettably, gave them a five and a quarter percent—gave all industry a five and a quarter percent sweetheart tax rate if they could—if they would repatriate money from abroad. The pharmaceutical industry repatriated 60-plus-billion dollars. Clearly, they're making money elsewhere by charging much lower prices.

And I—you probably detect I'm enormously frustrated, have been for a long while, with the FDA coming here, telling us what they can't do. I'm very interested in finding out what they can do to try to help consumers. And I think, you know, your first consumer's "bait and switch"—I think yours was "bait and switch." You came, talking about counterfeit drugs. There's nothing in legislation that any of the four of us have been talking about that has anything to do with counterfeit drugs. It has to do with safe reimportation of FDA-approved drugs.

Senator DeMint?

Senator DEMINT. Dr. Lutter, I, too, am disappointed in the testimony. We all know that the status quo is not acceptable, and we know denying importation and not having any kind of approval or certification is not working. The whole point of this legislation is to create a safe system.

Am I right in saying that the FDA oversees the importation of fruits, vegetables, meats, fruit juice, beer, wine from all over the world? Do you have a system that does that?

Dr. LUTTER. We inspect those products at the border, yes, Senator.

Senator DEMINT. But you're responsible for the health of the American people when it comes to products coming in from all over the world that we eat and drink.

Dr. LUTTER. We are responsible for the safety of food and beverages that we regulate, yes.

Senator DEMINT. And I would assume that's a very complex system of understanding points of origin and what is brought in, who the suppliers are. I assume the FDA is very involved with making sure that these products are safe.

Dr. LUTTER. These products, unlike drugs, do not contain active pharmacological ingredients that are being prescribed to sick people.

Senator DEMINT. But they could have disease, they could be tainted, there could be a lot of dangers, right?

Dr. LUTTER. There are problems of food-borne illness, and we actively fight that domestically in imported products.

Senator DEMINT. OK. Are you aware that most of the—or a lot of the drugs that are made in this country are made from imported ingredients?

Dr. LUTTER. I'm aware that there's active trade, if you will, in active pharmaceutical ingredients.

Senator DEMINT. Does the FDA inspect these foreign plants where these ingredients are made?

Dr. LUTTER. We inspect facilities where active pharmaceutical ingredients are manufactured.

Senator DEMINT. Well, isn't it possible that the line you inspect is not the line they actually ship these ingredients to the United States?

Dr. LUTTER. I suppose it's possible. The question is whether or not it would be violating our regulations. And I'd have to get back to you on that.

Senator DEMINT. Is it not the exact same situation you're saying you can't do with finished products?

Dr. LUTTER. I'm not sure I follow your questioning.

Senator DEMINT. Is not the situation with finished products, as far as developing some international safety system, very similar, if not exactly the same, as assuring that the ingredients for the same pharmaceuticals—

Dr. LUTTER. Yes—

Senator DORGAN.—are safe?

Dr. LUTTER.—Senator, let me try—if I could try and answer your question, and that of Chairman Dorgan, in a slightly different way. And I'm sorry that you're disappointed with the testimony. I thought I was being invited to talk about policy implications of imported drugs, broadly, rather than the particular bill that you're—

Senator DEMINT. We're well aware of the Administration's position, and we really didn't need that repeated today. And we have—there are several good proposals, with a lot of detail, which the Administration is very aware of. There's no reason that we can't have some testimony as to what the possibilities are of creating these safety—or safeguards that we've got in this legislation. So, I—forgive me for being impatient, but I see a lot of inconsistency in what we're talking about. If the drugs that are made in this country come from ingredients from inspected plants, you're telling me that you can somehow guarantee that safety, but, if they're made here and put in tamperproof containers and sent to some other country that is within an FDA-inspected distribution system, that somehow that's not safe. It—I hope you realize that what you're saying is very difficult to absorb.

Dr. LUTTER. A key concern that we have with, I think broadly speaking, the type of proposal that you're endorsing is, the implications for FDA of having to approve the foreign products, because you're asking me to speak particularly about the legislation. I'm not prepared to offer technical assistance, but I have been briefed on the broad theme, so let me speak a little bit about—

Senator DEMINT. You do know what we're doing now, as far as inspecting plants for the ingredients of pharmaceutical products that are made in this country—foreign plants. I mean you're aware

of your policies and procedures, and how that's done—I'm assuming you are.

Dr. LUTTER. Yes.

Senator DEMINT. OK.

Dr. LUTTER. But then if the proposal were for the FDA to allow commercial importation of FDA-approved products that are made abroad, presumably it's the foreign versions of FDA-approved products that are already for sale in the United States. If that were the legislative proposal that's being considered, then I think the question is, what does this really mean for FDA program management and the review of such applications? And one way of thinking about this is, really it amounts to a substantial new FDA program that would review applications for foreign products to see if they're safe, effective, and equivalent to U.S. products. So, it looks a little bit like our generic drugs program. And our generic drugs program currently has roughly 200 employees who are approving 500 abbreviated new drug applications annually. And that gives you some idea of the magnitude of the task that we would be faced with if one were to set up a program wherein we would have to approve foreign products as safe and effective and equivalent to U.S.—

Senator DEMINT. You realize what we're asking—

Dr. LUTTER. We believe this is a very, very significant expansion of an existing FDA program.

Senator DEMINT. But you realize what we're asking is not to approve a drug that's made in another country, but just to create a safety loop of distribution, that we can oversee, that's primarily re-importing products that were made in the United States, under FDA approval and certified plants, that are—

Dr. LUTTER. But it's—

Senator DEMINT.—reimported into this country.

Dr. LUTTER. Senator, I'm not familiar with the details of the legislation that we're discussing. If you want technical assistance—on it, I'm very happy to come and offer that at a later time.

Senator DEMINT. Well, I think that's probably what we're going to need to do.

Thank you, Mr. Chairman. I yield.

Senator DORGAN. Let me call on Senator Snowe, as the—OK, Senator Vitter.

Senator VITTER. Thank you, Mr. Chairman.

Dr. Lutter, I take it that your testimony comes out of the FDA's central mandate to protect safety, including of prescription drugs. Is that correct?

Dr. LUTTER. Yes, sir.

Senator VITTER. Is there any greater mandate or responsibility that FDA has?

Dr. LUTTER. Our overall mission is to protect and promote public health, and that's our overall mission.

Senator VITTER. So, is there any other—is there any greater mandate than that safety—

Dr. LUTTER. No.

Senator VITTER.—concern that you have? And so, these sort of problems and dangers are very concerning to you because of that mandate, I assume. Is that correct?

Dr. LUTTER. Yes, sir.

Senator VITTER. So, what regulatory regime—what solution are you putting in place in light of these dangers?

Dr. LUTTER. These dangers are very problematic from the viewpoint of protecting Americans and promoting—their public health—

Senator VITTER. That's my point. So, what's the FDA's solution to this?

Dr. LUTTER. Our key solution—I need to back up and say why this is so problematic, and then I'll elaborate on the solution. This is very problematic precisely because there's a huge volume of imported parcels coming into international mail facilities, which contain unapproved products. We don't know where they're from, we don't know what they are, and we lack the resources, we lack the ability to identify what they are at the border, and to stop them. Therefore, our key program is to emphasize, instead, public education, to tell consumers what risks they face buying these products on the web. Everybody has a home computer, they think they can click on the keyboard, they think they can find an international website, they see somebody reassuring, wearing a white coat and with a stethoscope, and they think they can buy something that is what their doctor really wants them to have and is equivalent to what their U.S. trained and licensed pharmacists would give. And they discover, instead, that that's not the case. And we think that our key job, and one of the most effective ways that we can communicate these risks is to go public with them. And that's why what you see here is a collection, if you will, of the messages that we've communicated to the public and to you. They're on our website, they're in our press releases over the last year and a half, indicating—in fact, going way back before then, about the risks that Americans face when they buy these drugs on the Internet—

Senator VITTER. So protecting safety is your top mandate. This sort of stuff is happening. You have highlighted that. That's a big danger. And so, the FDA response is to tell people, "Don't do it." That's basically the solution, the FDA's solution.

Dr. LUTTER. That has been the—

Senator VITTER. How has that strategy been working? How effectively have you reduced the activity of getting drugs from abroad? What are the statistics there?

How's that strategy working?

Dr. LUTTER. We wish we had statistics on that. We do not. The best available statistics that we have to date are the ones that we released in December 2004, and we have no updates since then. It's very difficult for us actually to count the volume of drugs coming in at the border, because we don't always know what parcels are containing pharmaceutical products.

Senator VITTER. And what were those statistics from December 2004?

Dr. LUTTER. December 2004, we estimated, given the data that we had, that there were 10 million parcels arriving annually at international mail facilities, and they contained roughly 25 million prescriptions.

Senator VITTER. And was that on the rise, or was—

Dr. LUTTER. That had definitely been rising over—relative to recent years.

Senator VITTER. OK. You get the sense that, in light of your solution to the problem, that that trend has been reversed? Do you think it's declining right now?

Dr. LUTTER. The broad perception is that it has declined, but it's unclear as to why. The key reason that it may have declined is the success of Medicare Part D, which provides prescription drug coverage to elderly Americans over 65.

Senator VITTER. Well, maybe I'm just out of step with the broad perception. It is not my perception that it has declined. It is my perception that it's increased 50-fold, up to the point that you are talking about, and has continued to grow from that point. I don't know at what rate. I don't know if the pace has slowed. But my perception is that it is a curve that is going up and up.

So, I would just suggest that, when the FDA's top mandate is safety, when the FDA knows there are problems out there, and dangers, and your only solution is press releases that say, "Beware," I would propose that it's patently clear that that is a failed strategy and that if you take your mandate seriously, you'd better do something else, like a regulatory regime. What's your response to that?

Dr. LUTTER. Well, the regulatory regimes that we implement are under the authority of the laws that we've been entrusted to administer. And the key challenge here with respect to the international mail facilities, it's virtually impossible. My predecessor testified it would take an army to actually identify what are the problems—what parcels at the border contain pharmaceutical products and what they are, given the procedures and the due process that we're asked to follow. We cannot stop these at the border with the resources that we have. And the key reason for that is essentially the impossibility of identifying what each parcel contains, and then examining them to see what they may contain before making decisions on what to do with them.

Senator VITTER. Well, I would just end by saying I agree with you, it's impossible to set up that system to stop parcels at the border. What is possible is to regulate the sources that are allowed to come into the country to advertise those to the American people, so the American people have confidence in those sources, and use those sources. That's the sort of regulatory regime I'm talking about, which, of course, the FDA, right now, has full authority to implement.

Thanks. I have no further questions.

Senator DORGAN. Senator Snowe?

Senator SNOWE. Thank you, Mr. Chairman.

You were saying that you don't have the resources. I think the point of this legislation is that we provide you the resources, and the funding provided in our bill was estimated by CBO as being more than adequate to implement this legislation and allow FDA to do what you would be required to do. So, if you had these resources, would you be able to do what is required in this legislation?

Dr. LUTTER. We believe there are a variety of technical issues associated with the legislation, as I understand it, and we probably

should look forward to a different opportunity to offer the technical assistance that's been provided. But I think a key question is the ability to stop the imports at the border, at the international mail facilities; in particular, the ability to stop them, provided that there is a implicit message being conveyed through legalization of commercial imports about the safety of foreign products themselves. And the question is, even if one had a regulatory system that allowed for FDA review of the foreign equivalents to ensure that those were safe and effective, and we were given adequate resources to ensure that, and then, of course, we'd have to see whatever resources—whether these were, in fact, adequate—but, even if we had that, there's a question of, how do you actually stop the problem that Senator Vitter has just alluded to at the border?

Senator SNOWE. Well, I don't think there's anything magical about it. It's really having the will to do it. I'm sensing you're either unable or unwilling. If we gave you the resources and gave you the statutory authority—and that's what we have outlined in this legislation, you know, that we import from manufacturers in more than 40 countries, where you may, on average, inspect a plant once every 7 years? In our legislation, we require inspections randomly, but not less than 12 times a year—12 times a year for wholesalers which import, as well as for those exporting pharmacies which would directly serve consumers. So, you know, I just don't understand why we're hearing here today, I think, you know, bureaucratic intransigence about coming up with a way in which to allow it to happen. And, while you're talking about American consumers misled by buying drugs from “bait and switch” and Canadian websites. Well, FDA could list which ones are legitimate for consumers. I mean, why isn't there the can-do spirit? Instead it's can't-do, and we're seeing everything done to deny consumers access to affordable medications. And we are talking about brand name drugs. You were referring to generics earlier. What we're talking about is brand names, frankly, because consumers don't have access to affordable brand name medications. So, that's what our legislation addresses.

Can you tell me, in the incidence of counterfeiting, what do you have for statistics here in the United States? Do you have a rate of counterfeiting? Because there's obviously a serious problem within our borders. Do we have a rate of incidence regarding counterfeiting?

Dr. LUTTER. Senator, if I could just go back to one—

Senator SNOWE. Yes.

Dr. LUTTER.—comment you made a moment—

Senator SNOWE. Yes.

Dr. LUTTER.—ago, about why we don't list legitimate foreign websites, and that's really that we have no ability to know which ones are legitimate, because they can take down their websites, they can change the names, we don't have authority to inspect foreign pharmacies to see what they're doing. So, as much as—

Senator SNOWE. Well, we would give you that, under our legislation. See, that's the—

Dr. LUTTER. We'd be happy to review that legislation in detail and get back to you on that.

Senator SNOWE. So—OK.

Senator SNOWE. Well, it is amazing that you weren't, because this has been an outstanding issue, frankly, for a decade here. I mean, this is not a new issue. I think Senator Dorgan introduced that bill, back in 1999—and in 2000 we saw the MEDS Act passed. Now we have, you know, run the gamut on establishing the standards and getting advice from all, you know, corners on this debate, and perspectives, and getting the very best advice how to go about certifying it.

So, on the rate of incidence of counterfeiting within our borders, do you have any idea what the magnitude is?

Dr. LUTTER. We had a public meeting as part of a counterfeit drug task force in February of last year. We were very concerned about developing an estimate. We asked that of all the attendees in the public meeting, and we got no reliable estimates of the prevalence of counterfeit drugs in the United States. That's essentially because it's extremely difficult even for a trained pharmacist to distinguish between an authentic and a counterfeit product. We have opened, last year, 54 new criminal investigations into counterfeiting in the United States. That's a significant increase in the rate of newly opened counterfeit cases relative to about 6 years ago, around 2000. We'd had several years in a row where we were opening less than ten cases annually. So, in that sense, what we perceive is that there's increased sophistication, increased networks establishing counterfeit drugs in the United States, but we have no estimates on the prevalence. We believe that it's very low. We believe that the overwhelming share of all—of finished pharmaceutical products sold in the United States are safe and effective, genuine FDA-approved articles.

Senator SNOWE. Well, we wrote a letter to the Commissioner of FDA, back in October, asking for details upon which blanket warnings are issued regarding counterfeit drugs. Do you have any specific data on seizures of prescription drugs at the border? Do you have any data so that we know specifically what the basis was for claims of counterfeiting?

Dr. LUTTER. Well, I think it depends a little bit on the nature of the seizure. Some of them are ongoing criminal investigation cases, so I'm not sure that's something that we wish to talk about. In other instances, we have conducted blitzes of intercepting all products, and partly to motivate the public health messages, that we think are so important to communicate to the American public the risks of imported drugs. And, in those instances, we undertake some analysis of the nature of the products, yes.

Senator SNOWE. Well, the—first of all, I think that would obviously be helpful to everybody to know exactly what was the basis for the seizure, what was the information and data to support it, what was it all about, because it would be helpful to everybody to know exactly, you know, what issues were involved, useful to all of us in this process. But I guess the point here is the need to be setting up a system. And, you know, I sense that if you have the resources, and the statutory authority, it could be done. I mean, we do oversight in over 40 countries, in terms of manufacturing medications that come in use here in the United States.

So, what's the issue, really?

Dr. LUTTER. The letter accompanying the December 2004 HHS Task Force Report on Importation was signed by Secretaries Thompson and Evans of Commerce, and it outlined conditions under which commercialized drug importation, could in principle, would have to be satisfied in order for it to be done safely. And those are available there. I think you're familiar with several of them. It's included that it should be limited to Canada, and it said that it should be limited only to a set of drugs that was relatively high volume and where there was reason for there to believe that there would be significant savings. And it also limited it to products where there are no special handling concerns, such as biologics or injectables, which are relatively easy to counterfeit, that these are issues that were outlined there, and that we share as being important to address in any potential legislation.

Senator SNOWE. Yet, on the other hand, you know, we can talk about the European Union being engaged in parallel trading for 30 years without consequence, without incidence. There has been a truly remarkable track record. There's no reason why we can't import, based on the safety standards that have been included in this legislation and the resources which the bill provides to do it, and the requirement for numerous inspections on the part of the FDA. So, I think that, when you consider all of that, it's a very different system. We just don't employ a simple certification, we set which standards have to be in place, and the resources in which to do it. And I think that's the critical difference from other approaches.

Thank you, Mr. Chairman.

Senator DORGAN. Thank you.

Dr. Lutter, because of the confusion here, what I'd like to do is send you a series of questions about the legislation that I have described, and ask for the FDA's response to those questions, giving us your evaluation of the safety provisions in the legislation. So, we will do that—with your willingness to respond to them, we'll do that within the next week, get those questions to you.

Dr. LUTTER. Thank you.

Senator DORGAN. All right. Thank you for being here, Dr. Lutter. Thank you for your testimony.

The second panel today that we will hear from will be Billy Tauzin, CEO of PhRMA. Bill Tauzin is a former colleague of ours who served in the U.S. House for many years. John Vernon is a Professor of Finance at the University of Connecticut. He has a Ph.D. from the City University of London, and a Ph.D. in Health Policy and Management from the Wharton School of Business, University of Pennsylvania. Stephen Schondelmeyer is Professor and Head of the Department of Pharmaceutical Care & Health Systems, University of Minnesota. William Schultz is a Partner at Zuckerman Spaeder, LLP, previously was Deputy Commissioner for Policy at the Food and Drug Administration. And, finally, Nelda Barnett, a Member of the Board of Directors of the AARP.

We thank the five of you for being with us today. And I—we will begin with our former colleague, former Congressman Tauzin.

Mr. TAUZIN. Mr. Chairman, thank you very much.

Senator DORGAN.—if you will pull that microphone closer to you, we'd appreciate it—you may proceed.

**STATEMENT OF HON. W.J. BILLY TAUZIN, PRESIDENT AND
CEO, PHARMACEUTICAL RESEARCH AND MANUFACTURERS
OF AMERICA (PhRMA)**

Mr. TAUZIN. Thank you very much, Senator.

I haven't had the chance to be on this side of the podium for a while, so let me first thank you, Senator, for allowing me to come and visit with you today on this important topic. You've pinned it correctly, it is a matter of life and death. And I want to talk a little bit about that today.

I've given you an extensive written testimony. I won't read that, but I'll call your attention to parts of it, beginning on page 2, which tell the story about where we've been, so that we can get some idea about where you and others might want to go, or not go, in the future, when it comes to drug safety in our country.

I was in the Congress in 1987 when Chairman John Dingell executed a series of hearings on this important topic. I was then a Democrat, working with Chairman Dingell on the issue, and we had some extraordinary hearings. It was prompted by a discovery, in 1984, that nearly 2 million counterfeits of G.D. Searle's Ovulen 21 birth control pills had been brought into our country as counterfeits. And there was a great deal of information developed in that series of hearings. I call it to your attention. You ought to go back and read it. It basically describes why the 1988 PDMA was passed, why Congress, in 1988, decided to prevent the reimportation of drugs that have left the control of the manufacturer and had gone out into the marketplace in other countries, and might be part of the process of reimporting those products into our own country after they've left that chain of control.

The Commerce Committee, in that series of hearings, concluded, and I quote, that the—"permitting reimportation of U.S.-origin goods prevents effective control of even routine knowledge of the true sources of merchandise in a significant number of cases." It went on to say that, "the reimportation resulted in pharmaceuticals which had been mislabeled, misbranded, improperly stored, or shipped." As you know, it's not just whether the drug contains the right content, it's how well it's been handled, whether it's been refrigerated properly, handled properly, stored properly, labeled properly. In fact, we concluded that reimportation resulted in those pharmaceuticals entering the country that had exceeded their expiration dates or were flat-out, bald counterfeits, and that they were being injected into the national distribution system for ultimate sale to American consumers.

The Committee further concluded—and this is very, very important, Mr. Chairman—that the very existence of the market for reimported goods here provides the perfect cover for foreign counterfeits, and, as a result of those findings, Chairman Dingell, the Congress, in the House and the Senate, concurred in the adoption, in 1988, of the prohibition against reimportation. There was an exception. The exception was, as you described it today, for the manufacturer, the original manufacturer in a foreign country, to be able to ship into this country. However, in those cases, the manufacturer controlled the chain of custody, from the plant inspected by the FDA all the way through the market into the United States. In effect, we, in 1988, said, "Look, we're not going to let drugs that have

gone out of the chain of custody come back into this country, because we can't trust it. Counterfeiting is too serious," in 1988, "for us to trust that system." We said, "We're going to put it on the backs of the pharmaceutical industry to be responsible, from the manufacturing plant overseas to the consumer in America, for that chain of custody, and the FDA will manage that inspection and that safety system." We, in effect, created a closed regulatory system to protect American consumers from the dangers of these imports.

Now, that was 1988. And the simple question I ask you today is, have things gotten better or worse? Madam Snowe, you asked that question, just a minute ago, "What's the status? Is it getting better or worse?" Mr. Vitter, you asked it, "What's the status in this country?" I call your attention to two articles, one of which I'll send over to the desk, which is an article that was included in *Parade* magazine in *The Washington Post* on March 5. What I want to quote from, a *New York Times* article that came out on February 20 entitled "In the World of Life-Saving Drugs, a Growing Epidemic of Deadly Fakes." For a long time in this debate in Congress, the question has been, show us the bodies, where are the bodies? Well, the bodies are piling up all over the world. Read the article. According to this article, estimates of deaths now caused by fakes run from the tens of thousands a year to 200,000 or more. The World Health Organization has estimated that a full fifth of the 1 million annual deaths from malaria would be prevented if the medicines, in fact, were genuine and were taken properly. China is obviously the biggest problem, the source of most of these counterfeits. The article goes on to say that the counterfeiters in China are not selling them to the Chinese. They're smarter than that. They understand they'd get hauled off to jail if they start killing Chinese citizens with fake drugs. The article goes on to say they don't want anybody beating down the door in the middle of the night, dragging them away, so they make their drugs for sale outside the country. It goes on to say that not only do the pills look correct, as did the cardboard boxes and the blister packaging and the foil backing, but they found 12 versions of tiny holograms added to prevent forgery, even a secret X-52 logo visible only under ultraviolet light was present.

What they're basically saying is, they can't tell the counterfeits from the real products anymore. When they're out of that chain of custody, when you permit them into this system, you're literally allowing an open door for those types of products to come into America.

The most frightening aspect of what's going on in the world, Mr. Chairman, is that these counterfeiters are beginning to make drugs that appear to work. For example, they'll contain drugs that apparently fool the patients into thinking the pills are working. The *Parade* article tells the real story. It's not necessarily the toxic chemicals that are found in a counterfeit drug that are killing people. It's the fact that they're getting drugs that don't contain the active ingredients that you're supposed to have to get people healthy and to battle disease.

Now, it's one thing for your constituents to walk across the border and to buy a drug if they really want to take that chance in

Canada. By the way, I've got a letter from Canada saying they will not, and cannot, be responsible for the safety of drugs imported from Canada into the United States. That's our job, over here, to make sure it's safe. And it's one thing for a citizen to voluntarily walk across the border and buy those drugs; it's another thing for me to bring my child to a hospital, in America, where those counterfeit drugs have been brought in and mixed in with the safe system we have, and for me not to even know that my child is getting a drug that is not only doesn't contain the ingredients necessary to save his life, but, in some cases, may be diluted, polluted—even contain pond water, in some cases, we've discovered. So, it is a matter of life or death, Mr. Chairman.

Now, as I said, some things have changed since 1988. You know, I'm no longer a Democrat. I became a Republican. I'm no longer in Congress. I left. Some people say both of those are good things. But the bad thing is, this is getting worse, not better. And opening the door to it, to American consumers, who unknowingly will be taking these fake products in increasing numbers, is the scariest thing I can think of right now.

Look at the *Parade* article. The *Parade* article talks about 600,000 Lipitor tablets that were discovered, counterfeited, received by patients like you, taking them, thinking they're taking the cardiovascular medicine they need, and taking nothing but cornstarch. Fake products. Look at it, and you'll see some numbers, Senator Snowe and Mr. Vitter, 40 million estimated by the National Association of Boards of Pharmacy in this country—40 million fake prescriptions already in America, getting worse. And we're only a 1 percent problem, according to them. In the world, it's becoming a 20-percent problem. In the parallel trade in Europe, it's growing rapidly. Three countries in the former Soviet Union are now in the EU, and the counterfeits in those countries are enormous. In Borat's Kazakhstan, for example, our researchers tell us, 50 percent of the drugs there are likely counterfeit. The same is true in Mexico today.

Open those borders, given our closed regulatory system, and open it up to those drugs, that's what the FDA's trying to tell you would be a serious mistake for consumers in America. That's the life-or-death decisions we have to make here.

Let me conclude. When I officially retired from Congress in 2005, I was already gone. I had left in 2004, when I was diagnosed with cancer, as you know.

I didn't leave to take a job with the pharmaceutical companies or the Motion Picture Association. I left to go to Johns Hopkins and M.D. Anderson to battle for my life. And there were some tough moments. I took the last sacrament and said goodbye to my family during that process. I got a very generous finding at M.D. Anderson, that I had a five percent chance to live. Thanks a lot. But somehow I survived.

And in that worst year of cancer, of surgery and treatments and chemo and radiation, they gave me 3 weeks off. I took one of those weeks to come to work here in Congress. That's the one week I spent working with you in 2004, when I left for cancer treatment. And I gave one speech to Congress. I've got a copy with me today. That speech I gave was to the Appropriations Committee on the

House side. It was a Cassandra warning. I brought it to you. I'll give it to you, Mr. Chairman. It was a warning. It was a plea to Congress to please end the filibuster in the Senate and pass the energy bill that contained \$20 billion for my City of New Orleans, Mr. Vitter, to save us from what happened. I talked about going down and seeing the simulation of the storm that was coming. I talked about the fact that New Orleans was about to drown. And I begged Congress, in that one appearance in 2004, not to have to come back one day with a red-faced commission and admit that we could have stopped it and we didn't do anything about it before it happened. I concluded with these words, "Please help me place into law some system that the Corps and the great people of my state can collectively work to begin doing something about the 35 square miles of wetlands. That's the only—that the critical land mass—that's the barrier between us—life and death. That's the barrier between us and the storms that churn in the Gulf that are about to destroy not only the cities and the communities, but the lives of the people I represent." That was the one speech I gave in 2004. Nobody listened.

I'm going to ask you, please, Mr. Chairman, as one who's just gone through it, who's had to count on a medicine to save my life, whatever you do on this issue, take seriously the admonitions of Donna Shalala, take seriously the admonitions of Tommy Thompson, take seriously the admonitions of the current Secretary, when they tell you that they cannot—they cannot, today, stop this flood of imports that is only a one percent problem in America today, that's a 20 percent problem in the world.

Senator DORGAN. Mr. Tauzin—

Mr. TAUZIN. It is a matter of life or death. Don't accept responsibility for the consequences of opening that door wide open to all of these fakes.

Senator DORGAN. Mr. Tauzin—

Mr. TAUZIN. Thank you, Mr. Chairman.

Senator DORGAN.—thank you very much.

[The prepared statement of Mr. Tauzin follows:]

PREPARED STATEMENT OF HON. W.J. BILLY TAUZIN, PRESIDENT AND CEO,
PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA (PhRMA)

Mr. Chairman, Senator DeMint, and Members of the Subcommittee:

Thank you for the invitation to participate in today's hearing on pharmaceutical importation. My name is Billy Tauzin and I am the President and Chief Executive Officer of the Pharmaceutical Research and Manufacturers of America (PhRMA). PhRMA is the Nation's leading trade association representing research-based pharmaceutical and biotechnology companies that are devoted to inventing new, life-saving medicines that help achieve longer, healthier, more productive lives.

Much has changed since the debate over legalizing importation began nearly a decade ago. Unlike the situation in 2000, millions of seniors who lacked prescription drug insurance and were paying for their medicines out-of-pocket now have comprehensive prescription drug insurance through Medicare Part D. Today, we know much more than we did in 2000 about the growing problem of counterfeiting and the seriousness of the problem. Moreover, we have evidence that foreign governments are not willing or interested in taking responsibility for assuring the safety of drugs imported into the U.S.

My testimony today begins by reviewing current law governing drug safety and importation. This portion of my testimony also explains that importation would effectively circumvent the other drug safety provisions carefully constructed over the course of nearly a century. My testimony then focuses on five main points: (1) Importation opens our borders to drugs from anywhere in the world and there is no

plausible way of limiting importation to Canada or Western Europe; (2) Safety testing, inspections, chain of custody requirements and other attempts to “guarantee” safety provide no assurances that imported drugs will be safe; (3) Projections of potential cost-savings from importation are very small and the largest beneficiaries are arbitrageurs; (4) Importation is not free trade, it is price controls which lead to delays and denials in patients’ access to medicines; and (5) There are better, safer alternatives for patients to access needed medicines, including the Partnership for Prescription Assistance (PPA) and Medicare Part D for seniors and the disabled.

Overview of Current Law Related to Importation

Over the years, a number of bills have been proposed that would legalize the commercial and personal importation of unapproved prescription drugs from foreign countries. It is my belief that opening our closed system in this way would circumvent a system that was carefully constructed and developed over the years to protect the health and safety of the American public.

The regulatory system that governs development, approval, and marketing of new drugs in the United States is the most complex and comprehensive in the world. To ensure that Americans have the safest drug supply in the world, it has become increasingly comprehensive and more robust over time. As far back as 1938, the Federal Food, Drug, and Cosmetic Act (FDCA)¹—which remains in place today—prohibited the marketing of any drug not shown to be “safe for use under the conditions prescribed, recommended, or suggested” in its labeling.² In 1962, the Food and Drug Administration (FDA) obtained explicit authority to demand proof that a drug is effective and to prescribe the tests that a manufacturer must perform before its product can be approved for marketing.³ Since that time, several amendments have expanded, strengthened, and refined the regulatory scheme.⁴ These include the Prescription Drug Marketing Act of 1987 (PDMA), under which Congress, following an investigation of incidents of counterfeit drugs reaching American consumers, closed the U.S. prescription drug supply to products that have circulated overseas, beyond the jurisdiction of FDA and outside the control of the manufacturer.

As a consequence of this comprehensive framework, FDA currently regulates virtually every stage in the life of a prescription medicine sold in the U.S., from pre-clinical testing in animals and human clinical trials before the medicine can be marketed, to manufacturing, labeling, packaging, and advertising when the drug is marketed, to monitoring actual experience with the drug after its sale to consumers. In particular, the FDCA prohibits the introduction into interstate commerce of any “new drug” (which covers virtually every prescription drug) that is not the subject of a FDA-approved new drug application (NDA) or abbreviated new drug application (ANDA).⁵

Importation of a prescription medicine constitutes introduction of that medicine into interstate commerce and thus is subject to the FDA approval requirement.⁶ If a company that holds an approval for a drug manufactures a version of that drug product in a plant that is not listed in the relevant NDA or ANDA or fails to manufacture according to specifications in the approved application, FDA considers that version an unapproved drug, and it cannot be imported or otherwise introduced into interstate commerce.⁷ Foreign versions of drugs that are approved in the United States often are manufactured by companies that do not hold an approved NDA or ANDA. Even if the foreign version is made by a company with a U.S. approval, the foreign version often does not comply with the terms of the approved NDA or ANDA and thus is unapproved. That is because the U.S. has some of the toughest drug approval requirements in the world. For these reasons, the importation of a drug purchased in a foreign country will usually violate the statutory requirement for FDA approval—requirements that have been established to protect consumers and that no one would advocate repealing. Yet permitting importation of drugs not meeting these standards would have the same effect as repealing current consumer protections, since these unapproved drugs would be mixed into the U.S. drug supply.

There are occasions where some drugs that are available overseas are manufactured in the United States and then exported. But in those instances, the FDCA prohibits the importation (or “reimportation”) of these drugs, even if they are manufactured in full compliance with the approved NDA.⁸ Congress added this prohibition on reimportation to the law in the PDMA, following a series of hearings that documented adulterated and counterfeit drugs entering the U.S. In 1984, for instance, nearly two million counterfeits of G.D. Searle’s Ovulen 21 birth control pills were found to have been shipped to Miami and New York from Panama. Based on a robust record and exhaustive investigation, the U.S. House of Representatives Committee on Energy and Commerce concluded that permitting reimportation of U.S.-origin goods “prevents effective control or even routine knowledge of the true sources of merchandise in a significant number of cases.”⁹ The Committee further

found that reimportation resulted in “pharmaceuticals which have been mislabeled, misbranded, improperly stored or shipped, have exceeded their expiration dates, or are bald counterfeits, are injected into the national distribution system for ultimate sale to consumers.”¹⁰

The Committee also concluded that “the very existence of the market for reimported goods provides the perfect cover for foreign counterfeits.”¹¹ As a result of these findings and the conclusion that reimportation posed a grave risk to consumers, Congress prohibited the reimportation of approved drugs that have left the United States.¹²

There is an exception for the original manufacturer, who is an integral part of this closed regulatory system and subject to FDA authority and oversight at all times.¹³ However, in such instances, the manufacturer’s own importation of drugs that have never been outside its control is comparable to shipments between its manufacturing plants and warehouses within the United States. It is entirely different from the importation of drugs that have been placed into the wholesale and retail distribution systems of foreign countries, where they are no longer subject to FDA jurisdiction.

Notably, FDA has a very limited exception to the statutory prohibition on importation of unapproved drugs which it developed in the early 1990s when it announced a policy of “enforcement discretion” with respect to personal importation of certain unapproved drugs.¹⁴ Under this policy, FDA personnel may permit the importation of a drug if: (1) it is clearly intended for personal use; (2) the intended use of the drug is clearly identified; (3) the drug is intended for treatment of a serious condition for which satisfactory treatment is not available in the U.S.; (4) the drug is not known to present a significant health risk; and (5) the drug is not approved in the U.S. FDA officials will presume commercial use, rather than personal use, if the supply exceeds what one person might take in three months. FDA guidelines direct agency personnel to look for either: (a) the inclusion of the name and address of a doctor licensed in the U.S. and responsible for the patient’s treatment with the product, or (b) evidence that the product is intended for the continuation of treatment begun in the foreign country. However, the personal use policy does not apply to the importation of unapproved foreign versions of drugs available in the United States, or to reimportation of drugs in violation of the PDMA. Rather, it applies only to the personal importation of drugs for which there is no approved U.S. source. This kind of importation remains technically illegal. The policy represents a limited exercise of enforcement discretion in the interest of individual patient treatment.¹⁵

In 2000, Congress authorized an additional exception to the prohibition on reimportation. The Medicine Equity and Drug Safety Act (MEDS Act) added a new section 804 to the FDCA under which pharmacists and wholesalers would be permitted to import drugs from a list of designated countries, including Canada and the countries of the European Union.¹⁶ During the debate on the MEDS Act, however, concerns were voiced that section 804 would be ineffective (at reducing consumer prices) and unsafe (by allowing the influx of counterfeit and adulterated products). Congress responded to these concerns in part by delaying implementation until the Secretary of HHS could “demonstrate” that the law would pose no additional risk to public health and safety and that it would result in a significant reduction in the cost of covered products. Secretary Donna Shalala concluded on December 26, 2000, that it was “impossible . . . to demonstrate that [importation] is safe and cost effective.”¹⁷ Similarly, Secretary Tommy Thompson, citing an analysis by FDA on the safety issues and an analysis by his planning office on the cost issues, decided not to “sacrifice public safety for uncertain and speculative cost savings.”¹⁸

As part of the Medicare Prescription Drug, Improvement and Modernization Act of 2003, Congress replaced the MEDS Act with a new section 804. Reimportation language was included in the drug benefit legislation—despite enactment of a prescription drug benefit for Medicare beneficiaries—primarily because proponents of importation were working separately from the Medicare conferees to address access issues. Notably, however, the drug benefit that became available to seniors in 2006 provides much safer and effective ways for Americans to access affordable medicines. Company and state patient assistant programs that can help the under and un-insured also exist. These options are all safer than the importation of foreign products.

This reimportation language in section 804 of the FDCA differs markedly from existing legislative proposals. The legislation would only permit reimportation from Canada and it would require reimported drugs to comply with sections 501, 502, and 505 of the FDCA. In other words the drugs could not be adulterated, misbranded, or unapproved new drugs.¹⁹ Most importantly, the provisions require that the Secretary determine importation would be safe and create significant cost sav-

ings before it can proceed. To date, no Secretary has been able to make such a determination.

Importation of Medicines into the U.S. That Have Been Outside the Jurisdiction of the FDA Is Inherently Unsafe

Importation of medicines into the U.S. that have been outside the jurisdiction of FDA is inherently unsafe. There is no assurance that an imported drug meets FDA's stringent requirements for quality, purity, safety, effectiveness or proper labeling. As FDA has documented, many of these imported drugs are unapproved, contaminated, counterfeit, or have been stored, handled or shipped under substandard conditions.

The current system has been effective in the U.S. for protecting public health, but it faces increased threats with the proliferation of Internet pharmacies outside the U.S. and outside the jurisdiction of FDA. The safety concerns that exist today are many. A recent example illustrates the potential dangers and reinforces concerns over proposals to legalize importation. According to FDA, recently patients ordering drugs online for depression and insomnia instead received schizophrenia medication that caused them to seek emergency medical treatment for breathing problems. Side effects ranged from muscle spasms to difficulty breathing. According to FDA, while none of the cases resulted in death, in at least three cases, patients required a trip to the emergency room.²⁰ Legislation that would legalize the importation of medicines would place significant, additional burdens on our current system and will increase safety concerns that exist today.

Proponents of importation believe that with certain modifications—such as end product testing, chain of custody provisions, requiring the use of anti-counterfeiting technology, or limiting importation to Canada—importation can be done safely. The fact is no modification can guarantee safety that equals the safety of the current closed system that Congress established in 1987 precisely to protect consumers from the dangers of importation—dangers that have not abated in the intervening 20 years.

Limitations on Safety Testing

The safety, quality, and authenticity of pharmaceutical products that are imported into the United States cannot be assured by inspection and/or testing programs to meet the levels of safety, quality and authenticity achieved in today's system. Although terminal testing (*i.e.*, testing a product after it has been manufactured) may provide some useful information about product quality and safety, such testing is inherently limited and can never, by itself, guarantee the safety and quality of products as complex as pharmaceuticals. As the FDA and other experts recognize, the only way to assure the safety and quality of pharmaceutical products is to strictly control the conditions under which they are manufactured and distributed.

cGMP Requirements: Safety and Quality Cannot Be "Tested Into" A Product

FDA's current Good Manufacturing Practice (cGMP) regulations are based upon the fundamental quality assurance principle that quality, safety, and effectiveness "cannot be inspected or tested into a finished product" but instead "must be designed and built into a product."²¹ FDA has reiterated this bedrock principle on numerous occasions, most recently in connection with its 2003 initiative to modernize the cGMP regulations.²²

Consequently, those regulations impose strict controls on all aspects of the manufacturing process, including (1) the qualifications and responsibilities of employees and consultants; (2) the design and maintenance of manufacturing facilities; (3) the design, construction, cleaning and maintenance of manufacturing equipment; (4) the receipt, storage, testing and acceptance of pharmaceutical raw materials and components, including containers and closure systems; (5) the manufacturing process itself, including reprocessing procedures; (6) the packaging and labeling of finished drug products; (7) the storage and distribution of final products; (8) required laboratory testing procedures; and (9) recordkeeping requirements.²³ Failure to satisfy any of these cGMP requirements renders the affected drug product "adulterated" and thus illegal in the United States—even if testing fails to reveal any obvious deficiencies in the product.²⁴

The cGMP regulations recognize that routine end-product testing is inherently limited and cannot be relied upon as the sole basis for assuring quality and safety for a number of reasons. First, many end-product tests have limited sensitivity and may fail to detect substances, such as impurities or degradants that are present in a drug product at low levels.²⁵ If these substances are dangerous at low levels or have an adverse effect on product quality (*e.g.*, accelerate degradation of active ingredient), the end-stage testing will fail to reveal that the drug product may be un-

safe, unstable or ineffective. In essence, such testing would yield an unacceptably high rate of “false negatives,” *i.e.*, finding no quality or safety problems when such problems actually exist.

Second, drug products often are extremely complex, and end-product testing does not reveal all variations that may occur in the product that may impact on safety and effectiveness. Even seemingly minor changes in manufacturing process or storage conditions may introduce variations in the product, such as new impurities, that cannot be predicted or easily tested. Oftentimes, these variations can have a significant impact on safety and effectiveness. For example, testing might be conducted to demonstrate that a drug product contains the proper strength of a specific active ingredient; however, such testing would not detect other variations in the product caused by manufacturing changes, such as increased pill hardness or contamination with cleaning chemicals, that could have a significant impact on safety and effectiveness. While dissolution and impurity testing might be added to the battery of tests conducted on the drug product, such testing still would not detect meaningful variations in the drug product, such as new or different impurities or changes in the drug’s stability profile. Because of the complexity of drug products, end-product testing simply cannot measure all of the possible variations that could affect safety and effectiveness.

Because of these significant limitations, FDA does not rely upon terminal testing alone to assure the safety and quality of drug products. Instead, through application of the cGMP regulations, FDA seeks to minimize the variability in the manufacturing process itself. As FDA recognizes, safety and quality cannot be “inspected or tested into” a drug product; they must be built into the product through rigorous approval requirements and strict controls over the conditions under which drugs are manufactured and distributed.

Limitations of Safety Testing of Imported Drug Products

These significant limitations on the use of end-product testing to assure safety and quality are not restricted to the manufacturing context but apply with even greater force to the importation context as well. Safety, quality, and authenticity cannot be “inspected or tested into” imported drug products any more than it can be inspected or tested into domestic drug products. These attributes instead must be built into imported drugs by strictly controlling the distribution system. The greatest assurance that drug products are safe, effective, and authentic comes from maintaining a closed, closely-controlled distribution system.

Testing for Counterfeits

Counterfeit drug trafficking is one of the primary safety concerns associated with importation. FDA estimates that counterfeits make up 10 percent of the global medicines market.²⁶ The latest estimates by the World Health Organization (WHO), the Organisation for Economic Co-operation and Development (OECD), and the Pharmaceutical Security Institute (PSI) show that “. . . 50 percent of illegal Internet sales are counterfeit.” According to the WHO, “. . . the message for now is: do not take the risk of buying your medicines from unknown sources, such as the Internet. If you must buy from the Internet, ensure that the website is that of a pharmacy you know and trust.”²⁷

A recent article in the *Financial Times* reinforces concerns with counterfeit medicines. A report by the International Narcotics Control Board, which monitors compliance with U.N. drug conventions, cited “growing concerns” about the unregulated market for medicines that is exposing patients to “serious health risks”. The report “expresses concern about the rise in counterfeit drugs . . .” and the health risks of the Internet medicines market. *Financial Times* reports that, “The findings mark the latest escalation in international concern about the mixing of criminal, narcotic and prescription medicines, and heightened worries about counterfeit drugs.”²⁸

According to a February 2005 *Business Week* report, “The global counterfeit business is out of control, targeting everything from computer chips to life-saving medicines.” The story reported that, “Chinese police last year conducted raids confiscating everything from counterfeit Buick windshields to phony Viagra. In Guam, the Secret Service uncovered a network selling bogus North Korean-made pharmaceuticals, cigarettes and \$100 bills.” The report also found that Pakistan and Russia are “huge producers of fake pharmaceuticals.”²⁹

And, the problem is expected to grow quickly over the next several years. In fact, a study by the Center for Medicine in the Public Interest estimates that counterfeit drug sales will reach \$75 billion in 2010, a 92 percent increase from 2005.³⁰ Both the FDA and industry have grappled with this problem for years and have devised many strategies for combating the problem both domestically and internationally. Indeed, FDA issued its final report detailing new strategies for keeping counterfeit

drug products from entering the U.S. drug supply. Significantly, none of these strategies relies upon end-product testing as the sole, or even a significant, weapon in the fight against counterfeits, effectively illustrating why such reliance on testing can not achieve adequate levels of safety in the importation context.

This is because end-product testing simply is not adequate to identify counterfeit drugs or prevent them from entering the U.S. drug supply. While random sampling and inspection might be acceptable in the manufacturing context, it will never be sufficient to detect counterfeit drugs entering the U.S. from abroad. This is because “counterfeits can easily be commingled with authentic product, either by the case, by the bottle, or by the pill . . .”³¹ Consequently, as FDA itself concludes, “[n]o random sampling plan will be able to detect and protect against such criminal conduct since the threat does not depend upon the nature of the reimported product, but upon the integrity of those handling it.”³²

This would suggest that in order to identify counterfeits, an inspection and testing program requiring authentication of *all* drug products offered for importation would be necessary. Such inspection and testing would be extremely cumbersome and expensive. Large shipments would need to be removed from shipping containers and broken down into individual units for inspection. Then each individual unit would need to be inspected or analyzed separately before being repacked into shipping containers.

Yet even if a 100 percent inspection program were feasible from a practical perspective (which it is not), it still would not be sufficient to assure the safety and authenticity of imported drug products. This is because both visual inspection and product testing have significant practical and scientific limitations.

Visual Inspection

Visual inspection of drug packaging and labeling is not a viable method for accurately identifying counterfeits. From a practical standpoint, drug packaging and labeling—and the overt counterfeit resistant features incorporated therein (*e.g.*, color-shifting inks, holograms)—are too varied and numerous to provide for the real time verification of drug products. It simply is not realistic to expect inspectors to be familiar with the wide variety of overt features used on the thousands of different drug products likely to be imported. This problem will be exacerbated by the need to rotate overt features on a regular basis to stay one step ahead of the counterfeiters.

Second, packaging and labeling, and even counterfeit resistant technologies, can themselves be counterfeited, often within 12–18 months. The counterfeiters are becoming increasingly sophisticated and are making use of advanced technologies to duplicate the packaging and labeling of authentic drugs. As a result, counterfeit products are becoming increasingly difficult to detect, even to trained experts. Given the sophistication of today’s counterfeiters, visual inspection can no longer be expected to reliably detect counterfeit products presented for import.

Finally, visual inspection is of little or no value when a drug product has been repackaged. Such repackaging removes or destroys the drug’s original packaging and labeling as well as any counterfeit resistant technologies incorporated by the manufacturer. In such situations, inspectors conducting a visual inspection would have little or no basis for determining whether a product is authentic because they would have no authentic product against which to compare it. This likely will be a major problem because virtually all drugs that are imported have foreign packaging and labeling and thus would need to be repackaged prior to importation. Repackaging is subject to minimal oversight, and it was implicated in a recent counterfeiting incident, including one that led to the recall of 200,000 bottles of counterfeit cholesterol-reducing medicine.

Chemical Analysis and Authentication of Covert Features

Covert features and chemical analysis offer more accurate methods of authenticating drug products, but they have their own limitations. Most significantly, such methods do not provide real time verification of a drug’s authenticity. Covert features and taggants typically require specialized equipment or testing to authenticate and can and should be authenticated only by the manufacturer. These tests often cannot be performed onsite or require a manufacturer’s representative to travel to the site. In addition, tests for taggants may take up to several days to perform in order to accurately determine whether the drug is counterfeit or not. This may be problematic if a large amount of drug is of questionable authenticity as it would have to be withheld from commerce until the testing is completed.

Chemical analysis of imported drugs has another problem. Since random sampling methods likely could not be employed (for the reasons discussed above), chemical analysis would need to be performed on all drug products offered for importation.

This not only would be prohibitively expensive but also counterproductive, since such testing would destroy the very products being tested.

Further, according to the Department of Health and Human Services' Task Force report on importation, issued in December 2004, while a number of new anti-counterfeiting technologies show potential for assuring the safety and authenticity of prescription medicines, until they are universally adopted they cannot be relied upon to secure the safety, efficacy, and integrity of the global market. The report also found that "widespread adoption of authentication technologies, while theoretically able to secure the U.S. drug supply, is a daunting task that could raise the cost of imported drugs thereby reducing any expected savings from importation."³³ Estimates from the Congressional Budget Office (CBO) suggest a counterfeit-resistant technology mandate could substantially increase the cost of any importation scheme. The mandate in H.R. 2427 (an importation bill introduced in the 108th Congress) could "raise the cost of prescription drugs by as much as \$2 billion in the first year." CBO found that the cost of such a mandate would be "significant."³⁴

Finally, the identities of covert features and chemical taggants incorporated into drug products are (for good reason) closely held secrets by manufacturers. In addition, for the many drug products that do not incorporate taggants, there is no simple laboratory test that can verify authenticity. Consequently, authenticity testing would either have to be conducted by the manufacturer or would require the disclosure of trade secret information by the manufacturer to the laboratory or facility conducting the test.

Safety Testing

Safety testing for imported products suffers from many of the same limitations as authenticity testing and has some additional limitations as well. Visual inspections, for example, would be even less effective at identifying safety problems than authenticity problems. This is because most safety problems do not leave overt visual clues. Accordingly, visual inspection likely would not detect dangerous impurities in a drug product; stability problems caused by improper storage conditions; or degradation of the active ingredient. On the contrary, visual inspection is likely to identify only the most obvious safety problems, such as opened or water-damaged drug products.

Likewise, chemical testing does not provide an adequate assurance of the safety or quality of imported drug products. As discussed above, end-product testing has significant limitations because of the complexity of many drug products and the lack of sensitivity of many tests. Just as in the manufacturing context, end-product testing of imported drugs simply cannot measure all of the possible variations that could affect safety and effectiveness.

For all of these reasons, the safety, quality, and authenticity of pharmaceutical products that are imported into the United States cannot be assured by inspection and/or testing programs but instead must be based on strictly controlling the conditions under which they are manufactured and distributed. This means maintaining to the greatest extent possible the closed distribution system in the U.S. that Congress enacted to reduce risks to U.S. consumers.

Chain of Custody Requirement Does Not Guarantee Safety of Imported Drugs

The inclusion of a chain of custody provision, otherwise known as a drug pedigree requirement, also does not equate to today's closed system and the level of safety it provides. In testimony on July 9, 2002, before the Senate Special Committee on Aging, FDA stated:

"Because we could not go certify and look in the other countries, the bill that they refuse to implement or decline to implement would have replaced the normal quality control system with a testing process with a paper or so-called pedigree process that attempted to follow the trail of the drugs, but both Secretaries [Shalala and Thompson] found that the paper process could be forwarded by faking documents and that you really couldn't adequately test these products, either economically or feasibly."³⁵

It is inappropriate and dangerous to rely solely on chain of custody or pedigree papers to authenticate an imported medicine. Such documents can be easily forged, for example. According to the HHS Task Force report on importation, "Paper pedigrees, which are in use today, have significant limitations. They are subject to failures to keep adequate records and can be forged, thus making them an unreliable means for documenting the chain of custody."³⁶

Limiting Importation to Canada Does Not Guarantee Safe Importation

On its face, limiting importation to drugs imported from Canada appears to be safe. In practice, a drug could be imported from *anywhere* in the world, as long as it entered into the U.S. through Canada. There is no effective way to prevent the transshipment of drugs from Third World countries into Canada and then into the U.S. The FDA has already warned that if importation from Canada were enacted into law, Canada could become a gateway for counterfeit drugs.

First, the Canadian government is on record saying that while it regulates drugs manufactured for its citizens, it cannot vouch for the safety of medicines that are then exported to the U.S. According to its then-Assistant Deputy Minister, Health Canada, “The Government of Canada has never stated that it would be responsible for the safety and quality of prescription drugs exported from Canada into the United States, or any other country for that matter.”³⁷

Second, buying medicines from a Canadian website does not guarantee the product actually came from Canada or that it is safe and effective. For example, last August, the FDA issued an advisory to consumers warning them against purchasing prescription drugs from websites that have orders filled by Mediplan Prescription Plus Pharmacy or Mediplan Global Health in Manitoba, Canada (pharmacies that were “certified” by the Canadian International Pharmacy Association), following reports of counterfeit versions of prescription drug products being sold by these companies to U.S. consumers. Lab analysis of the intercepted products found counterfeit versions of several popular medications, including medicines for high cholesterol, gastroesophageal reflux disease (GERD), arthritis-related pain, high blood pressure and breast cancer.³⁸

According to FDA, “In our experience, many drugs obtained from foreign sources that purport and appear to be the same as U.S.-approved prescription drugs have been of unknown quality. We cannot provide adequate assurance to the American public that the drug products delivered to consumers in the United States from foreign countries are the same products approved by FDA.”³⁹ A FDA analysis of three commonly prescribed drugs purchased from a website advertised as Canadian showed that so-called “Canadian Generics” bought from the website were fake, substandard and potentially dangerous. One was a controlled substance. According to FDA, “This firm shipped drugs that were the wrong strength, including some that were substantially super-potent and that pose real health risks as a result, drugs that didn’t dissolve properly, drugs that contained contaminants, and drugs that should not have been given because of potentially dangerous drug interactions.”⁴⁰

In a series of “blitz exams” FDA discovered that drugs were being imported from alleged Canadian websites that were in fact from other parts of the world. According to then-FDA Commissioner, Mark McClellan, “During the import blitz, we have examples where our examinations revealed that products were manufactured in countries other than Canada, yet were exported from Canada. For example, at the Dallas, Seattle and Buffalo mail facilities, imported drugs were encountered which were manufactured in Canada, Mexico, Costa Rica, India, Pakistan, New Zealand, Taiwan, Thailand, and a host of other countries. However, in some cases, the drugs that had obviously been manufactured in other countries were exported from Canada.”⁴¹

A more recent FDA investigation reconfirmed the fact that many drugs being ordered from so-called Canadian pharmacies are in fact from other parts of the world. In December 2005, FDA announced the results of an operation in August of that year to confiscate parcels containing pharmaceuticals from India, Israel, Costa Rica and Vanuatu—43 percent of which had been ordered from Canadian Internet pharmacies. Of the drugs being promoted as “Canadian,” 85 percent actually came from 27 countries around the globe. Then-acting FDA Commissioner Andrew C. von Eschenbach stated, “These results make clear there are Internet sites that claim to be Canadian that in fact are peddling drugs of dubious origin, safety and efficacy.”⁴²

Recent news reports have found that some Canadian pharmacies now acknowledge that they are going to foreign countries to get their drugs to sell to U.S. consumers. An April 6, 2006, *New York Times* article reported that the Canadian online pharmacy industry is selling foreign drugs, instead of Canadian drugs, to American patients.⁴³ The article states that, “At their peak in 2004, the online pharmacies employed about 4,000 Canadians. That number has decreased to 3,000 with the squeeze in profits, company closings and the purchasing and stockpiling of supplies in Europe, Australia and New Zealand.” According to Daren Jorgenson, founder of Winnipeg-based *Canadameds.com*, “We’re filling 50 percent of our prescriptions [from international pharmacies].” Jorgenson’s website boasts, “Not just from Canada any more! Choose your country and your savings!”⁴⁴

The President and Owner of *CanadaRx.net* has also confirmed that his medicines are not coming from only Canada. According to Harvey Organ, “I can get drugs from

all over the world.”⁴⁵ A *Bloomberg* news article reported that CanaRx Services Inc., “has joined other Canadian Internet pharmacies in finding sources of drugs from partners in the U.K., Continental Europe, Israel, Australia and India.”⁴⁶ This is particularly troubling since according to a study by Temple University for Pharmaceutical Health Service Search, India is a worldwide leader in the production of counterfeit drugs with as much as 35 percent of the world’s drug counterfeiting originating in that country.⁴⁷

This is confirmed by data from Industry Canada, which shows significant increases in pharmaceutical imports into Canada in 2006 from the previous year. For example, according to the data, imports of pharmaceutical products into Canada were up significantly from many countries, including, for example: Singapore up 165 percent; Argentina up 913 percent; Bulgaria up 255 percent; Jordan up 823 percent; and Mexico up 284 percent, to name a few.⁴⁸

Expanding importation beyond Canada presents additional safety concerns

If importation were to be legalized beyond Canada, further safety concerns exist. While proponents of importation point to parallel trade⁴⁹ in the European Union (EU) as evidence that importation beyond Canada can be done safely, they often ignore the problems that exist with parallel trade in terms of safety. Specifically, EU member states have struggled with counterfeit drugs, safety issues arising from improper storage and handling, and safety issues arising out of repackaging and re-handling.

Parallel Trade and Introduction of Counterfeit Drugs

First, parallel trade in Europe has facilitated the introduction of counterfeit medicines in the destination countries. For example, in January 2005, the Council of Europe (CoE) released a report on counterfeit medicines in the EU. According to the CoE report, “Based on the results of the surveys conducted by the CoE, the counterfeit medicine problem is not insignificant in Western Europe and estimates provided by several respondents indicate that the problem is not likely going away in the foreseeable future. It affects all countries of the world. It is no longer safe to assume that the problem does not exist to any real extent in Western Europe and thus can safely be ignored by authorities in the latter. Although it can be assumed that Western Europe is relatively less affected by the counterfeit medicine problem than Eastern Europe, it has to be borne in mind that counterfeit medicines probably regularly transit through and exit Western Europe.”⁵⁰ If importation were legalized, these counterfeit medicines could then make their way into the U.S.

The CoE report found that parallel trade in the EU provides for the inadvertent entry of counterfeit drugs. According to the report, “The existence of a significant level of parallel trade in the EU, in the absence of adequate controls on repackaging and relabeling, provides an opportunity for the inadvertent entry of counterfeit medicines into the market. . . . Furthermore, parallel trade means that any counterfeit product within the legitimate distribution chain in one MS [Member State] can easily contaminate other MSs.”⁵¹

European health officials have discovered counterfeit versions of a cholesterol-lowering medicine in the supply chains of the U.K. and Netherlands. A parallel trader illegally purchased the counterfeits from outside Europe and sold it to a large wholesaler within the U.K. Dutch health authorities also found counterfeit cholesterol-lowering medicines in their own country’s pharmacies.⁵²

At a meeting of the WHO’s International Medical Products Anti-Counterfeiting Taskforce in 2006, the European Commission announced that in the past years, it had witnessed 27 cases of counterfeit drugs in the *legitimate* supply chain. In addition, the EC saw another 170 cases through the Internet and what it calls the “illegal” supply chain.⁵³

According to an investigation into the links between organized crime, terrorism and counterfeit medicines conducted for the Stockholm Network by a former detective superintendent, “There is no effective method within the U.K.—or to a greater or lesser extent across Europe—of identifying counterfeited pharmaceuticals before they are dispensed.” The report also found that the “rapid, legal growth in the movement of medicines around the world via parallel trade in Europe and re-importation into the United States provides more opportunities for counterfeit and substandard medicines to enter the legitimate distribution chain.”⁵⁴ A study by Patricia Danzon, a health care economist from the Wharton School, University of Pennsylvania, found, “Although parallel importers are required to obtain a license, chemical testing for equivalence is not performed, and instances of counterfeit products have occurred.”⁵⁵

Importation from any EU Country Would Open the U.S. to Drugs from Every EU Country

Because of the free flow of goods between members of the EU, any legislation that permits the importation of pharmaceuticals from any country in the EU is essentially permitting the entry of drugs from *every* country in the EU—it simply is not possible to prevent importation that includes any EU country from including every one of the EU countries. This would include, for example, a number of Eastern European countries with either known counterfeiting problems or neighbors with known counterfeiting problems. Many of these countries do not have pharmaceutical infrastructures even roughly comparable to ours. The WHO, in their 2006 estimates, warned that the countries in the former Soviet Union have counterfeit rates up to 20 percent.⁵⁶ As of 2007, there are three former Soviet Union countries in the 27 member European Union, this number will grow. As the EU expands, the risk of counterfeits from countries with weaker regulatory systems, such as the Ukraine is likely.⁵⁷

EU Countries Not Willing to Police Drugs Exported to the U.S.

Aside from growing concerns over counterfeit medicines in the EU, there also does not appear to be a willingness among countries in the EU to implement protections to ensure the safety of drugs exported to the U.S. if importation were legalized in the U.S. As part of the HHS Task Force's investigation into the feasibility of prescription drug importation, it requested comment from foreign health agencies on their willingness or ability to implement new or additional protections to ensure the safety of exported or transshipped drugs. However, *no comments* from foreign health agencies directly addressed this point. Further, none outlined a specific strategy for new steps to collaborate with the U.S. Government on the effective oversight of importation. The Task Force report stated, "Foreign governments have little incentive and limited resources to ensure the safety of drugs exported from their countries, particularly when those drugs are transshipped or are not intended for import . . . If foreign health agencies were willing to ensure the safety and effectiveness of drugs exported from their countries to the U.S., one would expect a greater global response."⁵⁸

Parallel Trade and Improper Storage of Medicines

Significant health issues are associated with improper storage of medicines during transit. Parallel imported goods must pass through the hands of various international trading organizations, and it is not always possible for regulatory authorities to ensure sufficient physical monitoring and sampling of these products. A WHO/World Trade Organization (WTO) Workshop paper found, "while parallel importers may themselves be required to comply locally with stringent drug wholesale regulations, there are many ways to circumvent drug regulations."⁵⁹

Parallel Trade and Safety Problems Associated with Repackaging and Re-Labeling

Parallel trade requires both repackaging and re-labeling, which can introduce a variety of safety problems. For example, parallel traders often discard the anti-counterfeiting measures that some packaging now incorporates. One member state medicines agency commented on a safety problem with parallel imports, which it attributed to relabeling. In its report for the years 1998–2002, the German Medicines Agency (BfArM) states:

Events worth mentioning in connection with parallel trade:

2001–2002

Complaints from consumers and diabetics associations related to reduced activity of imported insulin preparations; Results of the investigation: insulin content of the checked products, which are about to be administered by means of a pen, is in order, but possibly the functionality of the pens is affected by inappropriate relabeling of the vials; In essence products that are centrally approved in the EU are involved; Consequence of parallel import approval procedure: directions for proper labeling.⁶⁰

Importation Violates the Entire Approach to Ensuring the Safety of the U.S. Pharmaceutical Distribution System

The cornerstone of the U.S. pharmaceutical distribution system is total control of the process—from selection of raw materials, design of the manufacturing process, packaging of a final product, evaluation of storage conditions and careful selection of the distribution pathway. Importation is at odds with this system, increasing the chances for substandard, adulterated and counterfeit medicines to enter our system.

Clearly, no one would propose relaxing the current system for drugs produced under FDA jurisdiction, yet importation effectively does just that.

The examples mentioned here, and countless others not mentioned here, illustrate that legalizing importation opens an avenue for unscrupulous counterfeiters. In order to continue assuring American patients that the medicines they take are safe and effective, and meet the highest standards, the current system for manufacturing and distribution of pharmaceuticals must be maintained. Only the current system, with its full battery of quality testing conducted by the manufacturer, coupled with complete knowledge of the domestic distribution process can assure the safety Americans expect.

Evidence Suggests Minimal Cost-Savings from Importation

While importation is often identified as a way to reduce the cost of medicines for patients, the evidence suggests otherwise. Savings are not as significant as claimed for several reasons, including the fact that middlemen—or arbitrageurs—often benefit considerably more than patients and price differentials between the U.S. and other countries are often exaggerated.

Government Reports Find Cost-Savings from Importation Minimal

The HHS Task Force report on prescription drug importation found, “Total savings to drug buyers from legalized commercial importation would be one to 2 percent of total drug spending and much less than international price comparisons might suggest. The savings going directly to individuals would be less than 1 percent of total spending. Most of the savings would likely go to third party payers, such as insurance companies and HMOs.”⁶¹

Similarly, according to an April 2004 CBO analysis of H.R. 2427 (an importation bill that would have allowed importation from 25 countries), savings would amount to approximately 1 percent of total projected spending on drugs between 2004 and 2013. Most of these projected savings don’t even materialize for more than half a decade. Permitting importation only from Canada, according to CBO, would produce a “negligible reduction in drug spending.”⁶²

State Importation Experiments Have Failed to Show Savings

Several states and localities that have examined importation have cast additional doubts on potential savings that may accrue from importation. For example, the State of Illinois began its I-SaveRx program in October 2004 to allow people to refill prescriptions using foreign pharmacies. The state worked with pharmacies in Canada, the UK, Australia and New Zealand and the program was later expanded to four other states. According to the *Chicago Tribune*, in the first 19 months of the operation, the program served only 3,689 Illinois residents—and another 1,265 individuals in four other states, despite a massive promotional campaign by the state that utilized 521 workers in 28 state agencies at a cost of nearly \$1 million.⁶³

According to a January 2005 *Washington Post* article, Montgomery County, Maryland’s plans to make Canadian prescription drugs available to employees has “hit a snag” after an analysis by the county school system concluded that importation of prescription drugs from Canada wouldn’t save as much money as hoped and could be more expensive than domestic sources for drugs. In reaction to the findings, Superintendent Jerry D. Weast, in a confidential memo to the Board of Education (detailed by the *Washington Post*) wrote, “In many cases, purchasing medications from Canada would prove to be more costly.”⁶⁴

In November 2003, the Massachusetts Group Insurance Commission, the insurance administrator for state employees and retirees, examined importation from a state perspective and found, “the potential savings [of importation] would not be worth the liability risks and the disruption of existing insurance contracts.”⁶⁵

European Experience with Parallel Trade Demonstrates Profits to Middlemen, Not Savings to Patients

The European experience with parallel trade has demonstrated that the practice financially benefits middlemen rather than patients. According to a study by the London School of Economics (LSE) and Political Science, 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, “Although the overall number of parallel imports is continuing to increase, healthcare stakeholders are realizing few of the expected savings . . . profits from parallel imports accrue mostly to the benefit of the third-party companies that buy and resell these medicines.” The study found savings to insurance organizations ranged from .3 percent to 2 percent, while parallel trader mark-ups ranged from 12 percent to 54 percent.⁶⁶

Prescription Drug Price Comparisons Between the U.S. and Other Countries are Often Deeply Flawed and Exaggerated

Supporters of importation often point to retail prices in the U.S. and compare those prices to government controlled prices in Canada and various other countries as evidence that importation will provide a means to lower prices for U.S. consumers. As with all products, prices vary from country to country for a host of reasons including income differences and exchange rates. For pharmaceuticals, government-imposed reimbursement and price controls in other developed countries are another factor generating cross-national price differences. While the price paid for a given medication may be cheaper in a foreign country than it is in the U.S., it is not always the case and such comparisons are flawed for a number of reasons.

Before addressing these flaws, I note that the current debate sometimes seems to incorrectly assume that medicines are the only product for which prices vary internationally, and that this suggests manufacturers somehow engage in inappropriate practices. In fact, prices for computers, food, cars and other consumer goods in the U.S. are not priced the same as they are in Italy, Canada, France, or any other country. This has been graphically illustrated in the new car market. An article published in the *Associated Press*, "Auto Industry Attacks Canadian 'Gray Market' Discounts," illustrates this point. The article notes that, "Savings from the cross-border trade can be substantial. For example, a loaded Dodge Caravan costs \$31,000 in the U.S., but just \$21,000 in U.S. dollars in Canada, said David Pierce, owner of Pierce's Superstores in Great Falls, Mont." Mr. Pierce went on further to say, "[T]hat even his wholesale cost is \$6,500 more than is charged a retail customer in Canada . . . even when he's charged a customer \$2,000 for an aftermarket warranty, the Caravan he has bought from Canadian exporters will cost \$8,000 less than the same model meant for American showrooms."⁶⁷

Most price comparisons also ignore the fact that pricing differentials on other health care services vary more from country to country than do pricing differentials for medicines. According to a study by Patricia M. Danzon and Michael F. Furukawa that compared average price levels for pharmaceuticals in eight countries—Canada, Chile, France, Germany, Italy, Japan, Mexico and the U.K.—relative to the U.S., U.S.-foreign price differentials are roughly in line with income and smaller for drugs than for other medical services.⁶⁸ In fact, when looking just at health care, drugs account for only about 7 percent of the lower per capita spending in Canada than the U.S., while other health care services account for about 93 percent of the lower health care costs paid by Canadians.⁶⁹

Further, only a small minority of consumers in the U.S. pay the "retail" price for prescription drugs. The overwhelming majority pay substantially discounted prices through pharmacy benefit managers (PBMs) and health plans, many of which negotiate on behalf of tens of millions of patients and are part of the way that U.S. imposes market-based cost containment in contrast to the government price controls imposed in parts of Europe and Canada. As mentioned above, for Medicare beneficiaries, passage of the Medicare prescription drug benefit has increased the number of Medicare beneficiaries with comprehensive prescription drug coverage from 24.3 million (or 59 percent) in 2005 to 39 million (or 90 percent) today. This coverage has amounted to average savings of \$1,200 per beneficiary. According to a January 2006 investigation by AARP, Medicare drug plans that cover all of a beneficiary's drugs can cost *less* than buying the same drugs across the border. The AARP calculation, which took into account premiums, deductibles, and copayments, was based on real combinations of drugs taken by beneficiaries living in different parts of the country, as well as the cost of six commonly used brand name drugs.⁷⁰

Like Medicare beneficiaries, insured Americans enjoy significant discounts on the medicines they purchase as a result of large, powerful purchasers (often representing tens of millions of Americans) such as pharmacy benefit managers (PBMs) and managed care organizations. A PBM "can negotiate discounts at both ends of the pricing chain: from the manufacturer and from the retail pharmacy."⁷¹ A study in *Health Affairs* found "to the extent 'list' prices fail to report the impact of discounts and rebates in the United States, alleged price advantages in Canada are overestimated. It is likely that only Americans who find themselves without prescription drug coverage are charged prices that exceed Canadian prices."⁷²

Even those consumers who buy at retail can save considerably depending on where they buy their drugs in the U.S. For example, according to the New York City Council's Investigations Committee Chair Eric Gioia, "At a time when Americans are flocking to Canada for cheap prescription drugs, New Yorkers could be saving more than 50 percent on their prescription drug purchases just by traveling to a different borough." An investigation conducted by Council Member Gioia's committee staff found that by traveling to a pharmacy perhaps only a few blocks away from where they usually shop, consumers could save up to \$80 on a single prescrip-

tion.”⁷³ Similar studies have been done in other parts of the country and have resulted in similar findings.⁷⁴

Finally, generics now make up about 60 percent of all prescriptions in the U.S., a much higher percentage than in most developed countries. Generic medicines are often priced at significant discounts in the U.S. compared to Canada and represent a viable option for patients looking to lower their health care costs. FDA conducted an analysis of prices actually charged on customer invoices for a sample of the detained foreign generic medications encountered in the shipments. FDA converted the price paid to U.S. dollars and checked the prices at four U.S. pharmacies. In *every instance*, a U.S. pharmacy price for the FDA-approved generic drug was less than what consumers had paid for the foreign generic drug ordered from Kohler’s Drugstore in Canada.⁷⁵ In light of the heavy use of generics in the U.S., price comparisons that focus on only a few brand drugs while excluding generics also exaggerate cost differences experienced by consumers.

Importation Is Not Free Trade, it Is the Importation of Foreign Price Controls

Some who support importation have argued that importing prescription drugs from other countries is a means to utilize the free market to bring lower cost medicines to American consumers. Apart from the likelihood that for the reasons specified above importation will not achieve the cost reductions claimed by its proponents, this argument also ignores the fact importation would promote trade in medicines that are subject to government price controls—the antithesis of free trade. Economists and trade experts have argued that importation is not a free market principle, but rather is a mechanism to “import” a foreign government’s price control regime. For example, according to John E. Calfee, American Enterprise Institute (AEI), “Congress should dismiss all possibility of these scenarios by rejecting the drug importation legislation. It should not fall into the trap of thinking that as long as controls over U.S. prices were introduced by the government of a foreign country we would still have a free market. We wouldn’t have a free market, and we wouldn’t get the benefits of one.”⁷⁶

Commentary in *The Wall Street Journal* explained, “In effect, re-importation of drugs would import something else to the U.S.: price controls, where the lack of such practices is the oxygen that allows pharmaceutical research to thrive. Drug-price controls are pernicious. While controls on oil and other products tend to be short-lived, as voters eventually object to the resulting shortages, the effects of drug regulations are more difficult to observe since they mainly affect medicines that haven’t been invented yet.”⁷⁷

The lack of a free market in Europe has led to a decline in the European pharmaceutical market and an exodus of the pharmaceutical industry from Europe to the U.S. The exodus from Europe results in part from the more hospitable business climate in the U.S.—for example, the science and technology base in the U.S. and the opportunity for public-private research partnerships—the European pharmaceutical industry and the European Commission, however, concluded that the exodus results primarily from the price control policies and cost-containment measures that lead to a lack of competition in the European market. The European Federation of Pharmaceutical Industries and Associations (EFPIA) has explained that the “European pharmaceutical industry has lost its competitiveness because there is a problem of price—and innovation is not compensated.”⁷⁸ EFPIA adds, “Europe lacks a climate which favours and rewards innovation. . . . Compared to the U.S., Europe is seen as a less attractive R&D investment location in terms of market size and incentives for the creation of new biotech companies.”⁷⁹

According to a report by the U.S. Department of Commerce, price controls maintained by OECD countries reduce the amount of global pharmaceutical R&D below what it would otherwise be under market conditions similar to those in the U.S. The study estimates that this reduction falls in the range of \$5 billion to \$8 billion annually, once prices were fully adjusted. Based on an estimated cost of developing a new drug, an increase in R&D of \$5 billion to \$8 billion could lead to three or four new molecular entities annually once markets fully adjust.⁸⁰

By using simulation experiments under multiple price control scenarios, John A. Vernon, an economist at the University of Connecticut, estimated that the pharmaceutical industry’s output of new medicines under price controls would significantly decline. Regulation of pharmaceutical prices in the U.S., similar to what is done in Europe, could have a “precipitous effect on pharmaceutical innovation in the long run.”⁸¹ Importation of prescription drugs could also have significant implications for U.S. intellectual property rights for prescription drugs, potentially upsetting the careful balance between encouragement of innovation and ensuring patient access to new medical discoveries.

Price Controls Often Lead to Delays and Denials in Access to New Medicines

As nearly all would agree, new medications are a critical element of quality health care. Yet many patients in countries that employ cost-containment measures, such as price controls, often wait years before gaining access to breakthrough drugs. According to the Department of Commerce report, "Such controls can also delay or reduce the availability of some innovative medicines in foreign countries, with the effect of limiting competition and requiring national health systems to forego the benefits of these innovations in reducing health care costs."⁸² These restrictions on patients' access to medicines through government price controls is not an approach that would benefit U.S. patients.

While drug approval is handled in the European Union by a centralized body called the European Medicines Agency (EMA), each Member State of the EU has control over price and reimbursement decisions. In the majority of Member States, a marketing authorization alone is not sufficient to enable a prescription drug to actually be sold. The medicine will only appear on the market once the competent authorities have set a price and/or the medicine has been registered on the positive list defining the conditions under which it is covered by public health care insurance for residents of the particular Member State. According to a report by the G10 Medicines Group, "The price negotiating systems and reimbursement structures in a number of Member states can lead to significant delays."⁸³

This was corroborated by a February 2003 report in *Business Week*, which stated, "Once a drug is approved by the European Agency for the Evaluation of Medicinal Products, national governments must debate whether to make the drug available through their health systems and at what price. The process, which usually involves negotiations with manufacturers, who are under pressure to extend deep discounts, can drag on for several years. . . . As a result of price controls, European consumers are heading toward second-class citizenship when it comes to access to medicine."⁸⁴

In some markets, patients must wait more than 2 years after marketing approval before gaining access to a new medicine (if at all).⁸⁵ European Union Directive 89/105 requires that applications to the competent authorities to secure a price or reimbursement for new medicines must be decided within 90 days, or 180 days where it is necessary to agree price before applying for reimbursement.⁸⁶ Only 7 countries presently comply with the requirement for countries to provide decision within 180 days: U.K., Germany, Denmark, Sweden, Ireland, Cyprus and Estonia. Poland has approved only a handful of new medicines for the past 8 years, and Austria, Belgium, France, Greece, Czech Republic, Italy and Slovenia have delays of over 300 days. Again, this approach, which is inherently part of government price control schemes, is a poor precedent of policy in the U.S.

An ongoing analysis by the European Federation of Pharmaceutical Industries and Associations (EFPIA) indicates that many EU Member states are not meeting the standard set out in the EU Directive 89/105 as of June 2006. For example, patients in very few EU countries have access to all new medicines that received marketing authorization from EMA between January 1, 2002 and December 31, 2005. In fact, doctors in only 2 of 18 EU countries monitored can prescribe all medicines approved during this time period to their patients. In the other 16 countries between 55 percent and 79 percent of EMA approved medicines are available. The average waiting time for these medicines becoming available varies widely.⁸⁷

Government Price Controls and Related Policies Lead to Less Diffusion of New Medicines

A 2002 survey entitled, "Diffusion of Medicines in Europe," found shortfalls in the diffusion of state-of-the-art medicines between European countries for 20 key diseases. The study noted that the shortfalls in diffusion of new medicines was in large part the result of European price containment measures. According to the study, "The most important factors for the diffusion of innovative medicines are policy related. Some examples are drug pricing policies, insufficient recognition of the (global and long term) economic effects of innovative medicine, inadequate governmental planning and last but not least cost containment strategies of every kind."⁸⁸

For example:

Cardiovascular Disease—In Germany, 87 percent of all patients with coronary heart disease there was a lack of provision of modern lipid-lowering drugs.

In Italy, 83 percent of eligible patients did not receive statins.

Diabetes—In Germany, 30 percent of at least 4 million diabetes patients are not treated with drugs at all.

Multiple Sclerosis—In France, “less than 50 percent of patients [with Multiple Sclerosis] eligible for treatment with beta interferons actually receive it (only 10,000 from about 25,000 to 30,000).”

Schizophrenia—In France it is estimated that there are 4.4 schizophrenia sufferers for every 1,000 people aged between 31 and 50 years, but *only 2.4 people for every 1,000 are treated*. For the treated patients the level of the use of innovative second generation drugs continues to be at a very low level.

Depression—“The European average shows that *only 18 percent of patients with severe depression received treatment with antidepressants*.”

In Germany, of the percent of patients treated with antidepressants, “*only one in three received an up-to-date treatment* with modern antidepressants (SSRIs). The other 8 percent are treated with older substances with more side effects or less effective drugs like herbal preparations.”

In France, “recent studies have shown that *50 to 70 percent of patients with symptomatic depression are not treated* at all, either with interpersonal or behavioural psychotherapies nor with antidepressant medication or a combination of both.”

Safe Alternatives in the U.S. for Those That Cannot Afford Their Medicine

While importation is often hailed as the only solution for individuals who lack prescription drug coverage and cannot afford their medicines, in fact there are better, safer ways to ensure that patients have access to affordable medicines.

PhRMA member companies have long offered patient assistance programs to expand access to medicines for patients. In 2005, PhRMA joined with public and private voluntary organizations to create the Partnership for Prescription Assistance (PPA), which offers a single point of contact to about 475 patient assistance programs and sources of government assistance. So far, the PPA has helped more than 3 million patients find programs that provide free or nearly free medications. In 2005, pharmaceutical companies gave away \$5 billion in medicines to patients in need. More than 1,300 partners make up the PPA, including groups such as the American Academy of Family Physicians, the American Cancer Society, Easter Seals and the National Association of Chain Drug Stores.

In addition to the PPA, since January 1, 2006, Medicare beneficiaries have had access to comprehensive prescription drug insurance. They have a wide range of coverage choices at various price points, including prescription-drug only plans and “Advantage” plans that also cover hospital and physician services. The new Medicare benefit has greatly expanded access to prescription drugs for older Americans, many of whom have substantial medicine needs. First year indications show that the results are even better than anticipated—for seniors and for the health care system. For example, according to an Amundsen Group study, average out-of-pocket costs for beneficiaries who had no drug coverage in 2005 and who have enrolled in coverage through Medicare Part D have been reduced by half, despite an increase in the number of medicines used. Further, the percentage of previously uninsured patients who spend more than \$50 out-of-pocket per month fell from 34 percent in 2005 to 18 percent in 2006.⁸⁹

State PAP programs, Medicaid and SCHIP are also options available to patients who cannot afford their medicines. Today, there are millions of people eligible for, but not taking advantage of such programs. Helping to ensure patients are enrolled in such programs, which provide coverage for all services, not just medicines, would be a step toward better care for millions of patients.

The solutions detailed above provide practical options for many individuals to access affordable medicines that will not risk their health and safety.

Conclusion

Importation schemes are unsafe. At a time when we are struggling to combat counterfeit drugs and tighten security at our borders, we should be searching for ways to close existing loopholes in the drug distribution chain, not creating new ones by opening up the borders to foreign imports. While some believe importation can be done safely, even FDA recognizes that there is no technological “magic bullet” or inspection process that can protect against adulterated or counterfeit foreign drugs. Consequently, implementing importation would jeopardize the safety of millions of American consumers.

Importation would not result in cost savings. There is no indication that implementing importation would result in cost savings. The costs of counterfeit-resistant technologies and industry and government testing and inspections likely would run billions of dollars each year. If the experience in Europe is any guide, any cost savings resulting from foreign importation will be captured by the parallel traders rather than passed on to consumers.

Importation is poor public policy. Importation of foreign drugs is nothing more than importation of foreign price control practices. These have been a disaster for patients in foreign countries, limiting access to new medicines and significantly restricting research and development activities in foreign countries. American patients deserve better. For individuals who lack prescription drug coverage and cannot afford their medicines, there are better and safer ways to obtain needed medications, including the Medicare drug benefit, other government programs such as Medicaid, SCHIP and State PAPA, PPA, and shopping for lower prices in safe, legal U.S. pharmacies.

Endnotes

¹ Pub. L. 75-717, 52 Stat 1040 (1938).

² 21 U.S.C. § 355(d)(1).

³ Pub. L. 87-781, 76 Stat. 780 (1962), codified at 21 U.S.C. § 355(d)(5).

⁴ See, e.g., the Durham-Humphrey Act, Pub. L. 82-215, 65 Stat. 648 (1951) (concerning prescription requirement); the Drug Listing Act of 1972, Pub. L. 92-387, 86 Stat. 559 (1972); the Orphan Drug Act, Pub. L. 97-414, 96 Stat. 2049 (1983) (subsequently amended); the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. 98-417, 98 Stat. 1585 (1984); the Drug Export Amendments of 1986, Pub. L. 99-660, 100 Stat. 3743 (1986), the Prescription Drug Marketing Act of 1987, Pub. L. 100-293, 102 Stat. 95 (1988) (subsequently amended); the Generic Drug Enforcement Act of 1992, Pub. L. 102-282, 106 Stat. 149 (1992); and the Prescription Drug User Fee Act, Pub. L. 102-571, 106 Stat. 4491 (1992).

⁵ See 21 U.S.C. §§ 331(d), 355(a).

⁶ See 21 U.S.C. § 321(b).

⁷ 21 U.S.C. §§ 331(d), 355.

⁸ 21 U.S.C. § 381(d).

⁹ H.R. Rep. 76, 100th Cong., 1st Sess. 6-7 (1987).

¹⁰ *Id.*

¹¹ “*Dangerous Medicine: The Risk to American Consumers from Prescription Drug Diversion and Counterfeiting*,” 99th Cong., 2d Sess. 22 (Comm. Print 99-2 1986).

¹² The record supporting the PDMA was extensive and unambiguous, and the prohibition on reimportation was not controversial. In June 1985, the staff of the Subcommittee on Oversight and Investigations of the House Committee on Energy and Commerce published its first report on the drug diversion problem. Staff of Subcommittee on Oversight and Investigations of the House Committee on Energy and Commerce, 99th Cong., *Report on Prescription Drug Diversion and the American Consumer: What You Think You See May Not Be What You Get* (Comm. Print 99-R 1985). This report discussed the Ovulen 21 incident and laid the groundwork for the PDMA provision prohibiting reimportation. The subcommittee convened the first of eight public hearings on drug diversion and counterfeiting on July 10, 1985. Over 2 years, the committee would hear from state and Federal law enforcement officers, private investigators, state drug and narcotic agents, Customs officials, FDA officials, pharmacists, diverters, U.S. attorneys, pharmacy and pharmaceutical trade associations, pharmaceutical sales representatives, and senior enforcement officials from state regulatory agencies. Two more Subcommittee reports were released, “*Dangerous Medicine: The Risk to American Consumers from Prescription Drug Diversion and Counterfeiting*,” 99th Cong., 2d Sess. (Comm. Print 99-2 1986), and “*Uncertain Returns: The Multimillion Dollar Market in Reimported Pharmaceuticals*,” 99th 2nd. Cong., Sess. (Comm. Print 99-GG 1985). Final legislation passed in early 1987. As Mr. Waxman pointed out on the day it passed the House, the PDMA “is a very important public health measure. It will provide additional assurances to American consumers that drugs they purchase will always be safe and effective. . . . The bill was developed after one of the most extensive investigations the Energy and Commerce Committee has conducted on a health-related matter. . . . [The Subcommittee] discovered that all the efforts of the FDA to approve drugs for safety and effectiveness could be for naught if the wholesale distribution system didn’t handle drugs properly or allowed counterfeit drugs to be passed along to consumers.” 133 Cong. Rec. 10962 (May 4, 1987). He added, “[t]he bill is not controversial and has enjoyed bipartisan support.”

¹³ 21 U.S.C. § 381(d).

¹⁴ See FDA Regulatory Procedures Manual, “Coverage of Personal Importations.”

¹⁵ FDA has repeatedly expressed concerns about the safety of mail-order personal imports, and in 2001 the agency recommended that the policy be rescinded. See Letter from FDA Acting Principal Deputy Commissioner to Secretary of Health and Human Services (requesting that HHS Secretary revoke the personal importation mail policy) (May 24, 2001); see also *Examining Prescription Drug Importation: A Review of a Proposal to Allow Third Parties to Reimport Prescription Drugs*, hearing

before the Subcommittee on Health of the Committee on Energy and Commerce of the U.S. House of Representatives, 107th Cong. 2d Sess. 40 (July 25, 2002) (“[W]e stand by that recommendation and believe that we should work with the Congress to develop legislation that would indeed give FDA the ability to screen these drugs and turn them back.”) (William K. Hubbard, Senior Associate Commissioner); Continuing Concerns over Imported Pharmaceuticals, Hearing before the Subcommittee on Oversight and Investigations of the Committee on Energy and Commerce of the U.S. House of Representatives, 107th Cong. 1st Sess. 48, 62, 72, 76 (June 7, 2001) (Hubbard).

¹⁶Pub. L. 106–387, 114 Stat. 1549, 1549A–35 (2000).

¹⁷Letter from Secretary Donna Shalala to the Hon. William J. Clinton (December 26, 2000).

¹⁸Letter from Secretary Tommy G. Thompson to Senator James Jeffords (July 9, 2001).

¹⁹21 U.S.C. § 384(c).

²⁰Gregory Lopes, “Patients Get Wrong Drugs Online; Anti-Psychotics Substituted for Depression, Insomnia Medicine,” *The Washington Times*: February 17, 2007.

²¹61 Fed. Reg. 20104, 20105 (May 3, 1996).

²²See Draft Guidance for Industry: PAT—A Framework for Innovative Pharmaceutical Manufacturing and Quality Assurance (August 2003); see also Guideline on General Principles of Process Validation (May 1987).

²³See 21 CFR Part 211.

²⁴21 U.S.C. § 351(a)(2)(B).

²⁵See Guideline on General Principles of Process Validation at 3.

²⁶See FDA, Counterfeit Drugs Questions and Answers, available at: <http://www.fda.gov/oc/initiatives/counterfeit/qa>.

²⁷World Health Organization, “WHO and partners accelerate fight against counterfeit medicines; Up to 50% of medicines sold through rogue websites are fake,” November 15, 2006.

²⁸“Internet Medicines Market ‘Poses Risk to Patients’ Health,” *Financial Times Online*, March 1, 2007.

²⁹*Business Week*, “Fakes!” February 7, 2005.

³⁰*21st Century Health Care Terrorism: The Perils of International Drug Counterfeiting*, Center for Medicine in the Public Interest, September 20, 2005.

³¹Letter dated July 17, 2002, from FDA to the Honorable Thad Cochran.

³²*Id.*

³³*Report on Prescription Drug Importation*, HHS Task Force on Drug Importation, U.S. Department of Health and Human Services, December 2004.

³⁴Congressional Budget Office, “Would Prescription Drug Importation Reduce U.S. Drug Spending,” April 29, 2004.

³⁵Statement of William K. Hubbard Senior Associate Commissioner, Policy, Planning and Legislation FDA before the Special Committee on Aging U.S. Senate: July 9, 2002.

³⁶*Report on Prescription Drug Importation*, HHS Task Force on Drug Importation, U.S. Department of Health and Human Services, December 2004.

³⁷Diane Gorman, Assistant Deputy Minister, Health Canada, Letter to *The Washington Post*, May 9, 2003.

³⁸FDA News, *FDA Warns Consumers Not to Buy or Use Prescription Drugs from Various Canadian Websites that Apparently Sell Counterfeit Products*, P06–123, August 20, 2006.

³⁹Letter from FDA to Robert P. Lombardi, Esq. of The Kullman Firm: February 12, 2003 <http://www.fda.gov/ora/import/kullman.htm>.

⁴⁰*FDA Test Results of Prescription Drugs from Bogus Canadian Website Shows All Products are Fake and Substandard*, FDA Press Release, P04–65, July 13, 2004.

⁴¹“Recent FDA/U.S. Customs Import Blitz Exams Continue to Reveal Potentially Dangerous Illegally Imported Drug Shipments,” FDA Press Release, P04–07, January 27, 2004.

⁴²FDA News, “FDA Operation Reveals Many Drugs Promoted as ‘Canadian’ Products Really Originate From Other Countries,” December 16, 2005.

⁴³Clifford Krauss, “Kinks in Canada Drug Pipeline,” *New York Times*: April 6, 2006.

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The New York Times—February 20, 2007

IN THE WORLD OF LIFE-SAVING DRUGS, A GROWING EPIDEMIC OF DEADLY FAKES

By Donald G. McNeil, Jr.

Asia is seeing an "epidemic of counterfeits" of life-saving drugs, experts say, and the problem is spreading. Malaria medicines have been particularly hard hit; in a recent sampling in Southeast Asia, 53 percent of the antimalarials bought were fakes.

Bogus antibiotics, tuberculosis drugs, AIDS drugs and even meningitis vaccines have also been found.

Estimates of the deaths caused by fakes run from tens of thousands a year to 200,000 or more. The World Health Organization has estimated that a fifth of the one million annual deaths from malaria would be prevented if all medicines for it were genuine and taken properly.

"The impact on people's lives behind these figures is devastating," said Dr. Howard A. Zucker, the organization's chief of health technology and pharmaceuticals.

Internationally, a prime target of counterfeiters now is artemisinin, the newest miracle cure for malaria, said Dr. Paul N. Newton of Oxford University's Center for Tropical Medicine in Vientiane, Laos.

His team, which found that more than half the malaria drugs it bought in Southeast Asia were counterfeit, discovered 12 fakes being sold as artesunate pills made by Guilin Pharma of China.

A charity working in Myanmar bought 100,000 tablets and discovered that all were worthless.

“They’re not being produced in somebody’s kitchen,” Dr. Newton said. “They’re produced on an industrial scale.”

China is the source of most of the world’s fake drugs, experts say. In December, according to Xinhua, the state news agency, the former chief of China’s Food and Drug Administration and two of his top deputies were arrested on charges of taking bribes to approve drugs.

The director, Zheng Xiaoyu, was in office from the agency’s creation in 1998 until he was dismissed in 2005 after repeated scandals in which medicines and infant formula his agency had approved killed dozens of Chinese, including children.

“The problem is simply so massive that no amount of enforcement is going to stop it,” said David Fernyhough, a counterfeiting expert at the Hong Kong offices of Hill & Associates, a risk-management firm hired by Western companies to foil counterfeiters.

The distribution networks, he said, “mirror the old heroin networks,” flowing to Thai distributors with financing and money-laundering arranged in Hong Kong. The penalties are less severe than for heroin.

Daniel C. K. Chow, an Ohio State University law professor and an expert on Chinese counterfeiting, said he believed that the authorities would pursue counterfeiters “ruthlessly” for killing Chinese citizens but be more lax about drugs for export.

“The counterfeiters aren’t stupid,” he said. “They don’t want anyone beating down the door in the middle of the night and dragging them away, so they make drugs for sale outside the country.”

A spokesman for the Chinese Embassy in Washington said that he had “no idea” whether most of the world’s counterfeits came from China, but that Mr. Zheng’s arrest proved China was cracking down. He also said counterfeiters would get the same punishment no matter whom they hurt.

Many of the fake artesunate pills found by Dr. Newton’s team were startlingly accurate in appearance—and much more devious in effect than investigators had suspected.

Not only did the pills look correct, as did the cardboard boxes, the blister packing and the foil backing, but investigators found 12 versions of the tiny hologram added to prevent forgery.

In one case, even a secret “X-52” logo visible only under ultraviolet light was present, though in the wrong spot.

Another hologram was forged by hand, Dr. Newton said, by someone who obviously spent hours with a pin and a magnifying glass making tiny dots on a circle of foil to imitate the shimmer.

But the most frightening aspect appeared when the pills were tested. Some contained harmless chalk, starch or flour. But the latest, he said, contained drugs apparently chosen to fool patients into thinking the pills were working.

Some had acetaminophen, which can temporarily lower malarial fevers but does not kill parasites. Some had chloroquine, an old and now nearly useless anti-malarial.

One had a sulfa drug that in allergic people could cause a fatal rash.

And some had a little real artemisinin—not enough to cure, but enough to produce a false positive on the common Fast Red dye test for the genuine article.

Those would not merely fool a laboratory, Dr. Newton noted. They could also foster drug-resistant parasites, so if patients were lucky enough to get genuine artemisinin treatment later, they might have already developed an incurable strain and could die anyway.

Such resistant strains could spread from person to person by mosquito and ultimately render the drug ineffective, as already happened with chloroquine and Fansidar, two earlier malaria cures.

“We make no apology for the use of the term ‘manslaughter’ to describe this criminal lethal trade,” Dr. Newton and his co-authors said last year in an article in *The Public Library of Science Medicine*. “Indeed, some might call it murder.”

In the United States, finding counterfeit drugs in pharmacies is very rare, “but we’ve seen a lot from Internet sellers posing as legitimate pharmacies,” said Dr. Ilisa Bernstein, director of pharmacy affairs for the Food and Drug Administration.

Thus far, few counterfeits of life-saving drugs have been found in the United States. Most are drugs used or abused for fun, like Viagra, the painkiller Oxycontin and sleeping pills. Investigators have, however, found fake statins, which could eventually lead to a heart attack, and fake Tamiflu, which could be fatal in a pandemic of lethal flu.

Fake drugs have a long history; the film noir masterpiece “*The Third Man*,” based on a real criminal case, involves adulterated penicillin in post-war Vienna.

And in the 1600s, after conquistadors discovered that South American cinchona bark cured malaria, Europe was flooded with fake bark. "It caused a great loss of confidence in it as a cure," Dr. Newton said. "We're seeing history repeat itself."

The problem with antimalarials is worst in Asia, but is growing rapidly in Africa. For example, in September, Nigerian authorities found \$25,000 worth of counterfeit malaria and blood pressure drugs concealed in a shipment of purses from China.

The temptation for counterfeiters is likely to grow because money to fight malaria is being poured into the Third World.

President Bush's \$1.2 billion Malaria Initiative avoids the problem by buying directly from Western pharmaceutical companies like Novartis, said Dr. Trenton K. Ruebush II, an adviser to the initiative.

By contrast, the Global Fund to Fight AIDS, Tuberculosis and Malaria gives money directly to poor countries to buy their own drugs, and sends auditors to follow up. But 80 percent of the world's nations, pharmacology experts estimate, lack drug agencies capable of detecting sophisticated counterfeits.

"The countries are supposed to purchase from W.H.O.-qualified manufacturers, but there are places where things can go wrong where we wouldn't necessarily have control," said Dr. Bernard Nahlen, the fund's malariologist. "In some countries, there is, let's say, a certain lethargy about paying attention to these issues. You have to take the government's word for it, and anybody can pull the wool over anybody's eyes."

The Global Fund, which appointed a new director on Feb. 8, is considering adopting central purchasing, a spokesman said.

A global alert system for counterfeit drugs has existed for 16 years, first by fax, and now on the World Health Organization website, said Dr. Valerio Reggi, chief of the anticounterfeiting task force created last year by the organization.

"But it isn't used very much," he said. "Regulators are human beings, and it's difficult to identify a benefit for those who report to it."

Dr. Reggi said the task force would try to change that by drawing attention to the problem and getting harsher laws passed. As he pointed out, in many countries, "counterfeiting a T-shirt means 10 years in jail, but counterfeiting a medicine can be a misdemeanor."

Parade Magazine—February 18, 2007

PRESCRIPTION DRUGS SEEMS SAFE, BUT BEWARE—IS YOUR MEDICINE DANGEROUS TO YOUR HEALTH

By Tom Zoellner

Some call it the most perfect crime in medicine: Buy some empty gelatin capsules, fill them with worthless powder, print up a phony label and sell them to a drug wholesaler who has no scruples or just chooses to look the other way. The unsuspecting consumer who buys the drugs from his corner pharmacy will almost certainly never discover why he is getting sicker instead of better. This is called "drug counterfeiting," a business that has expanded in the last 5 years. Phony drugs already have taken the lives of several Americans, and the perpetrators have walked off with nearly \$35 billion in black market profits.

Thankfully, the chances are fairly slim that your daily pills could be fakes, but the problem is worsening as counterfeiters become more savvy. The World Health Organization estimates that up to 10 percent of the medications sold globally are actually counterfeit. The number in the United States is much lower—experts peg it at 1 percent—but the practice is growing as dealers of illicit street drugs like cocaine and Ecstasy discover there are more profits and less risks in selling phony tablets of drugs like Ambien, Lipitor and Cipro.

"We're seeing a lot more of this than ever before," says John Theriault, vice president for global security at the pharmaceutical giant Pfizer. The problem has become serious enough for Pfizer to develop its own private team of 17 former law-enforcement agents to investigate counterfeit drugs. Theriault, an ex-FBI agent, says his team has come across drug labs in homes, hotel rooms and overseas warehouses.

Phony pills are put in conventional plastic bottles that sometimes have labels soaked off from legitimate shipments. One such case in 2003 involved as many as 18 million tablets of bogus Lipitor that had been manufactured in Costa Rica. The counterfeiters had purchased their ingredients from the Hong Kong office of a Swiss company and even embossed the fake product with a real-looking Pfizer logo. The "Lipitor" was then marketed through a drug wholesaler operating in the Midwest and sold through legitimate pharmacies. The pills reached Pfizer's attention only after American customers began to complain about their bitter taste. It's possible

that more than 600,000 people could have received bottles containing the fake Lipitor tablets.

But not every counterfeit drug is cooked up in an illicit lab. Some unscrupulous suppliers have been known to boost their profits by “uplabeling”—for example, passing off a 10mg dose of a drug as 40mg. Expiration dates may be altered too. Experts say the vulnerabilities in the supply chain also can be traced to secondary drug wholesalers, who face pressure to keep costs low and may not be inclined to scrutinize the source of their purchase. Where the drug changes hands several times, that’s where you have the problem, says one industry expert. The bogus drugs go from a wholesaler’s warehouse to a retail pharmacy and into a consumer’s medicine cabinet.

Not surprisingly, the Internet is another common source of counterfeits. Direct-to-consumer websites offer great deals that are literally too good to be true. “You can find plenty of ‘Canadian’ sites that aren’t really Canadian,” says Pfizer spokesman Bryant Haskins. “They’re decorated with maple leaves, but we’ve tracked them to Belize, Russia, Vietnam—all over the place.”

The deception often goes further than that. “Overseas counterfeiters are also known for selling ‘generic’ versions of drugs where no generics exist,” points out Joan Todd of Eli Lilly and Company. “The consumer assumes that somebody out there is regulating this. But anybody can set up a website and sell fake medicine.” In one notorious case, Lilly investigators found a machine used to create bogus drugs in which a toilet seat had been jerry-rigged into the device. “This obviously does not adhere to good manufacturing procedure,” remarks Todd dryly.

Last year, the U.S. Food and Drug Administration investigated 53 cases of drug counterfeiting—up from six just 5 years ago. Though it is difficult to chart how many people unwittingly ingest counterfeit drugs each year, the injuries and deaths likely number in the hundreds. Experts say that thousands of Americans doubtlessly have been affected without even knowing it.

Most ersatz-drug fatalities almost certainly have escaped notice, explains Haskins. Autopsies are not routine for the sick or elderly, and few doctors would ever suspect that the drugs they prescribed were nothing more than useless filler. What harms a patient is usually not toxic substances in the phony drug but a lack of the potentially lifesaving medication they are supposed to be receiving.

Besides, drug counterfeiters rarely set out to kill their customers—such a move would invite police attention and run contrary to their economic interests. The logic is similar to that of a parasite, which seeks not to kill the host but to feed off it for as long as possible. This is why expensive drugs that treat long-term conditions such as AIDS are the most likely to be counterfeited. Erectile-dysfunction drugs are also a prime target because of the big money involved—and the disinclination of many patients to complain about a lack of results.

Solving this problem will not be quick or easy. Rep. Mike Rogers (R., Mich.) has proposed raising the penalties for prescription drug counterfeiters from 3 years in prison to 20 years, putting the perpetrators on an equal plane with heroin dealers. The bill he proposed died in committee last session but was reintroduced earlier this month.

The Food and Drug Administration also has encouraged drug companies to track their pills after they leave the factory. GlaxoSmithKline, for example, now inscribes its pills and packages with invisible text symbols to authenticate its product. But these markings would be checked only after a counterfeit suspicion arises.

Tracking is becoming easier, however, with a technology known as Radio Frequency Identification (RFID), an advanced variety of bar code that is now used in the E-ZPass highway toll system, among other places. This technology would allow officials to scan entire pallets of drugs instead of checking individual barcodes. Such a system would make it hard to slip bogus products into the supply chain, because drugs could be tracked from factory to pharmacy counter. Progress with RFID has been slow due to the high costs involved. So far, only limited shipments of expensive drugs like the painkiller Oxycontin contain RFID tags on their labels.

One thing everyone agrees on: The problem is becoming widespread, and the supply chain is still vulnerable. Up to 40 million of the prescription bottles handed out in the U.S. today are filled with substances that aren’t what they claim to be, according to the National Association of Boards of Pharmacy.

“If the system becomes further compromised, it will get to the point where it’s very difficult to fix,” says Carmen Catizone, the association’s executive director. “Imagine someone going to the emergency room for a heart attack and being given counterfeit drugs by the hospital staff. This could cripple the whole health-care system.”

How to Protect Yourself

Here are a few precautions you can take to avoid counterfeit drugs:

Don't buy prescription drugs online unless it's through the website of a legitimate pharmacy.

Look closely at your medicine. Note any signs of runny coloring or shoddy logos on the pills.

Watch for changes in appearance or taste in the prescriptions you regularly take.

Bring any reliable medication that suddenly begins to have no effect to your doctor right away.

Learn more about the counterfeit drug problem in America:

On its website, the U.S. Food and Drug Administration posts the latest warnings about counterfeit drugs and offers other important consumer information. <http://www.fda.gov/oc/initiatives/counterfeit/>.

Report a suspicious drug:

The National Fraud Information Center/Internet Fraud Watch (NFIC/IFW) tells you step-by-step how to notify authorities if you think a drug you've bought is fake. <http://fraud.org/fakedrugs/>.

Senator DORGAN. I've given you a bit more time.

You've chaired these hearings before in the Congress, and——

Mr. TAUZIN. I apologize.

Senator DORGAN.—understand we have five witnesses on this panel, and I want to hear the rest of them. But we appreciate your testimony.

William Schultz is a partner in Zuckerman Spaeder. He was previously the Deputy Commissioner for Policy at the Food and Drug Administration, which is the position that Dr. Lutter now holds.

Mr. Schultz, thank you for being with us, and you may proceed with your testimony.

**STATEMENT OF WILLIAM B. SCHULTZ, PARTNER,
ZUCKERMAN SPAEDER, LLP**

Mr. SCHULTZ. Thank you, Mr. Chairman and members of the Committee. I appreciate the opportunity to testify on the Pharmaceutical Market Access and Drug Safety Act of 2007, S. 242.

This carefully crafted and comprehensive bill, if enacted, would significantly improve the safety of drugs used by patients in the United States today. It would also make safe, affordable drugs available to many Americans who are, today, using drugs for which no generics are available, and who can't afford the brand prescription drugs that they need.

One only has to listen to the testimony of Dr. Lutter to understand why this bill would improve the safety of drugs used in this country today. As Dr. Lutter has told us, today we are being flooded with counterfeit and otherwise unsafe drugs. We also know that every year American patients purchase millions of prescriptions by mail order from Canada. I think Dr. Lutter said the 2004 report had the number 25 million prescriptions coming across the borders in that year.

So, the question before Congress is not whether to allow patients to import drugs from Canada because, as a country, we already do that. Instead, I submit that the real question before the Committee is whether S. 242 will make drugs imported from Canada safer.

There are at least five reasons why American citizens will be significantly better off if S. 242 is enacted.

First, the bill will carefully regulate Canadian exporters and U.S. importers. Even the FDA, at times, has conceded that drugs from legitimate Canadian pharmacies are safe. They're probably as safe as drugs sold in the United States. The problem is that, today, American consumers have no way of knowing which drugs they purchase are from legitimate exporters and which ones are not. Under the bill, the FDA will approve each Canadian exporter, and the exporters from other countries that the agency designates as having acceptable drug-approval systems. The bill also directs FDA to list safe Canadian sources on the Internet so that patients can know which Canadian exporters are legitimate.

Second, under the bill, the FDA would regularly inspect foreign plants that manufacture drugs exported to the United States. Although, as was pointed out before, to date FDA does inspect foreign facilities that manufacture U.S. drugs, it does not inspect plants that manufacture Canadian drugs, even if they are imported into the United States.

Third, the bill allows U.S. wholesalers and pharmacies to import drugs from Canada, and this system would allow for even more complete protection, because it provides for monitoring the chain of custody from the manufacturer to the wholesaler. A mechanism is also provided for FDA to examine any differences between the imported drug and the drug sold in the United States.

Fourth, the bill has an innovative provision that would direct the Federal Reserve Board to issue regulations to stop credit card payments to persons illegally exporting the drugs to the United States.

And, fifth, the bill provides the FDA with the necessary resources. Today, the agency has little or no resources to inspect foreign facilities that inspect Canadian drugs—manufacture Canadian drugs or to monitor imports. The user-fee provision in the bill would provide those resources.

Mr. Chairman, today consumers are purchasing millions of dollars of low-cost prescription drugs from Canada. They are also purchasing inferior drugs from Canada and other countries in an effort to gain access to affordable medicines. But, today, consumers do not know how to separate the good drugs from the bad drugs. This bill would create a stream of safe and affordable drugs from Canada and other countries certified by FDA. It will make it easier for the agency to keep unsafe drugs out of the United States, to the great benefit of American patients.

Let's not forget what's at stake here. There are many important drugs that patients in this country need for which low-cost, generic drugs are not available. These same drugs are available in Canada at a significantly lower price, often at savings as much as 50 percent. If this were any other product, our trade policy would allow consumers to purchase a less-expensive alternative, if they wished. And this is not just a matter of saving money, as it is with most products. For many patients, it's a matter of their health, because they cannot afford the drug at the U.S. price. Today, the only way for these patients to protect their health is to break the law, and, even when they do so, they do it at the risk of importing fraudulent and a potentially unsafe product. S. 242 will make those patients law-abiders. It includes important measures which will go a long

way toward assuring that the drugs being imported in this country are safe and effective.

I'd be happy to answer any questions.

[The prepared statement of Mr. Schultz follows:]

PREPARED STATEMENT OF WILLIAM B. SCHULTZ, PARTNER,
ZUCKERMAN SPAEDER, LLP

I appreciate the opportunity to testify on the issue of drug importation. I have been working on issues related to food and drug law for my entire career. I have worked on these issues as a public interest attorney, a Congressional staffer, an FDA official and now as an attorney in private practice. I have worked on issues related to patients obtaining drugs from foreign sources both inside and outside of the Food and Drug Administration. During my tenure with FDA, I initiated a study of the sale of prescription drugs over the Internet. This examination was precipitated by, among other things, concerns over patients obtaining illegal drugs from foreign sources. During my time in private practice, I became involved with issues related to the importation of drugs from Canada. In 2003, I represented a Canadian pharmacy that wanted to develop a mechanism for U.S. citizens to legally obtain FDA approved prescription drugs at lower prices. The following year, I represented the State of Illinois during its efforts to assist their citizens in obtaining lower priced prescription drugs from Canada. Specifically, I helped these clients understand FDA requirements and policies in this area.

I am here today to express my support for the Pharmaceutical Market Access and Drug Safety Act of 2007 (S. 242). This legislation addresses a substantial and serious problem—patients illegally obtaining potentially dangerous prescription drugs from foreign sources. For the reasons discussed below, I believe this bill would significantly advance public health by creating a safe means for U.S. citizens to obtain lower-priced prescription drugs from countries that have appropriate protections in place through an FDA-controlled mechanism.

In my testimony today, I will start by discussing the problem with the current system of regulation and then explain why I think this legislation would give U.S. citizens far more protection than they have today.

I. Consumers Currently Are Purchasing Drugs From Foreign Sources and Current Law Is Not Protecting Them

The Food Drug and Cosmetic Act (the “FD&C Act”) does not permit individuals to purchase prescription drugs from Canada or any other country. Nevertheless, U.S. consumers are doing just that, and for all practical purposes, much of this activity has been blessed by FDA. For example, FDA regularly permits patients to bring with them into the United States a 90-day supply of drugs that they purchased outside of the United States. Even though this activity is technically illegal, as a matter of its enforcement discretion FDA permits the import of prescription drugs for personal use. This policy has been in effect for many years, during both Democrat and Republican administrations.

In other instances, FDA policy does not permit the activity. For example, there is a well-known and widespread practice of consumers illegally purchasing prescription drugs from foreign Internet websites and mail order companies. Although FDA has not condoned this practice, it has not been able to effectively stop it. As FDA has repeatedly told Congress, thousands of packages containing prescription drugs from foreign countries enter the United States daily. Neither FDA nor U.S. Customs and Border Protection (“Customs”) can effectively police this practice. Moreover, the law, as it currently stands, makes it extremely difficult and burdensome for FDA and Customs to stop the illegal packages that they are able to identify.

It is not difficult to understand why consumers import drugs from Canada and other countries. The price difference between prescription drugs purchased in the United States and those purchased in Canada is significant. The difference can be as much as 50 percent. For many patients, this is the difference between being able to obtain needed medicines and forgoing such medicines. In recent years, the number of prescription drugs being brought or shipped into the United States from Canada and other countries has been rising dramatically.

Because the FD&C Act does not specifically permit patients to obtain their prescription drugs from foreign countries, it does not include any protections for consumers who are engaging in it. As FDA has repeatedly told Congress, the risks to patients are real and they are great. Most patients are probably receiving medicines that are comparable to those sold in the United States. But others may be receiving medicines that are expired, subpotent, contaminated or counterfeit. The labeling

may be in another language, thus depriving the patient of important information about the drug. Moreover, if the patient experiences problems and they manage to trace it to the drug (which is not likely since they usually assume the drug they got is safe and effective), they probably have no recourse. FDA's ability to take action against foreign suppliers is quite limited. The current system leaves American patients who obtain their prescription medicines from foreign countries completely unprotected.

II. The Bill Would Give Patients Who Receive Their Prescription Drugs From the Designated Countries Important Protections

S. 242 recognizes, as have even FDA officials, that prescription drugs sold by Canadian pharmacies are safe. The challenge is to prevent the import of unsafe drugs from Canada and other countries. The bill addresses this issue in two ways. First, it creates a mechanism for individuals to obtain prescription medicines for their personal use from registered Canadian pharmacies (or from pharmacies in another permitted country if FDA determines that that country's pharmacy laws are equivalent to Canada's). Second, it creates a mechanism for U.S. pharmacies and wholesalers to commercially import medicines from a defined set of countries under controlled conditions. Both provisions require that the drug be an FDA-approved drug and be manufactured in an FDA-inspected facility. I will discuss each of these provisions separately.

A. Personal Importation

S. 242 creates a legal mechanism for Canadian (and potentially other FDA designated) pharmacies to ship drugs to U.S. consumers who have a valid prescription. As I stated earlier, U.S. citizens have been receiving low price drugs from Canada for many years. By formalizing and adding specific requirements for individual supplies, the bill is adding protections for those citizens. I believe the protections in the bill address many of the concerns that have been raised by opponents of the practice. For example, FDA must approve and inspect the Canadian exporter. Today many of the drugs that are sold in the United States under approved new drug applications are manufactured in facilities located in foreign countries and FDA has the responsibility for inspecting those plants.

For Canadian exporters, the bill directs FDA to inspect no less than 12 times annually, which far exceeds FDA's inspection frequency domestically. Moreover, exporters are required to mark their packages in a way that allows FDA and Customs to identify legal imports. In addition, FDA can require exporters to incorporate anticounterfeiting technology or track and trace technology. The protections are designed to address the concerns that Canadian drugs are not actually coming from Canada or that Canada will become a dumping ground for counterfeit drugs and FDA will not be in a position to police the activity. Moreover, the bill directs FDA to publicly list safe sources of Canadian drugs so that patients will be directed to the sources listed by the Agency. Finally, by including a user fee for exporters, the legislation will ensure that FDA has the resources it needs to implement these provisions.

B. Commercial Importation

S. 242 also creates a mechanism for wholesalers and pharmacies to import prescription drugs from Canada, the European Union, Australia, New Zealand, Japan, and Switzerland. It includes safeguards to ensure that such products are safe. Wholesalers and pharmacies that want to participate must register with FDA. They must provide a full chain of custody and FDA may require anticounterfeiting technologies. Again, the bill includes requirements that are more protective than those imposed for drugs sold domestically. S. 242 also requires manufacturers of a drug sought to be imported to notify FDA of any differences in their drug from the U.S. approved version. FDA must approve the difference before the drug can be imported. Again, I applaud the sponsors of the bill for including user fees to ensure that FDA has the means to oversee the program as intended. The bill also allows FDA to ease its way into the new system by limiting the number of participating pharmacies and wholesalers and then allowing that number to increase gradually over time.

By creating a pathway for bulk importation, the bill provides a broader mechanism that allows consumers to obtain less expensive prescription drugs. If consumers have domestic access to lower-priced prescription drugs, they will not feel compelled to obtain their drugs from illegal, foreign sources. This legislation will significantly decrease the number of patients turning to illegal Internet pharmacies or mail order companies for their medications.

C. Stopping Illegal Imports

I believe that this legislation will succeed because it also attacks the problem defensively; in other words it includes provisions that make it easier for FDA to stop the illegal importation of drugs. Under current law, FDA is required to go through a number of time consuming steps if it wants to detain an illegally imported drug. Here a simple notice to the intended recipient of the drug explaining how they can import drugs legally from Canada is all that is required. Moreover, the bill directs the Federal Reserve Board to issue regulations to stop credit card payments to persons illegally exporting drugs to the United States. In my opinion, this dual approach to the problem of illegal drugs entering the United States—namely provisions to stop the entrance and provisions to permit a safe legal alternative—is an excellent way to effectively protect American consumers.

III. Conclusion

I support this legislation because it creates legal pathways for consumers to obtain lower priced prescription medications from designated foreign sources. As I stated earlier, these pathways are critical to patients who simply cannot afford prescription medicines at the prices they must pay in this country. This is the solution for patients who otherwise must either forgo their medicine or obtain it illegally and thus, potentially unsafely.

Opponents of this legislation have repeatedly expressed concern that it opens the door to dangerous foreign drugs entering the U.S. I disagree. These opponents are ignoring the world as it exists today and has for many years—where a growing number of Americans regularly import prescription drugs from Canada and other countries. In 2004, an HHS task force reported that in 2003 approximately 12 million prescription drug products had entered the U.S. from Canada alone. The report estimated that an equal amount currently is coming in from the rest of the world. I firmly believe that if Congress creates a legal mechanism for providing lower cost drugs, consumers will no longer resort to buying substandard or possibly dangerous drugs off of illegal Internet websites or mail order companies. Patients are resorting to this practice because their only other option is to go without their medicine. This legislation creates options: it creates pathways to ensure that patients have access to safe and effective, lower-priced medicines. Moreover, the bill puts an end to FDA's current policy, which effectively condones the breaking of the very laws FDA has been created to enforce. For this reason, I support passage of this legislation.

I appreciate the opportunity to testify today. I would be happy to answer any questions.

Senator DORGAN. Mr. Schultz, thank you very much for your testimony.

Next, we will hear from Dr. Vernon, John Vernon, Professor of Economics at the University of Connecticut.

Dr. Vernon, thank you for being with us.

**STATEMENT OF DR. JOHN A. VERNON,
ASSISTANT PROFESSOR, DEPARTMENT OF FINANCE,
UNIVERSITY OF CONNECTICUT SCHOOL OF BUSINESS**

Dr. VERNON. Thank you.

Mr. Chairman and members of the Committee, thank you for inviting me to testify on the policy implications of pharmaceutical importation.

My name is John Vernon, and I am a professor in the School of Business at the University of Connecticut, and a Faculty Research Fellow with the National Bureau of Economic Research. I also serve part time as Senior Advisor for Economic Policy at the FDA, though my testimony will be based on academic research I have undertaken at the University of Connecticut. The opinions I am about to express are entirely my own.

My testimony is neither in support of, nor opposition to, importation. Rather, I am only advocating that a balanced economic perspective be adopted on this important public policy issue, one that places the economic costs of importation on equal footing with the

economic benefits. To date, I do not think this has occurred. The economic costs, I fear, have received relatively little attention.

For the purposes of the points I wish to make, let us assume that a new importation policy will be effective in achieving its objective, it will significantly reduce drug prices in the U.S. Precisely how importation will achieve this objective is the subject of some debate, but one possibility is through a forced sales provision.

To begin, the economic benefits of pharmaceutical importation are obvious. U.S. consumers will pay lower prices for their prescription drugs. This is because most foreign governments regulate drug prices. The benefits of regulated prices are readily apparent and straightforward to measure. The same, however, cannot be said about the costs. This may explain why they have received less attention. Please allow me to explain.

Once a new pharmaceutical has been developed, which typically takes 12 to 15 years, and all the safety and efficacy data have been collected and analyzed, the marginal cost of a single pill is quite small. This is because the final product of the R&D is essentially just new information, much like computer software, information that has taken many years and hundreds of millions of dollars to obtain. In the absence of pharmaceutical patents and intellectual property rights and the ability of firms to price their products well above marginal cost, no firm or investor would invest the time or money needed to develop this information. Thus, there must be a sizable reward to induce the R&D. As is, only three out of every ten new drugs generate returns in excess of average R&D costs.

Pharmaceutical importation, precisely to the extent it is successful in lowering U.S. drug prices, will reduce the incentives to invest in R&D. The expected returns on R&D projects will fall, and some projects will be terminated, and some projects may not be initiated. The result will be a decline in the rate of pharmaceutical innovation. Fewer new drugs will be developed, and it will take longer to find cures for many diseases. Unlike the benefits of the policy, the costs of the policy are more difficult to appreciate and quantify. This is because of the time lag and uncertainty associated with the R&D process.

My research is focused on these costs, and, specifically, the economic relationships between pharmaceutical prices, profits, and R&D. My colleagues and I have studied the sensitivity of R&D spending to pharmaceutical prices and profits, using a variety of research methods. I will now summarize these results, and specifically the results from two recently published studies. Now, these studies have been vetted by the academic peer-review process and published in professional economics journals.

The first study used publicly available, firm-level data and exploited observed differences in U.S. and non-U.S. pharmaceutical profit margins. Using established economic models and statistical techniques, we estimated that a new policy that reduces pharmaceutical profit margins in the U.S. to non-U.S. levels will cause firm R&D spending to decline by between 25 and 35 percent. Pharmaceutical importation will theoretically have this effect.

The second study used publicly available, industry-level data, and studied the direct link between U.S. drug prices and industry

R&D spending. We estimated that for every 10 percent reduction in U.S. drug prices, industry R&D spending will fall by 6 percent.

In sum, the empirical evidence suggests R&D spending is very sensitive to pharmaceutical prices and profits, as predicted by economic theory. This is in contrast to some of the noneconomic notions one often hears, such as, “Lower prices and profits won’t reduce R&D spending, because firms will still have enough profit to cover their R&D,” and, “These firms have to invest in R&D. What else are they going to do?”

The point of my testimony is that the benefits associated with lower U.S. drug prices will unequivocally come at a cost: lower levels of R&D and a reduced rate of innovation. It is imperative, I think, that these costs be balanced carefully against the benefits of importing price-regulated pharmaceuticals from abroad. This is particularly true in light the recent evidence on the significant contributions of pharmaceutical and medical R&D to human health and life expectancies in the U.S.

Thank you.

[The prepared statement of Dr. Vernon follows:]

PREPARED STATEMENT OF DR. JOHN A. VERNON, ASSISTANT PROFESSOR,
DEPARTMENT OF FINANCE, UNIVERSITY OF CONNECTICUT SCHOOL OF BUSINESS

Mr. Chairman and members of the Committee, thank you for inviting me to testify today on the policy implications of pharmaceutical importation. My name is John Vernon and I am a professor in the School of Business at the University of Connecticut and a Faculty Research Fellow with the National Bureau of Economic Research (NBER). I also serve part-time as Senior Adviser for Economic Policy in the Office of Policy and Planning at the Food and Drug Administration, but my testimony will be based on academic research I have undertaken at the University of Connecticut. The opinions I am about to express are entirely my own; they do not necessarily reflect those of the institutions and organizations with which I am affiliated.

As you will soon see, my testimony is neither in support of, nor in opposition to, importation. Rather, I am only advocating that a balanced economic perspective be adopted on this important public policy issue—one that places the economic costs of importation on equal footing with the economic benefits. To date, I do not think this has occurred: the economic costs of importation have received relatively little attention.

For the purposes of the points I wish to make, let us assume a new importation policy will be effective in achieving its objective: it will significantly reduce drug prices in the U.S. Precisely how importation will achieve this objective is the subject of some debate, but one possibility is through a forced-sales provision (such as that contained in the recently reintroduced Pharmaceutical Market Access and Drug Safety Act of 2007).

To begin, the economic benefits of pharmaceutical importation are obvious: U.S. consumers will pay lower prices for their prescription drugs. This is because most foreign governments regulate drug prices, and importing drugs from these markets is simply an indirect price control—albeit one set by foreign governments.^{1,2} The benefits of lower, government-regulated prices are readily apparent and straightforward to measure. Unfortunately, the same cannot be said about the costs. This may partially explain why they have received less attention in the debate. Allow me to explain.

Once a new pharmaceutical has been developed (which typically takes 12–15 years), and all the safety and efficacy data have been collected and analyzed, the marginal manufacturing cost of a single pill is quite small. This is because the final product of the pharmaceutical R&D is essentially just new knowledge and information (much like computer software): information that has taken many years and hundreds of millions of dollars to obtain. In the absence of intellectual property rights (pharmaceutical patents), and the ability of drug companies to price their products significantly above marginal manufacturing costs, no investor or firm would be willing to invest the time and financial resources necessary to discover and develop this information. Thus, there must be a sizable reward to induce the R&D.

As is, only 3 out of every 10 new pharmaceuticals generate returns in excess of average R&D costs (Grabowski and Vernon, 2000).

Pharmaceutical importation, precisely to the extent it is successful in lowering U.S. drug prices, will reduce the financial incentives to invest in R&D.³ The expected returns on individual R&D projects will fall and some projects will be terminated (or not initiated). This is because these projects will no longer generate expected net returns for the firm's shareholders.⁴ The result will be a decline in the rate of pharmaceutical innovation: fewer new drugs will be developed and it will take a longer time to find cures for many diseases, all else considered.⁵ Unlike the benefits of the policy, which will produce immediate and observable savings through lower drug prices, the costs are more difficult to appreciate and quantify.⁶ This is because of the considerable time lag and uncertainty associated with the R&D process, which, as already noted, is very long, costly, and risky.⁷ My academic research has focused on these costs, and specifically the economic relationships between pharmaceutical prices, profits, and R&D.⁸

The sensitivity of R&D spending to pharmaceutical prices and profits has been studied with a variety of different research methods, including standard retrospective statistical analyses of industry and firm-level data, prospective simulation analyses, and financial event studies (Vernon, 2003, 2004, 2005; Giaccotto, Santerre and Vernon, 2005; Abbott and Vernon, 2007; Santerre and Vernon, 2006; Golec, Hegde, and Vernon, 2006; Golec and Vernon, 2007). The research findings have been strikingly consistent and robust. I will summarize the results from two recent studies (Vernon, 2005; Giaccotto, Santerre, and Vernon, 2005). Both have been vetted by the academic peer-review process and have been published in professional economics journals.

The first study utilized publicly available, firm-level financial data and exploited observed differences in U.S. and non-U.S. pharmaceutical profit margins (the latter were used to proxy profit margins in the presence of price regulation). Using established economic models and statistical techniques, we estimated that a new policy that reduces pharmaceutical profit margins in the U.S. to non-U.S. levels will cause firm R&D spending to decline by between 25 and 35 percent, all things considered. An importation policy that imports regulated prices from foreign markets will theoretically have this effect on U.S. profit margins.

The second study adopted a slightly different approach and used publicly available, industry-level data to study the direct link between U.S. drug prices and industry-level R&D spending (Giaccotto, Santerre, and Vernon, 2005). In this study, we estimated that for every 10 percent reduction in U.S. drug prices, industry R&D spending will decline by approximately 6 percent. This finding is consistent with an earlier study that also analyzed industry-level pharmaceutical R&D (Scherer, 1996; 2001).

In sum, the empirical evidence suggests firm R&D spending is very sensitive to pharmaceutical prices and profits, as economic theory predicts. This is in direct contrast to the ubiquitous noneconomic notions one often hears, such as "lower prices and profits won't reduce R&D spending because firms will still have enough profit to cover their R&D" and "these firms have to invest in R&D, what else are they going to do?"

The point of my testimony today is that the benefits associated with lower drug prices in the U.S. will, unequivocally, come at a cost: lower levels of R&D and a reduced rate of pharmaceutical innovation. It is imperative that these costs be balanced carefully against the benefits of importing price-regulated pharmaceuticals from abroad. This is particularly true in light of the recent evidence on the significant contributions of pharmaceutical and medical R&D to human health and life expectancies in the U.S. (Murphy and Topel, 2003; Lichtenberg, 2002).

Endnotes

¹ It is important to note that importing patented pharmaceuticals from outside the United States is not a free trade issue. This is a common misunderstanding. The rationale for free trade is based on the doctrine of comparative advantage: where countries specialize in the production of goods and services for which they are, comparatively speaking, low-cost producers, and then trade freely with other countries that are doing the same thing. Free trade is good for U.S. consumers, the U.S. economy, and the global economy. But pharmaceutical prices in Canada and elsewhere are lower because drug prices are regulated in those markets, and not because those countries have a comparative advantage in the production of pharmaceuticals (in the absence of price regulation, it is likely that prices would still be lower outside the U.S. because of lower per capita real income). It is imperative to understand that the real issue at hand is intellectual property rights. If patented pharma-

ceuticals are imported from abroad, the U.S. patent system is circumvented, and price controls will be indirectly imposed on pharmaceuticals in the U.S.

² It is likely that even in the absence of price regulation foreign drug prices would still be lower outside the U.S. because of lower per capita income levels (see Danzon and Towse (2003) for a detailed discussion and analysis.

³ Some researchers have suggested that an importation policy that reduces drug prices in the U.S. will actually increase firm profits (which would lead to increased R&D spending). But this “argument” assumes firm managers are currently not acting in the best interest of the firm’s shareholders and are, for lack of a better word, stupid. This “argument” does not have any economic merit.

⁴ The implicit argument being put forth is a net present value (NPV) argument. A real options framework, in the parlance of modern finance theory, will generate the same prediction (see Golec, Hegde, and Vernon, 2006).

⁵ The phrase “all else considered” is important here. The relevant comparison for assessing the impact of an importation policy on R&D spending and innovation is the counterfactual event of no importation policy. R&D and innovation are driven by a number of factors and even if an importation policy is enacted real R&D spending may continue to grow over time, but it would grow at a slower rate than would have been the case if the policy were not enacted. The relevant measure of the effect of policy is one that holds all other factors constant: the comparison of the reality with the counterfactual. Some of the research I will mention in this testimony can easily be taken out of context. For example, if the statement is made that pharmaceutical importation will reduce R&D by x percent, this is x percent relative to the level of R&D spending in the absence of the policy, not R&D spending in absolute terms.

⁶ To more formally consider the balancing of the costs and benefits with respect to a policy allowing pharmaceutical importation, the following may provide some clarification. Once a pharmaceutical product has been brought to market, pricing above marginal cost results in an underutilization of the new product (from a social welfare perspective). These costs are referred to as static inefficiency costs. Thus, a tradeoff exists between providing incentives for research and development (R&D), and thus innovation, and consumer access to today’s medicines: this is the balance the U.S. patent system tries to strike. While there is nothing sacrosanct about the current structure of the U.S. patent system for pharmaceuticals, or indeed the existing rate (and stock) of R&D investment, what is immediately apparent is that allowing importation of prescription drugs from price-regulated markets, while it will expand access to medicines already developed (the aforementioned benefits), it circumvents the U.S. patent system and allows foreign governments to set the price of pharmaceuticals in the U.S. This, as I have mentioned, will reduce the future supply of new drugs. These costs are referred to as dynamic inefficiency costs. The optimal policy (or patent system) will minimize the sum of the static and dynamic inefficiency costs.

⁷ The term risk here refers to the technical risk of an R&D project, which is the likelihood it will make it through the various stages of drug development and become a marketed product. This is quite different from financial risk, which is the risk faced by an investor who holds the market portfolio, *i.e.*, the relevant risk for determining the project’s cost of capital (or discount rate).

⁸ While understanding how R&D spending may be affected by pharmaceutical importation is important, what is most relevant is how this change in pharmaceutical R&D spending will influence innovation and public health. Obviously, measuring the costs associated with forgone future innovation is a near impossible task: there are many variables that can affect the outcome. However, because there is an overwhelming tendency for public policy debate to focus on the short-run benefits of lower (regulated) drug prices, it is critical that efforts be undertaken to at least approximate the magnitude of what the corresponding costs would be in terms of lower levels of innovation. Only then can the benefits of lower drug prices be weighed against the costs to determine if the policy is a good one. A very rough first approximation of the social costs associated with various pharmaceutical price-reduction policies (measured in terms of life years and dollars) may be found in Vernon (2004).

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Senator DORGAN. Dr. Vernon, thank you very much. We appreciate your testimony.

Dr. Schondelmeyer, why don't you proceed. You're from the University of Minnesota?

Dr. SCHONDELMEYER. Yes.

Senator DORGAN. And we appreciate, very much, your being here today.

STATEMENT OF STEPHEN W. SCHONDELMEYER, PHARM.D., PH.D., PROFESSOR OF PHARMACEUTICAL ECONOMICS AND DIRECTOR, PRIME INSTITUTE, COLLEGE OF PHARMACY, UNIVERSITY OF MINNESOTA

Dr. SCHONDELMEYER. Ja, you betcha.

Thank you very much, Mr. Chairman and members of the Committee. I'm Steve Schondelmeyer. I'm a professor of pharmaceutical economics and management at the University of Minnesota, where I direct the PRIME institute that does research on pharmaceutical, economic, and policy issues. My comments today are my own, and not those of any other body or organization.

I appreciate the opportunity to address this Committee, would remind you, as others have, that we still have a number of Americans who do not have health insurance or prescription drug coverage. So, the new Medicare Part D program certainly has helped drug coverage in America for some Americans, but it hasn't solved the access to drug therapy problems throughout the country, and there are still a number of people who do not have access.

Also, coverage does not solve the affordability problem, it only shifts it from the individual to the other private or public sources

who are paying for the drugs for those individuals. In fact, I would argue that coverage, especially when that coverage is under public programs, increases the importance of examining price as a part of the issue, because now we are paying for the costs of those medications out of the public coffers, and it is a cost to each of us, as taxpayers. And I think we all have a responsibility to use those resources wisely.

My comments today will be focused upon the potential role of drug importation and its expected impact on market prices and the presence of counterfeits in the U.S. marketplace.

Drug importation, I think, can be an important tool in this marketplace if we use it wisely and carefully.

Consumers are very price-sensitive. That's, in fact, why they go to Canada or the Internet to buy this same drug, the exact same drug, at a lower price. They are trying to express their demand. They're screaming in the marketplace, saying, "We need lower prices on drugs," but the manufacturers don't seem to hear that very well.

I think prescription drug coverage for some, or even all, consumers does not solve this affordability problem, because Medicare Part D, in particular, we subsidize the costs of that program. And, again, that puts it on the public rolls. Provision of coverage under public programs without meaningful market-based pressures and negotiation of price is much like writing a blank check to the pharmaceutical companies. And I think that's much the position we're in.

Other developed countries have brand name prices that are 25 to 60 percent lower than the price for the same drugs in the U.S. marketplace. While the U.S. may be willing to pay premium prices compared to other countries, we continue to experience this ever growing price premium compared to other countries, and not only is the price higher, but year-to-year increases in prices go up in the U.S. on average 3 to 7 percent a year; in other countries, the prices may go down 3 percent or up 3 percent in a range of about plus or minus 3 percent. The rate of growth of prices is much slower in other countries, as well. And that also creates a problem, and creates that gap of difference in price between the U.S. and other countries.

Yes, generics are an important part of the competitive pharmaceutical marketplace, but generic—and generics hold down U.S. drug expenditures, but they don't address the problem of the person who needs a single-source, brand name prescription drug that does not have a generic alternative. Generics aren't the answer. They might be, in a market sense, a part of the answer, but, for each individual patient who needs a specific drug, they hold no promise.

If no drug is available for an individual consumer, they face that monopoly price of the brand name country. As has been noted, the EU has experienced parallel trade for a number of years, and a large share of the trade in pharmaceuticals that occurs in the EU in certain countries comes through parallel trade and importation.

Importation, I think, is an important part of the big picture related to affordability of drugs in a society. The U.S. represents about 51 percent of the total manufactured-drug purchases in the

developed world. The EU countries are about 25 percent, and Canada is less than 5 percent. So, collectively, Canada and the EU are about 30 percent, the U.S. is 50 percent. If we took and—totally opened up with reimportation, I won't sit here and tell you that we will see EU or Canadian prices in the U.S., but we'll move closer to them. We will see the U.S. price go down some, we will see the EU and Canadian prices go up some. The end equilibrium price is much more likely to be close to the U.S. price than it is to the Canadian or European, primarily because we're such a larger share of the market to begin with. But I think we could easily see 12 to 20 percent drops in most drug prices in the U.S.

But, even more importantly, I think we would see a slowing of the rate of growth of those prices over time, which is as much a problem as the price itself. Both are important, both must be tracked.

Let me remind you, as we heard earlier today, that Congress passed the Prescription Drug Marketing Act of 1987, 20 years ago, and that Act required a pedigree, a paper or electronic process for maintaining the documentation of the source of origin and the traveling of that product through the channels of distribution. It wasn't until 1999 that the FDA first even promulgated regulations, nearly 12 years after the Act was passed. FDA had a law on the books they could have implemented that would have assured we knew where our product came from, and how it traveled through the market, and how it went out and came back into the U.S., and who made it, and where it was. They just recently have promulgated and begun to implement rules related to that pedigree. I think we need to look back at that pedigree process and move that ahead as quickly as we can to make sure we can assure we know where all the product in the marketplace comes from, and that it is safe and effective.

Major wholesalers and chains in the U.S. also have international operations in Canada, in Europe, in Mexico. And they're ready, today. They're doing business in those markets. It would take very little for them to begin to import products from their Canadian operations, their European operations, other sites.

The newer and most expensive drug products are the ones that are most often counterfeited. Why? Because they have the highest price and the highest profit margins, and the highest gross margin compared to their actual marginal cost of production.

Let me conclude by recommending that I think we need to encourage that pedigree process as quickly as possible. We need to eliminate or closely regulate the sale of drugs over the Internet, both domestically and internationally. That's not how you're going to—that isn't going to lower prices in the U.S., as a whole; it does, for each individual that buys there, but not for the market, as a whole.

Second, establish a pedigree system that must be initiated at the manufacturer level, must be—cannot be unreasonably withheld by the manufacturer from wholesalers and end-purchasers, and is required as the product passes to the wholesaler and pharmacy or any other end-purchaser.

Third, set uniform standards for the pedigree system so that we don't end up with a multiplicity of State requirements that would

proliferate and complicate the process and the cost of implementing the pedigree system, and bog it down, basically.

Fourth, authorize importation of pharmaceuticals through normal channels of distribution, manufacturers, wholesalers, chain warehouses, and community pharmacies.

Finally, prohibit manufacturers from manipulating the supply as a means of limiting importation from the markets with lower prices.

I would argue, members of the panel, that if you allowed importation through normal channels, your constituents could go to their corner drugstore and get their prescription at the same price that they find on the Internet or in Canada. They won't be using the Internet anymore, and FDA won't have to worry about shutting down those Internet sites, because your constituents will have a way to get that lower price that they're demanding.

Thank you very much.

[The prepared statement of Dr. Schondelmeyer follows:]

PREPARED STATEMENT OF STEPHEN W. SCHONDELMAYER, PHARM.D., PH.D.,
PROFESSOR OF PHARMACEUTICAL ECONOMICS AND DIRECTOR, PRIME INSTITUTE,
COLLEGE OF PHARMACY, UNIVERSITY OF MINNESOTA

Thank you, Mr. Chairman and members of the Senate Subcommittee for this opportunity to provide input into your deliberations regarding policy implications of pharmaceutical importation. I am Stephen W. Schondelmeyer, Professor of Pharmaceutical Economics at the University of Minnesota, College of Pharmacy where I also serve as Director of the PRIME Institute. The PRIME Institute focuses on pharmaceutical research involving management and economics. These remarks are my own views based upon my extensive research and experience with the pharmaceutical marketplace throughout the past thirty years, during which I have studied the economic behaviors and pricing policies of the pharmaceutical industry and have developed a broad understanding of the dynamics of the pharmaceutical marketplace. In particular, I have also examined the structure and financing of both private and public pharmaceutical benefit programs.

This Committee is considering issues that influence access to pharmaceuticals, one of the most important components of the health care system. Keep in mind that prescription drugs have a *universal demand*. That is, *everyone in society needs prescription drugs at some point during their lifetime*. Virtually everyone has used, will use, or should have used prescription drugs during their lifetime. During any given *week* one-half of the adult population uses one, or more, prescriptions and more than three-fourths of the population age 65 and over uses one, or more prescriptions.

While the new Medicare Part D drug program has provided coverage for many seniors and disabled, there are still about 47 million Americans with no health insurance and no prescription drug insurance. Affordability is still a problem for those uncovered person who must pay for their own prescriptions. Also, coverage does not solve the affordability problem, it simply shifts the issue of affordability from the individual to private or public sources. Employers are struggling with rising health care and prescription drug costs. Also, the total cost of the Medicare Part D drug program to society is a major cost that the Federal Government will struggle with in the years ahead. Coverage does not make price irrelevant, and in fact, public program coverage makes the price of prescription drugs an even more important policy issue for Federal and state governments. My comments today will be focused upon the potential role of drug importation and its expected impact on market prices and the presence of counterfeit drugs in the U.S. market. Drug importation is an important tool that, if used properly, can facilitate increased access and decreased presence of counterfeits in the market.

There are several major prescription drug issues which the Committee should address as part of health care reform. I want to address four issues, which are specifically mentioned in the Health Security Act, and which should be incorporated into any other package that emerges to reform health care in the United States:

1. economic forces are driving the demand for importation of pharmaceuticals;
2. generics are an important competitive factor in the U.S. market, but generics do not eliminate the need for more rational pricing of brand name drugs;

3. parallel trade is present in the European Union market;
4. the drug supply in the U.S. is safe, but counterfeits exist in the market;
5. high prices and low cost of production are major factors leading to counterfeits;
6. wholesalers and chains are positioned for a global market;
7. nontraditional distribution channels need to be monitored or eliminated; and
8. manufacturers will attempt to control supply to maintain prices.

Economic Forces Driving the Demand for Re-importation

Consumers are very “price sensitive,” that is, they are not willing to pay higher drug prices when the same drug is available in the market at a lower price. Consumers have been shopping with their feet (by traveling to Canada or Mexico) and with their fingers by shopping on the Internet. The behavior of consumers indicates that many are screaming that *price does matter*, but drug firms are not listening to these cries. Uninsured consumers may have to choose “your money or your life” when it comes to certain prescription drugs. In other words, a number of persons needing prescription drugs may have to forego needed prescriptions due to lack of resources and, or, high drug prices. This may include individuals without drug insurance coverage and persons covered by public programs with limited resources such as state Medicaid programs, state and Federal HIV–AIDs programs, and the Medicare Part D drug benefit. The total cost of the Medicare Part D drug program is projected to be considerably above the original projections.

Private employers are also concerned about rising health and drug benefits costs that are choking off corporate profits and global competitiveness. International drug prices *do differ* at the firm level and at the product level, if not also at the market level. While examination of drug prices at the aggregate market level is of interest, it is not particularly relevant to the individual who needs a specific drug product in the U.S. market. Consumers do not buy a “market basket” of drugs, but rather they buy only the one, or a few drugs, that they need at the time. Prices set by drug firms on the basis of differences in income levels across countries may have some logic from a macroeconomic perspective, but this approach does not take into account the income disparities experienced within a specific country. In particular, the U.S. has much greater income disparity and diversity than most other developed countries. Based on the price discrimination practiced by drug firms, the cash payers in the U.S. market pay the highest prices in the U.S., and for that matter the world, yet the U.S. cash payers are often among the lowest income persons within the U.S. Those without health and drug insurance may include part-time workers, workers who are at minimum wage and without employer-based health insurance, and others with limited resources. Lack of coverage for the individual, when not subsidized, still means the person has to pay the full cost of drug therapy.

Prescription drug coverage for some, or even all, consumers does not solve the affordability problem. Coverage benefits the individual when a public subsidy is provided to help cover the cost of drugs, but we all bear the total cost of drugs provided through tax-subsidized public programs. Provision of coverage under public programs without meaningful market-based pressure and negotiation of the price is essentially the same as writing “blank checks” for pharmaceutical firms. Other hearings in Congress have explored and examined the possible ways that the Medicare Part D drug program may exercise market negotiation power for better prescription drug prices.

Other developed countries (Canada, the EU, and others) have brand name drug prices that are 25 percent to 60 percent below the U.S. prices of the same drugs. While the U.S. may be willing to pay a premium price compared to other countries, we continue to experience an ever-growing price premium compared to other developed countries. Not only are the brand name drug prices typically higher in the U.S. than in other developed countries, but these other countries usually experience annual drug price changes in the range of plus or minus 3 percent versus price changes in the United States that may vary from plus 3 percent to plus 10 percent or more.

Generic Are an Important Competitive Factor

Generics are an important competitive factor in the U.S. prescription drug market, but do not solve the affordability and pricing problems. Certainly generics help to hold down the total U.S. drug expenditures. Even though generics account for more than one-half of all outpatient prescriptions filled in the United States each year, their relatively low prices result in generics accounting for about 15 percent to 20 percent of total drug expenditures. People are not going to Canada, or the Internet, to buy the \$4 generic prescriptions that are available through selected

Wal-Mart and Target stores. This limited set of generics, accounts for about 1 percent to 3 percent of total drug expenditures for persons who choose to go to Wal-Mart or Target stores.

In most cases, generics are less expensive in the U.S. than in Canada, or other developed countries. Generics may help lower the overall, weighted average market price, but generic prices are not relevant to the individual who needs a specific brand name medication with no generic alternatives. If no generic is available for your prescription, then you may face the monopoly brand name price in the United States.

Parallel Trade Is Present in the European Union Market

All EU countries engage in some parallel trade (importation) for prescription drugs. Greater than 10 percent of the drug supply flows through parallel trade in the U.K., the Netherlands, and Denmark. According to IMS Health, the European market “is a market that has exactly the same high quality requirements” across member countries. Parallel trade occurs and depends upon: price level in the destination country; price difference compared to the source country (~20 percent or more will lead to parallel trade); product volume available in the source country; product volume demanded in the destination country; costs of transportation, customs, and product verification; assurance that market conditions allow importers to make a reasonable profit; and legal and regulatory conditions that support the rights of importers.

Parallel trade with importation, and re-importation, is a part of the “big picture” needed for affordable drugs in a society. Importation, and re-importation, will help, but will not completely solve the pricing concerns for prescription drugs. Re-importation will not deliver Canadian, or EU prices to the United States, but some equilibrium price in between the U.S. price and the developed world price will be achieved. Keep in mind that the U.S. is the single largest pharmaceutical market in the world. For the 12 months ending in December 2006, the manufacturer prescription sales to the developed world were about \$388 billion and to the total world were about \$555 billion. The U.S. represents about 51 percent (\$198 billion) of the manufacturer sales to the developed world. In contrast, the top five countries in Europe are about 25 percent (\$96 billion) and Canada is 3.5 percent (\$14 billion) of manufacturer prescription sales to the developed world.

	Manufacturer Sales (\$ in billion)	Percent of Total World	Percent of Selected World
Total World	\$554.7	100.0	
Developed (Selected) World	388.3	70.0	100.0
U.S.	197.8	50.9	35.7
Europe (Top 5)	95.5	24.6	17.2
Canada	13.7	3.5	2.5
Australia/New Zealand	5.8	1.5	1.0
Japan	56.7	14.6	10.2
Latin America	18.7	4.8	3.4

Parallel trade through importation, or re-importation, from Canada, the EU, and selected other developed countries will not deliver Canadian, or European prices, to the U.S. in the long run (more than 2 years). Importation, or re-importation will deliver a developed world equilibrium price less than the U.S. price and more than the Canadian or EU price. In fact, the equilibrium price will be closer to the U.S. price than to the EU or Canadian price since U.S. accounts for more than 50 percent of market for developed countries while the other countries in the proposed parallel trade market are about 30 percent of the developed countries market. U.S. prices may decrease about 12 percent to 20 percent after implementation of parallel trade. As important as the price decrease, would be the effect on price changes over time. Parallel trade would most likely lead to slower inflation in brand name prices than the U.S. is accustomed to paying. The inflation rate would probably slow to about 2 percent to 4 percent per year rather than 4 percent to 7 percent per year.

The Drug Supply in the United States is Safe, But Counterfeits Exist in the Market

“The U.S. drug supply chain is probably the safest one in the world, and we’re working hard to keep it that way,” said Tom McGinnis, Director of Pharmacy Affairs, U.S. Food and Drug Administration (FDA). McGinnis went on to say “There’s a lot of money to be made in knocking off these kinds of products if you can get them into the distribution system.” [*Traffic World, Journal of Commerce*, “Securing the Drug Pipeline,” June 20, 2005] The FDA estimates that less than 1 percent of U.S. drugs are counterfeit or adulterated. The most frequently counterfeited drugs are

those with the highest prices (e.g., cancer and hematologic agents) and the highest volume (e.g., Lipitor). “America has become the go-to market for counterfeiters because we pay the highest prices of anyone in the world,” says Katherine Eban [Eban, K., *Dangerous Doses: How Counterfeiters are Contaminating America’s Drug Supply*.] High prices for drugs with relatively low marginal costs play a role in determining the types of drug products that are the target of counterfeiters. Lowering prices through parallel trade may, in fact, reduce the likelihood of counterfeits.

While importation of drugs from Canada and other countries is illegal, the current policy in the United States has been a somewhat passive tolerance of personal importation from Canada via the Internet and mail or through ‘drug trips’ to Canada or Mexico. This has resulted in sort of an individualized ‘wild west’ environment for prescription drug importation. That is, Americans can usually import prescription drugs via the Internet or in person as long as no one is watching and the quantity is limited (e.g., a 1 month to 12 month supply). This informal policy of allowing *ad hoc* importation does little, if anything, to prevent counterfeits and may also be harmful to patients by fragmenting their prescription drug records. With fragmented prescription drug records, physicians, pharmacists, and pharmacy benefit managers are less likely to have the information necessary to properly advise the patient on drug use, interactions, and potential consequences.

Congress passed the Pharmaceutical Drug Marketing Act in 1987, twenty years ago. The Act required that a “pedigree”—paper or electronic—be maintained to document the origin and source of a drug product all the way from the manufacturer to the end dispenser. The FDA did not even promulgate proposed regulations until 1999, and it announced in 2004 that it would delay the effective date of those rules until December of 2006. Certainly, the technology for these pedigrees has changed substantially over the past twenty years. Today, electronic pedigrees in various forms appear to be far more efficient than paper pedigree procedures. The pedigree can authenticate the source of a drug product and it may also serve as a means to track-and-trace a drug throughout the distribution chain and even for recalls, if needed for a drug product. After more than twenty years, it is time that this pedigree process be implemented.

If the pedigree process was in place, then the traditional drug distribution channels could effectively maintain the quality of the drug supply whether the drug originates in the U.S. or is imported by the manufacturer, wholesaler, or pharmacy. One step in this direction has been the recent action by the Healthcare Distribution Management Association (HDMA) in 2003. The HDMA adopted voluntary Guidelines for Pharmaceutical Distribution System Integrity, which encourages distributors to carefully scrutinize each of their business partners both upstream and downstream.

Wholesalers and Chains Are Positioned for a Global Market

In the year 2000, the National Wholesale Druggist Association (NWDA) changed its name to the Healthcare Distribution Management Association (HDMA). As described in the trade publication known as *The Pink Sheet*, “The change from emphasis on a ‘national’ organization to one defined by ‘health distribution’ comes as NWDA members face the legislated opportunity of moving products across borders to take advantage of different pricing levels.” [FDC Reports, *The Pink Sheet*, Vol. 62, No. 44, Oct. 30, 2000, p. 19] Indeed, major wholesalers and chains already have international operations and connections with Canada, Mexico, and European Union countries. “McKesson has operations to the north and south of the U.S. border that could help the company implement an import provision.” [FDC Reports, *The Pink Sheet*, Vol. 62, No. 44, Oct. 30, 2000, p. 8]

Bindley Western (now part of Cardinal Health) “CEO Bill Bindley told an Oct. 25 (2000) conference call that “we’re looking at drug import legislation, as are our competitors . . . if there is opportunity, you can be assured that we’ll be trying to take advantage of it.” [FDC Reports, *The Pink Sheet*, Vol. 62, No. 44, Oct. 30, 2000, p. 8]. Cardinal Health has wholesaling operations and interests in Canada and Europe. In addition to wholesalers, “some chains already operate internationally, ‘looking at a global market is something they’re already accustomed to,’” added Mary Ann Wagner, Senior V.P., Regulatory Affairs, National Association of Chain Drug Stores (NACDS). “NACDS members that operate in Canada include Cardinal’s Medicine Shoppe, Costco, and Wal-Mart. Chains could import drugs through their own distribution centers or agreements with wholesalers.” [FDC Reports, *The Pink Sheet*, Vol. 62, No. 49, Dec. 4, 2000, p. 14]

Non-traditional Distribution Channels Need to Be Eliminated or Monitored

There are, or have been in recent years, thousands of wholesalers in the United States although only about 46 of these firms are traditional, full-line drug whole-

salers. The three largest wholesalers (McKesson, Cardinal Health and AmeriSourceBergen) accounted for 92.7 percent of the U.S. pharmaceutical wholesale market in 2004. [HDMA Foundation, 2005–2006 HDMA Factbook: Industry Overview, 2005, p. 22]

Brand name drug firms are themselves, in part, responsible for many of the large number of faux wholesaler firms registered with states such as Florida and California. Most of these firms are not traditional wholesalers, but rather they are end-purchasers such as clinics and physician's offices. These end-purchasers have been induced to register as wholesalers by the pricing scheme of one or more brand name pharmaceutical firms so that the 'registered wholesaler' can benefit from special pricing when purchasing high cost specialty drugs from these certain manufacturers. These faux wholesaler pricing schemes have most commonly been developed for specialty drug products (*e.g.*, oncology and hematological drugs) sold to, and administered by, clinics and physicians' offices. The faux wholesaler may buy a larger quantity than required for their own needs in order to qualify for certain levels of volume discounts from the manufacturer and then they re-sell the excess quantity of product purchased to other clinics or physician's offices.

For example, the pricing scheme of TAP Pharmaceuticals for their Lupron product provided favorable pricing to clinics and physicians that were registered as wholesalers. The favorable prices to faux wholesalers were also hidden from private and public third party payers. This pricing scheme was the subject of legal actions that led to settlements with the U.S. Department of Justice (\$875 million) and with a class action group of plaintiffs. This proliferation of faux wholesalers to qualify for certain discounts created opportunities for counterfeit, stolen, or diverted drug products to also enter the distribution system. In some cases, the large wholesalers would buy drug product back from these faux wholesalers through what has come to be known as the "gray market."

The newer and most expensive drug products, also known as specialty drug products, have been one of the most often targets of counterfeiters. These drug products are targets because they have both very high prices and very high profit margins above the marginal cost of production for both legitimate and counterfeit product. One manufacturer (*i.e.*, Johnson & Johnson) has taken steps (Jan. 19, 2004) to assure that drug wholesalers "purchase J&J products directly from the manufacturer, in an effort to reduce counterfeits." [FDC Reports, *The Pink Sheet*, Vol. 65, No. 50, Dec. 15, 2003, p. 37] "J&J's current policy has stipulated that customers who purchase Procrit or any other Ortho Biotech product from a different source will have their account status immediately terminated. The more stringent policy will likely better secure the supply chain." This policy requirement by J&J is not expected to pose a major challenge for the three largest wholesalers (AmeriSourceBergen, McKesson, and Cardinal) because these firms have committed to "eliminating purchases from secondary wholesalers as part of anti-counterfeit measures." [FDC Reports, *The Pink Sheet*, Vol. 65, No. 46, Nov. 10, 2003, p. 31]

Manufacturers Will Attempt to Control Supply To Maintain Prices

Even if importation is allowed, drug firms will try to limit importation by limiting supply into the lower-priced markets. This phenomenon has already been seen in Canada in response to Canadian importation into the U.S. market. "In a Jan. 3 (2003) letter, GSK (GlaxoSmithKline) said it would stop selling drugs to any Canadian distributor whose pharmacy clients are suspected of selling them to U.S. customers." The letter states "GSK will refuse to supply our products through your distribution centers until such time that we are satisfied that you are complying with our Terms and Conditions of Sale." [FDC Reports, *The Pink Sheet*, Vol. 65, No. 3, Jan. 20, 2003, p. 27] "Other companies, including Merck, have previously sent letters to their purchasers to remind them of similar reimport rules. GSK's move, however, appears to be the first time a company has set out consequences for failure to comply." The actions of GSK and other manufacturers have had some impact on drug supply in Canada. Keep in mind that the United States represents about 50 percent of the world pharmaceutical market, while Canada is only about one-tenth that size, or 5 percent of the world market.

Health Canada has also conducted inspections of "Canadian pharmacies that are thought to be acting as wholesalers for the purpose of exporting drugs to the U.S." The Executive Director of the Canadian National Association of Regulatory Authorities told the DHHS task force on drug importation at its April 27, 2004 meeting that if pharmacies "are purchasing drugs from other pharmacies, they're acting as wholesalers. And if they don't have an establishment (wholesale) license, that would be illegal. The Canadian authority is also looking for "unapproved drugs being dispensed." [FDC Reports, *The Pink Sheet*, Vol. 66, No. 18, May 3, 2004, p. 40] The

Health Canada official pointed out that “in terms of the exportation of drugs to the U.S., there’s nothing federally (in Canada) that prevents that (importation).”

Recommendations

The following recommendations are made to facilitate importation (and re-importation), while minimizing counterfeits in the U.S. market. Consumers and private and public programs are far more likely to benefit from importation through the traditional distribution channels in the United States. Internet purchases would drop dramatically, or virtually disappear, if American consumers can get the lower prices of foreign markets at their corner drug store. Also, the pharmacist can maintain a complete medication history and more appropriately provide counseling and medication therapy management.

1. Eliminate or closely regulate sale of drugs over the Internet, both domestic and international.
2. Establish a pedigree system that: (a) must be initiated at the manufacturer level, (b) can not be unreasonably withheld from wholesalers and end-purchasers, and (c) is required as product passes to wholesaler and pharmacy, or other end purchaser.
3. Set uniform standards for the pedigree system so that a multiplicity of state requirements do not proliferate and complicate the process (and cost) of implementing the pedigree system.
4. Authorize importation of pharmaceutical products through “normal channels of distribution” (*i.e.*, traditional wholesalers, chain warehouses, and community pharmacies).
5. Prohibit manufacturer manipulation of supply as a means to limit importation from the markets with lower prices.

Senator DORGAN. Dr. Schondelmeyer, thank you very much.

Finally, we will hear from Nelda Barnett, who’s a member of the Board of Directors of the AARP.

Ms. Barnett, you may proceed.

**STATEMENT OF NELDA BARNETT, MEMBER,
BOARD OF DIRECTORS, AARP**

Ms. BARNETT. Mr. Chairman and members of the Committee, I am Nelda Barnett, a member of AARP Board of Directors. Thank you very much for including AARP in your discussions about the implication of prescription drug importation for U.S. consumers.

Americans need affordable prescription drugs, but, for too many people, the price of drugs is beyond their means. Recent AARP studies reveal that drug prices continue to rise much faster than the rate of inflation. Our members tell us that these high prices are the single greatest barrier to obtaining needed medication.

Rising prescription drug prices affect every segment of the population. Though tens of millions of Medicare beneficiaries are now getting help with their prescription drug costs through Medicare Part D, beneficiaries are still feeling the effects of rising prescription drugs—costs—in the form of higher premiums, deductibles, co-payments, and, for some beneficiaries, lack of coverage in the donut hole.

Escalating prescription drug prices continue to hamper employers’ ability to provide health insurance coverage for their workers and families. Pressures also squeeze public programs at both the State and Federal level. Rising prescription drug prices plague Medicaid and put pressures on states’ ability to maintain current coverage levels, let alone expand eligibility to meet the increasing need as fewer employers provide access to affordable healthcare coverage.

Finally, rising prescription drug prices particularly hurt the almost 47 million Americans who lack health insurance. These individuals pay most of the highest prices in the world for the—for their prescription drug needs. Some don't fill prescriptions, because they cannot afford to do so.

Importation is not the sole solution to soaring drug prices in the United States, but it will create downward pressure on drug prices and provide consumers some immediate relief.

The simple fact is that importation is already happening. Many Americans already purchase their drugs from other countries. The trend is growing, and we have a responsibility to ensure that Americans can access lower drug costs safely.

Safety is critical in any importation system. The Dorgan-Snowe bill ensures safety and provides consumer protections, including anti-counterfeiting and anti-tampering requirements, mandatory labeling and chain-of-custody requirements. My written statement outlines these safety precautions and protections.

I would also like to add that a system of safe importation cannot be realized if the industry curtails supply. We believe that a vital component of the Dorgan-Snowe bill are the provisions that seek to prevent the drug industry from cutting off supply to countries engaging in importation to the United States.

AARP has endorsed the Dorgan-Snowe importation legislation, S. 242. We believe it meets the challenge of designing a prescription drug importation program that will ensure the integrity of pharmaceuticals and provide consumers access to lower-cost drugs.

Our members want Congress to enact bipartisan legislation this year to allow for safe, legal importation of lower-cost prescription drugs. AARP is pleased to see this Committee and Members of Congress from both sides of the aisle moving forward on this issue.

We understand the challenges Congress faces in designing a program that ensures the integrity of pharmaceuticals, but does not create an overly burdensome process that would prevent consumers from gaining access to lower-cost prescription drugs. We believe the Dorgan-Snowe legislation meets that threshold, and we urge its enactment this year.

Thank you, again, for inviting us here, and I'm happy to answer any questions.

[The prepared statement of Ms. Barnett follows:]

PREPARED STATEMENT OF NELDA BARNETT, MEMBER, BOARD OF DIRECTORS, AARP

AARP is pleased that the Committee is moving forward with the issue of prescription drug importation. Congress has been considering legislation to provide for importation of lower-priced prescription drugs for well over a decade, and we strongly urge you and your colleagues to take action this year to enact S. 242, the Pharmaceutical Market Access and Drug Safety Act. We believe this legislation includes measures to ensure the safety of imported prescription drugs, while at the same time allowing Americans to gain access to lower-priced prescription drugs.

Prescription Drug Prices Continue to Rise at Unsustainable Rates

Prescription drug costs continue to rise. Recent reports estimate that total spending on health care is expected to double by 2016, and much of this is due to rising prescription drug costs.¹

¹John A. Poisal, *et al.*, Health Spending Projections Through 2016: Modest Changes Obscure Part D's Impact, *Health Affairs*, 21 Feb. 2007.

A recent AARP study revealed that, on average, pharmaceutical manufacturer prices for the 193 brand name drugs most widely used by older Americans rose at nearly twice the rate of general inflation in 2006.² Reversing the trend between 2004 and 2005, when the average rate of increase in manufacturer drug prices fell, the 2006 average growth rate of 6.2 percent represents an up-tick from the 2005 average increase of 6.0 percent. For the 153 brand-name drugs that were in the market since 2000, this translates into a cumulative average price increase of 53.6 percent, over two-and-one-half times the general inflation rate of 20.1 percent over the same period.³

The new Medicare prescription drug benefit is helping tens of millions of Medicare beneficiaries better afford their prescription drugs. However, even with this new program, Medicare beneficiaries are still feeling the effects of rising prescription drugs costs in the form of the higher premiums, deductibles, co-payments and—for some beneficiaries—lack of coverage in the donut hole.

Medicare beneficiaries are not the only group impacted by rising prescription drug prices. Escalating prescription drug prices continue to hamper employers' ability to provide health insurance coverage for their workers and families. In addition employers are increasingly eliminating or curtailing their retiree prescription drug coverage.

Pressures also continue to squeeze public programs at both the state and Federal level. Rising drug prices also plague Medicaid, and put pressure on states' ability to maintain current coverage levels. These prices also hamper states' ability to expand eligibility to meet the increasing need as fewer employers provide access to affordable health care coverage.

Finally, rising prescription drug prices particularly hurt the almost 47 million Americans who lack health insurance. These individuals pay among the highest prices in the world for their prescription drug needs. Some don't fill prescriptions because they cannot afford to do so.

Public Support for Importation Grows

For the millions of Americans without drug coverage and those with limited coverage, importation is seen as an option to obtain access to affordable medications. A recent AARP poll found that AARP members overwhelmingly support Congress allowing for the importation of drugs from Canada and Europe.⁴ While AARP does not believe prescription drug importation is the sole solution to soaring drug prices in the United States, we do believe it is one way to begin to secure lower priced drugs.

Our members and their families question why brand name drug prices in Canada and other industrialized countries can be lower—sometimes by as much as 50 percent lower—than prices in the U.S. It is a national embarrassment that people from all over the world come to the United States to access our advanced medical systems while many of our own citizens need to look outside our borders in order to afford their prescription drugs.

The simple fact is that importation is already happening. In 2003, Americans purchased approximately 12 million prescription drug products (valued at almost \$700 million) from Canada alone.⁵ As prescription drug prices continue to rise, more and more individuals are choosing to import prescription drugs. We have a responsibility to ensure that Americans who choose to import prescription drugs do so safely. Congress can no longer afford to do nothing but hope that the millions of Americans who purchase prescription drugs from abroad do so without dire consequences.

Congress Should Act Quickly to Pass the Dorgan-Snowe Legislation

We believe that Congress should enact legislation that provides appropriate safeguards while at the same time ensuring a workable system for prescription drug importation. Currently, many prescription drugs sold for market in the U.S. are already manufactured abroad and brought into the U.S. safely and legally by prescription drug manufacturers. If these manufacturers can import drugs safely and legally, then a process can be created to allow American consumers to safely import drugs.

²David J. Gross, Leigh Gross Purvis, and Stephen W. Schondelmeyer, *Trends in Manufacturer Prices of Brand Name Prescription Drugs Used by Older Americans, 2006 Year-End Update*, AARP Public Policy Institute Data Digest #DD154 (Washington, D.C.: AARP), March 2007.

³*Id.*

⁴AARP Knowledge Management, *Medicare Price Negotiation of Prescription Drugs—A National Poll February 12, 2007*, page 8, available at: http://assets.aarp.org/rgcenter/health/rx_negotiation.pdf.

⁵HHS Task Force on Drug Importation, *Report on Prescription Drug Importation*, December 2004, at 11–12.

S. 242 balances the challenge of designing a prescription drug importation program to ensure the integrity of pharmaceuticals while at the same time providing consumers access to lower price prescription drugs. We strongly urge you and your colleagues to enact S. 242 this year.

Dorgan-Snowe Ensures the Safety of Imported Drugs

Access to lower-priced prescription drugs isn't enough. These prescription medications must be safe and efficacious. Recent news reports highlight an increasing problem with the use of counterfeit drugs. Implementing a system of safety procedures could begin to alleviate this serious problem.

AARP supports the approach taken in S. 242 to create a system that provides for importation of safe, effective pharmaceuticals. The legislation first legalizes personal importation from Canadian pharmacies and wholesalers. Regulation of the Canadian pharmacy system closely resembles its U.S. counterpart, and drugs purchased from Canada can be as safe as drugs purchased in the United States.

Under the legislation, importers and exporters must agree to allow their place of business to be inspected by the Food and Drug Administration ("FDA") not less than twelve times per year. The legislation also tasks the FDA with the responsibility of ensuring that the prescription drugs imported from abroad are comparable to drugs available in the U.S. market. If the difference between the foreign drug and its U.S. counterpart is minimal, the FDA can allow the drug to be imported into the U.S. However, if the difference is significant, a supplemental application may be required. If the supplemental application would not be approved, the FDA will prevent the importation of the prescription drug.

To ensure that the FDA isn't besieged with inspection and certification requirements, the legislation allows the FDA to phase-in its review of registered importers and exporters, provided that priority is given to entities that can process a high volume of sales. Likewise, the legislation also permits the FDA to phase-in its review of foreign versions of FDA-approved drugs to determine whether they are the same as their U.S. counterparts. AARP believes that phasing in these provisions will further bolster the safety of the importation plan by providing FDA the opportunity to conduct thorough inspections and review.

Pedigree Requirements

One way of effectively ensuring the safety of pharmaceuticals is the institution of pedigree requirements—the ability to trace a drug from the point of origin to the point of dispensing. In order to accomplish this task in an expanded international arena, the Dorgan-Snowe legislation mandates that importers and exporters may only purchase prescription drugs from a manufacturer or entity that can establish a drug's pedigree. These requirements include identification of the drug's prior sale or transaction and contractual authority to inspect records to determine whether an entity engaged in the system is in compliance with applicable safety and other standards. AARP believes that standards such as these are crucial to protecting the quality and efficacy of imported pharmaceuticals.

In order to ensure safety, pharmaceuticals imported from another country should be equipped with anti-tampering materials and anti-counterfeiting measures. As the technology in this area progresses, imported pharmaceuticals should be equipped with state-of-the-art devices, such as bar codes, and specialized ink, or other appropriate technology. The Dorgan-Snowe bill requires the use of anti-tampering and/or track-and-trace technologies to prevent counterfeiting of imported drugs.

Finally, S. 242 provides that pharmaceuticals imported by wholesalers and pharmacies be labeled in such a way as to indicate to the consumer that the drug has been imported under the new system. Consumers will thus expect to realize some savings from these pharmaceuticals.

Anti-Gaming Provisions

We recognize that some manufacturers are already curtailing their drug supply to Canada and other countries, which could lead to supply shortages or fear of retribution by entities that engage in importation. An importation proposal that does not seek to prevent entities from pressuring those who engage in importation will amount to nothing more than an importation system in name only. Our members do not want hollow promises of importation—they want legislation passed that will allow them the opportunity to fill their prescription safely and at a lower price.

Therefore, AARP believes that anti-gaming provisions are a vital component of any importation legislation. The Dorgan-Snowe legislation seeks to prevent entities—particularly pharmaceutical manufacturers—from eliminating or curtailing drug supply to those who engage in importation of prescription drugs to the U.S. so that the system can work as Congress intends.

Protection from Rogue Internet Pharmacies

Many consumers who choose to purchase prescription drugs from abroad do so through Internet pharmacies. Unfortunately, many consumers fall victim to rogue Internet pharmacies due in part to the inability to distinguish between reputable and fly-by-night operations.

The Dorgan-Snowe legislation instructs the FDA to maintain a website listing approved pharmacies. Having the FDA website as the point of contact for a list of approved pharmacies provides consumers with an official, secure source of information on safe drugs. However, not all consumers have access to the Internet; therefore, the legislation provides that the FDA must also maintain a toll-free number where consumers can get information on approved foreign sources.

Conclusion

The Dorgan-Snowe legislation provides for a safe and effective system for allowing importation of prescription drugs. Our members, and all Americans, need Congress to enact this bi-partisan, legislation this year. We are pleased to see this Committee and Members from both Houses of Congress and both sides of the aisle moving forward on this issue. AARP pledges to work with you to make safe importation a reality.

Senator DORGAN. Ms. Barnett, thank you very much for being here.

And thanks, to all five of you, for offering testimony today, testimony that is varied and different, and comes to different conclusions about this issue. We recognize it's a controversial issue. And that's precisely why we have asked witnesses to provide varied viewpoints.

Dr. Schondelmeyer, you heard Dr. Lutter, and you heard former Congressman Tauzin, describe—I think Billy Tauzin's comment was, "open the door to those products to come in," referring to the legislation that would allow importation. I think Mr. Lutter described the counterfeits and the specter of reimportation compromising our drug supply, amplifying the problem of counterfeits, and so on. You disagree with that? And you have indicated in your testimony, I believe, that you feel that safety provisions in the Dorgan-Snowe bill would, in fact, strengthen our confidence in the drug supply. Can you respond to that?

Dr. SCHONDELMAYER. Sure, I'd be glad to, sir.

First of all, I believe that the current system we have is much like the Wild West environment, where people can do about anything they want, in terms of buying prescription drugs on the Internet, as long as they keep the quantities low and they don't get caught in the process; or they can go across the border to Canada and Mexico, and we kind of look the other way and let them do it. And that's—so, the door is open. The back door, the front door is open already. I think the system proposed by the Snowe-Dorgan bill and similar bills really defines a process that closes the system and says, "We will use the traditional channels, the channels that FDA knows and works with. We will ask FDA to finally give us a pedigree chain-of-custody system that they've had authority to do for 20 years, and haven't done." And I think that will close the system and help keep counterfeits out of the market, rather than make them more available.

Senator DORGAN. Mr. Tauzin, what's wrong with that analysis, if anything?

Mr. TAUZIN. Well, there's a lot wrong with it. And we'll be happy to comment in much larger degree to you, to all of the points that we think are weak in the draft we've seen.

But one of the most important parts, for example, is that the FDA, under the bill, has no control over the shipper and where the drugs are coming from. There is no authorization, no possibility, as you heard from FDA, for them to regulate unregulated manufacturers in China and India and Kazakhstan, or wherever it may be coming from. The bill opens up importation, as you know, to many more countries—29 more countries—than does the current law, which applies to Canada. And even if you limited it to Canada, we're told that the drugs coming into Canada are coming from many other sources. There are figures we can give you on the incredible rising number of imports into Canada from strange sources around the world of drugs manufactured in establishments not regulated by the FDA, not controlled, nor even registered with the FDA. Under this bill, they would remain unregistered, uncontrolled, uninspected, and they would be allowed to ship into the authorized receivers in this country of those products, and they would be commingled with the supply in this country. It is—

Senator DORGAN. But, Mr. Tauzin—

Mr. TAUZIN. It is not a simple task. And my final thought, Mr. Dorgan, is—I mean, we're obviously willing to work with you on this. The law requires that if Donna Shalala and Mr. Thompson and Mr. Leavitt had been able to certify the safety, that importation would be allowed. The problem is, they have not been able to do so. It is not as easy as has been described here. And even, I think, the attempts in this bill to address those issues are going to fall woefully short. But we'll be happy to have those conversations with you about why we think that's true.

Senator DORGAN. I'll give you a chance to respond in a bit again, except I would observe that the counterfeiting that is described by you and Mr. Lutter is occurring under today's circumstances. And I believe that the legislation that we have drafted will, in fact, substantially reduce the opportunity for that. But let me ask Mr. Schultz.

Mr. Schultz, you, in a previous life, were the Deputy Commissioner for Policy at the FDA. You believe that, with proper resources, that there can be a regime of reimportation that does not threaten or compromise our prescription drug supply in this country. Is that correct?

Mr. SCHULTZ. Yes. And I've reviewed your bill. There are always going to be constructive suggestions and improvement and so on, but it's a very comprehensive, sophisticated approach that, most importantly, gives the agency resources to do the job.

Senator DORGAN. Let me ask if there's any of you on the panel who believes that the U.S. consumer should pay the highest prices in the world for brand name prescription drugs. Now, that, I believe, is now the case. You can contest that, if you like. But if that is the case—and I believe it is—does anybody believe that is the fair method of pricing prescription drugs, that the U.S. consumer should bear the highest cost?

Mr. TAUZIN. I don't.

Senator DORGAN. You don't?

Mr. TAUZIN. I think we have failed miserably in insisting that other people around the world bear the cost of R&D. Charlie Rangel, in an interview, Sunday, made it very, very clear. Congress-

man Rangel said, "You know, Americans pay the R&D expenses—for a lot of things, not just pharmaceuticals—for the rest of the world, and they don't bear a responsible share of the cost." And that's true. And that's a failure of our trade policies.

Senator DORGAN. So—

Mr. TAUZIN. But importing their price control systems into our country is not free trade, and it is not the kind of stuff that is going to lead to the investment in R&D and new drugs that we need for the world, much less for this country.

Senator DORGAN. So, if the consumer in the U.S. pays the highest prices in the world—80-year-old man sitting on a straw bale on a farm in southern North Dakota tells me his wife is fighting breast cancer for 3 years—3 years. They drive back and forth to Canada, because it's the only way they could afford Tamoxifen, at, you know, 80 percent discount. If—this is the case for American consumers, that they—

Mr. TAUZIN. Mr. Chairman, I read your story, a number of times. Tamoxifen, today, under the Medicare Part D, which is available to that couple you met, would cost 30 cents a day now.

Senator DORGAN. Yes, which—

Mr. TAUZIN. The prices—we've got a chart we'll show you, of the top ten medicines, where actually the prices under Medicare Part D coverage, where insurance—where seniors now have available coverage with those drugs—are lower than Canadian prices.

Senator DORGAN. That would work if you were 77 years old, but not if you're 57 years old.

Mr. TAUZIN. Well, as a matter of fact—

Senator DORGAN. So, it's part pragmatic—

Mr. TAUZIN.—that's why we put the PPA program together.

Senator DORGAN. But—

Mr. TAUZIN. This year, we've reached the 3.5 million mark of patients we've added to free medicine programs in this country, who are in that category, Mr. Dorgan. What we're saying is, there are better alternatives—

Senator DORGAN. I commend the industry for that, Mr. Tauzin, but—

Mr. TAUZIN. Thank you.

Senator DORGAN.—that is not a substitute for fair pricing. And I asked the question, anybody think that the current system, in which we pay the highest prices, is a fair system? All of you, I think—I don't think anybody volunteered to say, "Yup, sign me up." I think Americans ought to continue to pay the highest prices." If that is the case, then the question isn't whether we have a change, the question is, what is the change to try to resolve that?

Now, Dr. Vernon, you came with a study that says if you cut prices—that is, create a circumstance in which the market system, the U.S. consumer can access, through the market system, the FDA-approved drug at a lower price, the price it's being sold at in much of the rest of the world—if you do that, it would necessarily reduce the amount of research and development expenditures by the pharmaceutical industry. I understand the math of that, but I don't understand the circumstances of why you connect that price to R&D. How about connecting that to marketing, for example? My

feeling is that most of the drug industry spends more on marketing and promotion than they do on research and development, or—

Mr. TAUZIN. That's not true.

Senator DORGAN.—at least it's a very—well, we'll have the record—

Mr. TAUZIN. OK.

Senator DORGAN.—you may submit for the record—

Mr. TAUZIN. Yes, we will—

Senator DORGAN.—your evaluation—

Mr. TAUZIN.—do that.

Senator DORGAN.—of that.

[The information previously referred to follows:]

ADDITIONAL STATEMENT OF W.J. BILLY TAUZIN, PRESIDENT AND CEO,
PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA (PhRMA)

Mr. Chairman, I wanted to address the issue you raised regarding how much drug companies spend on research and development, marketing and direct-to-consumer advertising.

The biopharmaceutical industry spent \$55.2 billion in 2006 on research and development according to data from PhRMA's Annual Survey¹ and an independent analysis by Burrill & Company, an increase from \$51.8 billion in 2005.² By way of comparison, the biopharmaceutical industry spent \$11.4 billion on marketing and educational activities in 2005, including \$4.2 billion on direct-to-consumer ads, according to IMS Health.³ Notably, in October 2006, CBO reported, "The pharmaceutical industry is one of the most research-intensive industries in the United States. Pharmaceutical firms invest as much as five times more in research and development, relative to their sales, than the average U.S. manufacturing firm."⁴

Some critics of the biopharmaceutical industry have claimed companies spend more on marketing than on research. First, they reach this flawed conclusion by categorizing all selling, general, and administrative expenses reported in filings to the Security and Exchange Commission (SEC) as "marketing costs." However, this line-item includes such non-marketing costs as free medicines provided to low-income patients through patient assistance programs, distribution and shipping expenses, systems and IT support, and corporate functions (*i.e.*, legal, communications, dues, procurement, utilities and property taxes). As Princeton professor Uwe Reinhardt has written, "the [selling, general and administrative] category represents many expenses other than selling expenses and should not be seen as an estimate purely of outlays on marketing, as the industry's critics occasionally do."⁵ I hope that we can agree that these comparisons are not grounded in fact.

Second, the critics who make this point also fail to acknowledge that marketing expenditures help bring patients into treatment for previously untreated or undertreated conditions,⁶ and help improve compliance with physician-prescribed treatment.⁷ Moreover, there is a gap in "translating research findings into medical practice."⁸ Bringing health professionals FDA-regulated information regarding prescription medicines can help bridge this gap.⁹ Early intervention and improved compliance for conditions like high blood pressure, diabetes, and cardiovascular disease can help patients remain healthier and avoid high health care costs.

¹ PhRMA, Profile; Appendix: PhRMA Annual Member Survey (Washington, D.C.: PhRMA).

² Burrill & Company, analysis for PhRMA, 2006 and 2007. Includes PhRMA research associates and nonmembers.

³ IMS Health, Integrated Promotional Services™ and CMR, 5/2006.

⁴ Congressional Budget Office, Research and Development in the Pharmaceutical Industry; October 2006.

⁵ U.E. Reinhardt, Perspectives on the Pharmaceutical Industry; *Health Affairs*, September/October 2001.

⁶ J.S. Weissman *et al.*, "Physicians Report on Patient Encounters Involving Direct-to-Consumer Advertising." *Health Affairs* Web Exclusive, April 28, 2004.

⁷ Federal Trade Commission and Department and the Department of Justice, *Improving Health Care: A Dose of Competition*; July 2004.

⁸ C. Lenfant, "Clinical Research to Clinical Practice: Lost In Transition?" *The New England Journal of Medicine*, August 28, 2003.

⁹ Dubois, R., *et al.*, "Growth in Use of Lipid-Lowering Therapies: Are We Targeting the Right Patients?" *The American Journal of Managed Care*, October 2002.

The pharmaceutical industry's investment in the discovery of new medicines is yielding important results for patients. For instance, just over the last few weeks, the FDA has approved a medicine that represents an entirely new approach to treating high blood pressure¹⁰ and press reports^{11,12} indicate promising trial results for three new medicines to treat HIV, including two that are entirely new approaches to attacking this virus and one that overcomes resistance to earlier drugs of its type.

At the same time that medical advances continue to meet patients' health care needs, medicines remain a small part of overall health spending. According to the latest estimates by the Centers for Medicare & Medicaid Office of the Actuary (OACT), spending on prescription medicines accounted for 10 percent of national health spending in 2005, and 8.5 percent of overall growth of health care costs. Other services accounted for over 91 percent of overall cost growth. In 2005, prescription drug spending growth slowed for the sixth consecutive year, reaching its lowest level (5.8 percent) since 1977.

Senator DORGAN. But the fact is, it's a—if not, it's a very close second. And this morning I once again, as I was getting ready for work, was asked if I shouldn't ask my doctor about several kinds of prescription drugs. A substantial amount is spent on marketing and promotion. Did you study whether reducing the expenditure for direct television ads, for example, asking me whether I could ask my doctor if the purple pill was right for me or for my colleague Senator Snowe—if they reduced that expenditure, could that amplify and help with additional research and development?

Dr. VERNON. I appreciate that question. And I would add that all businesses and companies, and politicians, for that matter, invest in marketing. It's part of the business practice. And firms make decisions on how much they're going to invest in R&D based upon expected future returns. To the extent that marketing expenditures enter into that, or other factors, it will impact R&D investment. However, the focus of our study was on how we can measure expected returns by the industry, and identifying the precise empirical link between those expected returns, prices, and profits, and R&D spending.

Senator DORGAN. Who commissioned the study, Dr. Vernon?

Dr. VERNON. This was not commissioned, and it was not funded. This was part of my doctoral research and also some of the first few papers I published when I was on the faculty at the University of Connecticut.

Senator DORGAN. But you've previously done work for the pharmaceutical industry.

Dr. VERNON. I have previously received funding from various organizations, including the pharmaceutical industry, that's correct.

Senator DORGAN. Ms. Barnett, the AARP supports this piece of legislation. I think it goes without saying—and I shouldn't have to say it at this hearing, but I will—I don't think there's anyone that would in any way ever suggest that they want to compromise our drug supply or do anything to diminish the safety of our drug supply. The testimony by Mr. Tauzin and others today, about counterfeits—counterfeit drugs—is disturbing to all of us. That is existing under a circumstance where importation really doesn't exist in any

¹⁰FDA Press Release. "FDA Approves New Drug Treatment for High Blood Pressure;" March 6, 2007.

¹¹Lawrence Altman and Andrew Pollack. "2 New Drugs Offer Options to Fight H.I.V. in Novel Ways". *The New York Times*, February 28, 2007.

¹²Marilyn Chase, "Emerging Drugs Show Promise Against HIV.", *The Wall Street Journal*. February 28, 2007.

managed way. But tell me, about what you think about Mr. Tauzin alluding to the fact that, “Look, since we now have Medicare Part D, you’ve got access to prescription drugs”—Mr. Tauzin described Tamoxifen. Tell me why the AARP is supporting this legislation, if you have Medicare Part D.

Ms. BARNETT. Medicare Part D will only cover up to a certain part before the consumer then has to go into the donut hole, and, at that point, you don’t reach the amount, necessarily, that is there, that cost. But, on the other hand, not all people—over half of our members are ages 50 to 64, and they’re not—Medicare and the prescription drug benefit is not available to them.

Senator DORGAN. Can I just complain about starting—getting letters from the AARP at age 35 or whenever it was I—

Ms. BARNETT. Of course you can, but you don’t—

[Laughter.]

Senator DORGAN.—whenever it was I started getting them in my mail? I mean, I didn’t feel old at that time.

Ms. BARNETT. Was this perceived 35 or was it actual 35?

[Laughter.]

Senator DORGAN. No, it was—it was actually perceived.

Senator Snowe?

[Laughter.]

Senator SNOWE. Thank you very much.

And I want to welcome the panel.

Former Congressman Tauzin, you were mentioning about former Secretary of Health and Human Services, Secretary Shalala. And, it’s interesting, to examine the three objections that she had—if I can find them here—back in 2000, when she said that it was “impossible for me to demonstrate that importation is safe and cost-effective.” First, she said, based on the provision which “allows drug manufacturers to deny U.S. importers legal access to the FDA-approved labeling that is required for reimportation.” Two, that “the drug reimportation provision fails to prevent drug manufacturers from discriminating against foreign distributors that import drugs to the United States.” And, third, that “the reimportation system has both authorization and funding limitations . . . the law requires that the system end 5 years after it goes into effect.”

So, all of those issues, in one way or another, have been addressed by our legislation. So, I don’t think it’s safe to say that you can characterize those three problems, as she mentioned them as issues upon which she had to oppose the legislation. She was required to certify for safety. She didn’t have the resources, and she only had a simple certification. So, we have addressed all of those issues in our legislation.

Mr. TAUZIN. She was required to certify two things, as the current law requires the Secretary to do, that is, not only that you satisfy all the safety concerns, which we—which we agree, with her and the current Secretary, cannot be safely satisfied, even with this legislation. And we’ll elaborate, as I said, further to you on that. And, second, the cost-effectiveness of doing it. CBO estimated a cost savings, if you did pass this bill, of 1 to 2 percent over 10 years, with no cost savings at all in the first 5 years. That’s CBO estimates. There have been some other experiences that—you don’t

have to take my word for it. Go to Massachusetts and check with their program. They abandoned importation when they discovered that prices in America were actually lower for many drugs, including the generic products—

Senator SNOWE. Yes, but isn't that the choice of the consumer?

Mr. TAUZIN. I'm sorry?

Senator SNOWE. I mean, I think—isn't that the choice of the consumer? I mean, why is the industry so—

Mr. TAUZIN. Well, but—

Senator SNOWE.—vigorously opposed—

Mr. TAUZIN.—but the problem is—

Senator SNOWE.—to it if—

Mr. TAUZIN.—the problem is, you're not going to make it the choice of the consumer. I'll be buying this stuff from my hospital when I go to the hospital, whether I want to or not. There's nothing in this bill that says I can opt out.

Senator SNOWE. Yes. Well, let me make another point here. Well, you can opt-out—you set up a safety system. That's the point. Then the consumer makes the determination whether or not they want to have access to—

Mr. TAUZIN. I wish—

Senator SNOWE.—imported medications.

Mr. TAUZIN. I wish—

Senator SNOWE. And you mentioned China. Can I just make—

Mr. TAUZIN. Yes.

Senator SNOWE.—clear here?

Mr. TAUZIN. Yes, go ahead.

Senator SNOWE. China isn't on our list. OK? I'm just—make that clear. And let me just say, the European Union's been doing it—parallel drug trading without incident for the last 30 years, and they label what is imported and what is not. We don't even have a system set up in the United States for counterfeiting. I mean, that's the interesting point here. You know, for all that's been mentioned about the preponderance of domestic counterfeiting, nothing has been done to address that.

So, I think that the point is, here, we're setting up a system, and you would have the labeling of imported medications, which I understand—because that could mean there would be more competitive pricing in the United States. So, I make that point—

Mr. TAUZIN. I invite you to check with the EU lately. Parallel trading is becoming a huge problem. They discovered two things. The arbitragers pick up all the savings. The consumers and the payers don't get any savings.

Senator SNOWE. Well—

Mr. TAUZIN. And the second thing is that counterfeiting is rising dramatically in Europe, and it's coming from China. It goes through Thailand, it arrives in Europe, and—as it's arriving in America from all of the countries that you list in the bill. You can't control it as coming from only those countries anymore.

Senator SNOWE. Well, you know—but I think it's interesting—that where we manufacture—I mean, it's on the map here—is all over the world. You know, as I said, over 40 countries in which we manufacture. And that's what we've done. And we're talking about FDA-approved facilities. And I think it's very important to say

that. We do that with manufacturing medications in over 40 countries. We certainly can set up a system. And if you have recommendations how better to improve our legislation, I would hope that we would get those recommendations. And——

Mr. TAUZIN. Sure. And we'll talk to you about it.

Senator SNOWE. OK, great.

And, Mr. Schultz, you've been in the position of our previous witness. You were former Deputy Commissioner for food—for Policy, Food and Drug Administration, is that correct?

Mr. SCHULTZ. Yes.

Senator SNOWE. OK. So, you've had a chance—and I know you responded to the Chairman's question—and you may have some other follow-up recommendations on specifics—is that correct?—in our legislation. But, overall, do you think the framework that we have is doable? I mean, is this something that can be done for importation, based on our approach in this legislation?

Mr. SCHULTZ. Yes. I think it's a very sound approach. And I think the important point is that it's going to improve things, in terms of safety. I don't know if it's going to be perfect, but it's going to inject resources to the FDA, it's going to allow FDA to inspect facilities, and, where there are commercial sales, it will require a chain of custody. So, this is a terrific improvement.

I mean, if I could say a word about price, there are two points. One is, the people buying these drugs from Canada would be really shocked to know that CBO is saying they're not going to save money because they're saving money today. The second thing is that the reason those CBO estimates may have showed no savings is because so many people are doing it today. The problem is they're not necessarily getting safe products. And what you've done in your bill is to set up a system where consumers will have much more assurance from FDA of safety. There's never going to be a promise. There's nothing risk-free. But we'll be moving in that direction.

Senator SNOWE. No, I appreciate that and would appreciate your future input on our legislation. So, if there's anything we can do to make adjustments in that——

Senator DORGAN. If I might just——

Senator SNOWE. Yes.

Senator DORGAN.—for Senator Snowe—this issue of savings, the CBO actually scored the bill that we offered to the FTC reauthorization, and they scored a savings of \$6.1 billion over 10 years for the Government and \$50 billion over 10 years for consumers. So, the CBO score, the most recent score for legislation nearly identical to that which we've reintroduced, does show a savings, both to the Government and the consumers.

Senator SNOWE. Thank you.

Dr. Vernon, you were focusing on the decline in R&D spending. And, obviously, we'll look at the information that you've provided. But, you know, the industry has spent about, I think, \$5.6 billion more. At least based on the 2004 numbers, in the United States than in Europe, even though our consumers are paying \$87 billion on higher prices than, foreign consumers. So, I mean, I think that the fact is if you start to compare the R&D spending of the 12 largest pharmaceutical firms by revenue, it's interesting—they have an

average R&D investment of 14.7 percent of gross revenues, and you compare that with other firms with high R&D requirements and low marginal costs of production, they have a similar investment rate. It's 14.4 percent of gross revenues. And yet, they produce—if you're talking about microprocessors, software, electronics—similarly situated, they produce products which they improve every year, and they're offered at lower costs, and they do not increase pricing of old products at two and three times the rate of inflation.

So, I don't see, with importation that the problem is going to result in R&D decline. That's not to include, frankly, the \$30 billion that's spent by the American taxpayer in support of the National Institutes of Health and other means for the research and development for medications that consumers benefit from in other countries. And we're paying the higher prices.

So, I just don't see where the argument is here that it's going to have an impact on the research and development, given what we pay here in America today, given what the American taxpayer's paying. I don't see that the higher margin is increasing the rate of investment in the research and development. And you compare that with other companies, as you look at these charts—they're similarly situated, and yet we don't get the benefit of lower drug prices.

Dr. VERNON. I appreciate that, and I would make a couple of remarks.

The first is, I do agree that the U.S. is subsidizing R&D. And that's because foreign markets and governments regulate drug prices, and, in the U.S., we largely do not. I would say, also, that the link between R&D spending and prices and profits is unequivocal, and is based on over two centuries' worth of economists' thought. And economists are united on that issue. So, I don't think that's a question.

And I do have a question about the comparison you made between R&D intensities on the two charts you showed, Senator I think what's relevant is pharmaceutical R&D spending to pharmaceutical sales—and I'm not sure, of those companies up there, if what was being represented was pharmaceutical R&D or total firm R&D to gross firm sales. Because a lot of the companies in the industry are diversified into various different types of businesses, I think that's an important distinction that needs to be made.

Mr. TAUZIN. Senator, can I add a—

Senator SNOWE. Yes.

Mr. TAUZIN.—thought, too? The big difference in the R&D spending in our industry, as opposed to other industries, is that the moment they invent something and get a patent on it, they can go to market with it. On the other hand, our companies have to spend money, over 14 years of clinical trials, before their product can go to market within their 20 years of patent protection. So, there's a very different economic model that, frankly, is getting very threatened today. But, at the same time, even the Japanese companies that are part of our organization do their R&D in America right now. Most of the European companies do their R&D in America today. They've left the countries, where the governments have initiated price controls, to come to this country to do their research and development. That's a fact.

Senator SNOWE. Well, I'd just point out another quote here from Hank McKinnell, who is a former CEO of Pfizer, and he said, "It's a fallacy to suggest that our industry, or any industry, prices a product to recapture the R&D budget spent in development."

Mr. TAUZIN. And he's right.

Senator SNOWE. So, I think—

Mr. TAUZIN. He's right. But what he—what you fail to have there is the rest of his statement, which is that they price it in order to make sure they can cover the next 14 years of R&D development for the next product in the pipeline.

Senator SNOWE. Yes, but the industry overall is pricing so that the American consumer pays \$87 billion more—

Mr. TAUZIN. And we're spending in—

Senator SNOWE.—than consumers in other countries—

Mr. TAUZIN.—we're spending—

Senator SNOWE.—plus the \$30 billion—

Mr. TAUZIN.—well over \$60 billion in R&D—

Senator SNOWE. Plus—

Mr. TAUZIN.—every year.

Senator SNOWE. Yes, but—plus the \$30 billion by—financed by the Federal Government.

And one more point by Hank McKinnell, because I think it is—it is an interesting point. He says, "Competition is good medicine for economies. Name an industry in which competition's allowed to flourish—computers, telecommunications, small-package shipping, retailing, entertainment—and I'll show you lower prices, higher quality, more innovation, and better customer service. There's nary an exception. OK, there's one. So far, the healthcare industry seems immune to the discipline of competition."

And I think that's what it's all about, and that's what we're striving for. I think we have an obligation to set up a system of safety and allow the consumers to make that decision in what they—

Mr. TAUZIN. Give us a chance to—

Senator SNOWE.—get benefit from.

Mr. TAUZIN.—compete against another free market, and we'll compete. But those are not free markets, Senator you know that.

Senator SNOWE. Thank you.

Mr. TAUZIN. Those are controlled markets.

Senator SNOWE. Thank you.

Senator DORGAN. Senator Vitter?

Senator VITTER. Thank you, Mr. Chairman.

First of all, with Billy Tauzin here, let me just, apart from this issue, setting this aside for a few seconds, let me thank you for all of your service and leadership to our state, which was exemplary throughout your career.

Mr. TAUZIN. Thank you, David.

Senator VITTER. And I personally appreciate that, and the people of Louisiana appreciate that.

On this issue, Billy, you started your remarks by remembering your work with John Dingell—

Mr. TAUZIN. Yes.

Senator VITTER.—going back to 1988. I guess one thing I would say is, what do you think the prescription drug inflation—cumulative inflation has been in those 19 years since 1988?

Mr. TAUZIN. Good question. Let me—

Senator VITTER. It's been—

Mr. TAUZIN. Let me—

Senator VITTER. It's been enormous.

Mr. TAUZIN. Let me address it. It is not soaring. It is not enormous. AARP issued a report, I think, yesterday—again, doing what they always do, which is to compare a list of patent drug products that are used by seniors, and examines only those in the marketplace, instead of the whole prescription drug marketplace. If you look at the 60 percent of the drugs that are consumed in America that are generic, and combine them with the patent drugs that come out of this 14 year expensive process—combine them together, the inflation rate of drugs in America has been moderating over the last 5 years and is lower than the healthcare inflation rate again this year, falling every year. It is not soaring, it is not exponentially rising. It's rising at a lower rate than healthcare inflation, and moderating every year. In fact, the number of new drugs coming off patent are alarming, frankly, because, as those new drugs come off patent, a lot of the companies are going to be in a very difficult position over the next 10 years.

Senator VITTER. Well, first of all, I think what we're largely talking about in this debate is nongenerics, because the generic issue is largely solved, in terms of price competitiveness in this country. So, I do think we're basically talking about nongenerics.

Mr. TAUZIN. Well, but you can't—

Senator VITTER. And that—

Mr. TAUZIN.—you can't—

Senator VITTER.—cumulative—

Mr. TAUZIN.—not talk about it. Do you know, in Canada, that generics cost about 167 percent of U.S. prices? You can't just talk about one set of drugs. In—

Senator VITTER. Well, the problem—

Mr. TAUZIN. If you look at the ten—

Senator VITTER.—is, you don't have generics for everything.

Mr. TAUZIN. No, but if you look at the ten top drugs, six of them are generic variations—

Senator VITTER. Right.

Mr. TAUZIN.—right now. And, as you heard, you know, when you look at the amount of time that a patent drug has left in its patent life, and the fact that these drugs are coming off pretty rapidly over the next 10 years, that 60 percent is likely to rise in this country. We're one of the highest users of generic products in the world, at 60 percent. It is working fairly well. Do we still have a problem of uninsured? Yes. And we ought to address that.

But here's another feature I hope you think about when you think about this bill and other bills on healthcare. We're 10 percent of the market. The healthcare dollars spent in America, pharmaceuticals represent 10 percent of that. They represented 10 percent in 1978, and they represent 10 percent today. We are not the biggest problem in the healthcare cost equation. Ninety percent of the problem is in other healthcare cost areas. But do we have a problem making sure seniors have access to affordable prescriptions? Yes. That's why we passed Part D. Do we have a problem with the 20 some odd million Americans who are chronically uninsured?

Yes. We ought to address that. But to open the door to a problem that's a one percent of problem in America today, that could become a 20 percent problem, in terms of counterfeits hitting this market. Just to try to solve a 10 percent or 7 percent problem, which is the difference in Canadian cost to Americans today. It is, I think, very risky, Senator Vitter. That's all I'm asking you to think about.

Senator VITTER. Well, my point is that, since 1988, nongeneric drug inflation has soared. Since 1988, as a result, this commerce across the border in these drugs has soared. And, of course, that's directly related to price.

And so, in—with that history behind us, in the current environment, I simply think it is an unworkable and unreasonable so-called solution to the safety issue to say we're going to put our finger in the dike. It's not working. We're—we are being deluged with this issue, to some extent; and to, sort of, just say "no" isn't a policy—

Mr. TAUZIN. We're not saying there's—

Senator VITTER.—it's not a workable policy.

Mr. TAUZIN. We're not just saying no. We've instituted, this year, some very important initiatives. I want to tell you about them.

First of all, the drug distributors in this country, their association, it's finally kicked out the secondary marketers. They're no longer a part of their association.

If you look the problem in the U.S. drug marketplace in counterfeiting and uplabeling and the concern we have about danger to patients, it was primarily in that secondary market. That's where the counterfeiters play. And they're playing as good a game as they played with heroin.

Second, Senator Vitter, we're meeting, today, with the distributors and the pharmacists to see if we can't accelerate the work on RFID technologies, nanotechnologies, to protect our system even better.

We're not just saying no. We're doing things, we're trying to protect the people under 200 percent of poverty who are uninsured today, with the PPA program—3.5 million new Americans covered with free drugs because of our program. We're working on the uninsured problem all over America. We're working with the distributors to come up with track-and-trace systems that are really good in this country.

All I'm asking you to do is to understand that we can't pass those laws for other countries. And the FDA can't regulate the distribution chain in other countries. And if you expect them to do so by passing a bill, I just want to warn you, as I tried to warn you about New Orleans a few years ago, one day we'll rue the day we opened up that flood. One day in this country, the deaths are going to pile up the way they're piling up around the world with malaria right now. Please think about that.

Senator VITTER. Let me suggest two other things we can do, and you all can be helpful to address the problem. One is to be more helpful and to not oppose generic reform. And, quite frankly, too often, in my opinion, the industry has been an obstacle to pro-generics reform.

Mr. TAUZIN. Yes, but Senator Vitter, I—

Senator VITTER. The——

Mr. TAUZIN.—you know, I can't speak for what happened more than 2 years ago, but I can tell you this, we are very open to working with you, and all of you, in making sure that drug prices are affordable and available in this country to people. That's why we started the PPA program. We've got—we've got a very different organization today. Give us a chance to work with you. I think you'll see a different face of this industry.

Senator VITTER. The second area where I think we need a lot of work is trade policy.

Mr. TAUZIN. Yes.

Senator VITTER. This is all created by vastly different prices between U.S. and other countries. That is largely created by strong or weak price-control regimes elsewhere.

Mr. TAUZIN. Exactly.

Senator VITTER. Now, we essentially, in my opinion, do absolutely nothing to attack that through our trade policy. I'm not saying we have all the power to change that overnight, but we certainly have some leverage and some opportunity to attack that. In my opinion, neither the industry nor this administration does anything meaningful to attack that. And that price difference is what creates this entire debate.

Mr. TAUZIN. Can I paint a quick picture before you—how difficult it is? Not only do we have countries like Thailand, which is a military government now, stealing patents, they've basically said they're going to just take our patents and produce our products without regard to IP protection anymore. And they're executing that right now in Thailand.

Not only do we have situations like that, we've got the underdeveloped world that can't afford to pay even generic prices for some life-saving drugs, like HIV drugs. And we're trying to set up a system in the world to make sure critical life-saving medicines reach people in the underdeveloped world who, like in America, can't afford their drugs. Mr. Chairman, we are trying to help that situation.

Second, you have the developing world, the middle-index countries, if you will, who are, like Thailand, trying to literally take advantage of American R&D, and literally stealing from the American people, in my view, their rights to the R&D they've spent for these products.

And then you've got the developed work that is not taking its fair share of responsibility for paying for that R&D. And I concur with you on that. We need a much stronger emphasis at our State Department on insisting that the——

Senator VITTER. Well——

Mr. TAUZIN.—developed world do a better job of paying for——

Senator VITTER. Again, on the——

Mr. TAUZIN.—it's that simple.

Senator VITTER.—trade front, the only activity I've seen, until we put a stop to it a couple of years ago, was an effort to embed anti-reimportation policy in trade agreements. That was the only effort I have ever seen, in terms of trade policy. I've seen no effort from the administration or the industry quite frankly, in trying to attack

the root issue of these price differentials, and trying to use all of our resources—

Mr. TAUZIN. Senator Vitter, I assure you, a lot of that—

Senator VITTER.—to solve that.

Mr. TAUZIN.—goes on. We belong to international organizations, the IFPMA. We to work with EFPIA. We work with a group called Dolder, globally, trying to influence those decisions around the world. But, without the leverage of our government saying something is wrong when other countries can take advantage of the consumers in America who are spending their dollars on this R&D—without your leverage, they're not going to change their policies. It's that simple.

Senator VITTER. Also want to briefly address the R&D issue, which is very important, in my mind. And let me state, up front, I'm not for reimportation to import price controls into this country, and that sort of argument against it is often made; I'm for reimportation, because I don't think price controls can survive a full-bodied reimportation policy in this country and in other countries.

And so, with that in mind, Dr. Vernon, you suggested that reimportation will basically drive down R&D. Does that take into account the possibility—the probability, in my mind—that if you have a full-bodied reimportation policy, it's—it doesn't simply import those prices that exist now in other countries, but it actually changes them, it raises them, as Dr. Schondelmeyer suggested, and lowers our domestic prices?

Dr. VERNON. Well, I think that's an excellent question, and a very—and the answer is very complicated, and I don't have a full answer. I think that if reimportation were undertaken on a large scale, such that we had forced-sales provisions and we did see prices falling in the U.S., the question then is, would that have an impact on prices abroad? Many economists believe that prices abroad are lower, not just because of price controls and price regulation, but also because average per-capita incomes in those countries are lower.

So, I don't know that we would—exactly how that would play out. And it's a very complicated issue, in terms of how these foreign governments would respond, and in terms of how the U.S. Government would interact with these foreign governments and—

Senator VITTER. Well, let me just suggest one of the things that would happen is, their buying pool would no longer be simply in their country; it would involve our country. And so, the per-capita income of that buying pool will increase. What I think you're going to see is an equalization of prices. I'm not saying it would be immediate or complete. But I think what you would see is a drive toward equalizing prices worldwide.

Dr. Schondelmeyer, you alluded to that a little bit. How do you think that would work with a robust reimportation policy?

Dr. SCHONDELMAYER. If the U.S. began a full-bore reimportation policy, the Canadian Government, the EU countries, are going to have the drug companies coming into them the next day, and they're going to be saying, "We can't continue with the prices we're paying you. We've got to change something." It would disrupt the market, in the short run. But they will have to change something.

If we're going to use average per-capita income as our measure, let's look at the average per-capita income of the uninsured Americans. And it's lower than most of those countries that are getting lower prices in other—in Europe, so why aren't we giving that lower price to the 47 million—and that's probably more people in America than most of those other countries, as well—why aren't we giving them those lower prices, if we're going to use that as our measure of how you price drugs?

Senator VITTER. Let me just—

Dr. SCHONDELMEYER. I think it's unfair to price the U.S. as an aggregate, because we probably have the greatest income disparities of any country in the world, or any major developed country in the world, compared to the European countries. And—

Mr. TAUZIN. Senator Vitter, can I tell you what Canada plans to do—

Dr. SCHONDELMEYER.—that makes a mess.

Mr. TAUZIN.—if you pass this? They're not going to lower their price. They're going to raise their prices in Canada. What Canada has threatened to do, and what they're likely to do, is to pass a bill, which they've got ready to go, which will ban bulk exports to America. They don't want to become our pharmacy. And neither does Europe. And they say that very clearly in their policy.

Senator VITTER. Well, again—and that gets back to trade, too. The question is, are we just going to allow that without consequence? I don't think we should. So, I think there are ways to attack that. But, again, my point is, a robust reimportation policy doesn't simply import prices from other countries to here, it changes prices worldwide—it lowers prices in this country, it increases artificially low prices elsewhere. And what I think it does is do nothing worldwide with regard to what's available for R&D, but it redistributes where all that R&D money comes from so that we don't have to pay 98 percent of it, or whatever very high percentage we pay alone as Americans.

Mr. TAUZIN. There's another feature, though. And the other feature that you can't discount is the fact that other governments, because they are the payer—they have single-payer systems—have limited resources to pay for the drugs that are used by their citizens. And the way they handle that is, they cut off access. In Canada, for example, on average, 20 percent of the pharmaceuticals that are available to Americans are not available to citizens in Canada under their single-payer system. In Japan, only 69 of the top 100 medicines are available to their citizens under their single-payer system. So, you won't necessarily drive up their cost. What you're more likely to do is to see more limitations on access to their citizens. I don't want to see that—

Dr. SCHONDELMEYER. And it depends on—

Mr. TAUZIN.—imported into America, by the way.

Senator DORGAN. Dr. Schondelmeyer, you wanted to respond to that.

Dr. SCHONDELMEYER. Yes, it depends on which drugs we leave off of that system. If we leave off Nexium or Ambien CR or Clarinex that are very similar to other drugs that really don't have any therapeutic difference, maybe we're better off.

I would argue that we already have the effect of European price controls imported in our market in the prices that are being charged to Americans now. We don't have free market pricing. We don't have market-based prices. It's been acknowledged. Dr. Vernon said that does affect our prices, and we essentially are subsidizing the rest of the world. So, the effect of that price-control system in Europe and in Canada is already in our market, and we're paying for it. And unless we squeeze back gently in some way, we will continue paying that higher price. I think we have to squeeze back, in some way, to get those other countries—I think passing re-importation will work much faster than trade negotiations with other countries to tell them to raise their prices. If you start reimporting from their countries at their lower prices, those prices will go up much faster than any negotiations are going to accomplish on trade negotiations, country by country.

Mr. TAUZIN. Well, but don't leave with the perception that we're just talking about Nexium. In Canada, you can't get Avastin. That's the drug that saved my life. You can't get it in Japan. You can't get it in Europe, in England and Wales. Both Avastin and Erbitux were deemed not cost-effective in those countries under their single-payer systems. So, don't think it's just a purple pill or a pill that you have of choice. Sometimes it's the pill that'll save your kid's life. Don't forget that.

Senator DORGAN. Mr. Tauzin, you've lost none of your skill or aggressiveness.

[Laughter.]

Senator DORGAN. And we appreciate your being here. I appreciate the entire panel.

I want to put a chart up, here, that shows you something that FDA Commissioner David Kessler has said in a letter to us. He talked about—our proposal, quote, “. . . provides a sound framework for assuring that imported drugs are safe and effective. Most notably, it provides additional resources to the agency to run such a program, oversight by FDA of the chain of custody of imported drugs back to the FDA-inspected plants, a mechanism to review imported drugs to ensure that they meet FDA's approval standards, and the registration and oversight of importers and exporters to assure that imported drugs meet these standards that are not counterfeit.”

I wanted to put that on the record, only because there's a great debate about this, I—and I think you will admit we've tried to provide fair opportunity for alternative views with this hearing. It will not surprise you to know that Senator Snowe and I will very soon work with our colleagues on the Commerce Committee to try to move this legislation, and we would hope, obviously, to get a vote on the floor of the Senate. Identical legislation is existing in the U.S. House.

And we will keep the record of this hearing open for 2 weeks. Should our witnesses wish to submit additional views, we will accept that.

Mr. Tauzin, you indicate you want to work with us on a range of things. We welcome that.

Mr. TAUZIN. Thank you.

Senator DORGAN. We would say the same to all of the witnesses.

Obviously, you know from my statements, and, I believe, from the statements of others on the panel here, that we feel strongly about this, and we represent constituencies across our country that feel, as I offered the question today, they feel that they shouldn't be paying the highest prices in the world. They feel it's unfair.

And so, we hold a hearing today, invite you. All of you are great to come.

Dr. Vernon, I wasn't suggesting your research is worthless because of who you've previously worked with, but I did want to have that in the record.

All of you have taken some time to be with us and driven from Connecticut and Minnesota and across the street—

[Laughter.]

Senator DORGAN.—and Kentucky. And let me thank you for taking the time to be a part of this discussion.

This hearing is adjourned.

[Whereupon, at 11:55 a.m., the hearing was adjourned.]

A P P E N D I X

JOINT PREPARED STATEMENT OF THE CANADIAN PHARMACISTS ASSOCIATION, THE
ONTARIO PHARMACISTS' ASSOCIATION AND THE BEST MEDICINES COALITION

Do No Harm: Congress Should Leave Canadian Prescription Drugs Alone

Canadian pharmacists, pharmaceutical distributors and patients are extremely concerned by the proposed *Pharmaceutical Market Access and Drug Safety Act of 2007*, and its serious implications for the integrity of Canada's prescription drug supply.

We understand fully that your hearings will focus on the impact of this legislation on the United States and its citizens. As you proceed, however, we would urge you to widen your perspective to consider the repercussions of this legislation on Canadians and their healthcare system.

Our representatives would have liked to make these arguments directly to you. Your committee has however decided to invite only a few organizations to speak at the hearings, excluding any representation from Canada, the country most directly affected by this proposed legislation. Under these circumstances, we urge you to consider the issues in this written submission.

We would like to focus on three points. Allowing Canadian price-controlled medicines to be imported in bulk into the United States will have serious consequences for Canadians and will be of very little long term benefit to Americans. Not only will such a measure damage the Canadian drug supply, it will in all likelihood lead to increased drug prices for Canadians. *The Pharmaceutical Market Access and Drug Safety Act of 2007* is a quick-fix solution to a complicated issue which will not, given the differences of scale between Canada and the United States, significantly reduce the cost of prescription drugs in your country.

This proposed legislation also puts the health of Americans at risk by opening your borders to increased counterfeit drugs and criminal activity from outside North America. Although our submission does not address this issue in detail, we fully share the deep concerns expressed by organizations such as the American Pharmacists Association on this matter.

1. A Threat To Canada's Supply

Canada's supply of prescription medicines is not limitless. It is designed for the demands of a population of 30 million, not for a market ten times that size.

Lipitor[®], Zocor[®], Prevacid[®], Nexium[®] and Plavix[®] are among the top ten most prescribed medicines in the United States. Although widely prescribed in Canada, our domestic supply of these drugs could meet only a small fraction of U.S. demand. For example, the Canadian stock of Lipitor represents the equivalent of just 14 percent of U.S. demand. Similarly, Plavix stocked in Canada is sufficient to meet only nine percent of U.S. demand.

Table 1.—Supply of Leading Prescriptions in the U.S. Available in Canada

Rank (by number of prescriptions filled in the U.S.)	Product	Number of prescriptions: U.S.—2005 (millions)	Number of prescriptions: Canada—2005 (millions)	Canadian share of U.S. demand
1	Lipitor	79,170	11,24	14%
2	Zocor	27,839	1,77	6.4%
3	Nexium	27,341	1,94	7%
4	Prevacid	25,020	1,75	7%
8	Plavix	23,973	2,15	9%

Note: Based on 2005 figures, IMS Health.

At the request of some Members of Congress in 2004, Professor Marv Shepherd of the University of Texas at Austin provided a comparative analysis of the size of the pharmaceutical market in the United States and Canada. By comparing the total number of prescription drugs dispensed in Canada with the number of prescriptions filled in the United States every day, Dr. Shepherd calculated that Canada's annual supply of prescription drugs would be exhausted in 38 days if U.S. residents were to purchase all their prescriptions in Canada.¹

This scenario is obviously meant to draw out the worst-case outcome but it effectively illustrates that bulk imports by the United States will very significantly curtail the supply available to Canadians. Indeed, as Table 2 illustrates, if 10 percent of U.S. prescriptions were filled in Canada, this would lead to a minimal increase in the size of U.S. supply while significantly reducing the amount of drugs available to Canadians.

Table 2.—Projected Increase on U.S. Supply if 10% of America's Prescriptions Were Filled in Canada

Rank	Product	Number of U.S. Prescriptions	10% of Canadian Supply	Projected increase based on 10% of U.S. prescriptions filled in Canada
1	Lipitor	79,170,000	1,124,000	1.4%
2	Zocor	27,839,000	177,000	0.6%
3	Nexium	27,341,000	194,000	0.7%
4	Prevacid	25,020,000	175,000	0.7%
8	Plavix	23,973,000	215,000	0.9%

Note: Based on 2005 figures, IMS Health.

To further illustrate the differences in size between the two pharmaceutical markets, the number of U.S. seniors is greater than the total Canadian population. To supply just half of U.S. seniors, Canada would have to increase its total annual prescription drug supply by 2.5 times, an increase that pharmaceutical companies would not be capable of achieving.

Shortages of prescription drugs are already on the rise in Canada. The Canadian Pharmacists Association reported in 2004 that 80 percent of pharmacists had experienced one or more drug shortages weekly. Pharmacists surveyed also stated that shortages were becoming more frequent.² Shortages are caused by a variety of factors ranging from issues with the manufacturing process to shortages of raw materials and also exports to the United States through Internet pharmacies. It is clear, however, that actively seeking bulk purchases from Canada would seriously compound an existing problem with the Canadian supply.

2. A Threat to the Integrity of Canada's Price-Control Regimen

If passed, the *Pharmaceutical Market Access and Drug Safety Act of 2007* will, in effect, distort and disrupt the Canadian pharmaceutical market. It will do so by providing a strong incentive to big-box retailers present in Canada (either American owned or not) to re-route their stock of price-controlled pharmaceutical products for sale at a higher margin in their U.S. stores. This practice, known as "arbitrage," would completely corrupt Canada's price-control regimen.

The resulting shortages will unavoidably lead to higher prices in Canada, negating the intended benefit of this legislation to the U.S.

Canadian provinces already face tremendous pressure to keep the costs of healthcare manageable. This bill could seriously compromise the various measures put in place in Canada to negotiate lower prices for prescription medication. Not only would this legislation lead to shortages for Canadians, it could possibly force provincial governments to further limit the number of drugs placed on their formularies, thereby further penalizing Canadian patients by limiting their therapeutic options.

3. Limited Benefit to the United States

Although the impacts of bulk importation on Canada's domestic drug supply and on Canadian patients is real, what is less clear is the net benefit the legalization of bulk imports would have on America's supply and American consumers.

¹ Marv Shepherd, *Drug Importation Analysis: Comparison of the Canadian Pharmaceutical Market Size with the U.S. and Implications for Drug Importations*, Center for Pharmacoeconomic Studies College of Pharmacy, The University of Texas at Austin, May 5, 2004, p. 13, <http://www.utexas.edu/pharmacy/research/institutes/pharmacoeconomics/candrugmarket.pdf>.

² Canadian Pharmacists Association, *Administrative Burden on Canadian Pharmacists Due to Drug Shortages*, November 2004, http://www.pharmacists.ca/content/hcp/resource_centre/practice_resources/pdf/DrugShortageReport-Final.pdf.

Given the small size of the Canadian market, it comes as no surprise that the U.S. Department of Health and Human Services concluded in December 2004 that “total savings to drug buyers from legalized commercial importation would be one to 2 percent of total drug spending and much less than international price comparisons might suggest. The savings going directly to individuals would be less than 1 percent of total spending. Most of the savings would likely go to third party payers, such as insurance companies and HMOs.”³

Conclusion

Canada’s drug supply and price control systems were intended to meet the health care needs of Canadians, not to provide Americans with a quick fix or a band-aid solution to the cost of prescription drugs in your country. The real purpose of this bill is not the importation of cheaper prescription drugs, but rather the importation into the United States of Canadian price controls. The United States should not be cherry picking parts of Canada’s healthcare system.

Once U.S. demand depletes Canadian stocks, prices will almost certainly rise, narrowing or possibly even eliminating the difference between U.S. and Canadian pharmaceutical prices. In short, there is no long-term advantage to be gained in raiding Canada’s regulated market. Further, there is always the likelihood that the Canadian Parliament would simply ban bulk exports of prescription drugs to the United States. The undersigned organizations have called on the government of Canada to institute such a ban, immediately, in order to protect the Canadian drug supply and pricing system and to protect Canadian patients. In fact, Canada’s Health Minister has recently indicated to our organizations a willingness to pass legislation that would do exactly this.

The *Pharmaceutical Market Access and Drug Safety Act of 2007* is deeply flawed. It will not solve the problems of high drug costs in the U.S. but will certainly increase prices paid by Canadians and restrict the number and quantity of prescription drugs available to Canadian patients.

If adopted, it is clear that this proposed legislation will strain Canada-U.S. relations. We urge Members of Congress to consider this possibility. We call upon you to see beyond the narrow scope of domestic issues, and to consider the full range of consequences that would attend the passage of this legislation.

JEFF POSTON,
Executive Director,

Canadian Pharmacists Association.

MARC KEALEY,
CEO,

Ontario Pharmacists’ Association.

LOUISE BINDER,
Chair,

Best Medicines Coalition.

PREPARED STATEMENT OF PETER PITTS, PRESIDENT, CENTER FOR MEDICINE IN THE PUBLIC INTEREST

Mark Twain once said that there’s a simple solution to every complicated problem—and it’s usually wrong.

The issue of broader access to safe and effective drugs is an extraordinarily complicated problem.

And importation of foreign drugs is a simplistic solution with a container-full of unintended consequences.

Let me get one thing out of the way right away. If you walk into a pharmacy in Windsor, Ontario and have your prescription filled by a real pharmacist—the drugs you receive will be both safe and effective.

But—when the “learned intermediary”—a doctor or pharmacist—is replaced by a greedy intermediary (a storefront drug dealer or an unregulated Internet site) then all bets are off. Profiteers masquerading as pharmacists bode poorly for both safety and effectiveness. Those who support importation of foreign drugs are endangering the lives of Americans.

Recently an 81-year-old man suffering from epilepsy and an enlarged prostate purchased what he was led to believe were FDA-approved drugs from a website purportedly representing a Canadian pharmacy.

³Department of Health and Human Services, *Report On Prescription Drug Importation*, December 2004, p. 65, <http://www.hhs.gov/importtaskforce/Report1220.pdf>.

Upon receipt, he noticed that they were from India. He called the FDA, and we determined that not only were the drugs not from Canada, but they weren't even approved for use in the United States.

Nature abhors a vacuum. Large-scale importation (because those floodgates can't be opened only part way) will create the silent sound of drugs crossing the border from Canada and *thru* Canada into the United States.

And that vacuum won't be refilled with safe and effective drugs.

They'll be replaced with unapproved knock-offs, gray market substitutes, counterfeits, and *similares* from South America coming into the U.S. thru Canada. In fact, that's already happening today.

Recently, the Canadian Health Minister who, under tremendous political pressure to continue a charade, instead told the truth about the cross-border drug trade and the dangers that it poses to both Americans and Canadians.

"I want to make sure that we don't have . . . 250 million Americans buying drugs in Canada," he said in an interview Dec. 12 on a CTV television show in Canada. "We cannot be the drugstore for the United States."

Indeed. The Minister clearly sees that as the Internet pharmacy cowboys soak up the Canadian drug supply for their own profit, domestic Canadian pharmacists are reporting more and more shortages.

What's more, our neighbors to the north are becoming ever-more concerned about medicines from nations outside their regulatory purview—drugs that may be sub-potent, superpotent, expired, or just plain counterfeit.

The Canadian Health Minister recognizes the danger to the public health of Canada and his government is preparing to take action. Any American who wants a prescription from a Canadian pharmacy may soon be required to first visit, in person, with a physician in Canada.

Why such a dramatic departure from previous practices? Consider this . . .

Recently, a doctor in Toronto was indicted for co-signing 24,212 prescriptions for American patients he had never seen—at \$10 a pop. Health Canada means business, because when doctors start selling their signatures, health care consumers are being sold a bill of goods.

Canada's new policy will end importation "as we know it." The fantasy of "Canada-only" drugs will be showed to be just that. And, according to a recent poll, 54 percent of Americans oppose importing drugs from European countries.

The FDA is faced with enough challenges policing drug safety at home; do we really want them to stretch their resources even further and become responsible for drug safety globally?

According to the recent report issued under the signature of Admiral Richard Carmona, the Surgeon General of the United States, opening up our borders to drugs "*from Canada*" would result in an uncontrollable influx of untested, impure, expired, and counterfeit drugs from around the world. That's just a fact. It may not be politically popular, but facts are stubborn things.

The various state and local websites promising something for nothing have received, according to a recent *Wall Street Journal* article, "Tepid response."

That article continues, "With great fanfare, at least nine states over the past year launched websites to help their residents buy inexpensive prescription drugs from Canada. But so far, the sites aren't doing much business."

Fortunately, the American consumer is smarter than a lot of demagogues give them credit for.

People ask me—aren't the drugs from Canada coming into the U.S. genuine? Well, I can tell you this—the oxycontin and vicodin, the darvocet and the valium are—at least for now.

Illegal, unsafe importation presents the very real danger of turning the Internet into the 21st century's virtual drug cartel. And we must not let that happen.

"Buyer Beware" is bad health care practice and even worse health care policy. Americans deserve both safety and savings. Trade-offs are just not acceptable.

When the Governor of New Hampshire said he was going to start allowing the importation of Canadian drugs, my sound-bite was that while "Live free or Die" is a great state motto, it's irresponsible health care policy.

But consider Minnesota. Recently Governor Tim Pawlenty launched a state-endorsed website called "Minnesota RXConnect." This website provides both information on and facilitation to Canadian websites that illegally sell non-FDA approved pharmaceuticals. This action is unsafe, unsound, and ill-considered.

When you recommend that citizens go outside of our regulatory system and enter into a "buyer beware" gray zone, you assist those who put profits before patient health and, by the way, shine a bright light on a path that can (and, indeed, is) used not only by profiteers masquerading as pharmacists, but by outright criminals who do not pause before actively feeding counterfeit drugs into the marketplace.

During pre-announced visit by Minnesota State officials Canadian pharmacies were observed engaging in dangerous practices. Minnesota state officials noted dozens of safety problems. For example:

- One pharmacy had its pharmacists check 100 new prescriptions or 300 refill prescriptions per hour, a volume so high that there is no way to assure safety.
- One pharmacy failed to label its products, instead they just shipped the labels unattached in the same shipping container, even when patients received multiple medications in one shipment.
- Drugs requiring refrigeration were being shipped un-refrigerated with no evidence that the products would remain stable.
- One pharmacy had no policy in place for drug recalls. Representatives of the pharmacy allegedly said that the patient could contact the pharmacy about a recall “*if they wished*”.
- One pharmacy re-dispensed medicines that were not labeled and apparently had been previously returned by U.S. Customs.
- Several pharmacies failed to send any patient drug information to patients receiving prescription drugs.
- All of the pharmacies generally allowed customers to fax in their own prescriptions. This not only fails to assure the validity of the prescription; it means that patients can get multiple drug orders from a single prescription, including for more risky drugs.
- Only one of the pharmacies visited had a thermometer in their refrigerator to verify that labeled storage requirements were being met for refrigerated products.
- Many drugs obtained through at least one of the pharmacies were apparently not even of Canadian origin, and many of the drugs were obtained from a difficult-to-follow path of writing and rewriting prescriptions across multiple Canadian provinces.
- Equally concerning was the statement from one of the pharmacy presidents who allegedly said, “We won’t have any problems getting drugs. We have creative ways to get them.”

And these were *licensed* Canadian pharmacies!

A one-time pre-arranged “visit” to *any* Internet pharmacy is no substitute for a comprehensive system for assuring the safety of the prescription drugs used by Americans.

Minnesota officials *knew* these facts and *still* went ahead with their program.

Wisconsin residents who used Governor Doyle’s website received unapproved generics in place of the brand name medicines they were promised—despite their contractual promise to the Governor that they would only provide “FDA-Approved” drugs.

Sometimes a bargain is just too expensive—and nowhere is that more true than when it comes to counterfeit prescription medicines—the inevitable follow-on of the drug importation schemes under consideration by Congress.

Around the world, millions of people are exposed to a real health threat every day—the danger of taking the wrong medication. This spreading problem has nothing to do with patients mixing up their pills. Rather, it’s caused by the proliferation of counterfeit drug traffickers, who are profiting immensely from selling fake medicines.

To combat this threat, the FDA requires distributors to keep detailed records of the sources of the medications they dispense. But that’s a futile undertaking. Drug counterfeiters have become so sophisticated, they can produce drugs and packaging that cannot be differentiated from the real thing without complex chemical analysis. Paper “pedigrees” are next to useless.

With huge profits, counterfeiting is increasing at a phenomenal pace. The Center for Medicine in the Public Interest estimates that counterfeit-drug commerce will grow 13 percent annually through 2010. Counterfeit sales are increasing at nearly twice the rate of legitimate pharmaceutical sales.

Illegal drugs are a money machine. In 2010, it’s estimated that fake drugs will generate \$75 billion in revenues—a 92 percent increase from 2005. And the risks of detection and prosecution are low.

Authorities are concerned. The EU recently released statistics on counterfeit-drug sales in Europe. Canadian authorities have made some high-profile arrests. But overall, the results of enforcement have been marginal.

Two years ago, when the FDA claimed that counterfeit drugs were being used to fund global terrorism, some politicians accused the agency of being in the pocket of

Big Pharma. Today, these same politicians are strangely silent. The recent news that North Korea has gone into the business of manufacturing and selling counterfeit drugs has put a muzzle on the anti-pharma gang. Trashing patents to produce generics is one thing. Manufacturing totally useless fakes is entirely different.

It's not a stretch to call it health care terrorism.

The issue is global. National borders mean nothing to these criminals. Pharmaceuticals are easily smuggled, because medical supplies are a humanitarian need. Law authorities are frequently stymied. Our FDA must work with the World Health Organization, Interpol and other international public health and law enforcement organizations. Jurisdictions overlap. Fake drugs, substituted for the real thing, move under the cover of aid efforts. And then both can be sold to double profits.

The war against prescription-drug counterfeiters is hampered by what is known as "parallel trade." Individual drug packages—140 million last year—are imported to the countries of the European Union. Once inside the EU, a wholesaler is allowed to repackage each one before sale.

The intent is humanitarian. But the potential for abuse—and illegal profits—is enormous. At the most basic level, drugs are mislabeled. Dosages are misstated; a label indicates tablets instead of capsules; expiration dates don't match the medication; and labels are in the wrong language or outdated.

Even when the "confusion" is unintentional, the results are dangerous. A drug purchased by a consumer from an Internet pharmacy purported to come from a British pharmacist could originate in any EU nation. In Britain, it's estimated that parallel-traded medicines account for approximately 20 percent of all prescriptions filled. No one really knows what's happening in America.

Since the EU does not require the recording of batch numbers for parallel-imported medicines, there is no way to track shipments that are recalled. If a batch of medicines originally intended for sale in Greece is recalled, tracing where the entire batch has gone (*e.g.*, from Athens to London through Canada to Indianapolis) is impossible.

More dangerous than the lack of quality control is that such practices allow counterfeiters to integrate their products into legitimate supply chains. The WHO estimates that 8 percent to 10 percent of the global medicine supply chain is counterfeit—rising to 25 percent or higher in some countries.

The largest counterfeit market with close proximity to the EU free trade zone is Russia, where approximately 12 percent of drugs are said to be counterfeit. Now that the Baltic nations of Latvia, Lithuania, and Estonia have joined the EU, the WHO has warned that there is increased risk of counterfeits entering the supply chain.

It's time to stop accusing the drug industry of crying wolf about counterfeit drugs. Policymakers must confront the serious business of ensuring that drugs entering our markets are legitimate and safe. It's an area where mistakes are dangerous to everyone's health.

RESPONSE TO WRITTEN QUESTION SUBMITTED BY HON. BYRON L. DORGAN TO
RANDALL W. LUTTER, PH.D.

Question. The main point of your testimony was that counterfeit drugs are entering the U.S. drug supply. You also talked about online pharmacies that consumers thought were in Canada but turned out to be located in other countries. I don't think anyone disagrees that there are currently no regulations in place to protect consumers who are often forced to decide whether to import a prescription drug or forego filling a prescription altogether.

Where we disagree is what should be done to protect consumers, which is the mission of your agency. As you know, I have introduced legislation with Senators Snowe, Grassley, Kennedy, McCain, Stabenow and many others to put in place an effective regulatory framework to allow consumers to safely import more affordable, FDA-approved prescription drugs from Canada and several other countries. I was troubled that you had not taken the time to read this comprehensive legislation.

After you take the time to review our legislation, please let me know if you agree with the conclusion of Former FDA Commissioner David Kessler that the Pharmaceutical Market Access and Drug Safety Act of 2007:

1. "Provides a sound framework for assuring that imported drugs are safe and effective."
2. "Provides additional resources to the agency to run such a program."
3. Ensures "oversight by FDA of the chain of custody of imported drugs back to FDA-inspected plants."

4. Provides “a mechanism to review imported drugs to ensure that they meet FDA’s approval standards.”

5. Mandates “the registration and oversight of importers and exporters to assure that imported drugs meet these standards and are not counterfeit.”

If you disagree with Dr. Kessler, please provide a detailed explanation.

Answer. Thank you for the opportunity to testify at the March 7, 2007, hearing entitled, “Policy Implications of Pharmaceutical Importation for U.S. Consumers,” before the Senate Subcommittee on Interstate Commerce, Trade, and Tourism. The Food and Drug Administration (FDA or the agency) is responding to address the March 9, 2007, correspondence you sent in follow up to that hearing.

Your correspondence included statements made by former FDA Commissioner, David Kessler, at an April 19, 2005, hearing entitled, “Examining S. 334, to amend the Federal Food, Drug, and Cosmetic Act with respect to the importation of prescription drugs,” held by the Senate Committee on Health, Education, Labor, and Pensions. Dr. Kessler’s statements focused on the issues of safety, resources, supply chain security, and standards for approval of foreign versions of FDA-approved drugs. You asked that I explain my views on the “Pharmaceutical Market Access and Drug Safety Act of 2007” in the context of these issues. The bulk of this response details our views about these issues.

I would like to start, however, by commending you for your efforts to address American consumers’ concerns regarding access to affordable prescription medications. Nevertheless, the agency continues to have concerns with enacting such a sweeping importation program and fears that intermediaries would likely swallow the bulk of cost-savings, preventing American consumers from enjoying much, if any, practical benefit from such a program. We expect such a result might lead consumers to continue to look for substantial savings on their prescription medications by seeking products outside the legalized importation system, just as some do now. We continue to observe that many consumers buy drugs from foreign Internet sources even though generic versions of those products are approved by FDA and such products are generally cheaper in the United States than abroad.

We note that legalizing commercial importation may have unintended effects on protection of intellectual property and may reduce incentives for research and development, as noted in the 2004 report issued by the Health and Human Services’ (HHS) Task Force Report on Drug Importation.

Safety Concerns

We have safety concerns related to both the identification of unsafe and or non-compliant drug products and about the substitutability of foreign products for domestic products.

Identifying Unsafe/Non-compliant Drug Products

The section of the bill that would allow individuals to import a qualifying drug from a registered exporter would likely pose an overwhelming resource burden for the agency and create significant safety concerns. Under such a program, the anticipated high volume of products would make it extremely difficult for FDA and U.S. Customs and Border Protection officials to examine adequately all of the personally imported drug products to ensure that they comply. In fact, the HHS Task Force estimated that it would have cost \$3 billion annually to examine and process each of the 10 million packages that entered the U.S. in 2003. Even if a lower level of examination were considered adequate, the costs to FDA would still be very high.

Despite its registration and inspection fee provisions, the bill likely provides inadequate resources to conduct such examination on a routine basis. Resources are limited to 2.5 percent of the total price of qualifying drugs imported by registered exporters, an amount likely to be a small fraction of the cost of inspecting packages at international mail facilities.¹ This is a particular concern because, once personal

¹The 2004 HHS Task Force report noted that individuals in the U.S. imported from Canada some \$695 million of drugs amounting to 12 million prescriptions in 2003. Assuming that each parcel contained two and a half prescriptions, the value of a parcel would be approximately \$145, so that the revenues to FDA from each parcel would be about \$3.62, if the fees were capped at 2.5 percent of the price of qualifying drugs being imported. But the HHS Task Force report notes that the cost of inspecting packages in 2003 was about \$264 per package containing drugs, suggesting that the fees provided by the bill would be grossly inadequate for the tasks asked of FDA. Put differently, the fee revenue from importation of drugs from Canada at this scale, if capped at 2.5 percent of the price of the imported drugs, would provide less than \$20 million to FDA. The HHS Task Force report, however, noted that the total cost of inspecting

importation is given the appearance of legality, consumers may be less vigilant in scrutinizing the drug shipments they receive from abroad.

S. 242 would establish a complicated system for the regulation of imported drugs. This complex system is so vast that it would be enormously resource-intensive, likely much greater than the proposed registration fees and inspection fees could support. The bill and its associated fees also do not appear to account for the costs of the increased volume of packages likely to inundate the U.S., or address the accompanying and likely substantial enforcement work that will arise as a result of legalized importation as more unscrupulous vendors set up shop to circumvent the new U.S. system.

Lack of Substitutability

The proposed bill provides a mechanism for foreign imported products to be approved for distribution in the U.S. even though these products may not be bioequivalent to the FDA-approved product. This mechanism seems to by-pass the existing drug approval process for drug products that are not bioequivalent to an FDA-approved product, which is through the submission of a new drug application (NDA) that is thoroughly reviewed for safety and efficacy. Ultimately, the bill appears to establish for imported drugs an alternative to FDA's existing generic drugs program.

The bill would allow non-bioequivalent products to be sold in the U.S. as approved "variations" of the innovator product under the existing NDA, which would create confusion for doctors and pharmacists in prescribing or dispensing, respectively. Dr. Todd Cecil of the U.S. Pharmacopeia testified at the April 2005 Senate HELP hearing regarding pharmaceutical equivalence and bioequivalence and his concerns with this bill. In addition, doctors cannot anticipate which version of a drug product their patients will receive, and pharmacists may not know which version of a drug the doctor intended to prescribe. The possibility of confusion is significant and poses a real public health concern as this increases the chance of error in prescribing and/or dispensing of medications. In addition, the domestic and foreign versions of prescription drugs may become commingled in the drug supply chain. It is unclear whether a patient will be able to specify if he wants the foreign version or the original FDA-approved version when he gets his prescription filled at the pharmacy or receives medication at a hospital or other medical treatment facility.

Inadequate Resources

It is uncertain whether the anticipated fee revenues will be realized because the market response to legalization of importation cannot be accurately predicted. This uncertainty could pose problems for FDA's program, because large costs of starting and developing a program to regulate imports will have to be incurred even if the volume of legalized imports is initially low. Although the bill does assume certain sales volumes in the first several years for purposes of collecting inspection fees, with only a few registered importers and exporters participating initially, the high *pro rata* share of fees may actually discourage participation and make it difficult for FDA to collect fees at the designated levels. Even once a program is developed, the bill is not likely to provide the necessary funds to continue an adequate regulatory program if inspection fees are low because imports do not reach the anticipated levels.

Supply Chain Security

We are proud of FDA's efforts with supply chain stakeholders and states to maintain a safe and secure drug supply in the U.S. that is premised on a closed, tightly regulated system. The type of drug importation program in the bill would increase the number of foreign entities FDA would have to monitor and regulate. It can be difficult for FDA enforcement to reach foreign entities violating our laws and regulations. This bill would open the door to more entities outside our domestic legal framework. We also have grave concerns for consumers who may be harmed from products from these foreign sources. The bill does not take into account protecting the rights of the consumer if they are injured after using one of these products.

As we all agree, counterfeit drugs must be kept out of the U.S. drug supply chain. FDA is currently using its resources and authorities as efficiently as possible to secure the drug supply chain and protect American consumers from counterfeit and diverted drugs. Opening the U.S. drug distribution system to foreign markets would provide more opportunity for counterfeit drugs to enter our currently closed system and would significantly complicate FDA's efforts to investigate irregularities in the drug supply chain.

all incoming shipments in 2003 (including products from countries other than Canada), would have amounted to nearly \$3 billion, an amount more than 100 times greater.

Conducting foreign investigations and prosecutions is inherently costly and difficult and often is complicated by language barriers and issues of extraterritorial jurisdiction and extradition. We are concerned that the bill does not provide sufficient enforcement tools and penalties to deter foreign entities from introducing counterfeit or otherwise substandard drugs into the U.S. drug supply chain.

Approval of Foreign Versions

We believe the bill creates complicated application and inspection requirements for imported “foreign” versions of FDA-approved products. These requirements would be difficult to implement, as each foreign country has its own regulatory scheme and requirements for the information necessary to approve a drug product. FDA would essentially have to review foreign information in a foreign format, all in less time than is required for review of traditional NDAs. In addition, the bill would require imported “foreign” versions of a drug bear the labeling associated with the original FDA-approved product. This practice would essentially legalize the misbranding of these products, and raises concerns for FDA not only in the approval context but also in the counterfeits context. It is difficult enough for FDA and other Federal enforcement agencies to detect counterfeit drug products and packaging; creating a mechanism that would allow persons to label foreign drugs with reproductions of FDA-approved labeling would make it even harder to distinguish between “legal” foreign products and counterfeits.

U.S. consumers currently have a number of options available to them when looking for affordable medications within the closed U.S. drug distribution system. Many essential drugs have a generic alternative and some even have many generics, which are generally less expensive than the brand product. We continue to find that many consumers currently buying foreign products are actually trying to purchase, or are unknowingly receiving, a foreign product that often is more expensive than the U.S. product. In addition, the consumers are at risk when receiving foreign drug products, as there are documented cases where the wrong medication was received (the haloperidol case mentioned in my testimony). Many pharmaceutical companies and Pharmaceutical Research and Manufacturers Association of America offer discounts and sometimes even free medications for consumers who cannot afford them. Medicare Part D has also helped some seniors cut their prescription costs. Consumers should not feel restricted to higher priced innovator (brand) products.

Consumers must also understand that if a medication is costly, they should discuss other treatment options with their doctor and pharmacist, as most often there are lower-cost alternatives available. We will continue to strive to make more affordable medicines available to consumers, but we remain concerned about the implications of legalizing drug importation as one of those options.

In conclusion, I would like to reiterate concerns about the economic implications of prescription drug importation, as stated in the 2004 HHS Task Force Report on Drug Importation. Even if all the safety concerns could be allayed, these concerns would remain: that savings to U.S. consumers would be small as a percent of total drug spending; that implementing such a program would incur significant costs; and that legalized importation would likely adversely affect the future development of new drugs for American consumers. In 2004, the HHS Task Force Report noted that generic drugs account for most prescription drugs used in the U.S. and that these are usually less expensive in the U.S. than abroad. We thus have a well-functioning system of intellectual property rights that balances the short-term interests of consumers with the long-term research incentives.

Thank you for the opportunity to address some of our concerns with S. 242.

ATTACHMENT 1

PREPARED STATEMENT OF DR. BENJAMIN ZYCHER, SENIOR FELLOW IN ECONOMICS,
PACIFIC RESEARCH INSTITUTE FOR PUBLIC POLICY*

BEFORE THE COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS

U.S. SENATE—FEBRUARY 17, 2005

**Pharmaceutical Importation, Price Controls, Federal Price Negotiations,
and the Interests of Consumers**

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 from foreign consumers to U.S. consumers in the short run, with adverse consequences for U.S. consumers in 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

*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.

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

²See *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.

³See, 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.

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 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 drug¹⁰—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.

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

⁵In 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.

⁶This 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.

⁷See S. 334, the “Pharmaceutical Market Access and Drug Safety Act of 2005”; and S. 109, the “Pharmaceutical Market Access Act of 2005.”

⁸See fn. 1, *supra*.

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

¹⁰See, 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. Brantner, “Estimating the Costs of New Drug Development: Is It Really \$802M?” December 2004.

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 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,

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.

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 power¹⁴ 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 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.

ATTACHMENT 2

RESPONSE TO WRITTEN QUESTIONS SUBMITTED FOR THE RECORD BY THE COMMITTEE ON HEALTH, EDUCATION, LABOR AND PENSIONS, U.S. SENATE TO DR. BENJAMIN ZYCHER, SENIOR FELLOW, PACIFIC RESEARCH INSTITUTE FOR PUBLIC POLICY, MARCH 2005

Dear Mr. Chairman, and Distinguished Members of this Committee:

I submit respectfully for the record the answers below to the written questions addressed to me.

Questions From Senator Enzi

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

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

¹⁵See, 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.

¹⁶See Institute of Medicine, *Financing Vaccines in the 21st Century*, Washington D.C.: 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.

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. 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 improved 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. 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

¹Note 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.

²The issue of the efficient structure and length of patent rights in the pharmaceutical context is not addressed here.

³The 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.

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. 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 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. 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 pharma-

⁴In 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.

⁵See, 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.

⁶Note 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 controlled prices and market value might be captured in whole or in part by various transaction agents (“middlemen”) under a broad range of market conditions.

⁷See 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.

ceutical 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.

Questions From Senator Kennedy

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. Do you agree with that assessment?

Answer. 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 and possibly the short run, by inducing profit-seeking producers to reduce their U.S. prices.

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

Answer. 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 1b. Would increased generic savings impact innovation?

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

Answer. Yes; see footnote 5 above.

Question 2a. If so, should the Department of 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. 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 im-

⁸For 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.

⁹See 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.

proved 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 2b. Should comparative effectiveness play a role in approval or R&D or marketing incentives?

Answer. 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.

