

**EXAMINING THE IMPLICATIONS OF DRUG
IMPORTATION**

HEARING
BEFORE THE
COMMITTEE ON THE JUDICIARY
UNITED STATES SENATE
ONE HUNDRED EIGHTH CONGRESS

SECOND SESSION

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EXAMINING THE IMPLICATIONS OF DRUG IMPORTATION

WEDNESDAY, JULY 14, 2004

UNITED STATES SENATE,
COMMITTEE ON THE JUDICIARY,
Washington, DC.

The Committee met, pursuant to notice, at 10:03 a.m., in Room 2156, Hart Senate Office Building, Hon. Orrin Hatch, presiding.

Present: Senators Hatch, Kyl, Leahy, Kohl, Feinstein and Feingold.

OPENING STATEMENT OF HON. ORRIN G. HATCH, A U.S. SENATOR FROM THE STATE OF UTAH

Chairman HATCH. I am happy to begin this hearing.

Many Americans, especially senior citizens, are understandably seeking more affordable prescription drugs and are wondering if drugs imported from Canada and other countries may be the answer. Several bills have been introduced on this topic, including those by respectively Senator Grassley, Senator Gregg and Senator Dorgan, from whom we will be hearing shortly.

The purpose of today's hearing is to begin the Judiciary Committee's deliberation over the many issues related to drug importation that fall under our Committee jurisdiction. Today's hearing will largely focus on whether amending the longstanding, carefully crafted law, the Prescription Drug Marketing Act of 1988, that established a tightly regulated, closed system of prescription drug distribution in our country, will open the door to counterfeit and otherwise adulterated or misbranded drugs being widely distributed to an unwitting public.

Representative John Dingell, the dean of the House of Representatives and a prime sponsor of the 1988 PDMA law, succinctly summarized the problem: "The very existence of a market for re-imported goods provides the perfect cover for foreign counterfeits."

Now, we will hear today from the FDA, and the Bureau of Customs and Border Protection on the problem of counterfeit drugs. The FDA has documented many cases of what appear to be FDA-approved imported drugs that, in fact, were contaminated or counterfeit, contained the wrong product or the incorrect dose, were accompanied by inadequate directions or had outlived their expiration date. Unfortunately, the FDA has witnessed a sharp spike in such counterfeiting and their partners at Customs will tell us that this is not an easy crime to detect or to prevent.

Later in the hearing, we will hear from Rudy Giuliani, a former tough-nosed prosecutor, who will tell us why we should think twice before we do away with the protections in current law.

I am mindful that on several occasions the Senate has adopted an amendment offered by Senator Cochran that requires the Secretary of Health and Human Services to certify the safety of imported drugs before they can enter the United States. Neither Secretary Shalala nor Secretary Thompson—one a Democrat, one a Republican—could make that simple, but prudent, certification with respect to the additional risk to public health.

Given the testimony submitted by the Agency today, it seems that the safety of imported drugs remains in doubt in the minds of the experts at FDA and a strong case can be made that Congress would be well advised to retain the protection afforded by the Cochran Safety Amendment.

Frankly, it may be beneficial for Congress to receive the report from the Secretary's Task Force on Drug Importation before legislation is considered in this area. I recognize that the report is not due until after the election and that the strategy of the same is to attempt to use Election Day politics as leverage for legislation and that sound policy will not win out.

We all want medicines to be safe and affordable, yet we do not want to take steps that stifle the innovation that has made the United States the world leader in pharmaceutical development. Importing drugs from other countries in order to take advantage of other countries' price controls has other potential repercussions, including the prospect of diminished research into future lifesaving treatments. We need to think carefully about the long-term effect of this trade-off.

In this regard, I commend the efforts of Senators Kyl and Thomas for a hearing they recently held in the Finance Committee that examined the critical, yet almost totally overlooked, question of whether U.S. trade policy can be used to see that the citizens of our trading partners are paying their fair share of pharmaceutical R&D. The fact is that American taxpayers are putting up \$28 billion of their hard-earned money this year for biomedical research at the National Institutes of Health, while year in and year out many other countries essentially free-ride on U.S. research and development activities, and then set price controls on the approved drug products that are the fruits of this U.S.-financed research. It is the American taxpayer and consumer that is paying dearly.

Consideration of pharmaceutical importation raises many complex issues beyond the problem of counterfeiting. For example, concerns have been raised about the manner in which Senator Dorgan's bill, S. 2328, affects patent and antitrust law. The bill appears to alter current law with respect to domestic patent rights once overseas sales occur. One of the areas that this Committee should explore as this debate moves forward is how the doctrine of international exhaustion of patent rights might be altered by the Dorgan legislation.

I would note that last year this Committee played a constructive role in correcting the excesses in the proposed changes to patent damages by the Gregg-Kennedy-McCain-Schumer bill even after it passed the Senate by an overwhelming majority. It can take time

to fully analyze and refine inherently intricate pharmaceutical-related statutes. For example, I think that most objective observers would now agree that last year's Senate-passed bill contained a blatantly unconstitutional provision relating to declaratory judgments that was corrected in large part by this Committee's involvement.

In short, as drug importation legislation is crafted and considered, this Committee must remain vigilant in examining not just the counterfeit problem, substantial as it is, but also patent issues and other matters under our jurisdiction such as any potential antitrust and Takings Clause issues. For example, the extent to which the Dorgan legislation appears to preclude manufacturers from charging exporters market-based prices for drugs, if they are higher than the lowest price-controlled price of the exporting country, deserves the scrutiny of our Committee. As a defender of, and believer in, property rights, including international property rights, I am always leery of systems that impose Government-mandated prices, sales or licenses.

Finally, I must note that I am far from certain that importation is the magic bullet that will, instantly and without repercussions, lead to lower drug prices. I am concerned that importation may eventually provide the bullet in a grand-scale game of pharmaceutical Russian roulette.

I am willing to continue to work with my colleagues on ways to make prescription drugs more affordable for the American public and to devise ways to do so that do not jeopardize patient safety or undermine the incentives for the discovery of the next generation of therapies.

This is an important hearing. Everybody who testifies here today is an important human being and person, and we look forward to hearing the testimony on both sides of these issues.

With that, I will turn the time over to the distinguished Ranking Member.

**STATEMENT OF HON. PATRICK J. LEAHY, A U.S. SENATOR
FROM THE STATE OF VERMONT**

Senator LEAHY. Well, thank you, Mr. Chairman. And I agree with you that this is an important issue, actually one that has profound implications for the American public. Actually, Vermonters were among the first to throw a spotlight on this whole issue of prescription drug importation. We followed this issue closely for years. We have been pushing for a consumer-friendly solution.

I am pleased that we on this Committee have the opportunity to restate the very compelling case for the establishment of a safe legal system to import portable drugs into the United States. I wish we might actually have a chance to vote on it on the Senate floor. We spend week, after week, after week debating issues that we know will go nowhere, but are designed to be used in campaign ads. It would be nice to actually debate something that might help the American people. Americans pay some of the highest prices for prescription drugs of any country in the world, despite the fact that many of these drugs are made right here. And we talk about research oftentimes as taxpayer-supported research that goes into these drugs. Prescription drugs become a lifeline not a luxury.

Now, when we were faced with this dilemma, and with Washington's unwillingness to help, many Vermonters and other Northern border citizens were among the first to take matters into their own hands. Congressman Sanders, who is going to testify, started leading trips to Canada 5 years ago, and he used it this way. I think, Congressman, you remember having these to go. He wanted to let Vermonters safely buy affordable medicines on the other side of the border, where struggling seniors are able to find savings of anywhere from 50 percent to 70 percent, and buses like this were powerful early symbols in opening this debate. They have been effective, much like Senator Dorgan's use of his famous orange rubber pylon in demonstrating the lack of security along the Northern border.

Incidentally, another issue, it would be nice if we could take time to pass the bill for homeland security. I understand the Justice Department now is turning loose a lot of the people that are picked up at the border who are illegal aliens because they do not have the people to hold them.

Now, American consumers did not take long to figure out the deck is heavily stacked against them. They found ways to vote with their pocketbooks and with their bus tickets. But meanwhile the White House, big drug companies and many in Congress have done all they can to thwart this. Now, those trips worked for a while. But for seniors who could not easily make the trek across the border, there had to be another option. That is where mail-order entered the equation. And now mail-order has drastically transformed the importation of medicine.

The fact is, again, to use a symbol of the bus, I think Congressman Sanders, and I and everybody else would agree this is not the way Americans should have—they should not have to get on a bus to go and get affordable medicine prescribed by their doctors. And the fact that they have had to resort to creative solutions like that should have shamed the Congress and the White House into acting long before now.

In my home State of Vermont, our Republican Governor, our Democratic attorney general, the mayor of our largest city have all spoken out on the unmet needs of the people of our State, but their pleas and those of State and local Governments have not been heard. At the same time, American consumers are moving ahead with or without us. They know they have been dealt a raw deal. They see this raw deal in black and white each month when they sit down at their kitchen tables to pay the bills. It boils down to access.

A prescription drug is neither safe nor effective if you cannot afford to buy it. And we have to recognize this imposes real dangers on American consumers when they cannot follow what their doctors have prescribed. And while we have to do more to bring affordable health care to the millions of Americans who are currently uninsured or do not have good coverage, we cannot deny them this immediate market-based solution.

And for many Vermonters purchasing drugs from Canada, it literally means the difference between following their doctor's orders or having to roll the dice with their health and sometimes with their lives by not having prescription medication. It makes a dif-

ference for the woman who has maxed-out her health plan's annual prescription drug benefit only 3 months into the year. It makes a difference for the elderly man on a fixed income who is unable to afford both the heart medicine he needs to live and the fuel bills he needs to keep warm.

As regulators and policymakers sit idly by in Washington, the pharmaceutical industry, in one of the most obscene moves I have seen, moving to cut off supplies to Canadian pharmacies in order to prevent Americans from purchasing their drugs at affordable prices. I wonder how these people sleep at night. Are we prepared to tell those in dire need that they have to go back to choosing between paying gas, food and heating bills or their medicine?

We owe it to the American consumers to stop asking whether we can set up a system to provide safe importation. Of course, we can. We should be coming together without further delay to establish a self-financed system and give FDA and Customs the resources they need. We put our stamp of approval in allowing American consumers to purchase prescription drugs from Canada three times over the past 4 years. Of course, it gets blocked by the Executive Branch. Let us hope someday we might actually do what the American people want us to do. The administration fought every effort we made during debate on the Medicare prescription drug bill to give some leverage to consumers and taxpayers.

In the last few days, we also have another thing which shows what the administration is doing to block this and to actually get in bed with the big drug companies. We have some very troubling and unpublicized provisions in the proposed Free Trade Agreement with Australia. That agreement that is negotiated by the White House seems to pose real threats to drug importation. It has new provisions not found in earlier agreement with other countries. It appears to have been written by the pharmaceutical companies.

We have a lot of capable witnesses this morning, and I will put my whole statement in the record, but I know Senator Dorgan, Senator Breaux, Senator Nickles here, and Senator Dorgan worked so hard on this. And Mr. Hubbard, Mr. Taylor and Mr. Durant will be coming here, Mr. Giuliani, Mr. Catizone, Ms. Jaeger, Ms. Disch, Professor Schondelmeyer, of course a fellow Vermonter, Dr. Elizabeth Wennar, who is the CEO and executive director of United Health Alliance in Bennington, Vermont. Her organization, which is really reflective of community physicians, rural hospitals, nursing homes, home health agencies in Southwestern Vermont, is a model for the rest of the country. They were a pioneer in importing prescription drugs from Canada by mail, and she has done extensive research on this.

Doctor, I thank you for being here.

So, Mr. Chairman, I will put my whole statement in the record, so we can get on with the hearing.

[The prepared statement of Senator Leahy appears as a submission for the record.]

Chairman HATCH. Thank you, Senator.

I would like to welcome our first panel of witnesses. First, we have one of our colleagues from the House of Representatives, Congressman Bernie Sanders. We are happy to have you here.

Representative SANDERS. Thank you very much.

Chairman HATCH. Next to testify will be Senator Don Nickles, who has been a strong supporter for protecting the health of the general public and has raised some serious concerns about imported drugs.

Next, we will have Senator Byron Dorgan, who is the sponsor of S. 2328, the Pharmaceutical Market Access and Drug Safety Act of 2004.

And, finally, we have Senator John Breaux, who led efforts on the Senate floor to advocate for consumer safety and drug effectiveness.

It is a diverse panel, and we are happy to have you here with us today, and we will begin with you, Representative Sanders.

STATEMENT OF HON. BERNARD SANDERS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF VERMONT

Representative SANDERS. Senator Hatch, thank you very much for allowing me to say a few words. Senator Leahy, thank you for your strong efforts on this issue.

Senator it seems to me that we are dealing with two issues here this morning. Number one, at a time when millions and millions of Americans are unable to afford the prescription drugs they need to stay alive or keep them healthy, the key question is whether the American people will be forced to pay, by far, the highest prices in the world for the prescription drugs they need or whether Congress will finally end that obscenity and allow Americans to pay world prices for the drugs that they need. That is Issue No. 1.

And the second issue, equally important, is whether democracy will prevail on Capitol Hill or whether the pharmaceutical industry, which has spent hundreds and hundreds of millions of dollars in recent years, with lobbyists, with advertisements, with huge amounts of campaign contributions, will be able to continue to force the American people to pay these outrageously high prices.

Senator this is not just about prescription drugs. It is about democracy. It is about whether senior citizens in the State of Vermont, who live on \$12- or \$15,000 a year, will get justice or whether big money will continue to prevail.

As Senator Leahy indicated, some 5 years ago, I became the first member of the U.S. Congress to take constituents over the Canadian border, and we border on Canada, as you know. And I will never in my life forget that trip, Senator. I had on the bus with me a number of women who are struggling with breast cancer, and many of these women took Tamoxifen, which as you know is a widely prescribed breast cancer drug, but a lot of these folks just do not have a lot of money. And when they went to Montreal and were able to purchase Tamoxifen for one-tenth of the price that they were paying in the United States, when they were able to purchase a drug which was keeping them alive, they could not literally believe that reality. They were stunned.

And all over this country, people are asking why is it that right across the Canadian border, in Europe, people are able to purchase the same, exact medicine, manufactured by the same companies, produced in the same factories, why are they able to purchase those medicines abroad for a fraction of the price that we pay in this country?

Now, the truth is the evidence I believe is overwhelming that the safety issue, the so-called safety issue, is a bogus issue. Senator, when we go out to lunch this afternoon, I am going to have—and I am happy to take you out to lunch this afternoon—and I will treat you to a salad.

Chairman HATCH. Oh, no, I have to eat a lot if I go to lunch.

[Laughter.]

Representative SANDERS. And we will have some lettuce and tomatoes that probably come from Mexico or somewhere in Latin America or maybe we will have some grapes that come from Chile or we will have some pork that comes from someplace. In the United States, we eat food that comes from all over the world, from farms and ranches, frankly, that we know very little about, and yet what we say is that is not a problem or it is a problem that we can deal with because we have confidence in our Government agencies to protect the safety of Americans, health safety.

Now, if we can eat food from all over the world, how is it that the Food and Drug Administration cannot regulate a handful of pharmaceutical industries and track the medicine that goes abroad and comes back? And obviously the answer is that in the House bill, which by the way, as you know, passed overwhelmingly with bipartisan support, in the Dorgan bill we have strong legislative language that makes sure that the FDA is watching and approving the medicine that comes back into this country.

Now, people say, well, we have a potential safety problem here. And it is a problem, but it is a problem that I am absolutely convinced the FDA and the U.S. Government can address. But, Senator, let us talk about another safety problem that does not get the discussion that it needs. Let us talk about elderly senior citizens in Vermont living on \$12,000 a year or \$14,000 a year who get sick, and in some cases die, because they cannot afford the medicine that they need. How many thousands of people are needlessly suffering, and in some cases dying, because they cannot acquire the medicines that their doctors prescribe?

Now, I do not know if you have had the same experience that I have had. But I talk to physicians in Vermont, and what they tell me is why should I bother making out a prescription for a patient when that patient cannot fill that prescription? They do not have enough money to go to the drug store to buy it?

So let me just conclude by saying this: The pharmaceutical industry is the most powerful lobby in the United States of America. They lie very often, they set up phony organizations very often, they put out misleading campaign literature very, very often, they contribute huge amounts of money to members of the House and the Senate. In Europe and all over the world parallel trading has been going on for a very long time. It seems to me that the evidence is overwhelming that we can stand up for the senior citizens of this country. We can stand up for the sick of this country. We can lower prescription drug costs by 25 to 50 percent by simply saying that for all those folks here who believe in free trade for every item in the world, why can we not have free trade for prescription drugs?

Senator Leahy was right. We have been talking about this issue year after year, after year. The American people have made it clear

in poll after poll this is what they want. And the spotlight right now is on the U.S. Senate, where I understand the votes are there to pass strong reimportation legislation.

Senator let us stand up for the American people. Let us have the courage to take on the big-money interests. Let us lower prescription drug costs by 25 to 50 percent, and let us give the American people the help that they are crying out for.

Thank you very much.

[The prepared statement of Representative Sanders appears as a submission for the record.]

Chairman HATCH. Thank you, Representative Sanders.
Senator Nickles?

**STATEMENT OF HON. DON NICKLES, A U.S. SENATOR FROM
THE STATE OF OKLAHOMA**

Senator NICKLES. Mr. Chairman and other members of the Committee, thank you for having this hearing and for having a divergent view of opinions on your first panel, and I expect on your subsequent panels as well.

And I compliment Representative Sanders. He is an articulate spokesperson for his party. I happen to have a different view, a strongly different view. I do not want to import the Canadian health care system or pharmaceutical system or price control system into this country. He does. I respect that, but I disagree.

He said that there would be savings of 25 to 40 percent. CBO did an analysis of H.R. 2427, the Pharmaceutical Market Access Act of 2003, which passed the House last year, and they determined the savings would be "The reduction in drug spending from importation would be small," 1 percent maybe. What would we get for that 1-percent savings? We would get a lot of safety problems. We would probably get a lot of counterfeit drugs. We would probably have a lot of people eventually die as a result of getting the wrong drugs or the wrong dosage, and probably more importantly than that, we would probably see a real deterioration of the research and development that we do in the pharmaceutical in this country.

Many, many of our colleagues, many, many of our family members have had very serious illnesses. Many of their lives have been saved because we have advance medicines in this country. I am excited to think what advances will be made in the next 5 or 10 or 20 years. Whether you are dealing with cancer or heart disease or Alzheimer's, you name it, there is a lot of progress in a lot of areas that will save lives.

I am really concerned that if in this effort to save not 25 or 50 percent, but maybe 1 percent, that we will jeopardize safety, and we will also very much jeopardize the improved quality of drugs that we are now in the process of making in this country. That would be a very shortsighted, and I think a very significant, serious mistake.

So I just wanted to mention that. I am concerned about quality. I am concerned about Canada's law. I do not want the import Canadian law. I read the Canadian Food and Drug Act, and I will just quote Section 37.1. It says, "This act does not apply to any packaged food, drug or cosmetic device not manufactured for consump-

tion in Canada and not sold for consumption in Canada if it is marked with export.”

Then, the Canadian deputy health minister stated, “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. Health Canada is first and foremost concerned about the health and safety of Canadians.”

And we dealt primarily with Canada in previous iterations of drug importation bills. Now, I believe in Senator Dorgan’s bill that has expanded to another 19 or 20 countries. I do not know what the laws are in those other 19 or 20 countries. I do not know that I want to know what the laws are in those 19 or 20 countries, but I am concerned. Do those countries allow or do they provide for safety and quality inspections for drugs that are imported into their country for export? Canada did not. And so if Canada was importing drugs from other countries that maybe had less quality control or maybe from countries or companies that had a significant counterfeit experience, but yet saved money, would we be importing those drugs? Canada has already said it is not going to be responsible for it.

So I think you could have a real deterioration of quality. We will hear from FDA or this Committee will hear from FDA shortly. They have repeatedly stated that we could not certify for the safety and quality of drugs that are imported from other countries. And so there was a reason why we put in language in the past that said, yes, importation is okay as long as the Secretary would certify that it was safe and cost-effective.

Both Secretary Shalala of the previous administration—Democrat administration under President Clinton—and Secretary Thompson under President Bush have said that was not the case. Their neck was on the line, that they were responsible, and they stated that they could not certify that those drugs would be safe.

I do not think we should ignore FDA nor do I think we should set up a system to be so intrusive to mandate companies that they have to sell any quantity to these 20 countries. You talk about an interference in free enterprise, I cannot think of anything. And I also understand that that was in the bill. I was reading that in Section 27, “Restraint of Free Trade,” basically mandating that U.S. manufacturers have to sell whatever quantity some importer for export might have in these 20 countries. That is such a violation, such an intrusion into the marketplace. It is almost an invitation for everybody to leave the United States. I hope, and expect, that that will not become law, and I will work to see that it does not.

Mr. Chairman, thank you very much for your allowing us to testify.

Chairman HATCH. Thank you, Senator Nickles.
Senator Dorgan?

**STATEMENT OF HON. BYRON L. DORGAN, A U.S. SENATOR
FROM THE STATE OF NORTH DAKOTA**

Senator DORGAN. Mr. Chairman, thank you very much. I am wondering if we should close the loop and tell Congressman Sanders that you are not going to have lunch with him?

[Laughter.]

Chairman HATCH. Actually, it sounded like a pretty interesting lunch—salad, pork, just about everything.

Representative SANDERS. It is on me.

Chairman HATCH. We will do it someday, Bernie.

Senator DORGAN. Mr. Chairman, this is a serious issue and requires, I think, thoughtful discussion. A man in North Dakota, about a week ago, came up to me and said, "You know, my wife has purchased Tamoxifen for 5 years in her battle against breast cancer, and she has traveled to Canada during the entire 5-year period to buy this Tamoxifen. She received an 80-percent discount on the price of Tamoxifen by driving across the border to buy the same pill, put in the same bottle, made by the same company, FDA-approved." Five years they did that.

The question I have is if she drove across the border for 5 straight years, why should her pharmacist not have been able to access that same supply of drugs and pass those savings along to that woman who was battling cancer?

Now, my colleague talks about importing Canadian law. Lord, we import everything from everywhere. We import Chinese law, incidently. Fruit of the Loom left America, as you know, to go to Mexico and China. So, if you are wearing Fruit of the Loom briefs, I assume you are importing part of Chinese law with whatever conditions existed with the production of Fruit of the Loom briefs.

But this is not about importing anybody's law. It is about using a market system to access a product. There is, in fact, a price control system in this country. There are price controls in the United States. It is just that the pharmaceutical industry controls the price, and the question is why should there not be a free market that is determining what pricing is with respect to pharmaceutical products.

Now, I hear all of this discussion about how difficult this might be. This is a pretty inventive country. Europe has done this for 20 years, and today if you are in Germany and want to buy a prescription drug from France, no problem. There is something called parallel trading within Europe. They do it every day. You are in Italy and want to buy something from Spain, no problem, parallel trading. They do it, and we have had them testify before our committees. It is routine. This is not some huge problem. It is routine, and it is done routinely in Europe.

Now, I have gone to a one-room drug store in Emerson, Canada with senior citizens. I have seen the savings that they receive by buying an FDA-approved drug put in the same bottle. So the savings are not a fiction. I have brought two bottles with me today, one Canadian and one U.S.

This happens to be Lipitor, but I could have brought any one of a dozen other bottles. Lipitor is the best-selling drug in our country. As you can see, not only the same size bottle, essentially the same colors. This is the same pill made by the same company, made in an FDA-approved plant. The only difference is—and, incidently, both made in Ireland—the only difference is one was sent to Winnipeg and one was sent to a drug store in North Dakota. Well, this costs \$1.01 per tablet in Winnipeg and this is \$1.86 per tablet in North Dakota. Why almost double the price for the North

Dakota consumer or for the American consumer? Because, under the current pricing scheme, the U.S. consumers pay the highest prices in the world.

Senior citizens are 12 percent of our population. They consume one-third of our prescription drugs, and many of them take multiples of prescription drugs. We all know these are wonderful drugs, but miracle drugs offer no miracles to those who cannot afford them. So our bill is an attempt to allow reimportation under safe conditions.

I introduced the first bill on this 5 years ago in the U.S. Congress, and we are not there yet. The debate is largely over in the public's mind. Mayors, Governors, Republicans, Democrats, Senators, Congressmen, are all supporting importation. It is just those who are at this point blocking it that do not yet understand it. The only way this continues to be blocked is the White House and the leaders of the House and the Senate. The votes exist in both the House and the Senate to do this. Mayors and Governors around the country are already moving full steam on this issue.

Now, at midnight, on the floor of the Senate, the Majority Leader, Senator Frist, in exchange for my allowing a vote on Dr. McClellan, has given me his commitment that we will be considering legislation that will lead to the reimportation of prescription drugs on the floor of the Senate. I read a statement in the paper yesterday that suggested some deviation from that, but that is a statement in the paper. I have not talked to Senator Frist about his statement, but my expectation is that he will keep the commitment he has made to me and that we will be voting on this issue in the Senate.

Again, this is not, Mr. Chairman, a small issue. And I do not denigrate the pharmaceutical industry. I understand, if you are in that industry, your responsibility to your shareholders is to extract the best prices you can, keep the profits as high as you can. But the need to take prescription drugs is not an option for some. Some take 5, 10, and 15 different prescription drugs every day, and especially some senior citizens who are reaching that time of life where they have less income simply cannot afford it.

And we believe an approach that is used in Europe routinely called "parallel trading," we call it "reimportation," is something that could be helpful in bringing down, putting downward pressure on the price of prescription drugs in this country.

And so, Mr. Chairman, let me thank you for holding a hearing. I know there is wide disagreement about this subject, but the fact is this issue is largely over. Ultimately, those who are now blocking importation legislation will not be able to continue to block it, and we will have reimportation and let the market system be the arbiter of these pricing policies on all FDA-approved drugs just as it is in Europe. And so, Mr. Chairman, thank you very much.

I have to leave, and my understanding is that you are not going to do questions of this panel.

Chairman HATCH. That is right.

Senator DORGAN. But let me thank my colleagues as well and understand that, while we have a disagreement, it is a respectful one, and I hope that this hearing will lead to movement on this leg-

islation that Senator Snowe and I and so many others have introduced.

[The prepared statement of Senator Dorgan appears as a submission for the record.]

Chairman HATCH. Thank you. We will not hold any of you here who need to leave. We know how busy you are.

Senator Breaux, you will be our last—

Senator LEAHY. Mr. Chairman, may I just ask consent, we have a statement by Senator Kennedy on this.

Chairman HATCH. Without objection, we will put that in the record.

**STATEMENT OF HON. JOHN BREAUX, A U.S. SENATOR FROM
THE STATE OF LOUISIANA**

Senator BREAUX. We will send each other copies of our statements so we can read them as soon as we get back to our offices.

[Laughter.]

Senator BREAUX. Thank you very much, Mr. Chairman, Senator Leahy, and Senator Feinstein, and Senator Kyl. Thank you for allowing a Congressional panel to present testimony.

I think I want to make three points:

First is: Why are we here? Well, we are here because a substantial number of American citizens, particularly senior citizens, are complaining loudly, longly, and very effectively to the Congress of the United States that their prescription drugs are unaffordable, that they cost too much. And they point out to us that some countries have drugs that are cheaper than ours. So what are you going to do about it, Congress?

Well, Congress has acted. Congress has acted responsibly. Just this year, the Congress passed, and the President signed, legislation that is going to spend approximately \$400 billion. For what? To help seniors in particular who have the biggest problem be able to afford adequate prescription drugs in a timely and safe manner. Four hundred billion dollars of tax dollars have been put into a Medicare program to assist American citizens to be able to buy their prescription drugs at an affordable price. We now have a discount card program in effect. If you are a poor senior couple, you can make as much as \$1,200 a year on going to your prescription drug bill. When the program is fully implemented, we are talking about prescriptions costing as little as \$1 to \$3 for seniors who have a difficult time paying for their prescription drugs.

Senator Leahy showed us the Vermont bus. I would suggest that people in that bus were not going to Canada to see a doctor, even though doctors in Canada are much cheaper. I would suggest that people on that bus were not going to Canada to go to a hospital, although hospitals in Canada are much cheaper than in the United States of America. Why? Why? Because they have insurance that covers their hospital bills. They have insurance that covers their doctor bills.

And I would suggest that when the Medicare prescription drug legislation fully is implemented, it will, for the first time, provide seniors a prescription drug insurance plan just like they have today with regard to doctors and hospitals, greatly alleviating the need to get on a bus and go to Mexico or Canada or import drugs from

anywhere else in the world. Congress has responded. Congress has acted responsibly. Four hundred billion dollars will help solve the problem so that we do not force our seniors to go to foreign countries for our health care. I think that is very significant.

Second point. Are drugs cheaper in Canada or in Mexico? Of course, they are. Drugs are substantially cheaper in Canada. Why? Not because of a U.S. drug conspiracy by the companies to sell products cheaper in another country, but because Canada and other countries arbitrarily, through Government policies, fix prices. They are forcing the United States' consumers to pay more for our products in this country because our citizens are forced to pick up the burden of what other countries should be sharing with us in terms of research and development. We are forcing American constituents and consumers to pay more because of flawed policies in other countries.

This is a trade problem, and it should be addressed through trade negotiations to tell other countries that we are not going to be buying your products or allowing you to market your products in this country if you continue arbitrary price-fixing policies that we condemn in this country. It is obvious that the answer to this problem is not to accept policies of foreign Governments that we criticize in our own country.

I would suggest that when Canada fixes wheat prices, which they do through a monopolistic system, do we say, "Bring all the Canadian wheat into the United States with no restrictions because, by golly, it is good for our consumers?"

When the timber that is grown in Canada is fixed because of governmental policies, do we say, "Sell all the lumber that you want in the United States at any price you want because it is cheaper than we can produce it in this country?" Of course, not.

When a dairy producer in another country can, because of fixed prices and subsidies in a foreign country, can sell milk in this country cheaper than we can produce it here, do we say, "Bring it all in"? Of course, not. We address it through tariffs and trade negotiations, and this is what we should be doing as well with regard to pharmaceuticals. We should not say, "Come on in. Bring it in because it is fixed prices, and we love it."

Not only does this legislation that is before us say, "You can bring it in," we actually demand that companies sell more than they need for the consumers of Canada so that they can, in reverse, bring it back to this country. A great shareholders' liability suit would I think prevail in that circumstance. That is not the way to address the problem.

Third and final point. It is a question of safety. My good friend Byron Dorgan brought out his two bottles. I am going to bring out two bottles as well. This bottle sells for \$2 a bottle. This bottle sells for about \$40 a bottle. It is a high blood pressure medicine. It looks the same, does it not? Same label. Same good marks on it. Same numbers on it as when it expires, when it was produced. It has the same company label on it. But this one, the real thing, which costs more, is real. It actually solves a person's high blood pressure problem and keeps them perhaps from dying because they are taking the proper pharmaceutical medicine.

This, on the other hand, is filled with something that if you eat enough, it may fill you up, but it is not going to take care of your high blood pressure because it is fake. It has not one single safe ingredient in it that this one does. Is it cheaper? Yes, it is a lot cheaper, but it is not real. It is fake.

If we get one mad cow that comes across the border from Canada, this country goes berserk. We stop imports. Other countries stop exports because one cow came over which had mad cow disease. Should we not at least say to people who are taking medicine to save their lives that they are going to have the same belief and certainty that it is safe as if that medicine was produced in our country, and FDA said it was safe? Why make a special exception if it was produced in another country? Drugs come in from Canada, not just those that are made in Canada. They are made in Singapore, Ecuador, Thailand, Indonesia, Pakistan. Canada is and will become a great funnel for foreign drugs which are unsafe, and in many cases counterfeit if we take that approach.

I would suggest that Congress has already done what is right. Let us make it work.

Thank you.

Chairman HATCH. Thank you. We appreciate all four of you and appreciate the testimony each of you have given. As you can see, there is a wide disparity of agreement and disagreement here.

We will put a statement by Senator Grassley into the record at this point or at the appropriate point, and let me introduce our second panel.

We have Mr. William K. Hubbard, the associate commissioner for policy and planning for the Food and Drug Administration; Mr. John Taylor, the associate commissioner for regulatory affairs for the Food and Drug Administration; and Elizabeth G. Durant, director of trade programs for the Bureau of Customs and Border Protection.

We want to welcome all of you here. Senator Kyl, if you will take over for a few minutes. I will be right back. I just have to step out for a minute. But we will begin with you, Mr. Hubbard and then go right across the table.

I will be right back.

STATEMENT OF WILLIAM K. HUBBARD, ASSOCIATE COMMISSIONER FOR POLICY AND PLANNING, FOOD AND DRUG ADMINISTRATION, AND JOHN TAYLOR, III, ASSOCIATE COMMISSIONER FOR REGULATORY AFFAIRS, FOOD AND DRUG ADMINISTRATION

Mr. HUBBARD. Thank you, Mr. Chairman. If it is acceptable to the Committee, Mr. Taylor will make a couple of brief remarks about FDA's policy in this area, and then I have got some exhibits that I would like to show the Committee about some of our concerns.

So, with that introduction, Mr. Taylor?

Senator LEAHY. Excuse me, if I might, Mr. Chairman. Are those these things that were just handed to us a couple minutes ago?

Mr. HUBBARD. Yes, those are our exhibits, essentially.

Senator LEAHY. I will tell you what, I will read them, if that saves you the time, but go ahead.

Mr. HUBBARD. Thank you. Go ahead.

Mr. TAYLOR. Thank you. Mr. Chairman and members of the Committee, I am John M. Taylor, associate commissioner for regulatory affairs of the Food and Drug Administration. With me, is Mr. William K Hubbard, associate commissioner for policy and planning.

We appreciate the opportunity to discuss with you issues relating to counterfeit drugs and importation of prescription drugs into the United States.

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

Nonetheless, FDA continues to have serious public health concerns about the importation of drugs outside the current safety system established by Congress under the Food, Drug and Cosmetics Act. When it comes to buying drugs, absent our existing regulatory protections, FDA has consistently concluded that it is unable to endorse a buyer beware approach.

Currently, the new drugs market in the United States, regardless of whether they are manufactured here or in a foreign country, must be approved by FDA based on demonstrated safety and efficacy. They must be produced in inspected manufacturing plants that comply with good manufacturing practices, and the shipment and storage of these drugs must be properly documented and, where necessary, inspected.

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

At the same time, inadequately regulated foreign Internet sites have also become portals for unsafe and illegal drugs. Fifteen years ago, after safety concerns were identified with the importation of significant volumes of adulterated and counterfeit drugs, Congress responded by passing the Prescription Drug Marketing Act. History has shown that the protections provided by Congress, coupled with FDA's regulatory system, have worked well. However, the very concerns that prompted Congress to pass the PDMA still exist today.

For example, FDA recently worked with domestic and international authorities to shut down a website advertising FDA-approved and safe European birth control pills and other drugs, but they were actually importing ineffective counterfeit products.

In addition, the Agency, in February issued a press release warning the public about an Internet site selling contraceptive patches that contained no active ingredient. The website that sold these products appeared to be a United States site. However, FDA determined that it was registered in New Delhi, India. FDA sought and

obtained the cooperation of the U.S.-based Internet service providers in discontinuing this site and three other related sites that were purporting to sell FDA-approved products, but in fact were selling drugs from unknown sources and of unknown safety and efficacy.

FDA believes that these four websites are indicative of the dangers consumers face when they purchase drugs off the Internet. Evidence strongly suggests that the volume of these foreign drug importations is rising steadily, presenting an even more difficult challenge for Agency field personnel at ports of entry, mail facilities and international courier hubs.

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

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

To help assess the extent of the problem posed by imported drugs, FDA and Customs conducted import blitzes at four international mail facilities last summer. We found that 88 percent of the drug products we examined were unapproved or otherwise illegal. Examples of the potentially hazardous products encountered during the blitz included drugs never approved by FDA, drugs withdrawn from the market, drugs requiring careful dosing, drugs without adequate labeling, drugs with clinically significant drug interactions, drugs inappropriately packaged, drugs requiring initial screening and/or close physician monitoring and controlled substances.

Clearly, many of these imported drugs may pose safety problems.

Chairman HATCH. What percentage was that again?

Mr. TAYLOR. Eighty-eight percent.

Chairman HATCH. Eighty-eight percent.

Mr. TAYLOR. Yes.

Chairman HATCH. In other words, you found 88 percent to have some problems one way or the other.

Mr. TAYLOR. Well, what we found were 88 percent of the products were unapproved, and then a subset of those had the safety problems that I just outlined in my testimony.

Chairman HATCH. Do you know what the subset percentage is?

Mr. TAYLOR. No, but I can certainly get that for you, sir.

Chairman HATCH. Okay.

Mr. TAYLOR. In conclusion, FDA firmly believes that we can and should do a better job of making safe and innovative drugs more affordable in the United States, but to succeed we need to find safe

and affordable solutions that do not put consumers at risk. The standard for drug review and approval in the United States are the best in the world, and the safety of our drug supply mirrors these high standards.

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

Thank you for this opportunity to testify. We look forward to responding to any questions that you may have, and I will now turn to my colleague, Mr. Hubbard.

Mr. HUBBARD. Senator Hatch, you know from your long experience with FDA that one of our main missions is access to pharmaceuticals for citizens, and we are very proud of the fact that, thanks to recent laws passed by Congress, Americans have access to the important new breakthrough drugs before anyone else in the world. But FDA's job is not a price-control job, it is a safety job, and we do have great concerns about importation as it currently exists because we do not believe we can safely look at these drugs. And I would like to show you a few examples.

When drugs come in, in huge volume into mail facilities, they come to a Customs inspector like this and are X-rayed to examine to determine whether there were are drugs in there. Then, they go into these bins, in massive numbers per day, and there might be one FDA inspector there who is incapable of opening all of these packages and making medical judgments about the quality of these products.

And, in fact, we also believe, because of this volume, enormous numbers of controlled substances are coming in. This mountain of controlled substances up at JFK is just a few weeks' worth that Customs has held pending disposition.

The Agency is totally incapable of screening all of these small Internet purchases. Now, Internet purchase of drugs can be fine if done legally. We are all familiar with legal Internet sites, such as cvs.com, and if you ask where are these people, for a legitimate site, it is easy to find out. You can inquire. Where do they say they are? They are in Rhode Island. Who runs that site? We know the name of the person. Where is that person? We know, by tracing back down the pipeline of the computer Internet system, that they are in Rhode Island. So it is very transparent.

We recently did a survey, however, of a thousand sites that appeared to be Canadian and found all sorts of problems that these sites are carrying out, such as selling controlled substances and such as saying they are FDA approved, when they are not. And of particular concern to me is the fact that they ask patients to disclaim any liability. They say, "If you are injured, we are not responsible. And if you do decide to sue us, you have got to come to our country and sue us there."

And that tells us that you have got a business that is not operating the way an American business was. No American drug store

would ask you to sign away your rights before you picked up a drug in an American drug store.

Chairman HATCH. So, now, when you say there are 47 sold controlled substances, are these sold over-the-counter or—

Mr. HUBBARD. No, they are sold over the Internet. They allow you to purchase a controlled substance from the Internet, and then it arrives in the mail—

Chairman HATCH. Is that with a doctor's prescription?

Mr. HUBBARD. In some cases, yes, but in many cases no prescription at all is required.

Chairman HATCH. So anybody can get these controlled substances.

Mr. HUBBARD. Absolutely. And we understand that teenagers are, in fact, using their parent's credit card to do just that.

Chairman HATCH. So, if somebody wanted to get Percocet or Percodan or—

Mr. HUBBARD. Absolutely, Vicodan, whatever, absolutely, Oxycontin.

And let me look at a couple of these sites that we examined. This is one, Pay Less Canadian Drugs. Looks fine, does it not? It has got all the right messages about being in Canada. So we ask, well, where do they say they are? They say they are in British Columbia. Well, when we go back and do the investigation of who they are, this one is registered to a gentleman named Anton Dvorak, the same name as the famous composer. Well, where is Anton Dvorak? Well, he is in the Czech Republic. You know, why, if that is a legitimate site, are they registered in the Czech Republic?

Another one, Canada Drug Store. When you ask, well, where do they say they are, they are in Winnipeg, but who is the registrar there? It is a Mr. Thuong. Where is Mr. Thuong? Well, he is in Vietnam. Now, why is he in Vietnam if this is a Canadian business? What is going on here?

Now, these sorts of problems suggest a sketchiness that raises real concerns for us. And in many of these sites, just in the last few weeks, they have decided not to sell drugs from Canada. They have decided to sell other things, such as sunglasses. Again, it raises questions about the legitimacy of these businesses.

Now, here is one that we took particular interest in because it appeared to be selling Chinese counterfeits, because when we searched for the Internet site, we learned that they were registered in Dandong, China, which is just on the border of North Korea. So we ordered the drugs from this business. When they came in, they had a postmark address of Dallas, Texas, but the return address was an address in Miami, Florida. Well, we asked the credit card company, well, who did you pay for this, and they paid a business on the Island of St. Kitts. And then we looked for a reorder number and found an 800 number, and we said, well, where is that 800 number, and we tracked it down to the country of Belize.

Well, now the important thing about this list is Canada is not involved at all, although the citizen was told you are getting a Canadian generic, and in fact none of those drugs on that website sell—there are no Canadian generics for those drugs.

So we actually purchased these drugs and did an analysis of them—of Lipitor, Viagra, and Ambien, Ambien being a powerful

sleep aid. We found that, in fact, there was some drug in there. These people had attempted to make the real drug. But in potency, they all failed, and in the case of Ambien, some of the tablets were more than double strength. So a senior citizen taking this powerful sedative could take one thinking they were getting the right thing and may not wake up at all because they are getting way overdosed with that drug, and of course underdosed with the others.

They, also, these drugs did not properly dissolve in some cases, which meant the body was not able to take them up and have the medicinal effect. And we found impurities, which is not uncommon for foreign drugs—cadmium, lead, things like that are a problem.

Here is an example of the dissolution issue. This is a calcium tablet that if you did a chemical analysis of would show as the very same drug as the approved marketed product, the legal product. But because it was made improperly, it did not dissolve. And as you can see, these tablets are going through this woman's body completely undissolved. She is eating rocks, but the chemical analysis would show this is a good drug. And that is an example of why dissolution to us is very critical. You take the pill, it dissolves in your stomach, enters your bloodstream. It has the medicinal effect you are looking for.

Now, I will close with a couple of comments about counterfeiting. These are dyes that fake counterfeiters use. They are very similar to what the Secret Service finds for counterfeit currency. People make up an imprinting dye. As you can see, there is the Pfizer name upside down. You pour your chemical in, and press it, and it makes the tablet. There is the other side of the tablet showing the code for the Pfizer brand.

And then we see at JFK these things pouring in from countries all around the world, looking just fine, because they were made on a machine that could duplicate the real drug.

And then, lastly, this is an example of one of the investigations Mr. Taylor has recently completed of a drug called Serostim for AIDS patients. As you can see, the authentic and the fake drugs were virtually indistinguishable. In fact, the drug companies tell us in some cases they cannot even tell themselves, on any sort of visual examination, whether a counterfeit drug is real or not. They have got to take it back and do sophisticated testing. So the possibility of counterfeiters using importation is a real concern for FDA.

So, with those remarks, Mr. Chairman, I would like to take questions or turn to Ms. Durant.

[The prepared statement of Mr. Hubbard appears as a submission for the record.]

Chairman HATCH. Ms. Durant?

Could I just ask one question? Those dyes look like they were contaminated themselves.

Mr. HUBBARD. Well, and, Mr. Chairman, I think we could show you, if there was time, photographs of some of these organizations and where they operate that are just unbelievable, in back-room toilets, using contaminated water. We ran across one recently that was a fertility drug for women seeking to have a child, and they used contaminated water. So, instead of getting the proper drug, the woman would be injecting into her veins bacteria which would

give her septicemia, blood poisoning. In other words, she would be killing herself. And that is sort of the level at which these people operate. Not only are they not selling a legitimate drug, but they are selling a dangerous drug. But visually that drug looks just fine. It is a clear liquid in a vial. It is packaged well. It is a very good product in terms of its appearance, but a very dangerous product in terms of its reality.

Chairman HATCH. Ms. Durant?

STATEMENT OF ELIZABETH G. DURANT, EXECUTIVE DIRECTOR OF TRADE COMPLIANCE AND FACILITATION, OFFICE OF FIELD OPERATIONS, BUREAU OF CUSTOMS AND BORDER PROTECTION

Ms. DURANT. Mr. Chairman, members of the Committee, thank you for this opportunity to testify. I am Elizabeth Durant, Director of Trade Compliance and Facilitation in the Office of Field Operations at the Bureau of Customs and Border Protection.

Today, I would like to discuss with you CBP's efforts to address the ever-increasing trend of personal and bulk importation of pharmaceutical products and controlled substances into the United States. Although the main focus of the CBP has shifted to protecting the United States from terrorist attacks, we also enforce over 400 requirements from more than 40 other Federal agencies at U.S. borders. These include the laws that prohibit the importation of illegal or unapproved pharmaceuticals that fall under the jurisdiction of the Food and Drug Administration, as well as those controlled substances that are under the jurisdiction of the Drug Enforcement Administration.

The issue of U.S. consumers buying prescription drugs from foreign sources has become a significant concern. A growing number of Americans obtain their medications from foreign locations. However, the safety of drugs purchased from these sources cannot be ensured. Drugs produced outside the United States may be counterfeit. Counterfeiting can apply to both brand name and generic drugs, where the identity of the source is deliberately and fraudulently mislabeled in a way that suggests that it is the authentic approved product.

The CBP is concerned with three avenues by which pharmaceuticals are imported: those that are purchased through the Internet and shipped through our international mail or express courier facilities, those carried into the United States by individuals transiting our land borders and bulk shipments of adulterated or counterfeit pharmaceuticals.

During the course of the past year, we have taken several steps to address each of these areas. Millions of packages come through the mail and express courier facilities every year. Thousands of packages, particularly in the mail, are found to contain illegal and unapproved pharmaceuticals. We also estimate that 10 million people cross the land border annually carrying unapproved products.

Additionally, we have found bulk pharmaceutical shipments that were attempted to be imported through the mail, potentially indicating that these products could be making their way to pharmacy shelves. In order to address what is clearly a growing threat to the public's health, CBP has been working cooperatively with the DEA,

the FDA, our own U.S. Immigration and Customs Enforcement, ONDCP and the Department of Justice attorneys in an interagency working group directed at addressing issues related to the importation of prescription drugs and miscellaneous pharmaceuticals.

The working group has conducted regular meetings since January 2004 and has achieved several key accomplishments since its inception, including conducting a joint interagency enforcement operation known as Operation Safety Cap, which was designed to look at passenger importations of pharmaceuticals from Mexico. Operation Safety Cap was an interagency plan to enforce the laws related to the importation of prescription drugs at the border.

Both FDA and ICE participated in the enforcement operation. The plan began with a public outreach, followed by an enforcement effort at the Ports of Andrade, Yuma, Tecate, San Luis and Calexico. The purpose was to evaluate compliance with laws related to the importation of prescription drugs.

During the course of the operation, there were several troubling instances of returning U.S. residents receiving different medications than the ones they thought were being prescribed. In one instance, there was no active ingredient on the unmarked, undeclared bottle that was brought into the U.S. The overall seizure detention rate was nearly 7 percent of the number of individuals inspected, which was significant enough to warrant additional enforcement efforts at our land borders.

Based on an operation nicknamed Operation Safeguard that we have carried out over the last couple of years, we have found the volume of pharmaceuticals shipped through international mail to be enormous. We have also found a significant number of these products do not contain an active pharmaceutical ingredient, but merely contain substances such as starch or sugar.

Other problems include expired materials, unapproved products, improper use instructions and products made in facilities not under proper regulation. The vast majority of the pharmaceuticals that enter the United States via the mail do so in a manner that, according to FDA, violates present FDA and other requirements.

It is clear that the importation of pharmaceuticals and controlled substances remains an overwhelming problem for CBP. We are working with the FDA, the DEA, ICE and other regulatory agencies to develop a more practical and workable approach to solve this huge problem.

I want to thank you and the members of the Committee for considering Customs and Border Protection in your review of the importation of pharmaceuticals and controlled substances. This is an issue that speaks directly to our mission. We will continue to make every effort possible to work with the Congress and our fellow inspection agencies to address the health and safety concerns of the American people.

Thank you, Mr. Chairman. I look forward to responding to any questions.

[The prepared statement of Ms. Durant appears as a submission for the record.]

Chairman HATCH. Well, thank you. I appreciate all that you three do and other people at your respective agencies do to try to protect the health and safety of our people in this country.

Just a few questions. I take it that you do not think that checking lettuce, and pork, and some of the items that Congressman Sanders said were so easy to do is the same as checking for pharmaceutical ingredients.

Mr. HUBBARD. It is a far different matter, Mr. Chairman, but perhaps Mr. Taylor could elaborate on that.

Mr. TAYLOR. Sure. It is a challenge, and it is not easy to do. However—

Chairman HATCH. Well, he seems to think all you have got to do is just do what you do for lettuce, and pork, and other food products that come into this country from all over the world. And if you can do it for them, why can you not do it for pharmaceuticals?

Mr. TAYLOR. Well, I think an important point to keep in mind is that a few years ago Congress passed the Bioterrorism Act, and in that act they provided strengthened statutory powers, both for the Bureau of Customs, and Border Protection, and FDA, to ensure that the food that is coming in from overseas is indeed safe.

One of the provisions requires prior notice of food before it is shipped here to the United States so that both FDA and Customs have an opportunity to check any packages that look like they could be potentially dangerous. It also provides requirements that all food processors throughout the world who are planning to ship food to the United States are registered, so that we have an inventory of facilities that we need to inspect if, Heaven forbid, there is a recall or something went awry with the food, and we need to determine the ultimate source.

So we have additional authorities that help us with this difficult task of dealing with imported food.

Chairman HATCH. I suspect it is a lot easier to check food substances than it is to check complex—

Mr. TAYLOR. That is absolutely right. A mere visual inspection of a drug, as each of us have discussed today, does not ensure that a product is safe and effective or that it is going to work as intended. One of the things that concerns the Agency is that the counterfeiters that we have seen recently have become more savvy not only in terms of how they manufacture the product, but also in terms of how they label the product and how they introduce that product into domestic commerce.

Mere visual inspection is not going to be able to discern in many cases whether a product is the authentic innovator product or counterfeit product.

Chairman HATCH. I have two bottles. This one is fake. This one is real. The fake is much heavier, probably two or three times heavier than this one. It could be lead pills, as far as I know. I mean, the fact of the matter is, is that it is clearly fake, and it clearly could damage somebody who is relying on the efficacy and the safety of these drugs. That is what the FDA is all about is safety and efficacy.

And some have said, well, we can just give you enough money, and enough facilities, and enough people, and you ought to be able to solve these problems for us. What do you think about that, Ms. Durant?

Ms. DURANT. Well, you saw the boxes. I would like to add to what Mr. Taylor said about the lettuce. They are largely commer-

cial shipments. They are in commercial quantities, in commercial shipments, and they are manifested, and automated, and brought in by brokers, and commercial operations. And we have a much better way to target suspect shipments because of our automation.

Our findings, at least in CBP, with this problem and one of the challenges for us is that most of this stuff is coming in for individuals, number one, of which there are many more smaller ones, and coming in through the mail, where we do not have a manifest. And so our targeting is—

Chairman HATCH. Coming in from hidden countries, and hidden distributors—

Ms. DURANT. Correct.

Chairman HATCH. —and people that you have no control over or any kind of—

Ms. DURANT. And no method of automating rules, and targeting and those things that we use with commercial shipments.

To answer your direct question, just the visual that was presented by Mr. Hubbard can show you that it would take millions of people, and then we would probably still be holding up a lot of the mail in order to segregate it. It is an overwhelming problem in our mail courier facilities at this point.

Chairman HATCH. Now, in your testimony, Mr. Hubbard and Mr. Taylor, you maintain that the public may be assured that the quality of drugs that consumers purchase from U.S. pharmacies remains high, but that the FDA cannot offer the same assurances about the safety, and efficacy, and quality of drugs purchased from foreign sources. That seems to be your testimony.

So what happens if a drug importation bill is signed into law this year? How will the FDA overcome that obstacle of reassuring the public that drugs purchased from foreign entities or Governments will be safe and effective? And how much will it cost the Federal Government to guarantee the safety of drugs imported into this country?

Mr. HUBBARD. Well, unfortunately, Mr. Chairman, the bills that are before Congress now, we fear, will not solve that problem, will not give FDA adequate authority to assure the safety of those products. So we would not be able to give the consumer the level of confidence that they would get. I mean, at an American drug store today, you have got a 99.9-percent chance of getting a good drug, virtually 100 percent. With these foreign purchases, we do not even know, but it is certainly not 100 percent, and it is a crap shoot.

Mr. TAYLOR. And, sir, I also might add that if, indeed, Heaven forbid, there is a problem with the drug domestically, we obviously have the ability, because we have jurisdiction here in the United States, to follow up, determine where that product originated from, we have an opportunity to go to District Court and bring civil or criminal remedies against whoever is responsible for introducing the counterfeit drug or the unapproved drug into the marketplace.

For many of these products that are coming in, in these individual packages from overseas, one of the main challenges is figuring out where those products come from. We obviously have several counterfeit drug cases that have originated from overseas. It is enormously difficult to figure out where the products originate from, for the reasons we have discussed. And then even if you do

identify who is responsible, without the help and concurrence of the regulatory body of a country where the suspects are identified, we do not have the jurisdiction to address them the way we do for those defendants who are located here in the United States.

Chairman HATCH. Just one last question. When we did this once before, they put \$23 million to defray the costs of protecting all of America from these type of knock-offs and counterfeits. What do you think about that? We could put up 23 million bucks. That is a lot of money, is it not?

Mr. HUBBARD. We once calculated that you could give us the U.S. Army, us and Customs, to look at this stuff, and it probably would be inadequate because you have got to literally open millions of small packages, and then you have got a bottle of pills in your hand. And so now that you have gone to all of the trouble of opening the box, and opening the bottle of pills to see what is in there, it does not tell you much.

Chairman HATCH. And if they look the same, they may be sugar pills, they may be lead pills—

Mr. HUBBARD. That is right.

Chairman HATCH. —they may be the real thing.

Mr. HUBBARD. Right. And then how do you know at that point that you opened it, it is any good? As you say, it could be a sugar pill. So you could spend a thousand dollars testing one pill and far outweigh the benefit of that pill. So that is the dilemma with these sorts of personal imports.

Chairman HATCH. Well, my time is up.

Senator FEINSTEIN?

Senator FEINSTEIN. Thanks, Mr. Chairman.

I must say I think your testimony was very powerful this morning, and it certainly concerns me. I come from California. A lot of people go to Mexico for their drugs because they are cheaper, specifically Tijuana. I wanted to ask you whether that presented the same problem.

I also want to just make a couple of things clear. You have one chart that says Canadian generics. This is off the Internet; is that right?

Mr. HUBBARD. Yes. That arrived by so-called spam e-mail to one of our employees. So we traced it back to that site to determine where it was. And as I said, the registrant of the Internet site was in China, but we believe the drugs actually come from the South American country Belize.

Senator FEINSTEIN. But they are sold, all of these drugs then on this site are sold in Canada.

Mr. HUBBARD. No, there is no Canadian connection at all. The point of that, Senator Feinstein, is—

Senator FEINSTEIN. It says, "Canadian generics."

Mr. HUBBARD. I know it does, and it is a lie, and that is the point because these websites pretend to be something else. The consumer is led to believe they are getting a Canadian generic of a drug regulated in Canada that is the same as they would get here. It is a total falsification. There is no Canadian connection, to our knowledge, with that website.

Mr. TAYLOR. And, Senator, what has happened is that the use of the term "Canadian" has become a marketing tool for many of

these Internet sites, knowing that consumers are more likely to purchase a product if it is from what they believe to be a Canadian website, as opposed to a Thai website or a Nigerian website. And in actuality, what we are finding in some of these websites is that the products are originating from countries all over the world just like the contraceptive patches that I noted earlier in my oral testimony.

Mr. HUBBARD. And that is not unique, Senator. There are many sites that pretend to be in Canada and are not.

Senator FEINSTEIN. Well, that is I think a real problem.

Let me ask you, you know, clearly, I think you know what the issue is. You know what people are doing today. They are probably going to continue to do it. I mean, it is easy for me to say because I would not want to take a chance with one of these drugs. But I think if people do not have money, and they are desperate, they may. The question is what can we do about it?

And my question is, is it possible to take high-selling drugs, say, like Lipitor and work out an agreement with the Canadians that if it comes through Canada that the Canadian FDA test it before it goes on the market for American use; is that a possibility?

Mr. HUBBARD. We have said repeatedly that for us to be able to assure the safety of these products, FDA would need to be given the statutory authority and the resources to assure the consumer that those are good drugs. Your suggestion may be one way. We have not examined that. I do not think the Canadians would necessarily want to take responsibility for American citizens, but—

Senator FEINSTEIN. But I would think the Canadian people would be a little upset when they see drugs being pushed as Canadian generics that are not. That is fraud. I mean, I am amazed. Why does the Canadian Government not crack down on that? This is where life is affected. You just pointed out where you have tested Ambien. It is sometimes double the dose. There is no consistency.

Mr. HUBBARD. That is right.

Senator FEINSTEIN. Somebody could die by taking an Ambien pill. It would seem to me that the Canadian Government should be interested in that. It would also seem to me that we ought to clearly bring this to the attention of the Canadian Government. My question is have we?

Mr. TAYLOR. Yes.

Senator FEINSTEIN. And what is the response?

Mr. TAYLOR. I think it is fair to say that we have had a modest level of success in working with them, and they certainly acknowledge the concerns that we have. The blitz results that I noted earlier and the background information that we found, we shared with the Canadian Government.

And to the extent that there is not greater involvement on their part, I think it is largely a question of competing priorities and resources and the fact that their organizations are focused on protecting Canadian citizens, just like FDA is focused on protecting U.S. citizens, and is not focused on ensuring that products that are coming to the United States are safe and effective.

Senator FEINSTEIN. No, but would these drugs not be available to Canadians as well?

Mr. HUBBARD. No. That website has no Canadian connection at all. It only pretends to be in Canada.

Mr. TAYLOR. That is right. It is marketed here to U.S. customers. It has no Canadian connection at all.

Senator FEINSTEIN. Wow.

Mr. TAYLOR. It just uses the Canadian name, quite frankly, as an imprimatur of legitimacy so that customers—

Senator FEINSTEIN. Well, let me ask you this. What do we do about going out and getting these registrants who have falsified and perpetrated a major fraud on Americans?

Mr. TAYLOR. Well, we open up criminal investigations, and we often work with our colleagues at Customs, but they are enormously complex because, using the example in my oral testimony the contraceptive patches, with the Internet technology being what it is, and even Mr. Hubbard's illustrates this, you need to—your preconceived notions about where the product originates changes as you move from one website link, to a website link, to another website link. The contraceptive patches, there were four or five website links between the site that was selling the drug and the site that was registered.

So we do work to try and determine who is responsible and bring them to justice. It is just that the investigations are very complex and often require the cooperation of the foreign body where the site is registered. And we have had some success. It is just very difficult to do.

Senator FEINSTEIN. Well, if we have an extradition treaty with that nation, it would seem to me the individual could be extradited.

Mr. TAYLOR. You are absolutely right, and they are. However, for some of our defendants, they are residing in countries where we do not have extradition treaties, knowing that we do not have extradition treaties, which is of course one of the challenges of bringing these people to justice.

Senator FEINSTEIN. Well, let me ask you this. Does the FDA make this information available on these sites or other sites that people should not use this site?

Mr. TAYLOR. Yes, we do. The information that Mr. Hubbard discussed was part of an FDA talk paper that was released last night warning people about this site. In the context of the contraceptive patches, not only did we put out two talk papers warning people about purchasing contraceptive patches, as well as any other products in those websites, we also put up links to our talk papers so that people could see what the actual websites look like.

We have an on-line, what we call an on-line pharmacy link at FDA's website, and it is one of the most-often used parts of our website. It gives people an opportunity to see what cases we have brought, what websites pose potential concerns. It also gives people guidance on how to purchase products over the Internet safely.

Senator FEINSTEIN. Let me ask you one other question. These drugs here that you have—Ambien, Lipitor, Nexium, Paxil, et cetera—are not like Tamoxifen, for example. Is there evidence of bogus Tamoxifen?

Mr. HUBBARD. Absolutely. As a matter of fact, one of the examples that Senator Dorgan gave was of a woman with breast cancer

who would travel to Canada to get Tamoxifen. And that may be an accurate example that he gave.

We have another example of a woman in Oregon who purchased Tamoxifen over the Internet from a Canadian website to treat her breast cancer. They did not give her Tamoxifen. They gave her something different, and she continued to take it. Her breast cancer continued to grow, and she did not know that she had been defrauded by this Canadian drug store.

So, for every example of a good drug, we can show you an example of a bad drug.

Senator FEINSTEIN. Now, supposing the American goes through a bona fide Canadian drug store—

Mr. HUBBARD. Well, in this case, it was a licensed Canadian drug store. The Canadian Government is not going to assure the safety of drugs for Americans. That is not their job. They have a very small FDA—

Senator FEINSTEIN. A Canadian could have bought that drug in a—

Mr. HUBBARD. Right.

Senator FEINSTEIN. Well, does not the Canadian Government assure the safety of drugs for its own citizens?

Mr. HUBBARD. Yes, I think generally they do. And I think—

Senator FEINSTEIN. Then, how would phony Tamoxifen be sold?

Mr. HUBBARD. Well, in some cases, the Canadian pharmacies do not bother to license themselves in Canada because they do not sell to Canadians. They only sell to Americans, and that way they can avoid licensure requirements in the provinces.

Mr. TAYLOR. And also, unfortunately, cancer treatments and HIV treatments are some of the most often counterfeited products because they are so expensive. And so we have seen instances where counterfeit cancer treatments have been introduced in the distribution chain. The reason I use that as an example is that you can have the proper practice of pharmacy, you can have a valid prescription. However, if steps are not taken to ensure that the product that you are getting is the FDA-approved product and is safe and effective, you can still, despite those protections being in place, receive a product that is not necessarily going to treat your condition.

Senator FEINSTEIN. What a surprise for all these men that use Viagra over the Internet.

[Laughter.]

Mr. HUBBARD. Well, if I may, Senator, even Viagra, you can argue that that Viagra, because it was subpotent, was not really a risk. The person just would not have the effect. But imagine if they decided, well, I did not get the effect with one, I will take two. And then the next prescription they fill has the American drug, which is fully potent, and they think, well, I needed to take two, and so then they take two with the American drug and have a heart attack or a stroke, that is a serious health risk.

Mr. TAYLOR. And in the Viagra that Mr. Hubbard highlighted as a part of this Canada generic site, Viagra is not supposed to be taken with Erythromycin. And on the approved label, that contraindication is actually on the label. On the product that I believe that was ordered pursuant to this website, they did not have that

warning about using the Erythromycin with Viagra, so there is a potential danger there by using the non-FDA-approved product.

Mr. HUBBARD. If you got Viagra from an American drug store, and the pharmacist had also given you Erythromycin, he would say to you, I cannot give you this because you are on Erythromycin. Those two will interact and harm you. But in this case, we actually told the Canadian generics firm, I am on Erythromycin, and they still sold the Viagra. So it is another example of the risk that these businesses put our citizens through.

Senator FEINSTEIN. Thank you. Very helpful.

Thanks, Mr. Chairman.

Senator KYL. [Presiding.] Thank you, Senator Feinstein.

Your questions and the testimony that has been presented here I think just make an overwhelmingly compelling case that it would be totally unsafe for us to rely on this importation, but that we have got a problem even today because we probably do not have the resources or the capability to inspect everything. And even though you may put on your website a warning to people about importing over the Internet, how many people are actually going to get that warning and how can you keep up with all of the different sites that pop up. I mean, can you?

Mr. TAYLOR. No, we cannot. We cannot. And make no mistake about it, we are only, as Ms. Durant said, FDA is only able to look at a very small number of these packages. I think Ms. Durant made an excellent point. The Food, Drug and Cosmetics Act was designed to deal with commercial shipments of drugs. I mean, the very language in it contemplates being able to look at and deal with big drums of active pharmaceutical ingredients, in quantities that are easier for the Agency to look at as part of our importation scheme.

With the advent of the Internet and with the increasing number of people seeking products from overseas, we now, estimates are 2 million, 5 million, 10 million, 20 million packages a year coming in just through the mail. We do not know the exact number, but I can tell you whatever number you use between that range, we simply are not able to look at all of those packages. And so, unfortunately, there are a large majority of packages that are coming in that concern us, but we just do not have the resources to deal with it.

Senator KYL. We have gone to a lot of trouble and expense in this country to create literally a gold standard, and the three of you are part of that. There are many public servants in the United States whose life is devoted to the safety of drugs, so that when an American buys a product in this country, you can count on it, and you have to be able to count on it because there is such a risk if there is something wrong with it because it relates directly to your health and perhaps your life, which is why we have devoted so much effort to this.

And I cannot imagine that if it were not for the fact that some people are having a hard time paying for drugs, I mean, this would not even be an issue, if you look at the Alar or it was mentioned the mad cow situation, those were both situations in which the whole world seemed to panic over what seemed to be a relatively minor matter. And yet, with drugs, there seem to be a willingness

to overlook all of these compelling safety warnings and concerns because of the cost issue.

And I just want to make a point again that was made by Senator Breaux earlier. Congress has already addressed the price issue. The Medicare bill that we passed last year has three very important provisions in it to provide pharmaceutical products to Americans and to reduce the cost of them. The first one has already taken effect. It is the drug discount card. And I have forgotten the average that it reduces the cost by, but it is something like by about 20 percent. And for those who are in the lower income brackets, it is essentially provided free. They get a \$600-per-person credit, and when the full bill kicks in, I think the total cost is somewhere between \$1 or \$3 per prescription.

So we have enabled people in this country, and when the full bill kicks in, in about another 12 or 14 months, we will have I think gone a long way toward reducing the cost of drugs. It seems to me, for that period of time, with the drug discount card available, we are exposing the citizens to a huge safety risk if we are not very, very careful.

Now, two things that have not been discussed here, and one was alluded to, and I would like to, in my time, get into:

One is the potential terrorist threat. I mean, we have had ricin scare here in Washington, the anthrax scare, and it seems to me, and I could point to some testimony and some material that has been written about the potential for terrorists to finance their activities through this kind of scheme, this counterfeit drug scheme, but also the ability to create panic, to sell panic in this country with some kind of counterfeit importation.

And, secondly, the liability question has been just barely touched on. And Senator Feinstein broke the code when she said why does not Canada be concerned about this, and of course the response was because Canada has nothing to do with it. The website says Canada, but there is no connection to Canada whatsoever. And so then what about liability? If you are taking both an American product and a product that you have gotten elsewhere, and you get sick how do you prove which one made you sick? How do the American companies protect themselves? Who could you go after if there is a problem with it?

The yellow light is on. So let me just ask you, just generally, all three of you, about the potential terrorist problem and the potential liability problem to be able to hold somebody accountable if something goes wrong?

Mr. HUBBARD. Perhaps Mr. Taylor can answer this question.

Mr. TAYLOR. As you said, in the past, counterfeit products, products across the broad spectrum have been used or linked to the funding of terrorism. So, obviously, we think it is a legitimate concern. We also know that products again just outside the pharmaceutical arena have been diverted and again used for terrorism funding. So we were concerned about that.

We were also concerned, as we always have been, about the tampering of products by anyone who wants to intentionally inflict harm on the American public. The Tylenol situation is something that we're all aware of. In that case, someone purposely tampered with a drug. We have had other situations where people have tam-

pered with all kinds of products that FDA regulates. So it is something that concerns us.

Mr. HUBBARD. And on the liability question, Senator, you are absolutely right. These websites usually require the patient to sign away any responsibility of that business for the safety of the drug, which as I said would never happen in an American drug store. And then they also asked people to promise not to sue them if they are injured, and then they say we want you to promise, if you do sue us, you will come to our country and sue us under our laws. You know, it is just almost ridiculous. These are provisions that would never appear in an American drug store, and so the patient is really hanging out there in terms of responsibility because what these businesses are really saying to patients are, "You are on your own. You take responsibility for your judgment in buying these drugs," and that is not fair.

Mr. TAYLOR. And just to give you one other tangible example. In the example of contraceptive patches that I noted earlier, the reason we found out about that is because a consumer purchased a product over what they thought was an American site, and the product came in a plain plastic bag, which caused the consumer to be concerned.

The consumer tried to figure out how to gain some type of recourse, how to figure out how to get her money back, how to figure out where to go to complain. Could not find anyone to complain to, and therefore notified the pharmaceutical company that manufactured the approved product and FDA, and that is how we found out about it, and it led to shutting down those four sites. But that was based on a consumer's desire to get some type of recourse, but not being able to find any forum for her complaints.

Senator KYL. Her case, before she used the product she took recourse.

Mr. TAYLOR. Absolutely.

Senator KYL. But for all of those who used the product first and then suffered the consequences, no recourse, bad situation. My time is up.

Senator Kohl?

Senator KOHL. Thank you, Senator Kyl.

Almost every day I hear from people in Wisconsin who are frustrated, very upset about the high cost of prescription drugs. And of course we know they have a legitimate right to feel this way because we are paying some of the highest prices in the world for medicines that are manufactured right here in America.

We often talk about the United States health care system as being the envy of the world, but that is just an empty promise, as we all know, if our lifesaving drugs are priced out of reach. Faced with the untenable choice of going broke or going without medicine, many Americans are going to Canada in search of affordable prescription drugs. Some States and local communities are doing the same thing. Wisconsin launched a website in February that connects consumers with three Canadian pharmacies. The website has had more than 145,000 visits this year alone. The Coalition of Wisconsin aging groups also has a prescription drug information center to help people find more affordable drugs, often in Canada.

It is my understanding that the results of both programs have been very positive, but as long as importation remains illegal under Federal law, we will not have a safety structure in place to prevent unscrupulous people from trying to taint the drug supply in the future.

As we debate here in Washington, it is clear that in reality drug importation is already happening. It is time to stop asking the outdated question of should we allow it and start finding solutions that will give consumers the price relief and the safety assurances they need.

The Pharmaceutical Market Access and Drug Safety Act introduced by Senators Dorgan and Snowe, of which I am a cosponsor, represents a real chance to finally make both of these goals a reality.

The drug industry continues to enjoy some of the highest profits of any industry in the world, as we know. In 2003, profits were more than three times the median Fortune 500 company. So it is time for Americans to stop footing the bill, although drug importation is, by itself, not the whole answer for high health care costs, I believe, and many people believe, it is an important part of the solution.

So members of the panel, as I have said, people do not understand why they must continue to pay the highest prices in the world for their medicines. They do not understand why the administration appears to stand in the way of fixing this problem. Most people in my State believe they are smart enough to utilize the free market to find the best price for their products. They believe that the Government should be smart enough to set up a system that allows them to safely shop around for the best price, whether that price is here or in Canada. After all, we import food from other countries with far fewer inspections than we are talking about for imported drugs under this bill. So why can we not assure people that just as we are in a position to set up safety standards for the importation of food, that we cannot also set up safety standards for the importation of these medicines.

Mr. Hubbard?

Mr. HUBBARD. It is just very difficult, Senator Kohl. These drugs were regulated by Congress in 1938 because they were considered to be special. You needed very precise manufacturing, very precise quality controls. And the source of inspection processes that you would do for produce or beef or whatever are far different and, in many ways, far easier.

With pharmaceuticals, you need a bubble around them that oversees their approval, their manufacture, their shipping, their dispensing to the patient, and that exists in the United States. When you go outside the country, you have broken that bubble, and you have made it far, far harder to understand how those products were made, and where they have come from, and whether they are made under quality control procedures.

I am not saying it is impossible, but unfortunately we have not heard a proposal yet that, in our view, gives as safe a system as we have now. It might be you can devise ways of importing drugs and ameliorate some of the safety concerns, but in our view, you are not going to have as safe a system as you have now because

you are simply going to be relying on drugs made outside of our control in most cases.

Senator KOHL. But it is true, is it not, that we have a satisfactory system to check on foods that are imported into this country?

Mr. TAYLOR. That is true, sir. But as I noted earlier, I guess to answer your broader question, I mean, what we think is necessary to set up the very system that you are contemplating are steps to add additional authorities that will add to the protective measures that are already in place, as opposed to detract from them.

And in the context of foods, a couple of years ago, Congress recognized that we were struggling with the increase of food shipments here to the United States, and they recognized the threat that was posed to the United States population by our limited resources to inspect that food, and that is one of the reasons why Congress passed the Bioterrorism Act, which gave us additional tools to check the food shipments that are coming in, it gave us additional tools to prioritize our inspections of those foods based on risk criteria, as well as giving us other opportunities to find more information about the food producers who are marketing products to American citizens.

So what I am saying is that, in order to do this correctly, what the Agency has said is we want to emphasize that to do this correctly and ensure that Americans are getting safe and effective products, that we need to make sure that any legislative proposal or any legislative discussion that is being engaged in recognizes the need to strengthen our protective measures and not to detract from them.

Senator KOHL. Well, I think my time is up, but I just want to make this point. Again, you appear, and I do not want to believe it is true, but you appear to be supporting an overall system that winds up costing American consumers more for drugs than people all around the world pay. Often, these are products manufactured right here in this country.

So it seems to me that instead of defending this system, you all need to come up with a way to work with us. I believe Snowe-Dorgan begins to move us in that direction, and the bill is going to reduce the cost of prescription drugs for Americans. I think we all agree with that, and yet you appear, and I do not believe you really intend to, but you appear to be supporting a system, whether it is a Medicare prescription drug bill that prohibits the Government, as you know, from negotiating with pharmaceutical companies on behalf of Medicare recipients—which is almost un-American in the sense that large consumers everywhere in our society negotiate for discounts on their purchases—so in that area, and in this area, saying that we have to have 100-percent safety certification before we can move forward, which is almost impossible to get, you appear to be supporting a system that is causing Mr. and Mrs. American to pay the highest prices, in many cases, in the world for products manufactured in this country.

Now, I am sure you recognize that there is a real, real problem here that we cannot just debate, but we have to come up with some answers.

Mr. TAYLOR. Senator, we absolutely agree, and we are completely sympathetic to the price issue. Our concern, though, here at the

FDA, and my concern, I mean, I run the enforcement and regulatory arm of FDA, is just to make sure that Americans have safe products.

I mean, any action that I took that would detract from achieving that goal would be equally responsible, and all we are saying is that, to the extent that there is a contemplation of additional legislative steps, that people keep in mind to ensure that these protections stay in place and are strengthened in light of the advent of the Internet, in light of the practice that we are seeing and not detract from those protections.

And even the State of Wisconsin, with their program, is facing some of the same challenges we are facing. I mean, I know that they have written a letter to their pharmacies who, outside the contractual relationship that Wisconsin has with those pharmacies, were sending in products that the State of Wisconsin deemed to be inappropriate. And that is the same challenge that FDA is facing, and we are sympathetic, but it just goes to show you that you just need to be terribly vigilant, no matter what program is being contemplated, to ensure that the public is getting what they think they are getting when they are purchasing products from these overseas sites or locations.

Senator KYL. Senator Feingold?

Senator FEINGOLD. Thank you, Mr. Chairman. Thank you for holding this hearing on a topic that is very important to the people of Wisconsin. It is no accident that in the middle of all of this that is going on in the Congress today that both Senators from Wisconsin would be here because of how important this is to our constituents.

Each year, I travel to all 72 counties in Wisconsin, and I hold a town meeting in each county. For the past 12 years, the high cost of health care and specifically the skyrocketing prices of prescription drugs has been one of the top issues raised at these meetings by my constituents all across Wisconsin.

I am a strong supporter of the bipartisan bill introduced by Senators Dorgan and Snowe that will help Americans purchase prescription drugs at reduced prices. Without it, Americans are at the mercy of the pharmaceutical companies, which are raising the prices of the most commonly prescribed brand-name drugs at twice the rate of inflation. It is our duty in the Senate to provide some relief. People in the United States pay substantially more for prescription drugs than people in any other industrialized country. I have long supported efforts to create a competitive marketplace for prescription drugs. Drug manufacturers are free to move their factories to countries that have cheaper labor or greater tax incentives and to buy supplies from countries with lower costs, but Americans cannot purchase the drugs they need that are offered at lower prices in other countries, and I do not think that makes sense.

A growing number of American seniors, including a growing number of Wisconsinites, are obtaining their prescription drugs from Canada, whether they cross the border in person, order their prescriptions on-line or go to one of the Canadian company storefronts that have opened up in this country.

I have heard from senior groups in Wisconsin that are concerned about the announcements by certain pharmaceutical companies

that they will discriminate against Canadian pharmacies that provide Americans the same discount that they provide to Canadians. To address this issue, I have introduced Senate bill 477, the Preserving Prescription Drug Discounts Act, along with Senators Leahy and Dayton, which would deny tax breaks to drug companies that limit supplies of prescription drugs to Canadian pharmacies that provide Americans with prescription drugs. If these drugs companies actively discriminate against American seniors, we should no longer provide them with tax breaks.

At least six major pharmaceutical companies have announced that they are going to take steps to curb the reimportation of prescription drugs from Canada into the U.S. by limiting supplies provided to Canadian pharmacies. I am concerned the drug companies are only starting with Canada and will then extend these discriminatory practices to other countries that Americans now or in the future will turn to for cheaper prescription drugs.

Seniors are forced to go to Canada because the price of prescription drugs in this country is out of control. The Congressional Budget Office estimates that brand-name drugs cost, on average, 35- to 55-percent less than other industrialized countries than they do in this country. Drug companies say they need to charge high prices to recover the enormous research costs involved in bringing new medicines to market. Yet that argument overlooks the fact that Americans already fund much of the research and development of prescription drugs through taxpayer-funded research conducted at the National Institutes of Health and through tax breaks to the drug industry.

It is simply unfair that some Americans cannot afford prescription drugs that their tax dollars helped develop. And when they try to go to obtain these drugs from Canada, they are discriminated against by the drug companies. It is far past time for Congress to allow Americans access to safe prescription drugs at the prices that the rest of the industrialized world enjoys.

Mr. Chairman, I just have one question for the panel. The U.S. General Accountability Office recently conducted an investigation that found that all of the prescription drugs they purchased from legitimate Canadian websites were safe, packaged correctly and required prescriptions from physicians. S. 2328, the Dorgan-Snowe bill, would provide consumers with access to Canadian websites that are regulated and assured to be legitimate and safe. This bill would also require the FDA to post the list of approved Canadian pharmacies on its website and through a toll-free phone number so Americans can check to see if they are dealing with a legitimate pharmacy, not a rogue website.

I would just ask the members of the panel, would not passing legislation such as S. 2328 be an improvement over the status quo?

Mr. Hubbard?

Mr. HUBBARD. As I have said to other members, we have said repeatedly that if Congress gave FDA the authority and the resources to set up a drug importation program, we would implement that as well as we could. Our concern is that the bills that have been introduced do not go far enough. They do not really solve the problem. In the case of the bill you are mentioning, we are concerned about its very broad scope. It allows drugs in that we do not

think should be allowed in, and it allows drugs in from many countries. It would just make it difficult for FDA to set up a meaningful program to screen those drugs. But we are happy to talk with you or other members about our concerns.

Senator FEINGOLD. But is it not the case, the provisions that I just outlined, not the broader elements, but those particular provisions would be an improvement over the current system; is that—

Mr. HUBBARD. Certainly a limit to Canada only would be one limitation that would be positive, but that still raises serious concerns for us, and again we would be happy to talk with you about those concerns.

Senator FEINGOLD. Mr. Taylor?

Mr. TAYLOR. Just two points. One, we are by no means saying that every single product that is purchased over the Internet or is purchased from Canada is unsafe or potentially harmful. But what we are saying is that you need to be vigilant, and you cannot assume that you are getting the same benefits as the FDA-approved product.

And then to your other point, generally, we are supportive of any attempt to provide us more information about the website or about an importer or exporter who is shipping products to the United States. I think I noted earlier that one of the main challenges we have is determining if, for example, a problematic product is shipped to the United States, figuring out where it originated from, figuring out who actually is behind the website.

So, to the extent that we are able to get more information, whether it is through the provision that you noted or through other steps, that is going to be beneficial to our enforcement and regulatory efforts.

Senator FEINGOLD. Thank you.

Ms. Durant?

Senator KYL. I want to thank the panel—oh, I am sorry. Did you have a comment, Ms. Durant? I am sorry.

Ms. DURANT. I just wanted to echo Mr. Taylor's comments. For Customs, this is a bit of a selfish thing for us. We want to be able to identify the good from the bad. We will work with FDA to do that. Today, it is just, as was noted in Mr. Hubbard's overheads it is overwhelmingly difficult for us to do that. So the more that we can refine it and be able to determine the risk of those that are not approved, the easier it is for us to enforce whatever is passed. So we could work—

Senator FEINGOLD. I take that to mean these specific provisions that I just outlined would be helpful in that direction.

Ms. DURANT. They would certainly help, yes.

Senator FEINGOLD. Thank you to the panel, and thank you, Mr. Chairman.

Senator KYL. Thank you, Senator Feingold.

Again, thank you to the panel for a very enlightening presentation. I appreciate your testimony. You are excused.

I am not sure that we have all of the members of the next panel present, but I would like to introduce them and please come forward for the ones who I think are here. And if I mispronounce your name, please correct me.

First, we have Mr. Carmen Catizone, who is the executive director of the National Association of Boards of Pharmacy and secretary of the Association's Executive Committee.

After Mr. Catizone, we have Dr. Elizabeth Wennar, who is the president and CEO of United Health Alliance of Bennington, Vermont, and principal of HealthInova of Manchester, Vermont. This says Manchester, and I am not sure that is correct.

Next, we have Ms. Joanne Disch, who is a board member of the AARP.

After Ms. Disch, we have Dr. Stephen Schondelmeyer, who is a professor of pharmaceutical economics at the University of Minnesota College of Pharmacy.

And, finally, we have Ms. Kathleen Jaeger, who is the president and CEO of the Generic Pharmaceutical Association, and I guess we have all five of the names I read. I welcome all of you here. As I said, if I mispronounced your name, please correct it at this time.

Let me mention to those in the audience and also those on the panel, as you can see by the in and out of members here, there are several conflicting hearings. I am supposed to be making a quorum in the Energy and National Resources Committee, as we speak, but I will stay here. At noon, there is supposed to be a vote on Senate floor, and so we will probably have to recess the hearing for a brief period of time at that time. Presumably, Senator Hatch will return at that time.

Let us begin. Let us just go left to right and start with you, Dr. Catizone, and did I pronounce your name correctly?

Mr. CATIZONE. Yes, you did, Senator.

Chairman HATCH. Thank you.

**STATEMENT OF CARMEN A. CATIZONE, EXECUTIVE DIRECTOR/
SECRETARY, NATIONAL ASSOCIATION OF BOARDS OF PHAR-
MACY**

Mr. CATIZONE. Thank you. Thank you for the opportunity to be here before the Committee this morning. As mentioned, I represent the National Association Boards of Pharmacy, whose members are the State provincial jurisdictions which license pharmacies and pharmacists in the United States, Canada, Australia, New Zealand, and South Africa. We do not represent the pharmaceutical industry. We do not represent pharmacists or pharmacies and, in fact, less than 1-percent of our funding is obtained from funding from pharmaceutical companies.

Our written testimony which was submitted in advance of the hearing provides critical information on the implications of the illegal importation of drugs from the perspective of the public health and patient safety. This morning, my comments will summarize that testimony and update the Committee members on the status of one of the most complex and emotional issues being debated today.

Frankly, the illegal importation of drugs is thriving. Despite the efforts of States to enforce the law and protect the public health, the flow of drugs across our borders is growing and is undeterred by warnings from the FDA and State agencies. Even though some 32 States have successfully prosecuted storefront facilities, pharmacies and disciplined the license of pharmacists and physicians,

millions of packages still enter the U.S. from Canada, Bulgaria, India and Pakistan.

What is most frustrating and disturbing to the State agencies that are charged with protecting the public health is that their efforts are thwarted by political ambitions in a desperately flawed solution to the public policy issue of access to medications.

Is the illegal importation of medications endangering patients in the U.S.? Yes. Do we have hard data to support that assertion to "qualify the bodies," as so many like to characterize the seriousness of this issue? Yes, but not to the quantity that people are requiring.

NABP has quantified complaints from patients who have received the wrong or counterfeit medications from illegal importation and included that in the written testimony submitted to this Committee.

NABP is also receiving new complaints every day as the problems from the illegal importation permeate and manifest throughout the U.S. medication distribution and health care systems. Unfortunately, the bodies, which so many have indicated must appear in emergency rooms before enforcement of existing laws can occur, are slowly surfacing and reports to the FDA and NABP. We will continue to monitor this situation and share our findings with this Committee.

Besides concern for public safety, NABP is also alarmed by the impact on State regulation the illegal importation of drugs is having. In States where Governors, mayors and other public officials are ignoring State and Federal laws and facilitating the illegal importation of drugs, State boards of pharmacy and the regulatory framework that protects U.S. patients are being ignored, bypassed and possibly destroyed. Again, more detailed explanation of this implication is included in our written testimony.

It does bear note to discuss recent actions in Rhode Island. Just last week, legislation requiring the Rhode Island Department of Health to license Canadian pharmacies became law. In a short time, the Rhode Island Department of Health will license Canadian pharmacies who are violating State and Federal laws and are acting based upon a law which the FDA has deemed unconstitutional. The only requirements for licensure in Rhode Island of the Canadian pharmacies is licensure and registration in the province where they reside, a fee, and a promise to follow the requirements of that province.

If other States follow Rhode Island's lead and their failure to require compliance with U.S. laws in patient safety standards, a race to the bottom will soon occur as States seek out the country with the lowest prices, ignorant or ignoring the standards in that country. Once one State has pushed the race to the bottom and has adopted drug approval and patient standards to a level far below the current U.S. standards, all States will be subject to those bottom standards because there will be no way to contain the imported drugs to that one State.

Can the situation be avoided? Can importation occur safely? The answer to both questions is, yes. The how requires the change in the current laws and support to establish an inter-border regulatory framework, organized through the FDA and the State boards of pharmacy. NABP respectfully requests that the Committee rec-

ognize that allowing and encouraging illegal importation, without the appropriate regulatory safeguards, is a serious threat to State regulation and patient safety.

NABP requests further that if importation is legalized, the appropriate inter-border regulatory framework, as defined by the FDA and the State boards of pharmacy be first established.

And, finally, NABP does not believe that even one patient should suffer or be harmed as a consequence of disregarding Federal and State laws that ensure the dispensing of safe and effective medications to U.S. patients.

Thank you.

[The prepared statement of Mr. Catizone appears as a submission for the record.]

Senator KYL. Thank you, Dr. Catizone.

Dr. Wennar?

STATEMENT OF ELIZABETH A. WENNAR, PRESIDENT AND CHIEF EXECUTIVE OFFICER, UNITED HEALTH ALLIANCE, BENNINGTON, VERMONT, AND PRINCIPAL, HEALTHINOVA, MANCHESTER, VERMONT

Ms. WENNAR. Thank you. I have introduced my written testimony, and I am not going to read from it. What I am going to do is also summarize mine and just try and make the relevant points.

It was mentioned earlier that United Health Alliance, which is an organization that exists in Southwestern Vermont, is organized and was organized many years ago for a multitude of reasons. It is made up physicians, a health system, a rural hospital, a nursing home and a home health agency. And we, although involved in facilitating importation of prescription drugs, this was not our major goal when we started things many years ago. One of our guiding principles, which is to help the people we serve become the healthiest in the Nation, became quite impossible for us to succeed at when we began to realize that the people we were serving could not comply with their treatment plans.

And compliance is a safety issue. It is a quality issue, and we looked at it from the perspective of, if an individual cannot take their medications as prescribed, then we were losing the battle. Physicians began to realize that they had an obligation. So these groups of physicians in this health system took it upon themselves to try and facilitate the process, exclusively from Canada. We are not talking about any country other than Canada. We became involved with pharmacies, legitimate pharmacies, in Canada and began to work with them in terms of bringing medications into the United States.

We were not looking at this from the perspective of whether it was legal. We were looking at it in terms of an ethical dilemma that we had. Writing prescriptions for things that people cannot afford was an ethical dilemma for the physicians.

So, as we began to see things become more and more successful, what started out as a very small program or initiative to serve individuals in the communities that we were serving, which are Massachusetts, Vermont and New York, began to grow. It grew hugely and very fast. To sort of cut to the chase, we ended up, this map that you see here, we ended up serving, wherever those dots are,

those were where the people ended up. It practically overwhelmed us. We were a small organization. We have now transferred that organization to another entity because it did overwhelm us. But having said that, I want to just make some quick observations, because when I became originally involved in importation, it was really from a research standpoint. I was looking at it in terms of a piece of policy under the Clinton administration that was being considered—

MEDSA, which was passed, but never was implemented. And here comes the issue again from the standpoint of considering a piece of legislation. My one piece of advice and hope is, if you do pass something, make sure it is something that can be implemented. It is a waste of everyone's time to work so hard and then have something that cannot be implemented and that is not meaningful.

Now, having said that, I am going to just quote some facts and observations over the last 7 years. These are my personal observations.

Number one, parallel trade has existed safely in the EU for years. There is no evidence that parallel trade promotes counterfeiting when the appropriate controls and regulatory processes are established.

Secondly, reimportation or importation from Canada exists. It exists because the U.S. consumer has taken it upon themselves to demonstrate it and to prove that it does work. Millions are currently utilizing this as a means to comply with their treatment plans now.

The Canadian system is well regulated and safe.

Canada, as does other countries, have an FDA or the equivalent of the FDA to do oversight.

Customer satisfaction and compliance for those that are utilizing mail-order from Canada appears very high.

Physicians are engaged in the process. They are engaged with their patients in the U.S. and with additional physicians in Canada. This helps with compliance, and it does help with oversight and quality. Compliance results in better outcomes and potentially lower cost to the overall health system result.

Guidelines and standards can be, and have been, established for oversight of mail-order. Accreditation processes must be much broader than just marketing via the Internet. In other words, the Internet is only a marketing tool. You cannot reach in there. There is no pharmacy that legitimately exists on the Internet. It is a marketing tool like anything else on the Internet.

The fact is U.S. consumers have created the mail-order industry in Canada. Legitimate mail-order in Canada welcomes standards and the regulatory processes that need to be put in place to provide safety controls for U.S. citizens, to protect them from unscrupulous providers via mail-order, particularly around the lifestyle and me-too drug medications that are being promoted along with controlled substances. Because what we are talking here are really about maintenance drugs, drugs for chronic disease management, the community-based pharmacist must be reintegrated into the health management plan. Mail-order in general, even in the United States, has successfully carved out the community-based phar-

macist from quality oversight. We propose that they must be re-engaged.

Recent reports that have been referenced already here, with relationship to the GAO and AARP's report and the Sagar report, which I have included as an exhibit in my testimony, are available for you to read.

Legislation is necessary to provide standards and oversight for what already exist.

The American consumer has already proved that importation from Canada can work. Millions of people are using it, have been using it for years, and are complying with their treatment plans.

Thank you.

[The prepared statement of Ms. Wennar appears as a submission for the record.]

Senator KYL. Thank you. And your full statement and any other written statements will of course—

Ms. WENNAR. All of the exhibits are included, yes.

Senator KYL. You bet. Thank you.

Ms. Disch?

STATEMENT OF JOANNE DISCH, BOARD MEMBER, AMERICAN ASSOCIATION OF RETIRED PERSONS

Ms. DISCH. Senator Kyl, I am Joanne Disch, a registered nurse, a professor and a member of AARP's board of directors. Thank you for including AARP in your discussions about the need for safe importation of prescription drugs.

Americans need affordable prescription drugs, but for too many people the price of drugs is beyond their means. Recent AARP studies that have been alluded to this morning 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 medications.

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. The examples that Mr. Hubbard gave earlier are frightening and actually, in my mind, they underscore the need for us to do something in this country to make safe what millions of people are doing on a daily basis.

Many Americans already purchase their drugs from other countries. This legislation would only make it safer for what they are currently doing on their own. The trend is growing, and we have a responsibility to ensure that Americans can access lower-cost drugs safely.

Safety is critical. It is possibly the most important factor, along with efficacy, in any importation system. The drafters of S. 2328, the Dorgan-Snowe bill, have improved their legislation to include additional safety measures and consumer protections, including anticounterfeiting, antitampering requirements, mandatory labeling and chain-of-custody requirements. My written statement outlines these safety protections.

I would also like to add that we believe 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 U.S. As we delay voting on this bill, we see this occurring on a daily basis.

As a result of these changes, AARP has endorsed the Dorgan-Snowe importation legislation. 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 legal, safe 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 that 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. However, this must be done. We must find a way to do this safely and effectively. Americans deserve our support through this important legislation. The Dorgan-Snowe legislation meets AARP's criteria, and we urge its enactment this year.

In conclusion, this morning, like millions of women across the country, I took my Tamoxifen. I am one of the fortunate ones who is covered by a comprehensive health plan, so I do not experience outrageous health care costs at this point in time. I am appalled, however, what other women face, whom I know, who are middle income and not just seniors, but women of all ages in this country who cannot afford their Tamoxifen.

I have spoken with women who have discontinued it knowledgeably and prematurely, knowing the likely consequences. I cannot imagine, from my own experience, what kind of a decision that must have to be. It is time to bring cost-effective drugs safely and affordably to all Americans.

Thank you again for inviting AARP here, and I will be pleased to answer any questions.

[The prepared statement of Ms. Disch appears as a submission for the record.]

Senator KYL. Thank you, Ms. Disch.
Professor Schondelmeyer?

**STATEMENT OF STEPHEN W. SCHONDELMEYER, PROFESSOR
OF PHARMACEUTICAL ECONOMICS, UNIVERSITY OF MINNESOTA
COLLEGE OF PHARMACY**

Mr. SCHONDELMEYER. Thank you, Senator Kyl.

I will provide a written statement as a follow-up. I was out of town last week and just received the invitation on Monday and worked the details out.

I am glad to be able to present to the Committee. I want to try to add an economic perspective to this, as well as the safety perspective. Safety does have a cost, and safety also is an issue that is driven by cost. If one cannot afford a medicine that they need and does not have access to it, then their health care will get worse, and that adds a cost.

And I think I have not seen good evaluations done of this issue, but just giving the number of people who express concerns about

ability to afford a medication and not getting it because of the cost, it would appear that the safety and cost problems are far greater from lack of access due to pricing issues than they would be from reimportation of legitimate products from legitimate sources to legitimate pharmacies and suppliers in the U.S. marketplace. So I think we need to evaluate how to try to make that system work better. But let us step back a minute and ask what are we seeing in the U.S. market?

First of all, from the things I hear today, and I have heard these before in other circumstances, this is a very scary marketplace, and this is the marketplace today without reimportation. Reimportation, I do not see anything in the legislation proposed that would authorize any of the counterfeits that were talked about today by FDA, that would authorize any of the Internet sites that fraudulently proposed to sell drugs that are not good-quality medicines, none of these bills authorize any of those behaviors. In fact, they give tools to FDA and tools to Customs and tools to other Government agencies to help address and solve some of those problems.

So I think, also, we have to step back and say we cannot draw upon the importation problems from illegal activities and assume that that is what the experience will be with legal importation with appropriately authorized tools and appropriately authorized resources for our Government agencies to address those issues.

But what is happening? Why are consumers going to Canada? Are these seniors who wantonly want to defy American law and importation issues? No, these are consumers who are very price sensitive and trying to make a market work. They are trying to express their concern about prices in the marketplace and saying, yes, drugs are very valuable to me; yes, drugs affect my very life and health, but I do not have the resources, given the current system, but I see an alternative, and that is because of the convenience of Canada or because of the convenience of the Internet I can order these medicines. And, yes, it is possible for people to prey upon and take advantage of people in those circumstances as long as they remain unregulated, as they are in the marketplace today.

So consumers are trying to make a market work, but we must also step back and remind ourselves that the pharmaceutical market is not a normal economic market. This is one of the most highly regulated industries we have. We grant monopolies, we grant extensions on exclusivities and multiple patents. And while those things do reward innovation, those are good, positive, in general, for society. Innovation that is not accessible to the public is of little or no value. And I would argue that in some cases we have pharmaceutical innovations that may be very beneficial medicines, but are not achieving a beneficial purpose in society because they are not reaching people due to lack of resources, a variety of other reasons why the pharmaceutical market does not work as a normal market. But let me address a couple of other points I have heard today.

First of all, coverage, the Medicare Coverage Act is a laudable program, but it does not solve the problem. First of all, the \$600 that seniors can receive in the interim period goes faster as drug prices go up, and \$600 covers about 4 to 6 months' worth of a

brand-name prescription drug, not even one drug for a whole year. So it does not really address the problem.

Generics do not solve the problem. Americans are not going to Canada to buy generic medications. We have, in general, the lowest-price generic medications in the world available in the U.S. already, and generics are an important part of this solution. We need to encourage and increase generics in every way we can, but they are not the problem either.

Counterfeits need to be addressed. Internet pharmacy needs to be addressed. But if we allow importation of legitimate prescription products from already inspected FDA plants to legitimate purchasers in the American market and especially pharmacies and wholesalers and if those drugs are available at the corner drug store, how many Americans would be going to Canada or the Internet to buy their prescription drugs? I would argue allowing re-importation will solve more of these problems than it will create.

Thank you, sir.

[The prepared statement of Mr. Schondelmeyer appears as a submission for the record.]

Senator KYL. Thank you.

And, finally, Ms. Jaeger?

STATEMENT OF KATHLEEN D. JAEGER, PRESIDENT AND CHIEF EXECUTIVE OFFICER, GENERIC PHARMACEUTICAL ASSOCIATION

Ms. JAEGER. Yes, thank you, Senator.

I am Kathleen Jaeger, and I serve as the president and CEO of the Generic Pharmaceutical Association. On behalf of GPhA and its members, we thank you for the opportunity to testify on the issue of drug importation.

Twenty years ago, when Senator Hatch and Congressman Waxman wrote the Hatch-Waxman amendments, the Nation faced a health care crisis similar to the one it faces today. Since that time, generic pharmaceuticals have played a critical role in the effort to contain rising prescription drug costs.

Senator Kyl, GPhA and all of its members are proud of our commitment to and our success at helping Americans access affordable, high-quality medicines. Today, generics account for more than 51 percent of all prescriptions filled in the United States. Yet generics represent less than 8 cents of every dollar Americans spend on prescription drugs.

Clearly, the existence of a healthy generic drug industry has enhanced access to affordable medicines, something all purchases should want to continue to encourage. Nonetheless, we well understand the frustration that consumers, businesses and health plans have with ever-increasing drug costs. As members of Congress struggle to respond to this frustration, it is critical to make certain that any policy option considered does not inadvertently undermine incentives for generic competition or sacrifice safety or quality of our medicines.

Unfortunately, as currently drafted, we believe the legislation before Congress on importation has the potential for these unintended consequences. Many of the members we have worked most closely with in ensuring greater access to more affordable generics

are now seeking to develop a workable approach to import less-expensive prescription drugs from abroad. We have great respect for these bipartisan efforts, whether it be initiatives drafted by Senators Dorgan, Snowe, Kennedy and McCain, by Chairman Gregg of the Health Committee or by Chairman Grassley of the Finance Committee.

GPhA, however, has serious concerns about the impact of proposed importations bills will have on the safety of the U.S. drug supply system and the unintended consequences they may have on the cost-saving opportunities that are already available to consumers. Because of these concerns, GPhA currently opposes importation. However, if Congress believes it is necessary to pursue legislation in this area, we believe the following issues need to be addressed:

First and foremost, the Food and Drug Administration must be provided with adequate resources and the authority to ensure the safety of this Nation's drug supply. GPhA recommends that oversight of safety issues related to importing drugs be the responsibility of FDA and that Congress ensure that any importation bill is accompanied by the necessary Agency funding to do this effectively.

Consumers should be confident that the same strict standards that the regulators require for domestic brands and generic drugs will be in place for imported drugs as well, otherwise this Nation's drug supply chain will be vulnerable to influx of inferior and potentially dangerous medicines, including counterfeit products.

Secondly, GPhA recommends that the importation program be limited in scope and actually provide cost savings to health care consumers. Permitting the importation of generic drugs has the great potential to be counterproductive. As you have heard today, U.S. generic drugs are not only cheaper than potential imported brand drugs, but as several reports suggest, U.S. generic drugs are more affordable than generics in Canada and other industrialized countries. If we permit the importation of generic drugs and their brand counterparts, we will, in effect, be encouraging the use of prescription drugs, which may be more costly than the generic drugs available in this country while substantially adding to the burden placed on FDA by importation.

Thirdly, while we prefer that the imported drugs be required to be therapeutically equivalent, we strongly recommend that the imported drug, if it is not therapeutically equivalent to the domestic brand here, consumers should be made aware of this difference through product labeling. FDA requires generics to be therapeutically equivalent to the reference brand drug before the Agency considers the two products interchangeable. Thus, if the imported product fails to meet this standard, FDA should have the authority to label drug products accordingly to ensure that health care professionals and consumers can make well-informed decisions about switching between products.

And, lastly, any importation programs should protect the important balance between innovation and access to generics by prohibiting importation during the 180-day exclusivity period for generic companies. If importation of foreign drugs is permitted during the 180-day period, it will undue the carefully crafted balance between

innovation and access that Congress has worked so hard to achieve.

Although the debate about importation continues, there are steps that now can be taken immediately to lower prescription drug costs. Generic pharmaceuticals are a safe, reliable solution to the problem of increasing costs of prescription drugs. Increasing access to, and utilization, of generics would benefit all consumers and health care providers.

And as Senator Hatch and this Committee recognized last month, one way to increase savings is to solidify a definitive, efficient pathway for affordable biopharmaceuticals. Another way is to increase generic utilization by substantially improving the funding for and the propriety of the timely approval of generic drugs.

So, in summary, if Congress is to pursue importation legislation, we strongly believe that it must address some of the flaws of the current pending bills, and we look forward to working with you and all interested members from both parties in this regard.

Thank you, Senator.

[The prepared statement of Ms. Jaeger appears as a submission for the record.]

Senator KYL. Thank you. And I want to thank all of you for being very conscious of the time constraints. The vote that I announced would occur has already begun. I am going to have to leave for that vote, and in consultation with Senator Hatch's staff, I have concluded that the best way for us to proceed is to recess the hearing at this time. I would hope that as many of you as possible could stay because it is very possible that Senator Hatch and other members of the Committee could be returning within just a few minutes to reconvene the hearing. And therefore, if it is convenient for you to remain, I am sure there will be members who will want to ask questions.]

So, if you could please indulge us, I would appreciate that. For the time being, this hearing will be recessed.

[Recess from 12:18 p.m. to 12:29 p.m.]

Chairman HATCH. [Presiding.] We are going to continue. I apologize for not having been here, but I had to manage the floor for about an hour.

Let me just ask you this question, and it may be the only one I ask. The AARP support of the Medicare Modernization Act was greatly appreciated by me, as one who worked very long and hard on that, along with others on the Conference Committee and elsewhere.

As you may recall, when we were drafting this law, the high cost of prescription drugs was heavy on everyone's mind. We made good progress on this issue by including provisions that not only expedited approval of generic drugs, which I know you appreciated, Ms. Jaeger, and the generic drugs are significantly less expensive than brand-name drugs, but also we required the Secretary of Health and Human Services to permit imported drugs into the country if the safety of these drugs could be guaranteed.

Now, to help with this monumental task, we asked HHS to submit a report to Congress on whether the safety of these drugs can be guaranteed, and Secretary Thompson has created a task force

to review this matter. Now, these recommendations should be provided to Congress no later than the end of this year.

My question to you is do you not think that it makes sense to wait to see what the task force recommends to Congress before we approve drug importation legislation, especially in light of what we have heard from the FDA today? I hate to have it on my conscience to vote for a piece of legislation that might lead to harm to a lot of Americans because of the crooks and vicious people out there and because of what we have heard today from the FDA, much of which I think a lot of us knew before, just to score cheap political points.

So I guess what I am saying is do you not think it is better for us to wait until we have the recommendations and see what they say, the experts say, before we rush pell-mell into this type of a situation, where we allow the reimportation of drugs in the way that has been proposed by the House yesterday, and of course maybe Senator Dorgan today?

Ms. DISCH. Well, I do want to affirm the fact that safety is of paramount concern to AARP, and this is why we worked very closely with not only Senators Dorgan and Snowe, but with the other several dozen who are supporting this bill.

Our concern is that we need to keep moving expediently forward, and I would respectfully disagree with the phrase "pell-mell" because we feel we have been working on this issue, with many others, and giving it due diligence. New information is always going to be helpful. We look forward to the findings from that because maybe it would indicate some new directions we should move, in addition to this bill. But we feel very supportive and very strong that the practices that are built into the current proposal in the bill really address our concerns about safety.

Chairman HATCH. Are you not a little bit concerned, though, with what the FDA just told us and Customs just told us today?

Ms. DISCH. Well, a comment that I had made in my earlier comments was it is very frightening, when I heard some of those stories. However, where it led me, when we heard about compelling evidence, it led me to the thought that we should do something today and vote this bill in because what it showed me is what the millions of Americans, who are currently using perhaps a rogue Internet access, what they are experiencing.

But the provisions of this bill are very clear in how they limit some of the horrifying examples that were given earlier today. This bill has addressed a lot of those and we feel really create a very focused first steps. Let us get more information, let us build on it, but we feel that the testimony today actually would suggest we need to act sooner than we even thought.

Chairman HATCH. But during that time, while we experiment with this type of legislation, without the full bureaucracy that it would take, that I think one witness said would be millions of people, what if we had a lot of people die because of knock-offs, because of out-of-date drugs and because of downright criminal activity with regard to this? I mean—

Ms. DISCH. Well, as a registered nurse, I am very concerned about not only people living and dying, but people with chronic illness who cannot either keep their disease under control or have at

least some functional life. What I think we have in our country is a lot of creativity. We have some models that some of the States have used with protections built in place. We have heard testimony this morning about some ways that we could learn from either other industries or other programs that, on an even smaller basis, have had very good effect in assuring safety and efficacy.

So I do not see us, and I do not believe the AARP board sees this, as just de novo starting from scratch. We have things upon which we can build.

Chairman HATCH. Ms. Jaeger, let me ask you this question. You testified that GPhA does not currently support the Dorgan bill. Now, are there any circumstances under which you would support it and, if so, what are those circumstances?

Ms. JAEGER. Well, as I said in our testimony, GPhA opposes all the importation bills that are currently before it. We think they are flawed because of some potential unintended consequences within. And, first and foremost, we think that FDA has to have the requisite authority and the necessary funding to ensure that our drug supply system remains safe. And until that occurs and until we can assure that the products coming into our country is being looked after and examined by FDA and are sure to meet the same strict standards that the domestic brands and the domestic generics meet, then we are going to have some concern about patient safety.

Our products, as mentioned in my previous testimony, generic drugs have to be therapeutically equivalent. And that means they have to be pharmaceutically equivalent and bio equivalent before they can be interchanged with a brand counterpart. Imported products coming in, as they stand right now, cannot, I mean, there are no standards there.

There are standards for pharmaceutical equivalents, but there are not the standards for interchangeability. And our concern there is that without interchangeability and without FDA providing some assurance to the consumer that these products are indeed interchangeable, you could potentially see some adverse events in patients, especially with products that are a narrow therapeutic index, a mental drug. There are a number of products on the market that swing one way or the other with respect to a drug blood level that could actually impact negatively the consumer and the patient.

Chairman HATCH. Well, let me just say that I am very concerned about it because it now takes up to 15 years of patent life and up to a billion dollars to develop a marketable drug, and we are the best in the world at doing this. And if I have my way, we will move into bio, and we will also move into embryonic stem-cell research that will open the door to even more, hopefully, beneficial therapeutics.

But I know one thing, I cannot ignore the testimony of the FDA here and the Customs people. I do not think there is any absolute way you can be sure, with the crooks that we have in the world today, that drugs imported, especially over the Internet, and even imported in bulk, are going to be what they claim to be. I sure do not want to risk our seniors. That is one reason why I work my guts to get the \$400 billion to \$530-plus billion bill through, to help those who are literally on the bottom of the totem pole.

I totally disagree with the distinguished Congressman from Vermont. It sounds good what he was saying, but the problem is that is what we are trying to do is take care of those people who are making \$16,000 a year and cannot afford their pharmaceuticals and take care of them with real pharmaceuticals that will help them with their health care.

And as Ms. Jaeger knows, I am the author of the Hatch-Waxman Act, which basically has brought drug prices down at least \$10 billion a year—they tell me even more now—since 1984. Some have called it the most important consumer bill in the last century, and it is certainly one of the most important consumer bills. And that was not an easy thing to do. It took a long time to get us to that point.

I just have to caution everybody. I would be very, very concerned, after hearing what the FDA has had to say, what Customs has had to say, that a generic bill is going to solve this problem, when you do not put the probably tens, if not hundreds, of billions of dollars in, with a huge upswing in Federal employment, to try and take care of it, which will not do it anyway because they will never have the capacities that the pharmaceutical companies themselves do to make sure that the drugs are efficacious and safe.

So it is a matter of great concern to me. It is a nice, easy political thing to do, but I think it could really backfire on those who are pushing these types of legislation because all you need is to have just one really bad episode, and I think people in this country are going to get up in arms.

But, in any event, I think it is important for us to try and bring that safety and efficacy process down from 15 years, maximum generally, down to a more reasonable level. That is one reason why we passed the FDA revitalization bill a little over 10 years ago, to create a central campus with state-of-the-art equipment, state-of-the-art facilities, to be able to bring all of these FDA top scientists together so that we can save money, save time, save costs and, in the end, hopefully, still have even better safety and efficacy in our domestic drugs and hopefully bring down costs.

These are some of the things that we are now doing. We just dedicated the first building last fall—last winter I guess it was in November—and I hope that we will proceed with that and continue to build that facility because we set the standards for the world. We have the greatest pharmaceutical companies in the world—no reflection on others that are co-equal. We have some great foreign companies as well. But I hope we will all think this through because I am very, very concerned about it.

I just want to thank each of you for being here. I apologize that I could not be here for all of your testimonies, but I will read them and pay very, very close attention to them. This is an area that I take a great deal of interest in. I would like to bring the cost of drugs down, but I want to do it in a way that makes sense not just because somebody, in a populist way, pops off about, well, we ought to do this. I think you have got to think it through, and it has got to be done right.

So, with that, I want to thank you all for being here, and we will release you from the witness table.

Ms. WENNAR. Mr. Chairman, may I just point out one thing?

Chairman HATCH. Sure.

Ms. WENNAR. I know we keep focusing on seniors. I would ask you to please consider the facts that we have had a large growth in people that are underinsured—

Chairman HATCH. I agree with that.

Ms. WENNAR. —and individuals that do not have any coverage for this. And so they are significantly at risk, also, and the Medicare bill does nothing for them, and we are seeing these numbers grow. In the provider network, we have more and more individuals that are coming in and telling us that they cannot afford or that they have maxed out on their benefits, and we are really only focused on Canada, in terms of things right now.

Chairman HATCH. Oh, no, we are focused on a number of other countries.

Ms. WENNAR. I understand that, but from the standpoint of what exists right now in this country, individuals, under personal importation, are bringing things in.

Chairman HATCH. I think your point is well taken. I have to say that Canada is probably the safest of the importing countries in his hemisphere, but there are lots of others through which these types of pharmaceuticals or knock-offs or false drugs or whatever they are can come.

So let us all work on it, and let us see if we can resolve these problems, but they are a lot tougher to resolve than meets the eye.

But thank you all for being here. We appreciate it.

If we can have order, we are going to call on Hon. Rudy Giuliani, former mayor of New York, former assistant attorney general of the United States, to testify before us today.

Mr. Giuliani, we are grateful that you took time to come down from New York today or I think it was New York. I know you had some difficulty with the weather and had a difficult time getting here, but we are grateful to have your testimony.

As you know, I have a great deal of respect for you. I knew you when you were an assistant attorney general of the United States and have watched you as the U.S. attorney in New York, plus as mayor. We are all very proud of your service and the great service you gave to the City and State of New York and to this country.

I have watched the various committees you have been on and so forth, and we are just grateful to have you here, and we look forward to taking your testimony here today.

STATEMENT OF RUDOLPH W. GIULIANI, FORMER MAYOR OF NEW YORK CITY, AND CHAIRMAN AND CHIEF EXECUTIVE OFFICER, GIULIANI PARTNERS, LLC

Mr. GIULIANI. Thank you very much, Senator, and thank you to the Committee. I appreciate the opportunity to testify.

Chairman HATCH. I apologize there are not more Senators here, but we just had a major vote, and we will see if some of them will come, but if they do not, you and I are going to have a dialogue because this is a very important hearing.

Mr. GIULIANI. I will briefly summarize the findings that we have been able to achieve to date and then leave the maximum amount of time for questions.

There is no question that the availability of safe, effective, and reasonably priced medications is a very, very critical one for Americans, and for people all over the world. The cost of medications is extremely high, and a lot of solutions have to be found to not only reduce the cost, but increase the access and availability of medications.

The concern that I have, however, is that in trying to find those solutions we do not take a situation that is already one that is dangerous, if not out of control, which is the importation of medicines into the United States and make it even worse, particularly at a time when we are trying very hard to establish some kind of orderly system for the movement of people and the introduction of goods and merchandise into the United States.

A couple of months ago, my firm, Giuliani Partners, was retained to do a study of the risks associated with the importation of medicines—how importation exists today, what would happen if it were expanded based on what the findings are to date. And maybe the best way to summarize it is to give you one experience, and that is inspecting the mail facility at Kennedy Airport, where a significant amount of merchandise that is coming into the United States is sorted and processed.

I visited Kennedy Airport, actually on March 17th of 2003, which was not an unusual day; in fact, it was described as a fairly light day, given I think some of the weather the weekend before. Generally, they have something like 40,000 packages a day that come in that should be inspected, packages that apparently contain drugs, medicine, and things like that.

Given the number of Customs and FDA officials that they have available at the Kennedy facility, which is one of the largest in the country, they are only able to inspect 4- to 500, maybe in a really intense day 600. So that is 4- to 600 out of 40,000 packages that are coming in. So it is not an exaggeration to say that most of the medicines and drugs that come into the United States are totally uninspected. No one has any idea what is actually in the packaging, since you are looking at 1 percent of the medicines that are brought in.

But then if you look at that 4- to 600 as a sample of what might be in that 40,000, in other words, the medicines that are put aside, what you find is that the overwhelming majority of them are FDA unapproved. Many of them have packaging that appears to have been tampered with, they come from an assortment of countries that would be as many as maybe 18 or 20 different countries around the world, and in some cases the medicine is expired.

In that particular examination we did on March 17th of 2004—what we found were antibiotics that were expired by a year, 2 years, and 3 years that were being sent in as efficacious medication today. We found a significant number of medicines that appeared to have been tampered with, appeared to be tampered with meaning the coloration of the medicine was different from the actual medicine.

It looked like the packaging had been opened. And you cannot really tell whether they are correct medications or of the right potency because there really are no field tests that can be done for determining whether or not a medicine that is coming in as an an-

tibiotic is actually that antibiotic or a medicine coming in as a medicine for cholesterol, a statin, is actually the right medication. All of these tests take a very long time to produce.

But by physical examination, they appear to be incorrect medications, and then some are clearly incorrect because they are expired by 2, and 3, and 4 years and, in some cases, they are medications that never should be self-administered.

I was particularly shocked to see hormone medications that are used for prostate cancer treatment, a treatment that I underwent, which were sent in what appeared to be packaging that had been tampered with, but it also contained the syringe so that it seemed like somebody was going to self-administer this medication. And this would be medication that really has to be done under the direction of a doctor. It has to be done on a scheduled basis, and it has to be done in a way to test whether or not the medication is actually working and what side effects it might have.

All told, I would have to say somewhere between 80 and 90 percent of the 4- to 500 packages that were put aside on that day appeared to have something either technically wrong or substantially wrong with them.

Chairman HATCH. What was that percentage again?

Mr. GIULIANI. Four- or five hundred packages, out of a total of 40,000, which would be 1 percent, actually get inspected, and of that somewhere between 80 and 85 percent appear to be incorrect, tampered with—

Chairman HATCH. Have some defect or some tampering.

Mr. GIULIANI. They have something wrong with them, anywhere from something substantially wrong with them, like they are out of date by a year or 2 or 3 years or they have been opened, or from just physical examination, when you look at them, they are a different color or a different shape than the actual medication. So you would have to wonder whether they have been tampered with or something has been substituted for the real thing.

That is not an unusual situation. I conducted this examination with my colleague, the former police commissioner of New York City, Bernard Kerik, and with Senator Coleman, who was with us that day. But what we were told is this was not an unusual day. This is typical for what goes on. And when you look at other tests that have been done, other inspections and examinations, including in Miami, which had been done by, I believe, the FDA, almost the same results, almost the same percentages.

So it raises real concerns that as we presently sit here, without any opening for any further foreign importation of drugs, the system that we presently have is a system that is unreliable, it is a system that is dangerous, and it is a system that creates the real danger that we are polluting the drug supply system in the United States, since these compromised, imported drugs can be mixed with drugs here in the United States.

Now, the kind of thought is that you could safely get most of these medications in Canada, but the problem is that medicines in Canada that are exported to the United States are not subjected to any of the inspections that go on for medications that are purchased in Canada. The Canadian government basically takes the position that it will inspect medications for domestic use, but it is

not going to waste the resources, the time and the energy, nor does it have the capacity—and from what I saw at Kennedy Airport and these other inspections, neither do we—to examine the medications that are for export.

So, in many cases, if you deal with some pharmacies in Canada, you may not be getting medication that really comes from Canada. It may be a reimportation of an importation that is coming from Pakistan or from Spain or from some other part of the world.

And in many cases, or at least I should say in the pharmacies that we have been able to look at in the 2 months that we have been doing this, the Internet pharmacies in Canada will require you to sign a waiver in which you agree that you will not proceed against them if they sent you the wrong medication, which of course would be kind of extraordinary if that same thing happened in an American pharmacy.

If you went into an American pharmacy with your prescription from your doctor for a serious medication or any medication, and the pharmacist filled the prescription and then handed you a waiver to sign saying that you would not proceed against him if he gave you the wrong medication or if he did damage or harm to you, that would raise real suspicions as to whether or not the system that you are using is a reliable one.

But that is essentially what the Canadian system is telling us. They are telling us that the medicines that we get, the pharmacies cannot really stand behind, and they cannot really vouch for because, in fact, many of those medications may be coming from somewhere else. They are coming from other parts of the world where the factories are not inspected in the same way, where the same kind of reliability does not exist.

So the whole thrust of this report, and it was a preliminary report—we are still conducting an analysis and investigation—that before we open up our borders to even more importation of drugs from foreign countries or on some kind of vast scale, we should straighten out the system that we presently have. We should have a system in which we inspect more, we inspect more effectively, we develop technology so that we can trace medication, and so that we have pedigrees. Everyone wants to see more access to medications, but we do not want to see a system in which we create enormous risk and danger to health. That would be counterproductive.

It reminds me when I was the mayor there was a tremendous desire for affordable housing because people could not afford housing, but that did not lead us to then create a system of housing that was dangerous. It led us to try to find creative ways to build housing that was safe and secure and satisfied the need of people for affordable housing, as opposed to running to a solution where you end up putting people in homes that are dangerous, homes that are poorly built, homes that might create other risks for their health. That is, essentially. . . . I mean, the pressure is understandable, but the solution has to be looked at very, very carefully.

So there is a great deal more that I could discuss, but I think I have summarized it. I am open to any questions that you have, Senator.

Chairman HATCH. Thank you. That means a lot to me, to have your testimony, because you have been there, you have studied it,

you have lived in one of the most complex, difficult cities in the world, difficult-to-manage cities in the world, and you managed it very, very well.

But you discussed a paper you wrote with interim findings on prescription drug importation from foreign sources. In that report, in your report, you state that the weaknesses in our existing system could potentially open the door for individuals interested in supplying drugs through illegal means, specifically, organized crime and terrorist organizations. Now, why do you believe that these types of activities would appeal to those groups, in particular?

Mr. GIULIANI. Because it is an easy, unfortunately, it is an easy and safe, from their point of view, and unaccountable way of getting things into the United States. You almost hate to repeat this, but of course they know it, so you are not really emphasizing anything they do not already know. If you have a system that people are using and relying on to get medications that are enormously important to them, and valuable to them, something that they are going to take, and you are sure they are going to do that, and it is a system that is virtually uninspected, which this system is, then it is one that can easily be exploited by organized criminals, drug dealers, and even by terrorists as a way of harming particular individuals. It can create confusion with our drug supply, polluting the drug supply in the United States, particularly if it were to be opened to even more foreign importation.

And that is the basic analysis of the people that I rely on to give me advice on this, people who have had a lot of experience with organized crime and terrorism. If the borders are porous and able to be exploited, then that is an invitation not just to terrorists, but to organized criminals and to drug dealers to take advantage of that.

Right now, that is the case. If you open it up to even more foreign importation on a vast scale, then it becomes even more of a temptation and even more difficult.

Chairman HATCH. How knowledgeable do you think, well, in your opinion, do you think our law enforcement agencies are about counterfeit prescription drugs, illegal Internet sales, et cetera?

Mr. GIULIANI. I think the law enforcement agencies are not extremely knowledgeable about that for understandable reasons. There are not the kind of tests, either chemical or technological devices, that make it easy to detect this. My experience, and that of Bernie Kerik, who was my partner in doing this, who was not only the former police commissioner, but was formerly a detective who investigated large-scale drug importation cases, is with heroin, and cocaine and illegal drugs like that, where there are field tests available. You have a very quick, immediately available test that you can use that at least will give you a fairly good indication of whether you are actually dealing with heroin, whether you are actually dealing with cocaine and roughly the potency of it.

Chairman HATCH. But that is a little bit different from the—

Mr. GIULIANI. That is a lot different than this.

Chairman HATCH. —complex pharmaceutical drug.

Mr. GIULIANI. There are no field tests that tell you that the Lipitor is actually Lipitor or that the antibiotic is actually an anti-

biotic. So it becomes very, very difficult when you have 40,000 packages a day and no field test for law enforcement to create that kind of security for us. So it is not their fault, but the processes do not exist to allow them to really secure our borders.

Chairman HATCH. It seems like, to me, you would almost have to produce a small pharmaceutical inspection companies that know everything there is in these pharmaceutical drugs, and there is, what, 60,000 pharmaceutical drugs in our society today?

Mr. GIULIANI. When we do the test, that is exactly the way it is done. The medicine is actually sent to the pharmaceutical company that manufactured it, and then they have to actually do the test to determine is this actually the medication that it purports to be? Sometimes it turns out that it is not.

Chairman HATCH. And who pays for that?

Mr. GIULIANI. That ultimately is paid for by the Government, I imagine. Actually, I do not know the answer to that, Senator. I would have to check.

Chairman HATCH. I cannot imagine pharmaceutical companies who will want to get in a daily inspection routine that they have to pay for.

Mr. GIULIANI. I will get the answer to you, but actually what I imagine is the Government pays for the part of it where it kicks it out, sends it over. I imagine the pharmaceutical companies do it as a way of protecting their brand.

Chairman HATCH. Sure. In the paper that we have mentioned, your paper, you mentioned the distribution chain being fairly straightforward, but there are chances for exploitation or abuse within the distribution chain; namely, there are no uniform standards for wholesalers you say or distributors, and there are thousands of secondary pharmaceutical wholesalers. There is no uniform mechanism to track the medicine from the point of being manufactured to the point of sale and repackaging these products. Of course, these are all points of vulnerability.

Could you talk about how we can make improvements in this distribution chain for pharmaceuticals or really is it even possible for us to do that?

Mr. GIULIANI. I believe that is possible. I think it is impossible, as you know, to create a perfect system, but it is certainly possible to create a much better system than we presently have to determine pedigree, to keep track of it.

Chairman HATCH. Do you have any idea what that would cost to do that?

Mr. GIULIANI. I do not know how much it would cost. I know it would cost a lot of money. But given modern technology, the ability to sort information, to track information, I think it is conceivable that you could develop a system that is a lot better than the system we have now, to check the pedigree of a medication, to check the points where it has been, to make sure it has come out of the right factory so that those factories have been inspected, and to create devices that would much more easily be detectable at the border. That is the kind of thing that really should be the emphasis of what we are doing in the next year or two.

Chairman HATCH. And you would have to have a lot of cooperation from the exporting country and companies.

Mr. GIULIANI. You would have to have a great deal of cooperation from the companies that—

Chairman HATCH. It would cost them a lot of money, too, right?

Mr. GIULIANI. You would have to have a lot of cooperation from the companies that are producing the medications. I expect that most of them would want to do that because they have a real interest in making sure that their medication is protected, and you would have to have cooperation from the countries through which the medicines pass.

Chairman HATCH. But would that not then raise the costs even more of the medications?

Mr. GIULIANI. It would probably raise the cost of some medications, but at the same time it would make it a lot more available. It would also make it a lot safer, in terms of determining whether or not you are actually using the medication that you are using.

The other thing about these Internet sales is very, very often people are not saving a great deal of money on the medication. It appears as if they are, but the fact is that when they get into repetitious purchases, they are often expending a good deal of money getting the medication, and it is not terribly different from what they would spend if they got themselves into a plan, into the right plan.

The savings are sort of unfairly distributed. Some people get them. Some people do not get them.

Chairman HATCH. What would be your biggest concern that you might have with regard to importation of drugs being legalized or legislation to legalize?

Mr. GIULIANI. My biggest concern with the present system, even before you get to the open it up even more, the present system is a system in which we are not inspecting anywhere near enough of the medications that come into the United States. We have not worked out systems for determining pedigree, for determining whether it is the proper medication. To add on top of that significantly more importation would take a system that is already, if not out of control, pretty close to it, and drive it to a much worse level of vulnerability to really exploit it.

Chairman HATCH. Now, I was interested to read in your report that the Canadian Government is not inspecting drugs that have been imported to Canada and then exported to the United States. In fact, the Canadian Government, as I understand it, has stated that it will not be held responsible for the safety and quality of drugs exported from Canada to other countries, including our country, the United States.

Personally, I find that to be quite disturbing, since most believe that drugs imported from Canada to the U.S. are safe. Do you care to comment on that?

Mr. GIULIANI. Well, I think it is something where people should be absolutely aware of this. I mean, they should understand they are taking this risk because I think there is an assumption, as you say, that if you are getting medicines from Canada, they must be safe because, by and large, for Canadians getting medications in Canada, their system is as safe as ours. If you are a Canadian citizen, you go to a Canadian pharmacy, you get medicines in a Cana-

dian pharmacy, it is roughly the same system that we have getting medications in an American pharmacy.

So people who are getting medicines through the Internet or by mail from Canada think they have the same protection as they would have if they were actually buying those medications in Canada in a Canadian pharmacy. They do not because the Canadian Government says we are basically going to save our resources to protect the domestic population in Canada, not to deal with all of this tremendous amount of exportation that is going on.

So they do not inspect the medications that are being exported, and they are being honest with us. They are being honest with the American public by telling us that, if we pay attention to it. They are telling us not to expect the same level of reliability and safety if you buy medications by mail or over the Internet from us as you would if you bought those same medications in a pharmacy in Canada because we simply do not inspect the medications that are going outside the country, and we cannot. We do not have the resources to do it.

Chairman HATCH. I understand that even some of the pharmacies they require a disclaimer.

Mr. GIULIANI. The pharmacies, I cannot say that all of them do because we have not looked at anywhere near all of them, but the ones that we did look at require written waivers to do business with them, so that you will not hold them responsible. So if there is something wrong with the medication, if you order one medication, but you get another or you get a medication that is not of the right potency, you cannot hold them accountable for that the way you would if you were dealing with the medication domestically.

I suspect—although I do not know the answer to this, it is a good question so we will find out—I imagine if a Canadian citizen goes into a Canadian pharmacy to buy that same medication, he or she does not have that waiver.

Chairman HATCH. I think that is right.

Mr. GIULIANI. The same way that we do not have it if you buy something in an American pharmacy.

Chairman HATCH. Right. That means Americans would have no legitimate legal right to pursue the pharmacy that sold them a dangerous drug.

Mr. GIULIANI. It means that Americans who do that have no right to pursue them. It also means that the system is not accountable. It means that those selling under a system like that knows that they are not going to be held accountable.

Chairman HATCH. Yes, that is right.

Mr. GIULIANI. So that if they have two available supplies of medication, the reliable one they are going to save for the domestic public in Canada, and theoretically, the less-reliable one they are going to sell by mail or over the Internet because there is no accountability for that.

Chairman HATCH. Yes, and sell that with impunity because there is no way you can have redress for that.

Now, as part of your investigation, you traveled to mail facilities to review the flow of prescription drugs into the facilities. What, if anything, surprised you or concerned you with these visits?

Mr. GIULIANI. Well, there were a couple of things. I guess the main thing would be the lack of resources. If you are going to be dealing with 40,000—that is the number they gave us for JFK, and I assume that is the correct number—40,000 packages a day coming in, it would seem to me that you would have to have more than two or three inspectors, that more resources have to be put into doing inspections.

And then the technology is outdated. They do not have modern tracking equipment. They do not have the kind of computer technology that a major multinational corporation would have if it had to deal with having to even spot inspect some portion of 40,000 packages a day. You would expect to see much more advanced technology being used to profile where you are going to look, to categorize different packages and kinds of packages you are going to look at more carefully. Even knowing what is going on in the area of inspection of passengers who are now traveling by air or inspection of cargo, which is now beginning to increase, the technology in both those areas is much more advanced than the technology that is being used for drugs.

And I think that is where some very useful things can be done. That is where a lot of improvements could be made so that you would have a safer system, and then if anybody wanted to consider expanding it, they would be able to expand from the base of a safe system rather than one that is exploited as much as this one is.

Chairman HATCH. Why do you believe that opening the borders for wholesale importation of drugs will increase the number of counterfeit drugs?

Mr. GIULIANI. Well, because you are just going to, by some very, very large amount, take that inspection percentage and reduce it dramatically. If 40,000 packages a day becomes 80,000 or 90,000 or 100,000 or 200,000, then, number one, there is even less safety and, number two, it is even more of an invitation to somebody trying to get things into the country to just play the odds and say to himself I can engage in a business of sending in ineffective or even dangerous medications, and nobody is going to catch me. Nobody is going to find out about it.

Chairman HATCH. There is a lot of money in this business, too.

Mr. GIULIANI. There is a tremendous amount of money in the business, and very often in some of these situations people think they are saving money, as I said before, but they are not because they are being charged sometimes very large amounts of money, and sometimes they are being charged that money for drugs that are not even working.

Chairman HATCH. That is the point or maybe are not even drugs.

Along that same line, what is your opinion about incentives for counterfeiting and diversion of prescription drugs compared to illicit narcotics?

Mr. GIULIANI. I think that the penalties for prescription drug diversion abuse probably should be increased. Because when most of the penalties were passed, this was not a major problem in the United States. Our major focus, when most of those penalties were passed, decided and amended, was back in the days in which our major problem was illegal drugs, and that was the real focus of not only the Congress, but State legislatures. All during the time I was

assistant U.S. attorney, United States attorney, the real focus was on heroin, cocaine, marijuana, illegal drugs like that.

Some of our drug abuse problem now, a much more significant percentage of it, is diversion of prescription medications, and it seems to me it would probably be a good time to take a look at, number one, the penalties, should they be increased because the problem is worse than it was 10, 15, 20 years ago, and, number two, it probably is a good time to even divert some of our resources to that area because that is an area now where abuse is growing.

Chairman HATCH. Just one last question. Why do you suppose that investigating and prosecuting illegal drug Internet sales or counterfeit drug cases are a lower priority for both Federal and State law enforcement agencies?

Mr. GIULIANI. I think it is, Senator, because we grew up in the era in which the dramatic focus was on heroin, cocaine, marijuana, and some of the other illegal drugs. It is really just a question of conditioning and culture, as it was when those illegal drugs were the real problem. And it takes a while, even for law enforcement, to catch up with the fact that, sure, that is still a problem, but this new problem has now become much, much worse; namely, the diversion and misuse of prescription medications, and particularly those that are controlled substances. That can create a real problem.

Chairman HATCH. Well, I will tell you, it is a scary area because there is such a desire of a lot of people to try to be able to try and reduce the costs of their pharmaceuticals because, let us face it, it is expensive in this country, and they are almost willing to do anything to reduce those costs.

But the testimony we have had here today is I think pretty frightening, and your testimony is as well because you and I both know that it does not take organized crime long to catch on to how they can make big, big bucks quickly. And diluting pharmaceuticals or selling knock-offs or even false drugs, fraudulent drugs, could be—and is in some areas—big business.

I just want to personally thank you for the efforts that you have made. Not only do you understand these areas very, very well, because you have been there. You have prosecuted cases. You have been a principal law enforcement official in this country for many, many years, but as a mayor you saw some of these things happening as well.

Let me just say that I want to thank you for your testimony and for your willingness to take the time to come down and be with us and help enlighten us on this particular set of subjects. And before concluding, I would just like to ask for unanimous consent to submit the written testimony of BIO, Health Care Leadership Council and the American Pharmaceutical Association into the record. I am also going to leave the hearing record open for one week for follow-up questions and other statements.

But above all, I think all of the witnesses here today have been excellent, but in particular, I am very grateful that you would take the time to come and discuss this with this Committee because these are important issues, and a lot of people in this country just buy off on the populist explosive comments of some people about how wonderful this is all going to be, without having the necessary

safety and efficacy concerns that we have got to have if we are going to make sure that our seniors and others receive fully potent and reliable pharmaceutical prescription drugs in our society.

So I, personally, appreciate all of the work you have done in this area, and I appreciate you being with us today.

Mr. GIULIANI. Thank you very much, Senator.

Chairman HATCH. With that, we are going to, I have nobody else to question, so we will recess until further notice.

Thanks for being with us.

Mr. GIULIANI. Thank you, sir.

[Whereupon, at 1:17 p.m., the Committee was adjourned.]

[Questions and answers and submissions for the record follow.]

QUESTIONS AND ANSWERS



NABP 100 YEARS

1904 BUILDING A REGULATORY 2004
FOUNDATION FOR PATIENT SAFETY

Drug Importation Hearing
July 14, 2004
Questions for Carmen Catizone
National Association of Boards of Pharmacy

Submitted September 1, 2004

HOW SAFE ARE MEDICATIONS PURCHASED THROUGH A US PHARMACY?

The distribution of medications from manufacturers or wholesale distributors to pharmacies and ultimately to patients is the safest system in the world. Although there has been a recent increase in the incidence of counterfeit drugs in the US distribution system, that increase is small and does not signal a compromise of the US distribution system. The oversight provided by the Food and Drug Administration (FDA) and state boards of pharmacy is the primary reason that the US distribution and dispensing system is safe without reproach. At every phase of the process from distribution to dispensing, all entities are licensed or registered with the FDA and a state board of pharmacy or appropriate state agency. The licensure and registration processes ensure the integrity of the drug product, the care provided to the patient, and the competence of the pharmacists. Anyone obtaining medications from a US pharmacy can be assured that the medication is genuine, safe, and effective and that the care provided by the pharmacist and pharmacy meets the standards of care set by state laws and regulations. NABP is not aware of any comparable system anywhere in the world.

WHAT CHALLENGES FACE US PHARMACIES IN GUARANTEEING THAT THEIR DRUG SUPPLY CONTINUES TO BE SAFE, ESPECIALLY IF A DRUG IMPORTATION BILL IS SIGNED INTO LAW?

The most significant challenge that would face US pharmacies and US regulators if an importation bill is signed into law is maintaining the integrity of the US distribution system. Importation proposals presently under consideration do not address this critical area of concern and do not consider that if the source of the medication cannot be determined and validated then it will not be possible to assure that the patient will receive the legitimate drug product or for that matter, a safe product.

National Association of Boards of Pharmacy

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The challenge to protect the integrity of the US distribution system would be considerable if importation is allowed without the appropriate safeguards (which presently exist with the US distribution system) and ongoing, real time monitoring of the source and distribution pedigree of drugs that originate from foreign sources. We are not aware of any drugs that would be imported under the pending importation proposals that originate from FDA registered facilities and satisfy the standards for safety and efficacy set by the FDA. Allowing for the introduction of such drugs into the US distribution system or the individual patient's medication therapy would create an insidious and incendiary presence that would fester over time ultimately manifesting in the injury or death of untold numbers of patients. If the US distribution system is compromised because of importation, then every drug administered or dispensed to every patient in the US becomes suspect and would certainly require a certification of authenticity or laboratory validation before dispensing or administration. Even the local pharmacy that purchases its medications from licensed and reputable wholesale distributors would not be able to guarantee that the medications which they purchase and dispense to their patients is the legitimate drug product without an authenticating process and system.

WHAT TYPE OF OVERSIGHT OR GUIDANCE DOES NABP PROVIDE TO PHARMACIES TO ENSURE THE SAFETY OF THEIR DRUGS?

NABP is the international association for state and provincial, pharmacy regulatory agencies in the US, Canada, Australia, New Zealand, and South Africa. Through these agencies a system of licensure/registration exists that ensures the safety of the medications dispensed to patients and the competence of pharmacists. NABP offers these agencies a variety of programs and services that assist state and provincial agencies fulfill their responsibility to protect the public health. Among the programs and services offered are national licensure examinations, licensure transfer clearinghouses, and model legislation to address changes in pharmacy practices and improvements to the medication distribution system. Two programs that particularly address the issue of the safety of medications is NABP's Verified Internet Pharmacy Practice Sites (VIPPS) program and the NABP Clearinghouse for the Licensure of Wholesale Distributors.

The VIPPS program was established in 1997 to accredit legal and safe pharmacies dispensing medications to US patients through the Internet. The program is an innovative service that combines effective state regulation with consumer knowledge and empowerment. VIPPS is a successful program recognized by federal agencies such as the FDA and CMS and featured in countless media such as CNN, CNBC, Fox News, Dateline, Time Magazine, US News and World Report, the Wall Street Journal, and the Washington Post. Information about the VIPPS program was included in our written testimony and is available from our web site at www.nabp.net.

The NABP Clearinghouse for the Licensure of Wholesale Distributors will be operational later this year. The Clearinghouse and Model Rules for the Licensure of Wholesale Distributors which NABP released earlier this year respond to a request from the FDA and wholesale distribution industry to respond to the problem of counterfeit drugs. Adoption of NABP's Model Rules and Clearinghouse will provide states uniform requirements and the tools necessary to eliminate illegal operators from the US distribution system and maintain the integrity and security of our nation's medication distribution system.

IF A DRUG REIMPORTATION LAW WERE TO PASS TODAY, SIMILAR TO THE ONE THAT SENATOR DORGAN HAS INTRODUCED IN THE SENATE, DO YOU BELIEVE THAT LIABILITY PREMIUMS WILL GO UP BECAUSE THERE WILL BE NO GUARANTEED THAT DRUGS WILL BE SAFE?

NABP is not directly involved in the determinations of insurance carriers and the premiums which are charged. However, from our perspective and knowledge of the US drug distribution system it seems logical that insuring a system where the source of medications cannot be verified or substantiated and the resulting risk from such a precarious situation would dictate higher insurance premiums for practitioners and pharmacies.

IT IS MY UNDERSTANDING THAT PRESCRIPTION DRUGS SOLD IN CANADIAN PHARMACIES ARE SAFE AND EFFECTIVE, BUT THAT DRUGS THAT ARE IMPORTED TO CANADA AND THEN EXPORTED TO ANOTHER COUNTRY, LIKE THE UNITED STATES, ARE NOT NECESSARILY SAFE AND EFFECTIVE. WOULD YOU CARE TO COMMENT ON THIS?

NABP holds the same understanding of the situation you described. From the information we have been able to obtain from Health Canada and provincial pharmacy licensing authorities in Canada, there is no regulation of the drugs imported into Canada and exported to countries such as the US. Therefore, although the medications that are dispensed to Canadian patients from Canadian pharmacies have been approved by Health Canada for safety and efficacy and regulated by provincial authorities for dispensing to patients, drugs exported to the US and other countries fall outside of this regulatory framework. In NABP's opinion, there is no way to know the source of the drugs, how they were manufactured or stored, or whether or not the drugs are dangerous.

WHAT ARE THE DIFFERENCES IN SAFETY PRACTICES BETWEEN US PHARMACIES AND CANADIAN PHARMACIES?

Essentially the practices for Canadian patients receiving medications in Canada and US patients receiving medications from US pharmacies are the same. Although there may be some nuances when it comes to the names of drugs or specific practice standards, overall the practice of pharmacy, standards of practice, and regulation of pharmacies and pharmacists are remarkably similar. The problem is not with the Canadian pharmacies that dispense medications within the federal and provincial systems of Canada. The problem rests with Canadian Internet Service Providers and other foreign entities that distribute drugs outside of the Canadian regulatory system and export these drugs to the US or use Canada as a transshipment point for pharmacies and operations located outside of Canada. In NABP's view, there is no regulation of this activity and no regard for the safety and efficacy standards set and monitored by Health Canada and the FDA and no regulation of the practice of pharmacy by state or provincial authorities.

Hatch Questions

1. *The AARP's support of the Medicare Modernization Act was greatly appreciated by me and many others in the Senate. As you may recall, when we were drafting this law, the high cost of prescription drugs was heavy on everyone's mind. We made good progress on this issue by including provisions that not only expedite approval of generic drugs and are significantly less-expensive than brand name drugs, but also require the Secretary of Health and Human Services to permit imported drugs into the country if the safety of these drugs can be guaranteed. To help with this monumental task, we asked HHS to submit a report to Congress on whether the safety of these drugs can be guaranteed, and Secretary Thompson has created a task force to review this matter. These recommendations should be provided to Congress no later than the end of this year. Don't you think it makes sense to wait and see what the task force recommends to Congress before we approve drug importation legislation?*

The Medicare Modernization Act created a task force to examine the issue of importation of prescription drugs. AARP was pleased to be able to offer testimony to the Task Force on March 19, 2004. We understand that the Task Force intends to release its determination in December 2004. We eagerly await the Task Force's recommendation.

In the meantime however, Americans of all ages – Medicare-eligible and non-Medicare-eligible alike – are already choosing to travel to Canada to purchase less costly medications, or to purchase prescription drugs via the Internet without any systematic U.S. oversight to assure safety. We need a system in place now that allows for safe and legal importation of lower cost drugs. AARP believes the Dorgan-Snowe bill includes the necessary safety protections. If the Task Force recommends other appropriate safety measures these could certainly be incorporated into an importation system. But we need to get that system in place now.

2. *Last month, AARP announced its support of the Dorgan importation bill, S. 2328. However, having read a statement the AARP submitted for a hearing on importation on May 20, 2004, to the Senate Committee on Education, Labor and Pensions Committee, I was quiet honestly surprised by your endorsement. For example, in your May 20 statement the AARP said it would only support legalizing importation through a system that "ensures safety." I find it hard to believe, for instance, that a system that "ensures safety" could be designed and implemented in just 90 days, as S. 2328 would require. In addition, there is no new funding to support this bill, aside from user fees that are not guaranteed to ensure that this program could be implemented "safely." What technical and legal assessments did AARP do in order to make its assessment that S. 2328 would ensure the safety of importation?*

AARP supports S. 2328, the Dorgan-Snowe legislation, because we believe that it will provide for a system for safe importation of prescription drugs. The legislation would allow for importation beginning with Canada. We believe that the Canadian pharmacy system is similar to its U.S. counterpart and thus implementing a system of importation from Canada would be relatively easy to establish. The legislation also includes a number of changes AARP advocated that further strengthen the safety provisions.

Neither S. 2328 nor the competing legislation proposed by Senator Gregg would rely on appropriations to fund an importation system. Rather both bills would fund the importation system through user fees. With the implementation of a new importation system, FDA will need additional resources to ensure the safety of imported drugs. AARP believes that the user fees called for in S. 2328 (both registration fees and user fees) would be sufficient to fund the importation system. However, should these fees fail to sufficiently cover the costs of implementation of the new program; AARP would support additional funding for FDA.

AARP employs several technical and legal experts – both in-house and available through consulting arrangements. These staff and consultants carefully reviewed the legislation, and determined that – with the changes incorporated into the final draft – the legislation would provide individuals access to safe lower-priced prescription drugs.

3. *In your previous statement to the Senate HELP Committee, you stated that AARP supported importation that “lowers drug costs.” Yet, there is nothing in S. 2328 that guarantees any potential savings from importation will be passed onto the consumer. In addition, the Congressional Budget Office, which examined a similar piece of legislation, found that savings would only amount to approximately 1 percent of total projected spending on drugs between 2004 and 2013. And, most of these savings won’t occur until the second half of the scoring window. How do you reconcile your position with the fact that savings, at least according to many experts, are not guaranteed?*

AARP believes that S. 2328 will provide individuals with an opportunity to realize savings on imported drugs. The legislation removes the technical barrier to personal importation, thus allowing individuals to travel to Canada and other permitted countries, and personally transport prescription drugs back into the United States. Individuals who choose to personally import prescription drugs will realize a savings; many prescription drugs sell at 30 percent and even 50 percent less overseas. In addition, the legislation provides that drugs imported under the new importation system must bear a label indicating that they have been imported. Consumers who purchase drugs bearing these labels should expect to realize some savings.

To date, the Congressional Budget Office (CBO) has not scored S. 2328, though it has, as you mention, scored other importation legislation. We believe that once CBO has an opportunity to examine this particular piece of legislation, it will find that, in fact, consumers will realize savings on imported drugs.

4. *AARP has urged the Committee to ensure that there are adequate FDA resources to effectively monitor and enforce these standards. While S. 2328 claims to guarantee safety by giving FDA additional authority and resources through user fees, the bill then caps those user fees at 1 percent. How does AAP feel about capping FDA's ability to ensure safety? Also, since there is no mechanism for how user fees would be determined in the first year, what does AARP propose as an adequate amount of funding to ensure the program is done safely? What studies have you done to back-up your estimates?*

AARP believes that the FDA should have appropriate resources to ensure the safety and efficacy of prescription drugs imported from abroad. At the same time, we believe that the user fees generated under S. 2328 will prove adequate to fund FDA's activities in this area. However, should the FDA's resource needs exceed the amount generated by the user fees, AARP would support additional funding for FDA. In addition, AARP would support granting the FDA with appropriate start-up funds to operate the program during its first year.

Leahy Questions

1. *I am proud to be one of the many co-sponsors of S. 2328, the Dorgan-Snowe importation bill, and I appreciate the AARP's support for the bill as well. The statistics you cite in your testimony about the dramatic rise in prescription drug costs over the last few years are both familiar and alarming. I have heard nothing that would give me hope that the skyrocketing costs would come back to earth, and that is a principal reason for my support for S. 2328. Do you agree that legislation is the only way to avert this escalating crisis? Do you think there is any likelihood that the pharmaceutical industry would limit its profits to the inflation rate?*

AARP believes that importation legislation is one tool to begin to secure lower priced prescription drugs for all Americans. We believe that there are other steps that should be taken to address the problem of soaring drug prices.

One such step is research into the comparable effectiveness of prescription drugs. AARP believes that appropriate non-biased information will help consumers, payers, and others armed with appropriate non-biased information make informed decisions about their pharmaceutical choices.

Earlier this year, AARP called upon the drug industry to voluntarily limit price increases. We have also launched a prescription drug Watchdog program in which we are monitoring prescription drug prices. We believe that reports such as these will highlight prescription drug prices and put pressure on the industry to lower their prices.

2. *Some witnesses and members spoke at length about safety concerns relating to importing prescription drugs. Of course, I share those concerns, and I believe that the Dorgan-Snowe bill addresses them. But I have yet to hear of any real-life stories of people harmed by prescription drugs bought in Canada, let alone of a large-scale problem with such purchases. Have you? Is there any reason you know of to believe that the Canadian pharmacy system is somehow deficient, leaving its own citizens exposed to unnecessary harm?*

AARP believes that the Canadian pharmacy system closely mirrors the standards in place in the U.S. system. While there have yet to be any large-scale problems with prescription drugs purchased in Canada, we fear that problems could arise because millions of Americans are now choosing to import prescription drugs without the benefit of appropriate safeguards.

3. *In my home state of Vermont, especially the northern part, we are accustomed to traveling back and forth across the border as one of the benefits of living there. You note in your testimony that people will continue to import lower-cost prescription drugs whatever we do here in Washington, and I want to make sure that the opportunity to purchase those drugs is available to my constituents, and the rest of the citizenry, whether they are lucky enough to live close to the northern border or not. A Vermonter who is closer to Boston than Montreal should still get the benefit, or at least that option. The use of new technologies to track drugs – like RFID tags – would be a useful way to help ensure that drugs shipped into this country are safe and effective. The Dorgan-Snowe bill requires safety measures, and I would be interested to hear the AARP's views on how we could use new technologies.*

AARP believes that a safe system of importation is paramount. The drafters of S. 2328 have worked to further refine the safety standards in the legislation. The legislation takes advantage of new technologies by requiring the use of anti-counterfeiting and track-and-trace technologies. The legislation also provides FDA with the discretion to choose the most effective and cost-effective technologies thereby ensuring use of the latest and best methods for the safe, reliable, and speedy distribution of prescription drugs.

4. *The subject of our hearing was "Examining the Implications of Drug Importation" yet a considerable portion of the testimony we heard focuses on an important but separate issue, that of problems with fraudulent internet or mail-order pharmaceutical distribution. These fraudulent operations should be targeted and shut down – regardless of the importation status of the drugs at issue. However, discussion of these illicit activities ultimately sidestep the core issue we examined at the hearing: the implications of legalizing drug importation. Establishing a system by which Americans can reliably purchase FDA-approved drugs from reputable foreign sources would look very different than our current unregulated system. Under the Dorgan-Snowe proposal for legalizing prescription drug importation the FDA and relevant agencies would be given resources and regulatory tools to implement a reliable system for drug importation that holds all parties accountable and tracks products from development and manufacture through distribution. Do you agree that such a system would be an improvement over the current situation? If not, why not?*

AARP believes the implementation of a well-regulated system of importation would allow individuals to purchase safe, effective, lower-priced prescription drugs. Such a system would be a remarkable improvement over the current unregulated system that exists today. It would also have the crossover effect of improving the safety of the domestic market by helping to prevent the sale of counterfeit drugs.

Many of issues raised by the FDA, Customs, and others focused on unscrupulous actors who prey on individuals attempting to purchase lower-priced prescription drugs. Unfortunately many Americans in their quest for lower-priced drugs often fall victims to these unscrupulous actors. The establishment of a legal, safe, FDA-regulated importation system would protect individuals from these unscrupulous actors.

U.S. Department of Homeland Security
Washington, DC 20229



U.S. Customs and
Border Protection

SEP 24 2004

The Honorable Orrin G. Hatch
Chairman
Committee on the Judiciary
United States Senate
Washington, DC 20510

Dear Mr. Chairman:

Thank you for your letter of August 4, 2004. In your correspondence, you requested that we respond to some additional questions that arose from the United States Senate Judiciary Committee hearing regarding, "Examining the Implications of Drug Importation," on July 14, 2004. Our response to these questions is enclosed. We have also enclosed a copy of the unedited hearing transcript with some minor grammatical changes that appear in red ink.

I appreciate your interest in Customs and Border Protection. If we may offer further assistance, please contact me at (202) 344-1760.

Yours truly,

A handwritten signature in cursive script that reads "Seth Statler".

L. Seth Statler
Deputy Assistant Commissioner
Office of Congressional Affairs

Enclosures

What are your agency's biggest concerns about the drug importation legislation before Congress, specifically, those proposals before the Senate?

U.S. Customs and Border Protection (CBP) is unable to comment on specific legislation. Conceptually legalizing drug importations would increase the number of pharmaceutical shipments passing through international mail facilities, thus creating significant inspectional resource concerns for CBP due to our responsibility to verify compliance of these drugs with enacted legislation.

One of the responsibilities of Customs is to detain all controlled substances. Are you seeing an increase in the importation of controlled substances? What steps are taken once these types of products are discovered by Customs? Are they destroyed?

It is CBP policy to seize all discovered controlled substances imported through international mail and express consignment facilities. When these types of products are discovered, CBP implements rigorous accountability and control procedures including quantifying the contraband, complying with legal case processing requirements, and ultimately destroying the controlled substance. These procedures require significant manpower resources. For example, we estimate that a CBP officer must devote 1 hour to processing every controlled substance seizure. To alleviate this workload burden, and to enable our field officers to spend more time on anti-terrorism activities, we support streamlining the processing of controlled substance seizures, including the ability to summarily forfeit and destroy controlled substances.

Over the past several years, has the level of prescription medicines entering the U.S. increased? If so, by how much in your estimation? I would be particularly curious to know how many ports there are in the U.S. through which drugs could enter and how many inspectors you would need to ensure counterfeits are not being brought into the U.S.

Currently, CBP cannot quantify the amount of pharmaceuticals imported into the United States via international mail or express consignments operators. CBP is working internally and with our partner agencies to develop a data capture methodology that will provide valid estimations of the pharmaceutical imports. Presently, CBP has 13 facilities located throughout the United States where inbound international mail is processed. The import of pharmaceuticals could occur at any one these facilities. Approximately 200 employees staff these facilities.

How realistic is it to assume we could make these resources available given, as you stated in your testimony, in the post-9/11 era we have had to refocus resources toward anti-terrorism efforts?

Since September 11, 2001, the newly created CBP has a primary mission of protecting the American Homeland and securing the Nation's borders. While our primary mission has changed, CBP still has the responsibility to enforce the laws for many different agencies. CBP has the twin goals of preventing terrorists and terrorist weapons from entering the United States, while also facilitating the flow of legitimate trade and travel. We use our resources to ensure that both of these missions are fulfilled.

Can you give us an example of the average number of prescription drugs that enter some of the international mail facilities on a daily basis? What patterns have you noticed developing, if any?

The volume of imported material into the United States is overwhelming. This international mail poses several unique challenges since it is not accompanied by any electronic manifest information. One of the results of not having any electronic means of capturing data related to mail is that we do not have any precise measurement of the number of pieces of mail, much less the content, that enters into the United States each year. While we do not have statistics on the total number of imports of pharmaceuticals or controlled substances, we can report on the number of seizures that we have made. In Fiscal Year 2003, CBP made more than 12,000 seizures of pharmaceuticals and controlled substances at our International Mail Branches.

If importation were legalized, presumably we would see an even larger number of drugs entering the U.S. Yet, none of the bills I have seen would provide any additional resources for the U.S. Customs Service to handle such an increase. Does this concern you?

As more people utilize the Internet to purchase prescription drugs, we undoubtedly will experience a substantial increase in the quantity of pharmaceuticals imported into the United States. CBP will require resources that will enable us to carry out our responsibilities with regard to inspecting and interdicting drugs that violate provisions of any future legislation.

In your opinion, would limiting ports of entry simply create a funnel effect rather than provide a legitimate tool to enable Customs to inspect prescription drugs if the system were to become an open distribution system to foreign imports?

The majority of pharmaceutical importations enter the United States through international mail facilities as a result of individuals purchasing drugs over the Internet. There are currently only 13 locations that clear mail for entry into the United States. Since the mail does not have any advanced manifest information, there is very little opportunity to identify parcels containing pharmaceuticals or controlled substances before they arrive at one of the mail clearance facilities.

I know that Customs has a very difficult task in trying to detect which parcels contain prohibited pharmaceuticals. How do you determine which parcels to examine?

All mail entering the United States is required to do so at one of 13 established United States Postal Service (USPS) gateways that are also a Customs and Border Protection (CBP) port of entry for mail (i.e., where there is an International Mail Branch, or IMB, co-located with a USPS facility). The Postal Service presents all mail to CBP personnel for manual examination at one of the IMBs.

CBP clearance of mail is based on a review of a paper customs declaration affixed to the piece and, if warranted, a physical examination of the item. CBP retains those items that are illegal or otherwise prohibited entry into the United States. The remaining mail is turned back to the Postal Service for entry into the domestic mail stream for delivery, and collection of duties and fees where applicable.

CBP uses a risk management approach to select mail for examination. The first criteria that CBP uses to target mail for further screening is based upon the country of origin. The "Countries of Interest List," which constitutes 69 countries, is the first list of priority mail that CBP officers screen. CBP officers also look at packages for enforcement segregation and generally look for items that, based on experience and the development of intelligence, have proven to contain narcotics or other contraband. Each IMB generally develops its own list of factors for selecting mail for enforcement examinations.

Could you talk about the large parcels of gray market pharmaceuticals that are being split up among mail parcels and being sent to the same mailing address? Are there any dangers of gray market drugs being sold in U.S. pharmaceuticals?

Through the multiagency task force, CPB works closely with the Food and Drug Administration, the Drug Enforcement Administration and, the U.S. Customs and Immigration Enforcement (ICE) to address the imports of all pharmaceuticals. Commercial quantities of pharmaceutical imports that are suspected of being gray market goods are referred to ICE for investigation.

Isn't it the responsibility of U.S. Customs to check and see if U.S. citizens are carrying pharmaceuticals over the borders? Under what circumstances are citizens allowed to bring these products into the U.S.? What procedures are in place through Customs for checking individuals who bring these products back into the country?

CBP maintains responsibility for ensuring that illegal pharmaceuticals are not imported by individuals entering the United States. The following are specific criteria relating to restrictions on drug importations:

Laws Governing the Importation of Pharmaceuticals by Individuals

The Federal Food, Drug, and Cosmetic Act (the Act) prohibits persons from importing into the United States any prescription drug that has not been preapproved for sale by the United States Food and Drug Administration (FDA), or which is adulterated or misbranded within the meaning of the Act. Moreover, in those instances where a U.S. manufacturer makes an FDA-approved prescription drug and sends it abroad, the Act also prohibits any person other than the original manufacturer from importing the drug back into the United States. Thus, in virtually all instances, individual citizens are prohibited from importing prescription drugs into the United States.

FDA's Enforcement Policy Regarding the Personal Importation of Violative Drugs

FDA has developed guidance entitled "Coverage of Personal Importations" which sets forth their enforcement priorities with respect to the personal importation of unapproved new drugs by individuals for their personal use. Under this guidance, as an exercise of enforcement discretion, FDA may allow an individual entering the United States to import a 3-month supply of an unapproved drug if the following conditions are met:

1. The intended use of the drug is for a serious condition for which effective treatment may not be available domestically.
2. The drug will not be distributed commercially by the importer.
3. The product is considered not to represent an unreasonable risk.
4. The individual seeking to import the product affirms in writing that the drug is for the patient's own use and provides the name and address of the doctor licensed in the United States, responsible for his or her treatment with the product, or provides evidence that the product is for the continuation of a treatment begun in a foreign country.

Additional Restrictions on the Importation of Controlled Substances

In addition to any FDA requirements, if the prescription drug is a controlled substance, the following restrictions also apply. The Controlled Substances Import and Export Act generally prohibits the importation of controlled substances by anyone who is not registered with the Drug Enforcement Administration (DEA) to do so. (21 United States Code, 952, 953, 957, 960) However, under certain conditions, the Act provides an allowance for travelers entering the United States who have a legitimate medical need for controlled substances during their journey. Specifically, as set forth in the DEA regulations (21 CFR 1301.26), an individual may enter the United States with a controlled substance listed in schedules II through V, which he or she has lawfully obtained for his/her personal medical use, or for administration to an animal accompanying him/her, provided that the following conditions are met:

1. The controlled substance is in the original container in which it was dispensed to the Individual.
2. The individual makes a declaration to CBP stating:
 - (a) that the controlled substance is possessed for his/her personal use, or for an animal accompanying him/her; and
 - (b) the trade or chemical name and the symbol designating the schedule of the controlled substance if it appears on the container label, or, if such name does not appear on the label, the name and address of the pharmacy or practitioner who dispensed the substance and the prescription number, if any.

3. The importation of the controlled substance for personal medical use is authorized or permitted under other Federal laws and state law.

While the foregoing requirements apply to all persons who seek to bring controlled substances into the United States for personal medical use, Federal law imposes *additional* restrictions where the person is a United States resident returning to this country through a land border (*i.e.*, returning by land from Mexico or Canada) and such person seeks to bring into the country a controlled substance obtained abroad for personal medical use but not obtained pursuant to a prescription issued by a DEA registrant. Under such circumstances, the U.S. resident may bring in no more than 50 dosage units of the controlled substance.

CBP officers verify that individuals entering the United States are in compliance with these restrictions through the agency's inspectional process. Undeclared pharmaceuticals and declared pharmaceuticals exceeding the allowances are seized. Subsequently, legal notice is provided to the violator and, in many instances, forfeiture proceedings commence. If the drugs are forfeited to the Government, destruction will occur.

Question Submitted by Senator Patrick Leahy

The subject of our hearing was "Examining the Implications of Drug Importation" yet a considerable portion of the testimony we heard focused on an important but separate issue, that of problems with fraudulent internet or mail-order pharmaceutical distribution. These fraudulent operations should be targeted and shut down – regardless of the importation status of the drugs at issue. However, discussion of these illicit activities ultimately sidesteps the core issue we examined at the hearing: the implications of legalizing drug importation. Establishing a system by which Americans can reliably purchase FDA-approved drugs from reputable foreign sources would look very different than our current unregulated system. Under the Dorgan-Snow proposal for legalizing prescription drug importation, the FDA and relevant agencies would be given resources and regulatory tools to implement a reliable system for drug importation that holds all parties accountable and tracks products from development and manufacture through distribution. Do you agree that such a system would be an improvement over the current situation? If not, why not?

While U.S. Customs and Border Protection is unable to comment on specific legislation, it is important to know that CBP takes very seriously its responsibility to protect the residents of the United States from illicit drugs and will verify compliance of importations with laws and regulations. To accomplish this, CBP will require adequate resources to ensure that it can inspect and interdict drugs violating provisions of any future legislation which may be enacted.

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**United States Senate
Committee on the Judiciary
“Examining the Implications of Drug Importation”
Questions for the Honorable Rudolph W. Giuliani**

- 1. You recently discussed a paper you wrote with findings on prescription drug importation from foreign sources. In your report, you state that the weaknesses in our existing system could potentially open the door for individuals interested in supplying drugs through illegal means, specifically, organized crime and terrorist organizations. Why do you believe these types of activities would be appealing to terrorist organizations and a threat to our homeland security? Your report had some sobering analysis about counterfeit drugs and terrorism.**

The review conducted by Giuliani Partners revealed a number of weaknesses in the current system of prescription drug distribution. Given these weaknesses, it is conceivable that narcotics traffickers, organized criminals and possibly terrorists may view it as an easier way of getting counterfeit or otherwise compromised medicines into the United States. In light of what is already known about such criminals and how they operate, for example, they will look for opportunities that offer low risk of getting caught or being subjected to stiff penalties but also offer a high profit. Because of the weaknesses in the system, marketing counterfeit drugs could be an attractive opportunity. Since the majority of medicines coming into the United States via the mails are rarely inspected, the system could easily be exploited as a way of harming particular individuals, and creating confusion with, or polluting, the drug supply in the United States. Like the Tylenol incident in Chicago, panic and fear in addition to injury are the results.

Experts who have studied this issue theorize that organized criminals, drug dealers or terrorists could produce and sell harmful or counterfeit drugs as a method of attack, or such groups could use the profits raised through the sale of such drugs to fund their activities. If the borders are porous then they may be vulnerable to exploitation. Unfortunately, based upon observations that have been made to date, such exploitation could easily occur. It seems counter-intuitive to open the borders with regard to this country's medicine supply when in all other aspects of border security and protection, this country is looking for ways to tighten security.

Given the weaknesses that have been identified in the current system, it can be penetrated by compromised medicines. If you open it up even further through commercial importation, then it becomes even more vulnerable to compromise and, thus, even more of a temptation to criminals.

- 2. How knowledgeable, in your opinion, do you think law enforcement agencies are about counterfeit prescription drugs, illegal internet sales, etc. as compared to illicit narcotics? Is it your opinion that we need to do a better job educating our law enforcement agencies about the potential dangers of these drugs?**

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Understandably, law enforcement agencies are not extremely knowledgeable about this issue for a number of reasons and a better job does need to be done in order educate them about the dangers such drugs pose.

The importation of prescription drugs from foreign sources is a relatively new practice. It has only been in the last few years that more and more people are going on-line and filling their prescriptions via the Internet. Further, counterfeit or otherwise compromised medicines are not easily identifiable. Neither chemical tests nor technological devices exist to detect them. This is unlike drug cases involving heroin, cocaine and other illegal drugs where field tests exist to provide, in a relatively short period of time, a fairly good indication of whether a substance is actually heroin or cocaine, and can also provide a rough indication of the potency of the drug.

Under the current system the pharmaceutical company that manufactures the medicine is primarily responsible for performing the confirmatory testing on the products that are suspected of being counterfeit. The pharmaceutical companies report that such testing is often times very costly and time consuming.

Given the current volume of packages containing alleged prescription drugs coming into the United States, an estimated 40,000 packages per day at the JFK Airport mail facility alone, it is very difficult for law enforcement to inspect such packages in a of meaningful way. Thus, it is not the fault of law enforcement; the means do not currently exist to allow them to adequately perform this function.

With regard to better educating law enforcement about the potential dangers of these drugs, as more is learned about this business and advances in technology are made, it will become easier to train law enforcement about what to look for and how to combat it. Such a process would be similar to what happened when techniques were developed to combat the trafficking of narcotics.

3. **In the paper, you mention the distribution chain being fairly straightforward but there are chances for exploitation or abuse within the distribution chain – namely, there are no uniform standards for wholesalers or distributors; there are thousands of secondary pharmaceutical wholesalers; there is no uniform mechanism to track the medicine from the point of being manufactured to the point of sale; and repackaging these products is a point of vulnerability. Could you talk about how we can make improvements in this distribution chain for pharmaceuticals?**

Although it is impossible to create a perfect system, it is certainly possible to create a much better system to address some of the weaknesses that currently exist in the drug distribution system. For example, electronic pedigrees, such as those using radio frequency or RFID technology, that will better trace the flow of medicines from point of manufacture to point of sale are being developed to replace paper pedigrees; uniform or minimum standards for

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wholesalers and distributors could be considered, such as those developed by the National Association of Boards of Pharmacy; the recommendations of the FDA's Counterfeit Drug Task Force could be considered for implementation (it suggests, for example, counterfeit resistant technologies, tightening requirements for repackagers and increasing criminal penalties for counterfeiting activities); the recommendations from the Florida grand jury report, which were similar to those made in the FDA report, could also be considered; and giving the FDA and other responsible agencies the necessary authority and resources to adequately address the current situation would all be steps to consider in order to improve and tighten up the distribution chain.

4. What is the biggest concern you have about drug importation being legalized?

The biggest concern about legalizing drug importation is that given what has been observed regarding the existing system, if it is opened further to authorize personal importation or, worse, commercial importation, then it will be subject to even greater exploitation and abuse. In view of the limits on staffing and resources, there are not nearly enough inspections being performed on the medications that come into the United States through the mails. An efficient system for determining pedigree, or for determining whether the medication is what it purports to be, have not been devised. And it is undisputed that the number of incidents involving counterfeit drugs is already increasing. In light of these facts, coupled with the other challenges to oversight and enforcement, the existing system must be improved before any sort of expansion or legalization is contemplated.

5. We have heard a lot from opponents of importation about the safety concerns they have regarding importation – why, in your opinion, have we not seen more adverse events if there really is a safety concern? I am going to ask you the same questions I asked our FDA witnesses – who is really being harmed by imported drugs?

Unfortunately, we may not know the answer to the question about who is being harmed. Currently, the importation of medicines from outside the United States is not legal, notwithstanding the FDA's personal use exemption, and, as a result, it is an unregulated practice. Since there are no systems currently in place to monitor this practice, there is no way to determine whether injuries result from taking compromised medicines. Some of those interviewed explained that the medicines being imported from foreign sources are often used for chronic illnesses, such as heart conditions, and if injury or death occurs, it is frequently assumed that it was a result of the condition and not the medicine. It is not usually a part of a physician's or emergency room's protocol to question where a patient may be filling his or her prescription. Thus, it is difficult to assess actual harm.

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6. Why do you believe that opening the borders for wholesale importation will increase the number of counterfeit drugs?

It is undisputed that even with our existing "closed" system of importation and distribution that the number of cases involving counterfeit drugs has increased. Further, it is known that this is a high profit, low risk business – the profit margins are large and risks of getting caught or severely penalized are relatively low – and, thus there is incentive for even greater exploitation. It remains unclear how a system of regulation and oversight could be implemented that will ensure safety when the prescription medicines may be coming from several different countries. The existing system is already overwhelmed. Given what we already know, if more drugs are imported from outside the country, the percentage of packages that can be inspected will, inevitably, be reduced dramatically. As a result, with fewer inspections there is even more of an opportunity for someone or some group to try to get counterfeit product into the country.

7. I was interested to read in your report that the Canadian government is not inspecting drugs that have been imported to Canada and then exported to the United States. In fact, the Canadian government has stated that it will not be held responsible for the safety and quality of drugs exported from Canada to other countries, including the United States. I find this quite disturbing since most believe that drugs imported from Canada to the United States are safe. Would you care to comment on this?

Many of those ordering medicines over the Internet from a Canadian website believe that they are ordering and receiving the same FDA-approved product that they would obtain in their local domestic pharmacy. This may not necessarily be the case. If it is a Canadian Internet pharmacy that has been inspected or approved by a provincial board of pharmacy, then the patient may be receiving a Health Canada approved medicine, which would be roughly equivalent to a FDA approved medicine. However, there are many Internet pharmacies that purport to be Canadian but, in fact, operate out of other countries and/or are not necessarily dispensing legitimate medicines. Thus, while the Canadian system is, by and large, as safe as the American system, not all Internet pharmacies are regulated by the Canadian healthcare system. Accordingly, when ordering on line, a person cannot necessarily be sure that the order is being placed with a legitimate pharmacy that is dispensing a safe product. And given that such pharmacies fall outside of the Canadian regulatory system, they are not being inspected in the same fashion as the legitimate pharmacies. Indeed, as noted in the question, the Canadian government did state in a letter to *The Washington Post* that "[t]he 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."

Another point to be made with regard to the quality of the medicines being obtained through the Internet is that many of the Canadian Internet pharmacies examined require written waivers in order to receive the medicines ordered.

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The intended purpose of such waivers is to preclude a patient from holding a pharmacy responsible in the event there is something wrong with the medication received. If a person orders one medication, but gets another or receives a medication that is not of the right potency, the patient may not necessarily be able to hold the pharmacy accountable in the same manner he/she could if the pharmacy in question were an American pharmacy.

In addition, a few of the state or city sponsored websites that have direct links to Canadian internet pharmacies have disclaimer language which reads "certain inherent risks in ordering any product through the mail..." and "importation of drugs from Canada is not legal..." Such disclaimers also state that the purpose of the website is only to provide information and that the state would not be liable for any damage that occurs through the use of the site. The result is that Americans who order their medicines over the Internet may have no recourse to pursue the Canadian Internet pharmacy in the event of a problem. As a result, there is a lack of accountability in such a system.

- 8. Question 5 repeated – see answer above.**
- 9. As part of your investigation, you have traveled to mail facilities to review the flow of prescription drugs into the facilities. What surprised you or concerned you, if anything, at these visits?**

There were a few of things that were not only surprising but also raised a great deal of concern. The volume and types of medicines that were coming through the mail was of great concern. There were thousands upon thousands of parcels of medicines being shipped from a variety of countries. There were drugs purporting to be Xanax, Valium and Vicodin, which are all controlled substances. There was Lupron, an injectable drug used to treat cancer that requires the very careful supervision of a doctor when administered. In addition, many of the parcels contained medicines that were non-FDA approved – for example, some were expired, some were improperly labeled or packaged and some were obviously of a size and color different from the original.

Another area of concern is the lack of resources for those agencies that are responsible for inspection and enforcement at these facilities. Given the volume of packages reportedly containing prescription medicines – an estimated 40,000 packages a day coming into the JFK mail facility alone - it would seem that more inspectors as well as additional resources are necessary to adequately perform the inspections. Further, the technology that is available at the facilities is either outdated or not available; for example, modern tracking equipment is not readily available and the computer programs being used did not appear to as useful as they could be. Also, the cumbersome bureaucratic process that the FDA must comply with in order to detain, return and/or destroy the drugs that are obviously non-FDA approved was quite surprising. This process could be streamlined so that more time could be spent on inspections.

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10. What is your opinion about incentives for counterfeiting and diversion of prescription medicines compared to illicit narcotics?

Under the current penalty scheme, it is far riskier for a person to engage in the illegal sale of narcotics than the illegal sale of diverted or counterfeit prescription medicines. Given the following factors - the weaknesses in the current system that were discussed previously, the fact that the punishment for getting caught engaging in such activity is comparatively light, and the large profits that can be made – there appears to be a greater incentive for people to break the law and engage in counterfeiting or diversion activity. Thus, the penalties for diverting prescription drugs or counterfeiting should be and re-examined and, in all likelihood, increased. An average penalty of three years for such an offense does not appear sufficient compared to the nature of the crime. Currently, it is a high profit – low risk business. When most of the penalties were passed, such activity was not a major problem in the United States. The major focus was primarily illegal drugs.

11. Why do you suppose that investigating and prosecuting illegal Internet sales or counterfeit drug cases are a lower priority for federal and state law enforcement agencies?

Historically, the major focus has been on investigating and prosecuting cases involving heroin, cocaine, marijuana, and other illegal drugs, particularly because of the violence and other associated crime that follows the drug trade. It takes time, even for law enforcement, to learn that, while heroin and cocaine are still a problem, there is this new problem, which is becoming much worse – that is the diversion, counterfeiting and misuse of prescription medications, particularly those that are controlled substances. Although law enforcement and prosecutorial resources are stretched rather thinly, they should begin to dedicate additional resources to investigating these types of crimes and abuses. It is not hard to imagine that given the money involved in this industry, the same people who are engaged in manufacturing, distributing and selling illegal drugs, could also become involved in the manufacture and sale of counterfeit prescription medicines.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

The Honorable Orrin G. Hatch
Chairman
Committee on the Judiciary
United States Senate
Washington, DC 20510-6275

OCT 26 2004

Dear Mr. Chairman:

Thank you for the letter of August 4, 2004, which posed questions to the Food and Drug Administration (FDA or the Agency) for inclusion in the record of the Judiciary Committee's July 14, 2004, hearing on the implications of drug importation. This letter also includes FDA's responses to Senator Patrick Leahy, who submitted questions to the Agency on August 27, 2004, and Senator Diane Feinstein, who submitted questions on July 15, 2004.

We have restated each of your questions, followed by FDA's response.

- 1) **In your testimony, you maintain that the public may be assured that the quality of drugs that consumers purchase from U.S. pharmacies remains high, but that FDA cannot offer the same assurances about the safety and quality of drugs purchased from foreign sources. So, what happens if a drug importation bill is signed into law this year? How will FDA overcome the obstacle of reassuring the public that drugs purchased from foreign entities or governments will be safe and effective? How much will it cost the Federal government to guarantee the safety of drugs imported into the United States?**

The practical and legal problems associated with ensuring the safety and quality of drugs imported from foreign pharmacies and wholesalers would be substantial. FDA and state boards of pharmacy do not have authority over the foreign drug distribution chain, nor does FDA have the ability to monitor and regulate the manufacture of drugs intended for markets other than the U.S.

As you know, foreign pharmacies and wholesalers are not subject to FDA or state oversight, not licensed in the U.S., not subject to review or inspection by U.S. regulatory bodies, not required to meet U.S. standards for storage and safe handling of drug products, and not subject to U.S. jurisdiction for failure to comply with Federal or state requirements.

The U.S. drug distribution system as it exists today is a relatively "closed" system. Most U.S. retail stores, hospitals, and other outlets obtain drugs either directly from the drug manufacturer or from a small number of large wholesalers. FDA and the states exercise oversight of every step within the chain of commercial distribution, thereby ensuring a high

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degree of product purity and quality. Moving from the current "closed" distribution system with relatively few importers to an "open-border" distribution system would create opportunities for bringing prescription drug products into the country that are manufactured or held outside the rigorous regulatory system overseen by the states and FDA. It would increase the risk that counterfeit, misbranded, and adulterated drugs would show up on U.S. drug store shelves and in American homes. Our criminal investigators also predict that counterfeiters will exploit the deficiencies in the incoming foreign products, thus creating another opening through which commercial volumes of foreign drugs would be unlawfully relabeled as American products in order to garner the prestige and price the approved U.S. drugs would command.

FDA drug approvals are manufacturer-specific, product-specific, and they include many requirements relating to the product, such as manufacturing location, formulation, source and specifications of active ingredients, processing methods, manufacturing controls, container/closure system, and appearance. Drugs that are imported outside of this regulatory process bypass these protections, and no amount of visual inspection at U.S. borders can provide the same level of assurance of safety, quality and effectiveness as FDA's drug approval process.

Anticipating the costs of any future importation program is a difficult exercise in that there are many variables that depend on the nature of the program enacted. It must also be noted that some legislative proposals would require that FDA perform inspections of foreign pharmacies. FDA does not have substantial experience in this area. The regulation of pharmacies has primarily been under the purview of state regulatory authorities. The costs associated with inspections of foreign pharmacies and/or wholesalers would certainly be quite large. So too would be the costs associated with any new testing or pre-approval program. The study currently being prepared pursuant to the Medicare Modernization Act (MMA) of 2003 is expected to address resource and cost questions associated with foreign importation of drugs.

- 2) **The Medicare Modernization Act of 2003 created a task force through the Department of Health and Human Services to make recommendations to the Secretary about the agency guaranteeing the safety of imported drugs. I was a member of the Medicare conference committee, and we worked very hard on this particular provision in the legislation. Our end goal was to require the Secretary of Health and Human Services to certify the safety of prescription drugs prior to allowing them to be imported into the United States. We asked HHS to conduct a comprehensive study and prepare a report to Congress on whether importation can be accomplished, and, if so, what needs to be done to guarantee the safety of imported drugs. The task force's recommendations are due at the end of the year. Could you provide us with an update on the work of the task force? Do you have any idea what type of recommendations that task force will make to Congress regarding the safety of imported pharmaceuticals?**

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Secretary Thompson created an intergovernmental task force, chaired by Surgeon General Richard Carmona, which is currently working on this study. The task force includes representatives from FDA, the Centers for Medicare and Medicaid Services, Customs and Border Protection (CBP), and the Drug Enforcement Administration (DEA). The task force has brought together a wide variety of stakeholders to discuss the risks, benefits and other key implications of importing drugs into the U.S., and to offer findings to the Secretary on how to best address this issue in order to advance the public health. The statutory language in the MMA and the conference report provide detailed, comprehensive questions to be considered in the importation study. As an integral part of the study process, the task force held a series of six meetings to gather information and viewpoints from consumer groups, health care professionals, health care purchasers, industry representatives and international trade experts, and a public docket for comments was opened as well.

- 3) **Many have raised questions about the public health impact that counterfeit drugs could have on individuals. What type of problems could individuals encounter from taking drugs from foreign sources? I hear questions about how many deaths or serious injuries have been caused by these drugs and the answer isn't that simple, is it? For example, if a cancer patient was taking adulterated Procrit, death from cancer could be accelerated and when that person did die, his death would be attributed to cancer, not the counterfeit drug. Could you talk about why we don't typically see deaths or severe illnesses from counterfeit drugs?**

FDA's goal is to prevent death or serious injury from adverse reactions to marketed drugs to the greatest extent possible. The Agency has not waited for these events to occur before becoming concerned about the importation of medications outside the regulatory system established by the Federal Food, Drug, and Cosmetic (FD&C) Act.

Consumers are exposed to a number of potential risks when they purchase drugs from foreign sources or from sources that are not operated by pharmacies properly licensed by state pharmacy regulators. These outlets may dispense expired, sub-potent, contaminated or counterfeit product, the wrong or a contraindicated product, an incorrect dose, or medication unaccompanied by adequate directions for use. The labeling of the drug may not be in English and therefore important information regarding dosage and side effects may not be available to the consumer. The drugs may not have been packaged and stored under appropriate conditions to prevent against degradation, and there is no assurance that these products were manufactured under current good manufacturing practice (cGMP) standards. When consumers take such medications, they face the risks of dangerous drug interactions and/or suffering adverse events, some of which can be life threatening. More commonly, if the drugs are sub-potent or ineffective, consumers may suffer complications from the illnesses that their prescriptions were intended to treat, without ever knowing the true cause.

FDA is generally unable to quantify adverse events directly related to imported prescription drugs for a number of reasons. First, the adverse event reporting system in the U.S. is not geared towards distinguishing between foreign or domestically obtained drugs. Second, there is a natural reluctance on the part of patients or their representatives to report adverse effects of drugs that are obtained outside of the normal, legal channels.

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While FDA has not quantified the number of deaths or serious injuries resulting from imported prescription drugs, we are keenly aware of testimony provided to several Congressional committees by families who have suffered the loss of loved ones as a result of taking prescription medications obtained through the Internet or foreign sources.

4) How is the FDA educating consumers about the dangers of imported medications? Are consumers taking these warnings seriously?

FDA has established a multimedia education program, "Buying Rx Drugs Online," which is centered on our website at: <http://www.fda.gov/oc/buyonline/default.htm>. The website includes information for consumers, including tips and warnings on how to spot health fraud, http://www.fda.gov/fdac/features/1999/699_fraud.html, frequently asked questions, <http://www.fda.gov/cder/Offices/DDI/FAQ.htm>, and where to report suspected "rogue" Internet sites, <http://www.fda.gov/oc/buyonline/buyonlineform.htm>. The "rogue" Internet site reporting page is one of the most frequently visited on FDA's website.

FDA's public outreach includes FDA *Talk Papers*, articles in *FDA Consumer* magazine, and information on FDA's website to help educate consumers about safely purchasing drugs online. Another central piece of our campaign is a brochure entitled, "Buying Prescription Medicines Online: A Consumer Safety Guide." The brochure was produced by the CybeRx Smart Safety Coalition, a partnership of Internet companies, trade associations, health and consumer organizations, FDA, and other government agencies. The number of consumer complaints received by FDA has grown steadily with circulation of the brochure.

FDA continues to post information on its website and provide information through the press about specific instances of fraudulent and dangerous products obtained from foreign sources. For instance, in February 2004, FDA issued a warning to the public about a foreign Internet site selling counterfeit contraceptive patches. These counterfeit patches contained no active ingredients and therefore provided no protection against pregnancy. Photos contrasting the legitimate contraceptive patch with the counterfeit were put on display on FDA's website. The Agency recommended that women who obtained these contraceptive patches not use the product and contact their health care providers immediately. FDA obtained the cooperation of a U.S.-based Internet service provider (ISP) in shutting down service to these websites.

5) I am interested in more details about the efforts FDA is taking with other Federal governmental agencies to develop more effective enforcement strategies. Could you please provide more details? Which agencies are you partnering with? What efforts are being undertaken by FDA and other agencies? Is FDA the lead agency in these efforts?

Several Federal agencies, as well as the states, have the authority to regulate and/or enforce U.S. laws related to the online sale of drug products. Working closely with the states is essential to regulate the sale of drugs effectively, as well as address the sale of prescription drugs without a valid prescription over the Internet. FDA has established partnership agreements with several state bodies, including the National Association of Boards of Pharmacies (NAPB) and the Federation of State Medical Boards, to coordinate Federal and state activities aimed at illegal practices associated with the selling and prescribing of prescription drugs over the Internet.

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FDA meets regularly with other Federal agencies and state officials to share information, discuss the roles and responsibilities of the agencies regarding online drug sales and identify opportunities for partnering in enforcement actions. FDA maintains strong working relationships with the Department of Justice (DOJ), including the DEA, the Federal Bureau of Investigation (FBI), the U.S. Postal Inspection Service, CBP, Immigration and Customs Enforcement (ICE), the Office of National Drug Control and Policy (ONDCP) and other appropriate Federal and state agencies. FDA believes that cooperation among Federal agencies is critical to addressing the sale of drugs to U.S. residents by foreign sellers. FDA is certainly the lead investigative agency in many cases, and often shares investigative responsibility in others.

In addition, an Interagency Pharmaceutical Task Force composed of participants from FDA, CBP and ICE, has been formed to delve into the drug importation issue and to explore the application of consistent, fair policies by regulatory and law enforcement agencies to deal with this problem.

The Task Force met for the first time on January 29, 2004, and has continued to meet monthly. The Task Force's main goals are to:

- Devise a mutually agreed upon strategy for enforcement, interdiction and disposition of unlawful pharmaceuticals entering into the U.S.;
- Make recommendations for appropriate statutory or regulatory changes to increase the effectiveness of its respective members' enforcement efforts;
- Propose joint enforcement operations at ports-of-entry;
- Mutually agree upon policies relative to unauthorized importation; and,
- Commit resources to carry out the strategy and policies that are developed by the Task Force.

The Task Force has established five subgroups that have focused on:

- Informing the public of the dangers associated with imported drugs;
- Enhancing intelligence sharing and targeting of information amongst the government agencies;
- Improving our procedures for handling imported mail at mail facilities and courier hubs;
- Establishing ties to industry so that we can form partnerships that will help us deal with the increase in imported drugs; and
- Reviewing legal and regulatory options for dealing with this problem.

FDA is also involved in the effort to combat the increase in the abuse of prescription drugs, which is evident in the increasing illegal sales of controlled substances on the Internet. In announcing the President's National Drug Control Strategy for 2004, ONDCP has brought together FDA, Federal substance abuse prevention and treatment agencies, and Federal law enforcement agencies to combat collectively the factors contributing to rising prescription drug abuse. The strategy incorporates (1) the education of medical professionals and consumers, and (2) outreach to businesses involved in Internet commerce, pharmaceutical

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manufacturers, and pharmacies. The new program also includes a range of activities designed to reduce the abuse of prescription drugs, and includes the use of web crawler/data mining technology to identify, investigate and prosecute "pill mills," Internet pharmacies that illegally provide controlled substances.

To the extent that resources permit, in conjunction with DEA, FDA plans to implement additional investigative efforts and enforcement actions to curb the illegal sale, use, or diversion of controlled substances, including those occurring over the Internet. Many of the e-pharmacies that sell these controlled substances are foreign-based and expose the purchaser to potentially counterfeit, contaminated, or adulterated products.

- 6) **How many consumers or foreign companies have been prosecuted for violating Section 801 of the FD&C Act for importing unapproved, misbranded, or adulterated drugs into the U.S.? Is it true that consumers and our government have only limited recourse against these foreign operators? Why? How may we improve this situation so our consumers can be better protected? Could you explain the history of this provision - what led Congress to implement this provision in the first place?**

Although the importation of unapproved drugs violates the FD&C Act, FDA has not sought to prosecute individual consumers who import these drugs for their own personal use. We have instead concentrated our enforcement efforts on commercial entities that systematically facilitate the importation these drugs or which attempt to commercialize the sale of foreign, unapproved drugs to U.S. consumers in violation of the FD&C Act.

While section 801 of the FD&C Act prohibits certain unlawful import activity, it does not contain specific criminal provisions. Offenses involving imports are typically prosecuted under the prohibited acts set forth in section 301 of the FD&C Act and through various sections of Title 18, United States Code (U.S.C). As your question suggests, U.S. law enforcement authorities face inherent difficulties in attempting to bring actions against a foreign entity illegally selling drugs to U.S. consumers. Although some fact patterns may provide sufficient evidence and jurisdiction to charge a person in a foreign country who sells drugs to a U.S. resident in violation of the FD&C Act, from a practical standpoint, FDA and the DOJ have a difficult time enforcing the law against foreign sellers. As a result, the Agency's efforts typically focus on requesting the foreign government to take action against the seller of the product, and/or asking CBP to stop the imported drug at a U.S. port-of-entry. For instance, OCI, via its participation at the Interpol National Central Bureau in Washington, D.C., recently reported the sale of counterfeit drugs at specific pharmacies along the Mexico/U.S. border to Interpol-Mexico City for appropriate follow-up by law-enforcement authorities in that country. The sale of drugs to U.S. residents via foreign websites is an extremely challenging area. Internet technology can obscure the source of the product as well as provide a degree of anonymity to those responsible for selling and shipping the product. The parties to a transaction can be dispersed geographically and usually never meet. Thus, the regulatory and enforcement issues cross state, Federal, and international jurisdictional lines.

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In 1988, Congress enacted the Prescription Drug Marketing Act (PDMA) to establish additional safeguards to prevent substandard, ineffective, or counterfeit drugs from entering the U.S. Under PDMA, it is illegal for anyone other than the manufacturer of a prescription drug to import that drug into the U.S. if it was originally made in the U.S. before being sent abroad. This law was enacted with strong bipartisan support because of high-profile cases of unsafe and ineffective drugs entering the U.S. in large volumes. In one instance, over 2 million unapproved and potentially unsafe and ineffective Ovulen-21 "birth control" tablets from Panama were distributed throughout the U.S. In another case, a counterfeit version of Ceclor, a widely used antibiotic at the time, found its way into the U.S. drug distribution from a foreign source. Over the years, FDA has employed PDMA and other authorities to build a drug safety infrastructure to ensure that Americans enjoy the highest-quality drug supply.

- 7) **You cite disturbing facts about how the internet has made it even more difficult for the FDA to detain and refuse mail imports for personal use due to the high volume of drug parcels entering the U.S. through international mail and courier services, and the requirement for notice and hearing and your agency's limited resources. I understand you are working on strategies to limit potential public health risk. Could you please expound on this in more detail?**

In January 2004, the Office of Regulatory Affairs (ORA) began a process to ensure that our personnel at the international mail facilities and air courier hubs had consistent procedures for handling imported drugs. Representatives from ORA headquarters and its regions, led by senior managers, began to meet and review the old procedures with an eye toward merging the experiences gleaned through FDA's import blitz examinations with the lessons learned through the use of the old procedures. Through this effort, the Agency drafted new procedures that will be used by all FDA personnel responsible for handling mail at the international mail facilities and the air courier hubs.

The procedures differ in some respects to reflect the difference between how the international mail facilities and air couriers conduct their business. For example, international mail importations are significantly different from importations via commercial carrier or air express carrier. They occur without any formal declaration or description of the packages' contents, entry documents are not provided, they are usually small in quantity and low in value, and they are generally addressed to private individuals rather than commercial organizations. For these reasons, they often require a significantly higher expenditure of resources relative to their overall quantity than do commercial or air courier shipments. Since mail importations lack formal declarations, the most effective way to determine if they contain FDA regulated pharmaceutical products is to physically open and examine them, but this is possible for only a relatively small fraction of that total. Historically, once selected by the screening process, the package was opened, contents examined, and an inspector makes an admissibility determination. However, efficient use of available resources mandates some method of invasive screening of the mail to select those packages with the highest probability of containing non-admissible products. The new mail facility procedure outlines how this can be accomplished through various means including:

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- The targeting of mail from countries with a history of shipping non-admissible products
- X-ray examinations; or
- Noting the visible characteristics of the package.

ORA fully implemented the new mail procedure on August 12, 2004.

In the context of the air courier hubs, the Agency also established a new procedure for the conduct of air courier import operations to ensure consistency and uniformity across the Agency. ORA implemented the air courier procedure during the week of August 9, 2004. The new procedure reflects the fact that there are some inspectional operations that are unique to air courier hubs. The oversight of these hubs has changed significantly over the last decade. Air courier operations have become more complex with the use of multiple, automated systems to help imported product move more quickly to keep up with customer demand. Therefore, in the context of the air courier hubs, there are some aspects of our import operations that must be addressed separately in a stand-alone procedure. For example, the air courier hub Agency personnel are responsible for making admissibility decisions based on the manifest and the other entry documents that the air couriers are responsible for submitting in order to gain the entry of their products.

8) I am interested in learning more details about the FDA's division of Import Operations – what is the purpose of this Division?

FDA's Division of Import Operations and Policy (DIOP), a division of the ORA provides direction, assistance, management and oversight of import operations at U.S. ports-of-entry, including investigational and compliance activities. This office serves as the Agency focal point for Headquarters/field relationships on all import programs, operations, and problems. DIOP establishes consistency for FDA import field activities by developing and implementing procedural policy and the operation of automated systems, and oversees the field import quality assurance program.

DIOP has primary responsibility for Chapter 9 of the Regulatory Procedures Manual (which covers the regulation of imported products) and develops Agency import policies, procedures, program, and assignments; including informational directives such as Import Alerts and Bulletins, and implements the laws and regulations involving imported products. The division coordinates Agency import activities with the Centers and FDA's Office of the General Counsel.

DIOP coordinates Agency import activities with CBP, including the development and institution of joint regulations, procedures, policies, and operations. It also coordinates activities with other Federal agencies and foreign governments through interagency agreements, memoranda of understanding, and informal working relationships.

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- 9) **Could you please talk about the responsibilities of the FDA's Office of Criminal Investigations? Does it work directly with the Division on Import Operations? Is the office of Criminal Investigations primarily responsible for following-up on drugs that have been imported into this country illegally? What has this office done on this matter? How many counterfeit drug cases has this office investigated? Which drugs are most likely to be counterfeited?**

The Office of Criminal Investigations (OCI), an Office within ORA, is responsible for all criminal investigations within the jurisdiction of FDA. Pharmacy sites and other Internet drug sites, whose operations involve potential criminal activity, as well as cases involving the introduction of counterfeit drugs into U.S. commerce, represent some of the criminal cases initiated by OCI. However, as indicated in response to an earlier question, the mere sale of prescription drugs over the Internet does not, in and of itself, constitute a criminal violation of the FD&C Act. OCI directs its limited resources against those Internet drug purveyors whose conduct is prosecutable under existing Federal laws. OCI then refers evidence of criminal violations to the respective U.S. Attorneys Office with the proper venue for the offense(s).

OCI has seen its counterfeit drug investigations increase to over 20 per year since 2000, after averaging only about five per year through the late 1990's. As of the July 14, 2004, hearing, OCI had opened 85 counterfeit drug cases since October 1996. These investigations have so far netted 77 arrests and 42 convictions.

OCI's experience suggests that drugs most likely to be counterfeited or those most susceptible to counterfeiting fall into several broad categories:

- **Expensive injectable drugs.** These include human growth hormones, Procrit, Epogen, Neupogen, and others. In many instances plain tap water or saline solutions could be substituted for the genuine clear liquid product and sold in counterfeit packaging to unscrupulous wholesalers for further distribution in the health care distribution system. This is a particularly egregious crime since many patients using these injectable drugs are among the most critically ill, in desperate need of therapeutic benefits, and most susceptible to infection or other complications from substandard products.
- **Commonly Prescribed Drugs.** These would include drugs such as Lipitor, Zyprexa, and Celebrex and many others. Criminals frequently counterfeit these products or put stolen, expired or foreign versions of these products into counterfeit packaging because they are in high demand and easily sold in the secondary wholesale distribution market. The health consequences of taking these type products are often not immediately identifiable, but nonetheless can lead to serious medical consequences.
- **Lifestyle Drugs.** The most commonly counterfeited drugs in this category are Viagra and other erectile dysfunction drugs. These drugs are most commonly sold over the Internet or through other non-traditional health-care outlets.

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A national list of drugs susceptible to counterfeiting was developed by the NABP as part of its new "model act" for pharmaceutical wholesalers. It is based in large part on Florida's new drug wholesaling law and in consultation with FDA. The Agency is in agreement with NABP that at this point in time these are the drugs or types of drugs most likely to be unlawfully diverted and counterfeited. Each of those drugs can be fit into a one of the categories discussed above.

OCI receives information on Internet crimes, drug counterfeiting, and other potential import offenses from FDA's District Offices, the Center for Drug Evaluation and Research, the various components of the ORA including DIOP, and from law enforcement, regulated industry, public health officials, private citizens, Customs officers, and numerous other sources. OCI frequently seeks to leverage its limited resources by conducting joint investigations with other agencies having jurisdiction. OCI currently has numerous ongoing investigations with DEA, CBP/ICE, FBI, USPIS and many state and Federal law enforcement organizations.

- 10) **I know that the FDA has convened a Counterfeit Task Force. I would like you to talk about how this task force is working on anti-counterfeiting technologies and what coordination is taking place between the Task force and law enforcement agencies?**

The Counterfeit Drug Task Force, which provided its report to the Commissioner on February 18, 2004, identified key areas in which drug manufacturers, packagers and wholesalers could incorporate various technologies into drug products and their packaging in order to reduce the likelihood of counterfeiting. These included unit-of-use packaging, tamper evident packaging, authentication technology, identification of products likely to be counterfeited, and radio-frequency identification (RFID) technology. The report is available at: http://www.fda.gov/oc/initiatives/counterfeit/report02_04.html.

First, the Task Force found that it would be beneficial for all manufacturers and re-packagers to analyze the costs and benefits of using unit of use packaging for each product, starting with newly approved products and products that are likely to be counterfeited, and to consider implementing unit of use packaging for products where the benefits are equal to or outweigh the costs. Unit of use packaging can be helpful, but only as one layer in a multi-layered anti-counterfeiting strategy. FDA intends to invite stakeholders and other interested individuals and organizations to submit research on the relative costs and benefits of unit of use packaging to assist FDA in developing future policy. We will also encourage standard setting bodies to develop standards for unit of use packaging with the goal of reducing its costs.

Second, tamper evident packaging may be beneficial in fighting counterfeiting of prescription drugs. It would be beneficial for manufacturers and re-packagers to consider using tamper evident packaging for prescription product containers, starting with products likely to be counterfeited or newly approved products, where the benefits are equal to or outweigh the costs. Tamper evident packing should be considered as one layer in a multi-layered anti-counterfeiting strategy.

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Third, the Task Force found that existing authentication technologies have been sufficiently perfected, and they can now serve as a critical component of any strategy to protect products against counterfeiting. The use by manufacturers and re-packagers of one or more authentication technologies on their products, particularly those likely to be counterfeited, would help protect the public health and diminish counterfeiting. To facilitate the use of authentication technologies on existing products, FDA plans to publish draft guidance on notification procedures for making changes to products (e.g., addition of taggants), their packaging, or their labeling for the purpose of deterring and detecting counterfeit drugs. FDA plans to continue to evaluate and disseminate information to stakeholders on developing forensic technologies (e.g., use of product fingerprinting, addition of markers) and other analytical methods that allow for rapid authentication of drug products.

Fourth, there would be great value in the creation of a national list of drugs most likely to be counterfeited based on factors that are likely to contribute to counterfeiting risk. FDA is encouraging stakeholders and standard-setting organizations to work together to create a national list of drugs most likely to be counterfeited, based on an assessment of criteria for determining counterfeit risk.

Finally, the adoption and common use of RFID technology as the standard track and trace technology, which should be feasible in 2007, would provide better protection against counterfeiting. RFID technology includes not only the silicon tags containing the electronic product code, but also antennas, tag readers, and information systems that allow all users to identify each package of drugs and its associated data. This data can be used not only to authenticate drugs but also to manage inventory, conduct rapid, targeted recalls, prevent diversion, and ensure correct dispensing of prescriptions. Acquiring and integrating RFID technology into current manufacturing, distribution, and retailing processes will require considerable planning, experience, and investment of resources. Therefore, each participant is best situated to determine the optimal path to adopting it.

FDA has identified near term actions to facilitate the performance of mass serialization feasibility studies using RFID and to assist stakeholders as they migrate towards the use of RFID technology. In the long term, after there is significant market place experience with RFID, FDA plans to propose or clarify, as necessary and appropriate, policies and regulatory requirements relating to the use of RFID. Labeling, electronic records, product quality, and cGMP requirements are issues that impacted by RFID.

During its deliberations, the Task Force met with several government agencies, such as the Secret Service, CBP, the Bureau of Engraving and Printing, and DOJ, as well as various individual private sector stakeholders. The Task Force has also reviewed reports prepared by, or on behalf of, Federal and state governments, and heard from the public, including such stakeholders as pharmaceutical manufacturers, wholesale distributors, pharmacy associations, consumer groups, academicians, independent consultants, and manufacturers of anti-counterfeiting measures.

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11) What are your agency's biggest concerns about the drug importation legislation before Congress, specifically, those proposals before the Senate?

At a time when FDA faces great challenges keeping the nation's supply of prescription drugs safe and secure, legislation to liberalize drug importation without providing concomitant enhancements in FDA's authorities and resources to help assure some level of safety for these imports could seriously compromise the safety and effectiveness of our drug supply. The volume of importation that could result from enactment of these bills could overwhelm our already heavily burdened regulatory system. In general, these bills fail to provide FDA with adequate authority or resources to establish and regulate the major new "legal" channels for incoming foreign drugs -- manufactured, distributed, labeled, and handled outside of our regulatory system -- or even to ensure their safety. Some of these proposals would even limit FDA's existing authorities, which are already being stretched. They would impose new restrictions on FDA's ability to inspect and test drugs, and FDA's authority to block the distribution of drugs we think are unsafe by undermining section 801(a) of the FD&C Act, which allows FDA to detain any drug that "appears" adulterated.

FDA drug approvals are manufacturer-specific, product-specific, and include many requirements relating to the product, such as manufacturing location, formulation, source and specifications of active ingredients, processing methods, manufacturing controls, container/closure system, and appearance. Under section 801 of the FD&C Act, only manufacturers may import drugs into the U.S. if those drugs were originally made in the U.S. before being sent abroad. Moreover, only FDA-approved prescription drugs may be legally imported into the U.S. Such drugs are produced in FDA-inspected facilities and are subject to strict controls under the U.S. regulatory system. Legislation allowing pharmacies or consumers to import drugs directly from foreign sources would bypass the protections provided by FDA's drug approval process and by state regulation of pharmacies that dispense drugs within their jurisdictions.

Some drug importation bills state that imports would be limited to drugs that comply with sections 501 (adulteration), 502 (misbranding) and 505 (marketing approval) of the FD&C Act. However, these bills fail to provide resources, authorities, or the procedural framework necessary for FDA to assure such compliance. As a practical consequence, the Agency would be forced in many instances to rely on visual examinations of incoming drug packages to determine whether a drug is FDA-approved and in compliance with the FD&C Act. A visual inspection, however, is not nearly sufficient to verify whether drugs are FDA-approved, manufactured in FDA-inspected facilities or in compliance with the adulteration and misbranding provisions of the FD&C Act. This is no substitute for the existing FDA regulatory process, which tracks prescription drugs from the acquisition of active and inactive ingredients to on-site inspection of manufacturing and distribution facilities, with documentation of appropriate product testing and handling.

Even if a manufacturer has FDA approval for a drug, a version produced for foreign markets may not meet all of the requirements of the FDA approval, and considered to be unapproved. Even if a drug bound for a foreign market is produced in the same plant as a similar drug approved for the U.S. market, FDA is not able to track that drug in foreign commerce before it enters the U.S. Consequently, it is difficult for the Agency to determine that a drug

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appearing at a U.S. border is in fact the one produced in the FDA-inspected plant, pursuant to FDA approval. These practical problems raise concerns about the safety and effectiveness of any drug that would be presented at a port-of-entry as "FDA-approved." Moreover, the bills do not provide FDA with the resources necessary to inspect all of the drugs that would be shipped into the U.S., thereby increasing the risk that increased levels of illegal drugs would enter the U.S.

As you know, when Congress enacted the Medicare Modernization Act of 2003, it recognized these safety issues and included a provision authorizing a program of drug importation, to be implemented only if the Secretary of Health and Human Services (HHS) could certify that implementation of the program would not compromise the safety of the U.S. prescription drug supply. At the same time, Congress directed the Secretary to conduct a comprehensive study and prepare a report to Congress on whether and how importation could be accomplished in a manner that assures safety. HHS is currently working on that study with the assistance of an intergovernmental task force, chaired by Surgeon General Richard Carmona. The Agency believes the cautious approach to importation legislation would be to consider the final analysis required by the MMA.

FDA's objections to legislative proposals that would create large, legal channels for drugs to enter our drug supply without assurances of safety are based on concerns that they will create substantial drug safety problems without clear, large-scale, long-term benefits. The Congressional Budget Office has estimated that the overall savings from even broad, multiple-country importation proposals would be marginal.

- 12) **I am very interested in hearing more about the blitz examinations of foreign drugs to the U.S. that the FDA conducted on mail shipments. My understanding is that the blitz examination that you conducted last summer found that 88 percent of the packages contained unapproved drugs, and that the blitzes conducted last November found that 69 percent of the imported drug shipments were not approved by the FDA. Is it true that most of these imported drugs were from Canada? Did these drugs actually originate in Canada or were they imported to Canada from other countries? What were some of the problems with the unapproved drugs that were discovered? Does this mean that we should assume that most of the drugs imported into this country are ineffective, counterfeit, or adulterated? What can consumers do to protect themselves?**

During the import blitz examinations conducted by FDA and CBP during the summer of 2003 at the Miami, New York (JFK), San Francisco, and Carson (CA) international mail facilities, FDA inspectors examined 1,153 imported products, the overwhelming majority of which were drugs. 1,019 (or 88 percent) of the 1,153 products were violative; and 861 of the 1,019 violative products (85 percent) were non-compliant because they appeared to be unapproved drugs. The imported drugs arrived from many countries; 16 percent entered the U.S. from Canada, 14 percent were from India, 14 percent came from Thailand, and 8 percent were shipped from the Philippines. The remaining entries arrived in lesser quantities from countries such as Mexico, Taiwan, Belize, Malaysia, Nicaragua, Romania, Cambodia and Uganda, to name a few.

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During the import blitz examinations conducted in November 2003 at the four international mail facilities in Buffalo, Dallas, Chicago and Seattle, and the two courier hubs in Cincinnati and Memphis, 3,375 imported products were examined, the overwhelming majority of which contained drugs. Of the 1,927 imported products examined during the blitz examinations at the mail facilities, 1,641 (85 percent) were deemed violative. The overwhelming majority of the violative products (69 percent) were non-compliant because they contained unapproved drugs. FDA attempted to document the country of export for those parcels containing drug products that were entered through the mail facilities. For example, of the parcels that entered through the mail facilities, FDA determined that Canadian parcels appeared most frequently (80 percent), while 16 percent were from Mexico, and the remaining 4 percent came from Japan, the Netherlands, Taiwan, Thailand and the United Kingdom.

FDA's review of the products found during the blitzes identified potentially hazardous products that included:

- Drugs different from those approved by FDA;
- Drugs requiring careful dosing;
- Drugs with inadequate labeling;
- Drugs inappropriately packaged;
- Drugs withdrawn from the market;
- Animal drugs not approved for human use;
- Drugs with dangerous interactions;
- Drugs that carry risks requiring initial screening and/or periodic patient monitoring;
- Drugs requiring risk management or restricted distribution programs; and
- Controlled substances.

The evidence gathered during the blitz examinations and in other instances where FDA has examined drugs imported by consumers raises serious concerns about the overall safety of this practice. Currently, drugs marketed in the U.S., regardless of whether they are manufactured in the U.S. or a foreign country, must be approved by FDA based on demonstrated safety and efficacy. They must also be produced in manufacturing plants inspected and operated in conformance with FDA's current GMP requirements, and their shipment and storage conditions must be properly documented and are subject to inspection. "FDA-approved" drugs have been sanctioned by FDA in all respects, meaning that they have been manufactured in a permitted and inspected manufacturing location, and that FDA has examined and endorsed the drug's formulation, the source and specifications of the drug's active ingredients, the processing methods used to manufacture the drug, the drug's container and closure system, and the labeling that accompanies and/or is placed on the drug.

This "closed regulatory system" has been very successful in preventing unapproved, adulterated, or misbranded drugs from entering the United States' stream of commerce. FDA cannot assure the quality of foreign drugs that have not been manufactured according to the exact specifications contained in an FDA-approved drug application even if they purport to be, or appear to be the same as U.S. approved medications. Likewise, the outlets that introduce these products may dispense expired, subpotent, contaminated or counterfeit product, the wrong or contraindicated product, an incorrect dosage, or medicine that is not

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accompanied by adequate directions for use. The labeling for these drugs is often not in English and therefore, important information regarding dosage and side effects may not be available to the consumer. There is no assurance that such drugs have been packaged and stored under appropriate conditions to prevent against degradation, and likewise, there is no assurance that these medications were produced under cGMP standards. Moreover, when drugs are obtained from foreign-based sources outside of FDA's closed regulatory regime, consumers have no recourse if they experience an adverse drug reaction. Consumers can best protect themselves by abstaining from the purchase of unapproved medications from foreign sources.

- 13) **As you know, today's counterfeiter is extremely knowledgeable and utilizes technology in order to create knock-off products that are so close to the original that it is often nearly impossible to tell them apart. In some instances, counterfeiters today are at work long before a drug even reaches the market. For example, some drugs have even been counterfeited and then sold in the U.S. before they were even approved for use in the U.S. market. How do you propose to fight counterfeiters who are increasingly sophisticated, and how long and how much money will such an effort take?**

Because the capabilities of counterfeiters continue to evolve rapidly, there is no single "magic bullet" technology that provides any long-term assurance of drug security. However, a combination of rapidly improving track and trace technologies and product authentication technologies should provide a much greater level of security for drug products in the years ahead. Similar anti-counterfeiting technologies are being used in other industries, and FDA intends to facilitate their rapid development and use to keep our drug supply secure against counterfeits.

Track and trace technology, and other modern electronic technologies, are rapidly approaching the state at which they can reliably and affordably provide much greater assurance that a drug product was manufactured safely and distributed under conditions that did not compromise its potency. FDA has concluded that implementing and adopting this technology is a much more reliable direction for assuring the legitimacy of a drug than contrived reliance paper records, which are more likely to be incomplete or falsified, and that such technology may be feasible for use by 2007.

RFID tagging of products by manufacturers, wholesalers, and retailers appears to be the most promising approach to reliable product tracking and tracing. Significant feasibility studies and technology improvements are underway to confirm that RFID will provide cost-reducing benefits in areas such as inventory control, while also providing the ability to track and trace the movement of every package of drugs from production to dispensing. Most importantly, reliable RFID technology will make copying medications either extremely difficult or unprofitable. FDA is working with RFID product developers, sponsors, and participants of RFID feasibility studies to ensure that FDA facilitates the development and safe and secure use of this technology. FDA is also working with other governmental agencies to coordinate activities in this area.

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Authentication technologies include measures such as color shifting inks, holograms, fingerprints, taggants, or chemical markers embedded in a drug or its label. The use of one or more of these measures on drugs, starting with those considered most likely to be counterfeited, is an important part of an effective anti-counterfeiting strategy. Because counterfeiters will adapt rapidly to any particular measure and because the most effective measures differ by product, the most effective use of authentication technology will vary by drug product over time. FDA intends to clarify its policies and procedures to help manufacturers employ and update these technologies safely and effectively. In particular, FDA plans to publish draft guidance on notification procedures for making changes to products (e.g., addition of taggants), their packaging, or their labeling, for the purpose of encouraging timely adoption and adaptation of effective technologies for detecting counterfeit drugs. FDA also intends to continue to evaluate and provide information to stakeholders on forensic technologies (e.g., use of product fingerprinting, addition of markers) and other analytical methods that allow for rapid authentication of drug products.

Although technology offers much promise, it cannot be counted on alone to solve the drug-counterfeiting problem. As suggested in the Commissioner's Counterfeit Drug Task Force Report, we also need stronger laws and increased criminal penalties. A criminal commits a ten-year offense by counterfeiting a registered trademark (18 U.S.C. 2320), but only a three-year offense by counterfeiting a drug that could adversely affect an individual's health, as well as the public health at large. We are not surprised to find cocaine traffickers switching to pharmaceutical counterfeiting since they know the maximum penalty is three years' imprisonment and the sentencing guideline is the lowest among all Federal felonies, usually resulting in a probationary sentence.

- 14) **I have heard a lot about testing that we could do at the border to ensure that the drugs we are importing are in fact what they purport to be and that they are safe and effective. However, I have also heard that unlike narcotics, such as cocaine, field tests don't exist for prescription drugs – so, testing prescription drugs at the border, while it sounds good to many, may in fact not even be possible. Can you resolve this issue or not? Also, even if a drug was able to be tested for the active ingredient, would that guarantee that the drug was safe and effective and the same as the FDA-approved drug?**

As you state in your question, there is no simple field test for prescription drugs that can verify important safety characteristics. Simple tests are usually limited to determining the presence of the active chemical ingredient not the potency, authenticity, quality or handling. A battery of prohibitively expensive tests would have to be conducted to ensure that the product is authentic and does not contain impurities. Additionally, because it is not feasible to test entire shipments, it is possible that substandard or counterfeit product could be commingled with product in a manner that is difficult to detect. End product testing cannot substitute for in process controls. Sampling and testing final products for import cannot guarantee the quality and safety of the product.

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The testing system envisioned by currently proposed legislation is insufficient to ensure that only safe and effective prescription drugs are imported into the U.S. because, by legalizing importation, the proposed legislation would induce the shipment of millions of small drug parcels into the U.S. Under the current drug importation system, commercial shipments of bulk drugs are subject not only to FDA sampling and testing but are authenticated by other means and manufactured under process controls approved and inspected by FDA. A sampling system to test the millions of parcels of drugs sold by foreign retailers is not feasible for a number of reasons, including the sheer number of small packages that would come through U.S. ports-of-entry, and the difficulty of showing through testing that a particular product is authentic, of high quality, correct potency, and that it has been handled properly.

- 15) **Last summer, FDA was quoted as saying that the cost to implement H.R. 2427, the import legislation that passed the House of Representatives, could be \$2 billion in the first year alone. So, am I to understand that while the premise behind the importation legislation is to lower drug costs, the exact opposite might be the case given the cost of anti-counterfeiting technology?**

At the time that H.R. 2427 was being debated on the floor of the House of Representatives, FDA provided an estimate to then Chairman Billy Tauzin of the House Energy and Commerce Committee stating that the government resources associated with implementing this legislation could be substantial. We estimated that first-year costs to set up a regulatory program to sample small portion incoming commercial drug products in accordance with the requirements of the bill could be over \$50 million. Furthermore, FDA estimated, based on initial discussions with the Bureau of Printing and Engraving, that the cost of anti-counterfeiting technology contemplated by this legislation would be substantial and could raise the cost of prescription drugs by as much as \$2 billion dollars in the first year. In its own estimate of the costs and benefits associated with H.R. 2427, the Congressional Budget Office estimated that the reduction in expenditures on prescription drugs realized by U.S. consumers would be marginal.

- 16) **Some in Congress have suggested that in order to lower drug costs in this country, we should import drugs from price-controlled countries, such as Canada. In order to ensure that those drugs we import are safe, they have suggested the use of anti-counterfeit technology similar to that utilized to protect our nation's currency. However, according to the United States Secret Service, the branch of the government which investigates counterfeit currency, "Today's counterfeiter is able to produce counterfeit currency with basic computer training and skills afforded by trial and error and public education. Counterfeit passing statistics are likely to increase..." Moreover, as technology improves, counterfeiting gets easier. According to a report to Congress by the Secretary of the Treasury, "the Secret Service suspects that the counterfeiting of U.S. currency may become progressively easier as the generally available technology improves and the cost of computer equipment (including printers and scanners) decreases." Given this, is it fair to say that as anti-counterfeiting technology improves for prescription drugs, so will counterfeiting technology?**

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To respond to the emerging threat of counterfeit drugs, then FDA Commissioner McClellan formed a Counterfeit Drug Task Force in July 2003. That group received extensive comment from security experts, Federal and state law enforcement officials, technology developers, manufacturers, wholesalers, retailers, consumer groups, and the general public on a very broad range of ideas for deterring counterfeiters. Those comments reinforced the need for FDA and others to take action in multiple areas to create a comprehensive system of modern protections against counterfeit drugs.

As a result of the work by the Task Force, FDA issued its report on February 18, 2004, entitled, "Combating Counterfeit Drugs." The report concluded that because there is no single "magic bullet" against the increasing sophistication of counterfeiters, a multi-pronged strategy to secure the drug supply would be much more difficult for them to overcome than any single method. It could also be less costly, because a "one-size-fits-all" approach is unlikely to work for all parts of the complex prescription drug supply system. Second, although drug counterfeiters today are more sophisticated and better organized than ever before, there are many new technologies and approaches that have the potential to inhibit and contain counterfeit drug threats. While most of these new approaches have not yet been fully developed, implemented, and tested, they hold the promise of a more secure drug distribution system in the years ahead.

17) Can I get a list of the 47 safe drugs that one can buy on the Internet?

In the testimony of FDA Associate Commissioner Hubbard before the Judiciary Committee on July 14, 2004, Mr. Hubbard indicated that FDA had obtained as many as 47 different controlled substances from various Internet pharmacy sites. Although, no controlled substances may be legally dispensed without a prescription, in many instances, these websites dispensed the drugs without a prescription or with a prescription based only on an online questionnaire. FDA did not perform analytical testing of these drugs beyond identifying them as controlled substances; therefore, we cannot vouch for their quality or purity. An updated list, 51 total drugs, based on a review of websites on September 30, 2004, is enclosed.

18) What is the percent of subset of the 88% unapproved drugs?

In the testimony of John Taylor, FDA Associate Commissioner for Regulatory Affairs, before the Judiciary Committee on July 14, 2004, Mr. Taylor referred to the percentage of unapproved drugs discovered during our recent import blitzes. During the import blitz examinations conducted by FDA and CBP during the summer of 2003 at the Miami, New York (JFK), San Francisco, and Carson (CA) international mail facilities, FDA inspectors examined 1,153 imported products, the overwhelming majority of which were drugs. 1,019 (or 88 percent) of the 1,153 products were violative; and 861 of the 1,019 violative products (85 percent) were non-compliant because they appeared to be unapproved drugs. FDA's review of the products found during the blitzes identified potentially hazardous products that fit into these risk categories:

- Drugs different from those approved by FDA;
- Drugs requiring careful dosing;
- Drugs with inadequate labeling;
- Drugs inappropriately packaged;
- Drugs withdrawn from the market;

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- Animal drugs not approved for human use;
- Drugs with dangerous interactions;
- Drugs that carry risks requiring initial screening and/or periodic patient monitoring
- Drugs requiring risk management or restricted distribution programs; and
- Controlled substances.

FDA did not identify, nor document, the specific risk categories that each of the individual 1,109 violative products would fall within. For this reason, independent of the information provided here, we are unable to provide you with the numbers/percentages of violative drugs (subsets) that fall within each of the risk categories identified above. FDA will consider the usefulness of gathering this information in the future when subsequent import blitz examinations are conducted.

Questions from Senator Leahy:

- 1) **In your testimony you highlight the activities of criminals who are engaged in illegal distribution of narcotics and highly addictive controlled substances and in diverting, adulterating, weakening or counterfeiting pharmaceutical products for sale in the United States via the internet. This is a very important issue and one that I addressed in a letter to your Agency on November 4, 2003, to which I have yet to receive an answer. These fraudulent operations should be targeted and shut down – regardless of the importation status of the drugs at issue. However, your testimony’s reliance on these illicit activities ultimately sidesteps the core issue we examined at this hearing: the implication of legalizing drug importation. Your testimony described the current state of affairs of unregulated or under-regulated pharmaceutical distribution, but does not address the implications of legal importation under a system by which Americans can reliably purchase FDA-approved drugs from reputable foreign sources. Under the Dorgan-Snowe proposal for legalizing prescription drug importation the FDA and relevant agencies would be given resources and regulatory tools to implement a reliable system for drug importation that holds all parties accountable and tracks products from development and manufacture through distribution. Do you not agree that such a system would be an improvement over the current situation? If you do not agree, please explain. Also, please tell me when I can expect a response to my letter of last November.**

At a time when FDA faces great challenges keeping the nation’s supply of prescription drugs safe and secure, legislation to liberalize drug importation without providing concomitant enhancements in FDA’s authorities and resources to help assure some level of safety for these imports could seriously compromise the safety and effectiveness of our drug supply. The volume of importation that could result from enactment of these bills could overwhelm our already heavily burdened regulatory system. In general, these bills fail to provide FDA with adequate authority or resources to establish and regulate the major new “legal” channels for incoming foreign drugs -- manufactured, distributed, labeled, and handled outside of our regulatory system -- or even to ensure their safety. Some of these proposals would even limit FDA’s existing authorities, which are already being stretched. They would impose new restrictions on FDA’s ability to inspect and test drugs, and FDA’s authority to block the distribution of drugs we think are unsafe by undermining section 801(a) of the FD&C Act, which allows FDA to detain any drug that “appears” adulterated.

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FDA drug approvals are manufacturer-specific, product-specific, and include many requirements relating to the product, such as manufacturing location, formulation, source and specifications of active ingredients, processing methods, manufacturing controls, container/closure system, and appearance. Under section 801 of the FD&C Act, only manufacturers may import drugs into the U.S. if those drugs were originally made in the U.S. before being sent abroad. Moreover, only FDA-approved prescription drugs may be legally imported into the U.S. Such drugs are produced in FDA-inspected facilities and are subject to strict controls under the U.S. regulatory system. Legislation allowing pharmacies or consumers to import drugs directly from foreign sources would bypass the protections provided by FDA's drug approval process and by state regulation of pharmacies that dispense drugs within their jurisdictions.

Some drug importation bills state that imports would be limited to drugs that comply with sections 501 (adulteration), 502 (misbranding) and 505 (marketing approval) of the FD&C Act. However, these bills fail to provide resources, authorities, or the procedural framework necessary for FDA to assure such compliance. As a practical consequence, the Agency would be forced in many instances to rely on visual examinations of incoming drug packages to determine whether a drug is FDA-approved and in compliance with the FD&C Act. A visual inspection, however, is not nearly sufficient to verify whether drugs are FDA-approved, manufactured in FDA-inspected facilities or in compliance with the adulteration and misbranding provisions of the FD&C Act. This is no substitute for the existing FDA regulatory process, which tracks prescription drugs from the acquisition of active and inactive ingredients to on-site inspection of manufacturing and distribution facilities, with documentation of appropriate product testing and handling.

Even if a manufacturer has FDA approval for a drug, a version produced for foreign markets may not meet all of the requirements of FDA's approval, and considered to be unapproved. Even if a drug bound for a foreign market is produced in the same plant as a similar drug approved for the U.S. market, FDA is not able to track that drug in foreign commerce before it enters the U.S. Consequently, it is difficult for the Agency to determine that a drug appearing at a U.S. border is in fact the one produced in the FDA-inspected plant, pursuant to FDA approval. These practical problems raise concerns about the safety and effectiveness of any drug that would be presented at a port-of-entry as "FDA-approved." Moreover, the bills do not provide FDA with the resources necessary to inspect all of the drugs that would be shipped into the U.S., thereby increasing the risk that increased levels of illegal drugs would enter the U.S.

As you know, when Congress enacted the Medicare Modernization Act of 2003, it recognized these safety issues and included a provision authorizing a program of drug importation, to be implemented only if the Secretary of Health and Human Services could certify that implementation of the program would not compromise the safety of the U.S. prescription drug supply. At the same time, Congress directed the Secretary to conduct a comprehensive study and prepare a report to Congress on whether and how importation could be accomplished in a manner that assures safety. HHS is currently working on that study with the assistance of an intergovernmental task force, chaired by Surgeon General Richard Carmona. The Agency believes the cautious approach to importation legislation would be to consider the final analysis required by the MMA.

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FDA's objections to legislative proposals that would create large, legal channels for drugs to enter our drug supply without assurances of safety are based on concerns that they will create substantial drug safety problems without clear, large-scale, long-term benefits. The Congressional Budget Office has estimated that the overall savings from even broad, multiple-country importation proposals would be marginal.

FDA responded to your letter of November 4, 2003, on October 5, 2004. We apologize for the delay in responding.

- 2) **In your testimony you described at length various enforcement actions taken by the FDA. You also referred to proposals by state and local governments to import pharmaceuticals from Canada. Furthermore, as I described in my letter to your agency on November 4, 2003, millions of American seniors who cannot afford to purchase the medicine their doctors prescribe have individually turned to legitimate Canadian pharmacies to fill their prescriptions. Considering this scope of activity, what enforcement guidelines are governing your decisions to seek injunctions against some conducting or facilitating importation, but not others?**

FDA is both responsible for, and committed to, protecting the public health by assuring the safety, efficacy, and security of our nation's drug supply. This includes ensuring that America's citizens only have access to safe and effective medications, regardless of their source. In furthering this objective, FDA works to assure that the public has access to accurate, science-based information so that the medications they use will have their intended effect and will, indeed, improve their health. This role also includes educating the public about the incumbent risks of purchasing medicines outside of FDA's regulatory scope.

Although FDA is first and foremost a science-based, public health agency, without question FDA is also a law enforcement agency. Strong law enforcement tools, including sufficient statutory authority, coupled with a strong base of medical and scientific expertise, are vital to the Agency's ability to meet its mission of protecting and advancing the public health. This means that when necessary, FDA must reinforce its educational efforts and exercise its statutory responsibilities with the initiation of criminal, civil and regulatory enforcement actions.

Since 1999, FDA has reviewed potential enforcement actions and coordinated case assignments through the use of a case assessment or "triage" team with representatives from the Office of Enforcement and OCI within ORA, CDER, the Office of the General Counsel and the Office of Policy. FDA obtains information and "leads" regarding websites that potentially violate the FD&C Act through FDA's own internal monitoring of the Internet, consumers, the media, industry, and through state, Federal and foreign law enforcement agencies. The triage team then evaluates the leads and decides whether they should be pursued through a civil or criminal investigation. We give priority to cases involving unapproved new drugs, health fraud, and prescription drugs sold without a valid prescription, as well as products that have the potential for causing serious or life-threatening reactions.

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FDA has found that this triage process results in the more efficient, streamlined coordination of criminal and civil enforcement actions within the appropriate Agency components and reduces duplication of efforts. This process helps to ensure that decisions are made in a timely manner. In addition, during its deliberations, the triage team seeks to attain the appropriate balance between achieving a maximum deterrent effect versus the removal of harmful products from the market.

OCI bears the responsibility for overseeing those investigations of pharmacy and Internet sites whose operations involve potential criminal activity. The Investigative Analysis Branch analyzes the information collected by OCI. After the suspect sites are researched, and possible violations are identified, the appropriate OCI field office will receive assignments for investigative work, which often includes undercover buys. Further investigation determines whether the implicated pharmacies and doctors or other persons associated with the sites are legitimate and examines whether the relationships between the patient/doctor and doctor/pharmacy are bona fide. OCI has ongoing, cooperative relationships with CBP, ICE, DEA, FBI, the Postal Inspection Service and other state and Federal law enforcement agencies that have substantially enhanced FDA's investigative capabilities with regard to Internet drug sales. Please note, however, that criminal prosecutions of Internet website operators, and particularly domestic website operators, are very difficult given the complexities of state laws governing the practice of pharmacy and the absence of any Federal laws specifically addressing Internet pharmacy crimes.

Due to its limited inspectional and enforcement resources, FDA must carefully select those cases for which it seeks judicial and/or administrative remedies. For this reason, FDA has elected to focus its enforcement efforts on those entities that facilitate the importation of unapproved (and therefore illegal), foreign-based drugs on a large, commercial scale. This should not be interpreted to mean, however, that FDA is not concerned about the illegal importation of prescription drugs for personal use. As with the majority of its inspection and enforcement programs, FDA has employed a risk-based approach towards its operations at international mail facilities and courier hubs (through which the majority of illegal drugs arrive from foreign sources for personal use) so that we can more effectively target, identify and interdict these potentially unsafe and dangerous imported drugs. To this end, FDA staff utilizes the following factors in prioritizing its work in light of our limited resources:

- Affirmative risk of the product, including whether the product has been counterfeited in the past; and whether it is considered a "high risk" drug as established by CDER;
- Injectable drug products;
- Unlabeled suspected drug products;
- Compliance history and historical data of the exporter and/or importer and/or recipient;
- Non-English labeling;
- Bulk quantity suspected of commercial use; and
- Import Alerts/Bulletins.

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Questions from Senator Feinstein:

- 1) **It is my understanding that drugs imported for sale in Canada, or for subsequent export, must first be approved by Health Canada, Canada's version of the Food and Drug Administration, and must meet the requirements of Canada's *Food and Drugs Act and Regulations*. Drugs such as the ones obtained from paylesscanadiandrugs.com or DiscountDrugsofCanada.org would not be approved by Health Canada and subsequently would not be properly labeled with a valid Drug Identification Number (DIN). Is it not true that Canadian law would prohibit the drugs obtained from these types of websites from being sold in their country?**

FDA's primary mission remains to assure the safety of medications intended for use in the U.S. through the enforcement and administration of the FD&C Act. The Agency cannot speak authoritatively about the legal requirements of other nations, including Canada.

- 2) **Mr. Hubbard presented laboratory analysis of "Canadian generics." Do "Canadian Generics" refer to generic versions of brand name drugs manufactured in the U.S. or are they counterfeit drugs intended to mimic brand-name drugs in the U.S.? What percentage of drugs bought in Canada are generic versions of brand-name drugs manufactured in the U.S.?**

Mr. Hubbard's testimony referred to recent examples of the dangers associated with the purchase of prescription drugs from rogue pharmacy sites. Mr. Hubbard's testimony about "Canadian Generics" referred to FDA's examination of two websites having identical web pages headlined "Canadian Generics." These websites were marketing these "Canadian Generics" as generic versions of FDA-approved medications. FDA has purchased prescription drugs from both of these sites. We found that these drugs and their manner of sale pose potential threats to the health and safety of consumers.

There is at least one Canadian flag on every page of these sites, as well as the words "Canadian Generics." The websites say, "Order Canadian to get the biggest discounts!" The URLs from both of the websites where FDA placed orders suggest the sites are located in, and operated out of, Canada. Despite these representations, however, we determined there is no evidence that the dispensers of the drugs or the drugs themselves are Canadian. The registrants, technical contacts, and billing contacts for both websites have addresses in China. The reordering website for both purchases and its registrant, technical contact, and billing contact have addresses in Belize. The drugs were shipped from Texas, with a customer service and return address in Florida.

FDA purchased drugs described by the website as generic Viagra, generic Lipitor, and generic Ambien. None of these products, however, has a generic version approved in the U.S. or Canada. Both times, to obtain the drugs, an FDA investigator posed as a consumer and filled out an on-line questionnaire. The investigator was never asked to provide a prescription. After each purchase, the drugs arrived packaged in heat-sealed plastic bags in a manila envelope.

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Ambien is a controlled substance with a potential for addiction. In addition, for both purchases, FDA's "consumer" said in the on-line questionnaire that he is taking erythromycin. The use of Viagra with erythromycin is contraindicated and, more importantly, there is a warning on the approved labeling for Lipitor about concurrent administration of Lipitor with erythromycin. Despite these critical safety issues, the website operators sent the drugs.

The drugs received from the second purchase were tested in an FDA laboratory. All three samples failed, using the brand-name manufacturer's methodology. While all three samples had some level of active ingredient, the "generic" Lipitor and Viagra were found to be subpotent, while the "generic" Ambien was found to be superpotent. Two of the three drugs failed the dissolution parameters of the brand-name drugs. The third drug passed the dissolution testing, but only because it was superpotent. Two of the three samples also failed purity testing, while all three samples failed the USP criteria for content uniformity.

Consumers can, and should, be cautious when purchasing drugs online. There are legitimate sites that dispense drugs based on valid prescriptions. Consumers should check with their State Board of Pharmacy or the NABP to see if the online pharmacy possesses a valid pharmacy license and has met state quality standards. One option in choosing online pharmacies for their medications that consumers have at their disposal to protect themselves is the Verified Internet Pharmacy Practice Sites, or VIPPS system, developed by the NABP. This program verifies the legitimacy of Internet sites dispensing prescription drugs and provides a "seal of approval" to sites that apply and meet state licensure requirements and NABP's standards. Although participation in the VIPPS program is voluntary, the Agency believes this program is an example of one that is helpful in assuring consumers that the Internet site they are using is reputable.

Finally, FDA does not know the percentage of drugs bought in Canada that are generic versions of U.S. brand-name drugs manufactured in the U.S.

- 3) **With respect to personal importation, it is my understanding that the Dorgan-Snowe legislation would provide consumers with a list of FDA-approved Canadian pharmacies and the websites and phone numbers for those pharmacies would be made available to American consumers through FDA's website. I am told that there are between forty and fifty Canadian pharmacies that are significant exporters to the U.S. and that the Dorgan-Snowe bill would limit the number of approvable exporting Canadian pharmacies to a maximum of fifty in the first year of implementation of the bill. Is this accurate? Under the Dorgan-Snowe bill, does the FDA have adequate authority and resources to inspect and approve these Canadian pharmacies? Are there adequate safeguards in the Dorgan-Snowe to protect American consumers from potentially dangerous drugs obtained from these Canadian pharmacies?**

At a time when FDA faces great challenges keeping the nation's supply of prescription drugs safe and secure, legislation to liberalize drug importation without providing concomitant enhancements in FDA's authorities and resources to help assure some level of safety for these imports could seriously compromise the safety and effectiveness of our drug supply. The volume of importation that could result from enactment of these bills could overwhelm our already heavily burdened regulatory system. In general, these bills fail

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to provide FDA with adequate authority or resources to establish and regulate the major new "legal" channels for incoming foreign drugs -- manufactured, distributed, labeled, and handled outside of our regulatory system -- or even to ensure their safety. Some of these proposals would even limit FDA's existing authorities, which are already being stretched. They would impose new restrictions on FDA's ability to inspect and test drugs, and FDA's authority to block the distribution of drugs we think are unsafe by undermining section 801(a) of the FD&C Act, which allows FDA to detain any drug that "appears" adulterated.

FDA drug approvals are manufacturer-specific, product-specific, and include many requirements relating to the product, such as manufacturing location, formulation, source and specifications of active ingredients, processing methods, manufacturing controls, container/closure system, and appearance. Under section 801 of the FD&C Act, only manufacturers may import drugs into the U.S. if those drugs were originally made in the U.S. before being sent abroad. Moreover, only FDA-approved prescription drugs may be legally imported into the U.S. Such drugs are produced in FDA-inspected facilities and are subject to strict controls under the U.S. regulatory system. Legislation allowing pharmacies or consumers to import drugs directly from foreign sources would bypass the protections provided by FDA's drug approval process and by state regulation of pharmacies that dispense drugs within their jurisdictions.

Some drug importation bills state that imports would be limited to drugs that comply with sections 501 (adulteration), 502 (misbranding) and 505 (marketing approval) of the FD&C Act. However, these bills fail to provide resources, authorities, or the procedural framework necessary for FDA to assure such compliance. As a practical consequence, the Agency would be forced in many instances to rely on visual examinations of incoming drug packages to determine whether a drug is FDA-approved and in compliance with the FD&C Act. A visual inspection, however, is not nearly sufficient to verify whether drugs are FDA-approved, manufactured in FDA-inspected facilities or in compliance with the adulteration and misbranding provisions of the FD&C Act. This is no substitute for the existing FDA regulatory process, which tracks prescription drugs from the acquisition of active and inactive ingredients to on-site inspection of manufacturing and distribution facilities, with documentation of appropriate product testing and handling.

Even if a manufacturer has FDA approval for a drug, a version produced for foreign markets may not meet all of the requirements of the FDA approval, and considered to be unapproved. Even if a drug bound for a foreign market is produced in the same plant as a similar drug approved for the U.S. market, FDA is not able to track that drug in foreign commerce before it enters the U.S. Consequently, it is difficult for the Agency to determine that a drug appearing at a U.S. border is in fact the one produced in the FDA-inspected plant, pursuant to FDA approval. These practical problems raise concerns about the safety and effectiveness of any drug that would be presented at a port of entry as "FDA-approved." Moreover, the bills do not provide FDA with the resources necessary to inspect all of the drugs that would be shipped into the U.S., thereby increasing the risk that increased levels of illegal drugs would enter the U.S.

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As you know, when Congress enacted the Medicare Modernization Act of 2003, it recognized these safety issues and included a provision authorizing a program of drug importation, to be implemented only if the Secretary of Health and Human Services could certify that implementation of the program would not compromise the safety of the U.S. prescription drug supply. At the same time, Congress directed the Secretary to conduct a comprehensive study and prepare a report to Congress on whether and how importation could be accomplished in a manner that assures safety. HHS is currently working on that study with the assistance of an intergovernmental task force, chaired by Surgeon General Richard Carmona. The Agency believes the cautious approach to importation legislation would be to consider the final analysis required by the MMA.

FDA's objections to legislative proposals that would create large, legal channels for drugs to enter our drug supply without assurances of safety are based on concerns that they will create substantial drug safety problems without clear, large-scale, long-term benefits. The Congressional Budget Office has estimated that the overall savings from even broad, multiple-country importation proposals would be marginal.

FDA has not provided formal analysis of the various bills related to importation, however, there is no specific numerical limitation on the number of participating pharmacies currently contained in S. 2328.

- 4) **Do you believe that provisions in the Dorgan-Snowe bill will assist the FDA and Customs in ensuring that those [drugs from] Internet sites associated with FDA-approved Canadian pharmacies are manufactured in FDA-approved facilities? If not, how would the FDA recommend we go about tracking down where drugs obtained over the Internet are manufactured?**

While we have not provided a formal statement on the specific provision of S. 2328 you mention, please note that FDA drug approvals are manufacturer-specific, product-specific, and include many requirements relating to the product, such as manufacturing location, formulation, source and specifications of active ingredients, processing methods, manufacturing controls, container/closure system, and appearance. Under section 801 of the FD&C Act, only manufacturers may import U.S. made drugs into the U.S. if those drugs were originally made in the U.S. before being sent abroad. Moreover, only FDA-approved prescription drugs may be legally imported into the U.S. Such drugs are produced in FDA-inspected facilities and are subject to strict controls under the U.S. regulatory system.

Any legislation allowing pharmacies or consumers to import drugs directly from foreign sources, however, would bypass the protections provided by FDA's drug approval process and by state regulation of firms that dispense drugs within their jurisdictions. Any legislation requiring FDA to approve foreign pharmacies without the requisite regulatory authority to hold them accountable would fall short of the very high standards imposed on U.S. pharmacies by State Boards of Pharmacy. This regulatory authority over Canadian pharmacies currently resides with the Canadian government. Further, any requirement that FDA approve foreign manufacturing facilities must be accompanied by a strong approval process to ensure the safety and efficacy of the products produced in them. FDA inspection of facilities alone does not determine safety or efficacy of medications. The Agency would be happy to continue to offer technical assistance on any such legislation.

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As you mentioned in your letter, one of the toughest obstacles facing FDA and law enforcement with respect to Internet pharmacies is identifying the manufacturer and distributor. Internet technology can obscure the source of the product as well as provide a degree of anonymity to those responsible for selling and shipping the product. The parties to a transaction can be dispersed geographically and usually never meet. Thus, the regulatory and enforcement issues cross state, Federal, and international jurisdictional lines.

There are inherent difficulties faced by U.S. authorities in attempting to bring action against a foreign entity illegally selling drugs to U.S. consumers. Although FDA may have jurisdiction over a resident in a foreign country who sells in violation of the FD&C Act to a U.S. resident, from a practical standpoint, FDA and DOJ have a difficult time enforcing the law against foreign sellers when they are hard to reach and outside our borders. As a result, the Agency's efforts typically focus on requesting the foreign government to take action against the seller of the product, or asking the CBP to stop the imported drug at a U.S. port-of-entry.

The Agency responds to these challenges through our OCI Investigative Analysis Branch, which analyzes information collected by investigative staff, and after the suspect sites are researched and possible violations are identified, the OCI field offices receive assignment for investigative work, which often includes undercover buys. Further investigation determines the bona fides of the pharmacy and doctor(s), and identifies the relationship between the patient and doctor and the doctor and pharmacy. OCI has ongoing cooperative relationships with CBP, DEA, FBI, the USPS Inspection Service and appropriate state law enforcement and regulatory agencies. This has enhanced their investigative capabilities with regard to Internet drug sales.

FDA firmly believes that it can do even more to make safe and innovative drugs more affordable in the U.S., but to succeed, we need to find safe and affordable solutions that, when implemented, do not put consumers at risk.

Thank you for your continuing interest in these very important issues. The Agency appreciates the opportunity to testify before the Senate Judiciary Committee. Please let us know if we can be of further assistance to the Committee.

Sincerely,



Patrick Ronan
Assistant Commissioner
for Legislation

Enclosure

Controlled Substances Available Online	
Schedule II	
Active Ingredient	Brand Name
Codeine	Morphine methyl ester, methyl morphine
Diphenoxylate	Lomotil
Hydrocodone	dihydrocodeinone
Methylphenidate	Ritalin
Oxycodone	OxyContin, Percocet, Tylox, Roxicodone, Roxicet,
Schedule III	
Active Ingredient	Brand Name
Benzphetamine	Didrex, Inapetyl
Buprenorphine	Buprenex, Temgesic
Butabarbital	Butisol, Butibel
Butalbital	Fiorinal, Butalbital with aspirin
Codeine combination product 90 mg/du	Empirin, Fiorinal, Tylenol, ASA or APAP w/codeine
Dihydrocodeine combination product 90 mg/du	Synalgos-DC, Compal
Dronabinol in sesame oil in soft gelatin capsule	Marinol, synthetic THC in sesame oil/soft gelatin
Fluoxymesterone	Anadroid-F, Halotestin, Ora-Testryl
Hydrocodone combination product 15 mg/du	Tussionex, Tussend, Lortab, Vicodin, Hycodan, Anexsia ++
Ketamine	Ketaset, Ketalar, Special K, K
Methyltestosterone	Android, Oreton, Testred, Virilon
Morphine combination product/50 mg/100 ml or gm	
Nandrolone	Deca-Durabolin, Durabolin, Durabolin-50
Oxandrolone	Anavar, Lonavar, Provitar, Vasorome
Oxymetholone	Anadrol-50, Adroyd, Anapolon, Anasteron, Pardroyd
Phendimetrazine	Plegine, Prelu-2, Bontril, Melfiat, Statobex

Testolactone	Teslac
Testosterone	Android-T, Androlan, Depotest, Delatestryl
Schedule IV	
Active Ingredient	Brand Name
Alprazolam	Xanax
Butorphanol	Stadol, Stadol NS, Torbugesic, Torbutrol
Chlordiazepoxide	Librium, Libritabs, Limbitrol, SK- Lygen
Clonazepam	Klonopin, Clonopin
Clorazepate	Tranxene
Dextropropoxyphene dosage forms	Darvon, propoxyphene, Darvocet, Dolene, Propacet
Diazepam	Valium, Valrelease
Diethylpropion	Tenuate, Tepanil
Difenoxin 1 mg/25 ug AtSO4/du	Motofen
Estazolam	ProSom, Domnamid, Eurodin, Nuctalon
Flurazepam	Dalmane
Lorazepam	Ativan
Meprobamate	Miltown, Equanil, Deprol, Equagesic, Meprospan
Midazolam	Versed
Modafinil	Provigil
Oxazepam	Serax, Serenid-D
Pemoline	Cylert
Pentazocine	Talwin, Talwin NX, Talacen, Talwin Compound
Phentermine	Ionamin, Fastin, Adipex-P, Obe-Nix, Zantryl
Sibutramine	Meridia
Temazepam	Restoril
Triazolam	Halcion
Zaleplon	Sonata
Zolpidem	Ambien, Stilnoct, Ivadal
Schedule V	
Active Ingredient	Brand Name

Codeine preparations - 200 mg/100 ml or 100 gm	Cosanyl, Robitussin A-C, Cheracol, Cerose, Pediacof
Difenoxin preparations - 0.5 mg/25 ug AtSO4/du	Motofen
Dihydrocodeine preparations 10 mg/100 ml or 100 gm	Cophene-S, various others
Diphenoxylate preparations 2.5 mg/25 ug AtSO4	Lomotil, Logen

**Follow-Up Questions
Senate Judiciary Committee
September 3, 2004**

**“Examining the Implications of Drug
Importation”**

Kathleen D. Jaeger

President & CEO

Questions Submitted by Senator Orrin Hatch
Hearing before the Committee on the Judiciary
“Examining the Implications of Drug Importation”
July 14, 2004

What are your thoughts regarding the cost savings associated with imported prescription drugs?

GPhA fully agrees with the goal of the sponsors of importation legislation, which is improving access to affordable prescription drugs. We believe, however, that the best means of meeting this goal is through promoting the sales of FDA-approved generic products rather than importing drugs that are untested and potentially dangerous to American consumers. If Congress intends to enact legislation authorizing drug importation, we strongly advocate that it require (1) that any imported products cost less than products available in the United States, and (2) that any resulting savings be passed along to the consumer. We also highly recommend that any such legislation preserve the 180-day exclusivity provided to generic manufacturers who successfully challenge drug patents — an incentive that is vital to the health and viability of a strong, competitive generic industry.

Proponents of importation generally neglect to discuss the significant offsetting costs which are likely to negate or outweigh any potential savings. Given the likely costs of the sort of regulatory program needed to ensure consumer safety under any government-approved importation arrangement — as well as the attendant costs for the distribution of imported drugs and of liability associated with importation — the purported savings from importation may never be realized. Without adequate regulatory protections in place, importation would be likely to open the floodgates to questionable medicines. Proponents of unregulated importation tend to ignore the costs associated with medical treatment for consumers who have obtained poor quality drugs that do not work. They also overlook the costs associated with treating consumers of unregulated drugs that are contaminated or contain harmful ingredients. Nor do they take into account the cost of treating consumers taking unregulated imported drugs that are improperly labeled. The costs of restoring America’s health care system in the wake of unregulated importation must be calculated and given serious consideration before importation is endorsed as official policy.

Do you believe that consumers would save more money by purchasing generic products?

When purchasing imported drugs, consumers could unknowingly end up paying more than they would if they bought an equivalent FDA-approved generic pharmaceutical here in the United States. In fact, several studies suggest that, on average, U.S. generic drugs

are far more affordable than Canadian generics.¹ Some generic drug prices in Canada are 6 to 10 times more expensive than the U.S. generic equivalent.² If Canadians had access to generic drugs at the same prices that prevail in America, they would save an estimated \$400 million annually.³ In short, we firmly believe that promoting the more widespread use of FDA-approved generics would yield major savings without the offsetting financial costs and costs in terms of personal and public health associated with importation.

In your organization's testimony before the HHS Task Force on Drug Importation, it is stated that it seems "counterintuitive to permit the importation of unregulated imports if there is a less expensive generic already available to consumers here at home." Would you care to comment?

The driving purpose of importation measures is to provide cost savings to American consumers by importing less expensive foreign drug products. Yet it would seem counterintuitive to permit importation of unregulated drug products if there is a less expensive generic already available to consumers here at home. At a minimum, prescription drug importers should be required to establish that the proposed imported product has no lower cost generic equivalent approved in the United States. Moreover, the federal government should require that cost savings from importation be passed along to the consumer. Without this additional requirement, commercial entities could retain much of the difference in prices for themselves, leaving little or no cost savings for American consumers, while increasing risk, boosting costs to public and private third party payers, and potentially increasing manufacturer liability.

I know that one of the issues that you have raised about imported drugs concerns abandoning free market principles. It is my understanding that GPhA believes that if unregulated drugs are allowed to be imported to the U.S., we will be abandoning free market principles that have allowed the generic industry to provide cost-effective prescription drugs. Can you talk about this in more detail?

GPhA is committed to maintaining a balance between innovation and access. To that end, we also are committed to innovation in medicines and the preservation of intellectual property protections both in the United States and abroad. Our industry's success, and the resulting consumer savings, stand in stark contrast to the economic experiences of such other countries as Germany, France, and Italy, which undermine pharmaceutical competition — and, hence, competitive pricing — by government regulation. If we permit the unregulated importation of prescription drugs, we will in effect abandon the free market principles that have been so instrumental in allowing the generic industry to pro-

¹ Palmer D'Angelo Consulting Inc. Report Series, "Generic Drug Prices: A Canada-US Comparison," August 2002

John R. Graham and Beverly A. Robson, The Fraser Institute, "Prescription Drug Prices in Canada and the United States – Part I: A Comparative Survey," Public Policy Sources, No. 42 (2000) pp. 3-5

² Palmer D'Angelo Consulting Inc. Report Series, "Generic Drug Prices: A Canada-US Comparison," August 2002

³ Id.

vide cost-effective prescription drugs. In turn, this could disrupt this nation's balance between innovation and access in the prescription drug arena.

When prices of brand pharmaceuticals are heavily regulated by foreign governments, and in some cases the price of the generic is artificially inflated, there is less incentive for consumers to switch to generics. For example, both France and Italy maintain low brand prices through rigid regulation. As a result, the price differential between brands and generics is reduced, consumers are much less price-sensitive to generics, and the generic sector of the industry is small.⁴ Lower utilization rates decrease the market for generic manufacturers and result in reduced competition. By eliminating regulation of brand drug prices, the market and demand for generics would expand, leading to more manufacturers, greater competition, increased innovation, lower generic drug prices, and ultimately greater overall cost savings than currently realized through price controls.

You also mention that allowing the importation of unregulated drugs will "destroy the 180-day exclusivity incentive, causing our healthcare system to forfeit substantial future cost savings." Would you care to comment?

The 180-day exclusivity provision was one of the cornerstone incentives created under Hatch-Waxman. When a generic firm challenges a patent, they assume a significant risk and cost for this action. Patent challenges, however, create two important beneficial results. The first benefit of a successful patent challenge is to introduce a lower cost generic product often years before the innovator's patent is set to expire. Secondly, the generic firm benefits from a successful patent challenge by receiving generic market exclusivity for 180 days. This exclusivity period provides the financial reward for the risk, cost and uncertainty that accompany patent challenges. The 180-day provision has been instrumental in bringing consumers affordable medicines in an accelerated fashion, while saving billions of dollars in pharmaceutical costs for consumers and health care purchasers. For example, 11 successful generic challenges provided over \$27 billion in savings.

Importation will result in direct competition for generic firms that successfully challenge patents. No longer would the generic firm be in a position to rapidly establish a significant market share for 6 months after approval and to recoup the cost for challenging patents. Instead, the generic firm would be compelled to share the market with the lower priced imported brand product. The net result is that given the inherent risk of patent challenges combined with significantly reduced revenue based on competition from imported brand products, the incentive to challenge patents will clearly be seriously diminished. Ultimately, one can assume that fewer patent challenges will occur and American consumers will have far fewer lower cost, FDA-approved, therapeutically equivalent generic drug products available to them. These patients will be left to rely on high cost brand products or on slightly less expensive imported brand products that are therapeutically inequivalent to the product marketed in the United States.

⁴ P. Danzon, "Making Sense of Drug Prices," *Regulation* Vol. 23, No. 1, 58.

Any importation program should therefore preserve the important balance between innovation and access to generics by prohibiting importation during the 180-day exclusivity period for generic companies. By allowing importation during this vital period, current importation proposals could undermine the carefully crafted compromise that provides the critical incentive for generic companies to challenge questionable patents and bring affordable medicines to the market years ahead of the expiration date of the invalid patent. The 180-day period has been an extremely important reason why the generic industry has thrived over the past 20 years by bringing consumers accelerated access to affordable medicines. Changes enacted under last year's Medicare Modernization Act were designed to restore the original value and effectiveness of this provision. Through patent challenges, generic drugs have bought billions of dollars of savings to consumers. For example, in just one case, Prozac, a challenge brought generic competition to the market three years early, saving \$2.5 billion on that drug alone. However, if the importation of foreign drugs (which may not be therapeutically equivalent) is permitted during the 180-day period, it will undo the carefully crafted balance between innovation and access that Congress has worked so hard to achieve.

I was especially interested in your comments regarding potential liability issues associated with imported drugs. Your comments about who should assume the risk — should someone be harmed — is a difficult and troubling question, and one in which I have similar concerns. Even if the responsibility lies with the supplier of the drug, you heard the FDA's earlier testimony that many times, these places cannot be located. So what is the answer to this serious problem?

As the FDA testified before this Committee, under the current system, all entities in the pharmaceutical importation supply chain waive their responsibility for assurance of safety and for any liability for adverse effects suffered by the consumer. If an FDA-approved drug product is counterfeited abroad and brought into the country under the guise of importation, without other recourse available, it is quite possible that victims could try to hold the legitimate FDA-approved drug manufacturer responsible. Accordingly, pharmaceutical companies could potentially be forced to spend substantial resources defending themselves when a third party's product — a product clearly outside their control — harms a patient.

In addition to increasing the likelihood of counterfeiting, importation of unregulated drugs from other countries could undermine consumer confidence in FDA-approved drugs, both brand and generic. Generics sold in the United States must be therapeutically equivalent to their brand counterpart and accordingly are certified by the FDA to be interchangeable. If a generic drug approved in another country is imported, the drug may be therapeutically inequivalent to the brand drug manufactured and commonly prescribed in the United States. Most importantly, this difference could be harmful to patients as well as adversely affect future utilization of FDA-approved generic pharmaceuticals. FDA-approved generics are the *same* as their brand counterparts, yet they cost as much as 80 percent less. Through the education efforts of the generic drug industry along with the federal government, health insurers, and other private payers, generic drugs now account for over 50 percent of all prescriptions filled and provide billions of dollars of savings

each year. Any importation legislation should not undermine these efforts to promote cost-effective utilization.

Another issue concerns the safety of consumers if unregulated imported drugs are allowed into the United States. If we allow this to occur, without knowing whether or not the FDA can guarantee the safety of these products, we are essentially compromising the safety and health of Americans, aren't we? I know GPhA has strong opinions on this matter so I would like to hear your views.

Importation raises two distinct safety concerns. The first relates to substantially increased opportunity for counterfeit products. The potential dangers from the use of counterfeit drugs range from lack of comparable therapeutic effect to the version of the approved brand product offered for sale in the United States to serious illnesses and even fatalities. The second issue relates to potentially harmful differences between the regulated, FDA-approved product marketed in the United States and the same brand product marketed in other regions of the world.

1. Counterfeiting

Patients receiving a counterfeit imported drug product for treatment of a critical disease, such as heart arrhythmias or seizures, could experience a fatal outcome due to significant subpotency or superpotency. There is currently no reliable mechanism to track and trace drug products through the international supply chain. Indeed, in testimony before the HHS Task Force on Drug Importation recently, several panelists reviewed the severity of the prescription drug counterfeit issue facing multinational brand manufacturers. Counterfeiting is a problem found not only in developing countries; it has become a growing problem all over the world. Counterfeit prescription drugs have been repackaged and reformulated in foreign countries and then introduced into legitimate distribution channels. Counterfeiting activities are well-orchestrated business enterprises, with the goal of channeling counterfeit products into *robust* markets, such as the United States and Australia. Given the gravity and breadth of the worldwide counterfeiting epidemic that plagues the pharmaceutical industry even under the current system, safeguards against counterfeiting must be preserved and ultimately strengthened.

The opportunity to introduce counterfeit products into this supply chain is dramatically heightened when these products are outside of FDA control. Moreover, the level of FDA resources necessary to thwart this potential counterfeit activity could probably not be immediately realized. Without adequate resources and the time to train the requisite number of specialists to oversee such a critical program, the agency would be hard pressed to implement the necessary safeguards, provide the requisite oversight, and take appropriate enforcement actions to ensure that this nation's drug supply system remains secure.

Counterfeiters would therefore be able to exploit entry nodes that do not exist under the current system. As a result, importation without adequate safeguards could shred the fab-

ric of FDA's safety net that has protected consumers from the entry of unregulated drugs of questionable safety, potency and quality for more than 70 years.

2. Critical Therapeutic Differences

When American consumers receive a generic equivalent, they are assured that it will have the same safety and efficacy as its brand-name counterpart. The reason for this assurance is that FDA imposes strict standards for generic products, which in turn allow the consumer to switch from brand to generic, or generic to brand with the full expectation of therapeutic equivalence. The agency cannot assure that imported versions of the brand product meet these same standards of equivalence. Brand products manufactured in different regions of the world may have different formulations or specifications that result in different therapeutic profiles for the American brand product and the imported brand product.

While for some drug products this may not be critical, there are many products for which these potential differences can mean the difference between control of a disease and serious jeopardy to patient safety. For instance, therapeutic differences in a diabetic drug may result in loss of control of the disease. Therapeutic differences in certain medications to treat stroke or serious cardiac disease could result in serious and even fatal outcomes. Neither American consumers nor health care providers will be able to predict when differences between U.S. and imported brand products exist, although such differences clearly are bound to exist. Thus, the risk for consumers can be great. The very uncertainty inherent in importing drugs without adequate testing and sufficient safeguards is a risk that can be dangerously high for the American consumer.

Therefore, while we would strongly prefer that assurances are in place that imported drugs are therapeutically equivalent, we highly recommend that if an imported drug is therapeutically *inequivalent* to the FDA-approved domestic brand drug, consumers should be made aware of the difference through product labeling. To be therapeutically equivalent, the drug must not only have the same active ingredient or ingredients, route of administration, dosage form, and strength as its counterpart, it must also be bioequivalent. Generic drugs are required to be therapeutically equivalent to the referenced brand drug before they can be considered by FDA to be interchangeable with their FDA-approved domestic brand counterparts. Therapeutic equivalence allows the generic to be substituted with the brand without any adverse effects to the patient. Thus, if an imported brand is not considered therapeutically equivalent to its domestic alternative, FDA should be authorized to require that drug products be labeled accordingly to ensure that health care professionals and consumers are enabled to make well-informed decisions before switching between medication products.

Does your organization believe that any of the bills being considered by the U.S. Senate can guarantee the safety of imported drugs?

As we testified during the hearing and in our written statement, GPHA does not support any of the importation bills that have been introduced in Congress. We believe each of

these bills as currently drafted is flawed, and would lead to unintended consequences for consumers, the generic industry, and our nation's health care system. Although we oppose the bills, GPhA endorses the goal of the sponsors, which is to improve consumer access to affordable medicines. For more than two decades, American consumers, young and old alike, have come to depend on generic drugs to help them live longer, healthier lives at lower costs. Increased use of generic drugs is a proven cost containment measure and it is imperative that Congress, in its efforts to seek additional savings, does not undermine the positive steps to ensure timely access to generics recently enacted in the Medicare Modernization Act.

In pursuing their goal, proponents of importation should ensure that actual savings will be realized through their legislation and that the safety of the drug supply is not compromised. The FDA must have the requisite authority and the necessary funding to maintain the American gold standard for safety that is the envy of the world. However, until we can assure that the products coming into our country are certified by FDA and meet the same strict standards for domestic pharmaceuticals — both brand and generic — there will inevitably be concerns about patient safety.

As we have mentioned, FDA requires generic drugs to be therapeutically equivalent. That means they have to be pharmaceutically equivalent AND bioequivalent before they can be interchanged with a brand counterpart. An imported product should also have to meet this standard if a patient is going to substitute it for the brand medication. Additionally, the importation program should be limited to only those brand drugs without a generic alternative already available in the United States. Generic drugs in America are not only less expensive than the imported drugs from other countries, but they are also cheaper than generic drugs sold in foreign countries. Limiting the drugs that would be available for import would not only allow the FDA to focus its resources on a more limited population of drugs, but would also assure consumers were not paying more for their medicines.

Do you think it is possible for the FDA to be able to guarantee the safety of pharmaceuticals being imported into the US? Do you believe that the FDA has sufficient resources to handle this type of responsibility? Even if there were sufficient funding, isn't it possible that these costs would be passed along to the consumers purchasing these drugs?

It is essential that any legislation authorizing importation of pharmaceuticals into the United States be based on the full recognition that FDA is an agency which does not have the resources to meet its current obligations, even without any added responsibilities in overseeing unregulated imported drugs. Imported drugs should be tested by FDA to assure their therapeutic equivalence. To do so, FDA will need both expanded legal authority and sufficient resources. GPhA believes that any savings that accrue from importation should be fully passed along to consumers; otherwise, there is a real possibility that consumers could be buying more expensive, unregulated drugs from abroad.

Could you go into more details regarding GPhA's safety concerns regarding drugs that have been imported into the United States? Has GPhA's membership encountered specific problems regarding imported pharmaceuticals?

As noted above, our safety concerns are twofold, involving the possibility of counterfeit drugs and the potential of harmful differences between brand products marketed in the U.S. and those marketed elsewhere in the world. Counterfeiting drugs increases the likelihood of the lack of comparable therapeutic effect to the product marketed in the U.S., possible impurities or dangerous substances introduced in the drug manufacturing process, etc. Because of FDA's track record of regulating drug products, American consumers have confidence that the any drugs they take have the same effect at the same dosage levels; this confidence is inevitably compromised by the introduction of imported drugs into the American marketplace, with especially significant risks for anyone who relies on life-sustaining drugs for disease control.

At present, we are exploring whether GPhA's members have encountered problems related to imported pharmaceuticals. However, we do know that this issue is of grave concern to the brand sector, since counterfeiting activities have evolved into well-orchestrated business enterprises around the world.

Ms. Jaeger, you testified that GPhA does not "currently" support the Dorgan bill. Are there circumstances under which you would support it? If so, under what circumstances?

GPhA is uncomfortable lending its support to any such bill without the assurance of adequate resources and oversight authority for FDA to take on the expanded burden of assuring the health and safety of American consumers which would ensue with importation. In the end, this is really a matter of sufficient appropriations and authority for FDA to assume this expanded role. Furthermore, our residual concerns about the effects of any importation legislation on the generics industry remain, regardless of which bill moves forward. We feel that it is imperative that the 180-day exclusivity currently available to generic manufacturers under the Hatch-Waxman Act be preserved in any importation legislation. Otherwise, the incentives for patent challenges by generic manufacturers would be seriously eroded by the entry of imported pharmaceuticals. Finally, we strongly believe that importation should be restricted to drugs for which there is no American generic equivalent available.

**Questions Submitted by Senator Patrick Leahy
Hearing before the Committee on the Judiciary
“Examining the Implications of Drug Importation”
July 14, 2004**

I agree that it is in the best interest of the American consumer to ensure greater access to generic drugs which provide significant cost savings over brand drugs. I have sponsored legislation to do that in the past and continue to look at how we can do a better job in the future. The new President of the National Association of Attorney Generals happens to be the current Attorney General of Vermont, William Sorrell. AG Sorrell has stated that he wants to dedicate particular focus to answering the question of why Americans pay the highest drug prices in the industrialized world. One of his aims is to understand why cheaper generic drugs are not prescribed by more doctors and why they are not desired by more patients. Do you have any thoughts on these questions?

There are several factors which affect the utilization rate of generic drugs here in the United States, including consumer perception of generic drugs and prescriber practices. In 1984, the year the Hatch-Waxman Amendment was enacted, the generic utilization rate was just 19 percent. Today, FDA-approved generics account for more than 51 percent of all prescriptions filled in the United States. Yet generics represent less than eight cents of every dollar consumers spend on prescription drugs.

An overwhelming majority of Americans clearly understand the cost savings associated with generic drugs. According to a *Wall Street Journal*/Harris Interactive poll released in May 2004, 81 percent of Americans agree that “allowing brand drugs to go generic after a shorter period of time will save money for the U.S. healthcare system.” However, in a survey conducted by Medco Health Solutions, Inc., also released in May 2004, seniors were less likely to know that generic drugs are made from the same active ingredients as brand name drugs, that they are regulated by the Food and Drug Administration, and that they are just as effective as brand name drugs in treating the specified disease or condition.

According to the Medco survey, consumer willingness to choose generic drugs over brands varies dramatically depending on the seriousness of the medical condition for which they are seeking treatment. While more than 75 percent of adults polled would use generic medications to treat minor conditions such as a cold, flu, or heartburn, less than 50 percent would use a generic medication to treat heart disease — despite the fact that generic medications are the medical equivalent of their brand name counterparts, at a savings of up to 80 percent. The Medco survey updates data gathered in 1999, revealing that the percentage of adults considering themselves very knowledgeable about generics has jumped sharply in the last five years, from 11 percent to 19 percent.

Accordingly, while significant progress had been made in consumer education, there is still much misinformation and misperception about the equivalence and the effectiveness of generic drugs and their brand counterparts. Clearly, the solution to this matter is two-fold: (1) implement a national education program to educate consumers on the tremen-

dous economic and therapeutic benefits of generic drugs; and (2) take action against misinformation campaigns designed to produce confusion or infuse uncertainty into the minds of health care providers and consumers and to undermine formularies.

For example, some states have enacted laws that require Medicaid to pay for brand name drugs for particular patient groups even when generic equivalents are available — despite the fact that there is no clinical justification for favoring certain brands over their FDA-approved generic equivalents. State Medicaid Directors should be encouraged to consider undertaking a campaign to educate physicians and beneficiaries on the value and effectiveness of generic drugs.

The *Generics First* program initiated by Medco Health Services shows how effective a “counter-detailing” or generics education program can be. In 2002, Medco sent pharmacists to hold face-to-face clinical discussions with 1700 physicians in 10 states. In addition to the meetings, the pharmacists left patient education materials and generic samples behind that the physicians could provide to patients. The effort focused on educating the physicians on the availability, clinical benefits, and economic value of generics and encouraged their use as a first line treatment.⁵

According to published reports, at least six (6) states have experimented with similar “counter-detailing” efforts. *The Wall Street Journal* reported that in October 2000, a Florida “counter-detailer” visited 88 physicians who tended to prescribe brand-name anti-inflammatory drugs such as Vioxx and Celebrex. An analysis of those physicians’ prescribing habits done three months later showed a change in prescribing that was expected to save Florida \$196,000 a year.⁶

West Virginia launched a pilot “counter-detailing” program in 2002. The head of West Virginia’s Public Employee Insurance Agency predicted at the outset that a 2-percent increase in generic utilization (from 43 to 45 percent) would save his state \$1 million.⁷ We believe Medicaid programs can enjoy similar savings simply by increasing awareness of the safety and efficacy of generic versions of brand drugs.

GPhA also recognizes the need to educate consumers and health care providers about the tremendous value of generics. Toward this end, GPhA has developed consumer educational campaign materials designed to maximize awareness of generics. The data suggest that consumers are open to using generics when they feel confident that they will experience the same results as if they had used a brand name drug. GPhA’s consumer education campaign — with its tagline: “Same Medicine. Same Results. Lower Cost.” — directly addresses the core gaps in consumer understanding of the health and economic benefits of generics and will help increase generic utilization nationwide. GPhA’s consumer education campaign will focus on communicating this message to all Americans so they understand that generics “Improve Lives for Less.”

⁵ *The Bergen County Record* [newspaper], November 5, 2002

⁶ *The Wall Street Journal*, August 22, 2001

⁷ *The Washington Post*, August 5, 2002

This program can be made available and distributed directly or indirectly and customized to suit any health care provider's needs. For example, a state Medicaid program could partner with CMS and GPhA to promote generic product use and consumer acceptance within their program — without the added cost of developing such a campaign.

The subject of our hearing was “Examining the Implications of Drug Importation” yet a considerable portion of the testimony we heard focused on an important but separate issue, that of problems with fraudulent internet or mail-order pharmaceutical distribution. These fraudulent internet operations should be targeted and shut down – regardless of the importation status of the drugs at issue. However, discussion of these illicit activities ultimately sidesteps the core issue we examined at the hearing: the implications of legalizing drug importation. Establishing a system by which Americans can reliably purchase FDA-approved drugs from reputable foreign sources would look very different than our current unregulated system. Under the Dorgan-Snowe proposal for legalizing prescription drug importation the FDA and relevant agencies would be given resources and regulatory tools to implement a reliable system for drug importation that holds all parties accountable and tracks products from development and manufacturer through distribution. Do you not agree that such a system would be an improvement over the current situation? If not, why not?

We strongly agree with most Americans and you that the current prescription drug cost situation is unacceptable and needs to be improved to ensure access to more affordable medications. Not surprisingly, we believe that the increased use of generic drugs and enhanced incentives for them (either through generic-friendly benefit designs, removal of barriers to generic market entry, or federal reimbursement policies designed to maximize generic utilization in Medicaid and other public programs) would make an important contribution to this end.

As for the Dorgan-Snowe legislation as introduced, we believe it would need to be modified to ensure that the legislation did not unintentionally undermine the use of generic drugs which, as you know, are frequently less expensive in the US than in Canada. We welcome and applaud the sponsors' commitment to dedicating adequate resources to the Food and Drug Administration (FDA) to ensure the safety of this nation's drug supply. GPhA believes that this is critical. Without adequate resources and the time to train the requisite number of specialists to oversee such a critical program, the agency will be hard pressed to implement the necessary safeguards, provide the requisite oversight, and take appropriate enforcement actions to ensure that this nation's drug supply system remains secure.

As we have discussed with you and your staffs, we strongly believe that the importation program should be limited to those drugs that will actually provide cost savings to health care consumers—brand drugs with no generic competition. Permitting the importation of generic drugs has great potential to be counter-productive. U.S. generic drugs are not only cheaper than potential imported brand drugs, but as several reports suggest, U.S. generic drugs are generally more affordable than generics in Canada and other in-

dustrialized countries.⁸ Excluding generic drugs would have the added benefit of minimizing unnecessary and expensive administrative burdens on the agency. If we permit the importation of generic drugs and their brand counterparts, we will in effect, be encouraging the use of prescription drugs which may be more costly than the generic drugs available in this country while substantially adding to the burden placed on FDA by importation.

Finally, any importation program should protect the important balance between innovation and access to generics by prohibiting importation during the 180-day exclusivity period for generic companies. By allowing importation during this vital period, current importation proposals could undermine the well-crafted compromise that provides the critical incentive for generic companies to challenge invalid patents and bring affordable medicines to the market years ahead of the expiration date of the invalid patent. The 180-day period has been an extremely important reason why the generic industry has thrived over the past 20 years by bringing consumers accelerated access to affordable medicines. However, if the importation of foreign drugs is permitted during the 180-day period, it will undo the carefully crafted balance between innovation and access that Congress has worked so hard to achieve.

I look forward to continue our collaboration with Senators Snowe, Dorgan, Kennedy, Leahy and others on this issue and other issues centered on ensuring that Americans have access to affordable medicine.

⁸ Palmer D'Angelo Consulting Inc. Report Series, "Generic Drug Prices: A Canada-US Comparison," August 2002
John R. Graham and Beverly A. Robson, The Fraser Institute, "Prescription Drug Prices in Canada and the United States – Part I: A Comparative Survey," Public Policy Sources, No. 42 (2000) pp. 3-5

Dr. Elizabeth A. Wennar
Judiciary Committee Testimony July 14, 2004
Senator Leahy Follow-up Questions

Question 1. **Guidelines and safety measures.**

At the time we initiated our program to assist individuals there were no established uniform set of guidelines. We developed our own set of guidelines which assisted us in screening the mail-order pharmacies. They were limited by resources in terms of our ability to audit the pharmacies. That was then, now there are clear standards that exist for mail order through the Internet and Mailorder Pharmacy Accreditation Commission (iMPAC), which we began to require just prior to the transition of the program to another sponsor. This process mimics for mail-order pharmacies what we in this country require for other components of our healthcare system (hospitals, outpatient, physicians) with regards to quality oversight (The Joint Commission on Accreditation of Healthcare Organizations, better known as JCAHO). See www.impacsurvey.org or call Dana Noble, Executive Officer for Operations (800) 677-7019.

Question 2. **Estimation of Savings**

I think you can project savings based on this as follows:

Fact 1.

About three (3) years ago we did an informal study of the key mail-order pharmacies in Canada that were well established and we identified through information they provided that approximately 1.2 million individuals from the US were ordering from them (we only asked for individuals that had placed at least a second order through them). Not all were through our initiative, but we were interested in a rough estimate of how many individuals were utilizing this as a method to access affordable medications from Canada. Note: Numbers reported today are over 2 million individuals

Fact 2.

We also know that the price has gone up by about 5% over the last year since big Pharma began to cut supply in Canada. I would propose that in general there is not a huge variance in the pricing of the medications across the mail-order pharmacies in Canada as of the end of last year. This is for the ones that have the line share of the business from the US.

So, I would propose that you could project by decreasing the savings by 5-6% that was calculated in our original analyses and recalculate with 1.2 million for some idea of what the numbers would be as of the end of 2003. It's hard to know what's occurring right now because of the vigorous activity of the manufacturers to cut supply over the past several months. If you just want an estimate of what existed when we were doing this, I would have to "guesstimate" that we served approximately 100,000 people by the time we

stopped sponsoring the program. I am going to use the end of 2003 as a point in time so, if every six months (x2) they saved \$59,000 and you adjusted this savings down by 5% for increases in pricing then the estimated savings as of the end of 2003 would have been in the ball park of $\$57,900 (x2) = \$115,800 (x100,000/145) = +/- \80 million dollars average saving. If you adjust that number down because the shipping cost (which ranged at the end of 2003 from \$0 to \$19 US) which were not factored in our original analyses, you still end up with significant savings. In any event if you took the average shipping charge of \$10 and applied it here: \$10 every three months for reorders each year = $\$40US (x100,000) = \4 Million. Deduct the \$4 million and you still would have seen savings in the saving on average being about \$76 million.

Note: My understanding is that many mail-order pharmacies in Canada are currently waiving shipping fees for any order over \$100US.

If you would like for me to get a formal number from Canada as it exist today. I would be willing to make some inquiries in Canada.

Question 3. **Problems with Medications Received from Canada**

Our biggest complaint was that either drugs were held at the border. The other was that individuals could not get meds via Fedex. Timing of deliveries once they reached our border was the biggest issue. On the contrary, we actually had physicians occasionally call to tell us how impressed they were with the assessment by the pharmacists there (ie., some very good quality oversight).

Question 4. **Parallel Trade in the UK.**

They have approximately 30 years of experience and to date have had no issues with safety or counterfeiting. By design it is has worked and continues to do so. It is proven that parallel trade reduces costs of pharmaceutical spending for consumers, health providers and governments. I would be pleased to put you in touch with Secretary General of EAEPCC in the EU, Mr. Macarthur for additional dat.information.

Question 5. **Improvement over the current situation**

In answer to your question, yes I agree that the Dorgan-Snow proposal, with the above considerations, would be, not only an improvement, its right thing to do at this point. We just have to secure its ability to be implemented once passed.

I am not sure why we need to increase resources that much for the FDA to achieve the goals of any legislation that is to be passed. Second, I believe we have an ethical obligation to the American public to pass legislation like the Dorgan-Snow proposal in order to protect the consumer. We created this industry in Canada. There was no need for mail order there because the price is the same for Canadian citizens regardless of whether it comes through the mail or they walk in to the pharmacy. Legitimate mail-order pharmacies in Canada welcome the oversight and regulatory processes that would help differentiate them from unscrupulous predators on the internet. In order to do so, the

Dorgan-Snow legislation should not fragment the current health care system oversight by segmenting this out to a federal agency. They should focus their resources on identifying the “bad: guys and putting them out of business. I believe we should leave the standards development and accrediting process of legitimate mail-order to private organizations that have the experience and resources to do what they do well such as JCHAO (“Joint Commission”, iMPAC, VIPPS)) who then let’s the federal and state regulators (such as CMS for Medicare and Medicaid) that a particular component of our health care system (ie., hospital) know that the standards have been met. Once a mail-order pharmacy has met an accepted US-based set of uniform standards they would then be registered with the FDA and listed as approved on a website sponsored by the FDA. Only registered entities outside the US would be allowed to ship into the US.

Note: Each State has Pharmacy Board that has historically had oversight of whether mail-order into their states has to be registered or licensed. The new regs would have to somehow require each state to accept some uniform set of standards in order to ship into every state. In other words only those that the FDA has registered with them.

Please feel free to give me a call if you require clarification or need additional information.

Respectfully submitted,

Dr. Elizabeth A. Wennar

**Questions Submitted by Senator Patrick Leahy
Hearing before the Committee on the Judiciary
“Examining the Implications of Drug Importation”
July 21, 2004**

Questions for Dr. Stephen W. Schondelmeyer:

1. In his testimony Senator Nickles referred to estimated cost savings associated with legalizing importation. Based on your analysis and expertise, what do you estimate to be the cost savings of legalizing importation, particularly under the Dorgan-Snowe proposal?
2. We know that when patients cannot afford their medicine they do things like split pills, or skip doses or do not fill their prescriptions at all. Yet importation allows those same patients to consistently purchase their pharmaceuticals and fully complying with their treatment plans. Could allowing importation under the Dorgan-Snowe bill prove financially beneficial to the pharmaceutical industry?
3. The subject of our hearing was “Examining the Implications of Drug Importation” yet a considerable portion of the testimony we heard focused on an important but separate issue, that of problems with fraudulent internet or mail-order pharmaceutical distribution. These fraudulent operations should be targeted and shut down – regardless of the importation status of the drugs at issue. However, discussion of these illicit activities ultimately sidesteps the core issue we examined at the hearing: the implications of legalizing drug importation. Establishing a system by which Americans can reliably purchase FDA-approved drugs from reputable foreign sources would look very different than our current unregulated system. Under the Dorgan-Snowe proposal for legalizing prescription drug importation the FDA and relevant agencies would be given resources and regulatory tools to implement a reliable system for drug importation that holds all parties accountable and tracks products from development and manufacture through distribution. Do you agree that such a system would be an improvement over the current situation? If not, why not?

SUBMISSIONS FOR THE RECORD

Statement
of the
**American
Pharmacists
Association**

**On Examining the Implications of
Drug Importation**

**Submitted to the
Senate Committee on the Judiciary**

July 14, 2004



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**Statement of the American Pharmacists Association (APhA)
to the Senate Committee on the Judiciary
U.S. Senate**

On “Examining the Implications of Drug Importation”

July 14, 2004

The American Pharmacists Association (APhA) appreciates the opportunity to present the views of the nation’s pharmacists on the issue of prescription drug importation. APhA, founded in 1852 as the American Pharmaceutical Association, represents more than 50,000 pharmacist practitioners, pharmaceutical scientists, student pharmacists, pharmacy technicians, and others interested in advancing the profession.

The public pressure to address access to lower prescription prices has prompted Congress to look at the possibility of legalizing prescription drug importation. This charge carries with it a significant responsibility – to determine if prescription drug importation can be conducted safely, and its potential impact on public health, medical costs, and the development of new medications. To make this determination, Congress must consider a number of important questions ranging from the scope and volume of imported drugs, the adequacy of safety protections, and potential liability issues, to the need for modifications in manufacturing and distribution technologies, the drug distribution system, and state and Federal laws. It is clearly an arduous task – these are not easy questions to answer. But the public has “called the question”.

We understand why the interest in importation has escalated in recent years – many have rallied around importation as the “solution” to providing consumers access to lower cost prescription drugs. As pharmacists, we are concerned that some patients – especially seniors – face challenges in accessing valuable, but sometimes unaffordable, medications. Any pharmacist who has ever worked in a community pharmacy can vividly recall the ~~dismay of having to tell a patient – especially a senior on a fixed income – the cost of their medication, knowing that the cost may be more than the patient can afford.~~ The Association and our pharmacist members strongly support efforts to enhance patient access to prescription medications. However, we have significant concerns with proposals to “solve” the problem by expanding importation. Our concerns generally fit in two areas: the integrity of the drug product itself and the impact of importation on patient care.

The Integrity of the Medication

The current U.S. drug distribution system was not designed to facilitate prescription drug importation. The system was designed to keep unapproved and potentially unsafe medications from entering the U.S. drug supply. Current U.S. laws and regulations were put in place after several critical incidents resulted in patient harm. When patients were harmed by contaminated or ineffective medications, Congress took action to protect patients. Those actions included requiring evidence of safety and effectiveness,

controlling the production and distribution of products, prohibiting the importation of unapproved medications, and other efforts to limit the presence of counterfeit and contaminated medications. Intentionally circumventing the U.S. regulatory system creates an opportunity for mislabeled, mishandled, subpotent, or counterfeit drugs to make their way into the hands of patients.

Opening the Door to the Closed Distribution System

Most contributors to this discussion understand the merits of limiting any legalization of importation to certain countries. While some countries, such as Canada, may have a system to regulate medications comparable to our system, it is important to recognize that a program to import prescription drugs from Canada – no matter how carefully designed – will open the closed U.S. regulatory system to countries beyond Canada. “Opening the door” to Canada opens the door – period. Even if attempts are made to limit access to one country, or even to specific pharmacies, opening the system will create incentives for unscrupulous operators to penetrate the system. Consider, for example, how U.S. regulatory authorities will know that one package of prescription drugs crossing the U.S. border is “legitimate” (a prescription filled through an “approved” importation program) versus another package of prescription drugs entering the U.S. from an unapproved country or pharmacy. The perils of personal importation via the internet are many. If our closed system is opened, we must have strong measures – and enforcement behind those measures – to help decrease the likelihood of unscrupulous operators preying on consumers through their medicine cabinet. With our current system, few consumers perceive a threat from counterfeit medications – and that perception matches reality. But even with the comprehensive U.S. system, counterfeit drugs have penetrated our system. According to the Food and Drug Administration (FDA), the number of counterfeit drug investigations has increased four-fold since the late 1990s¹.

For example, last year 11,000 boxes of counterfeit Epogen® and Procrit® were found on pharmacy shelves and in patients’ homes. Three months later, the FDA discovered five lots of counterfeit Lipitor®. These examples support the need for review and refinement of our existing safety net, not the expansion of efforts to circumvent or relax that system. Poorly constructed importation relaxes that system, and damages our safety net. Just three months ago, the FDA warned of counterfeit Ortho Evra® contraceptive patches that contain no active ingredient and were being sold online by a company based in India. By opening the door to importation, we increase the risk the introduction of counterfeit medications into our drug supply.

One of the greatest challenges with importing pharmaceuticals that differentiates the issue from other trade/importation debates (such as food or cars) is that pharmaceuticals are affected by multiple factors that may not be readily apparent to consumers. The majority of American consumers are probably not aware that differences can exist between versions of a medication with the same active ingredients. Medications obtained outside of the U.S. may contain different formulations – with differences in the amount of active ingredient or differences in the type of inactive ingredients– both of which can

¹ William Hubbard. Statement before the Senate Committee on Finance Subcommittee on Health Care and Subcommittee on International Trade. April 27, 2004.

affect the product's stability and how the product works. Because of these differences, any safe importation system must limit importation to products approved by the Food and Drug Administration, not merely products that contain the same, or similar, active ingredients. Medications are different – and minor differences matter.

Storage and shipping conditions can also affect drug stability and potency. Consumers who obtain their medications outside the U.S. have no way to know how their medications were handled. Was the medication maintained at the correct temperature? Was the medication stored in the correct type of container? Was the medication properly protected during shipment? These questions must be addressed to assure that the FDA-approved product reaches the consumer as intended.

Impact on Patient Care

Importation not only weakens the U.S. system of medication regulation, it also directly impacts patient care. While much of the importation debate is driven by disparities in drug pricing, those disparities are evident only on the front end – when we only know the cost of the drug, not the value. The most expensive medication is the one that doesn't work: in the situation where the drug doesn't lower blood pressure appropriately, the consumer paid good money, but got no benefit. In addition to paying cash, they paid for it with their health as their condition went unmanaged. The value of a medication should be assessed after the consumer has used it, after consultation with their pharmacist and doctor to make the best use of it. But this collaboration is challenged in many importation scenarios.

Because of the stigma involved in importing medications, many patients do not tell their physician or pharmacist about medications they are securing outside of the U.S. This is understandable, but dangerous. Unless the patient provides this information, pharmacists and physicians have no way of knowing what a patient is taking. Pharmacists' ability to identify drug-to-drug interactions is extremely hindered, if not completely prevented, without knowing about a patient's entire medication regimen or the content and strength of a particular drug. If a patient obtains medications from multiple sources – in this case through importation and a local pharmacy – neither the domestic nor international pharmacist has the patient's complete medication profile. The pharmacist is unable to determine whether the new prescription will conflict with any other medications the patient takes, whether the new prescription has ingredients that duplicate a current prescription, or whether its mere presence suggests other medical problems for the patient that should be followed-up with the patient's physician. This virtual blindness compromises the ability of physicians to care for their patients and the ability of pharmacists to partner with patients to improve medication use and advance patient care.

Problems also occur when a patient suffers unexpected complications or does not respond as expected to a medication. Consider a patient working with their local physician to treat their high blood pressure. The patient imports a faulty medication that has no or little active ingredient. It is unlikely the patient will physically feel anything different; unlikely he would actually notice any difference in the product. Later the patient visits the physician and a blood pressure reading shows that the medication is not working.

Because of our trust in the medication supply, it is highly unlikely that the physician will consider that there was a problem with the medication. Rather, the physician will likely assume that the medication did not work and will consequently either increase the dose or choose another medication. This sets the stage for using a stronger, but potentially unnecessary, medication and increasing overall health care costs. It also sets the stage for a preventable medication error that could cause harm to the patient.

Any proposals to legalize importation must address concerns with coordination of care — the relationship among patients, pharmacists, and physicians that provides the best possible health care. Allowing the importation of unapproved products will exacerbate this concern; and supporting personal importation will continue to create challenges for individual health care professionals and their patients. All of these scenarios cloud the promise of improved health from medications.

The Need to Address Issues of Concern

When you consider all of the risks associated with the importation of prescription drugs, just a few of which have been described, it appears foolhardy to consider haphazardly opening our borders to imported pharmaceuticals. Allowing importation carries the risk that mislabeled, mishandled, subpotent, or counterfeit drugs will reach the hands of our friends, our family, our neighbors. It also disrupts the connections and improvements we are trying to make in the health care system.

But this discussion is not just academic — we know that unapproved and potentially unsafe drugs enter our country today. Despite laws generally prohibiting importation by anyone other than the manufacturer, illegally imported prescription drug products arrive in mailboxes every day. For example, recent examinations of mail shipments at four mail facilities by the FDA and the U.S. Customs and Border Protection Bureau found that of 1,982 packages examined, 1,728 contained unapproved imported pharmaceuticals.² The products included so-called “foreign versions” of FDA-approved drugs that may vary from U.S. standards in potency and purity, improperly labeled drugs, controlled substances, recalled drugs, drugs requiring special storage conditions, and drugs requiring close physician monitoring. The FDA also found that many of the drugs were manufactured outside of the U.S. in countries such as Canada, Mexico, Costa Rica, India, Pakistan, New Zealand, Taiwan, Thailand, and others.

Do importing consumers know about these challenges? Likely not. Do their doctors and pharmacists? They probably know of the challenges at some level, but they are not likely considering them in the context of their patient population. This situation is unacceptable. If we continue to allow importation without safeguards to assure the safety and quality of the medications, we risk further weakening the U.S. system of medication regulation, a system that has stood as the strongest in the world. More importantly, consumers are risking their health.

² Food and Drug Administration. Press Release: Recent FDA/U.S. Customs Import Blitz Exams Continue to Reveal Potentially Dangerous Illegally Imported Drugs. January 27, 2004.

The question to examine is not ‘do we allow importation?’ The question should be ‘what do we do to assure the safety and the integrity of the U.S. drug supply?’ There appear to be two options. One, we begin strictly enforcing current law that prohibits importation. Provide the FDA, the Drug Enforcement Administration, Customs Bureau, and other regulatory agencies the funds and resources necessary to enforce the law; and continue efforts to find other means of increasing access to affordable medications. But this option isn’t likely. As more than one supporter of importation has stated, there are no ‘bodies in the streets’ – no documentation of a consumer being killed by importing drugs. While enforcement of our laws may once have been an option, it doesn’t seem likely today. At a minimum, however, policymakers should avoid any further endorsement of this unregulated and unknown practice. Rather than endorsing this practice, we must continue to educate consumers on the risks. The status quo must change.

If the current law does not work, we are faced with the second option: developing a new system to assure the safety of our medication supply. A new system, regardless of whether or not it allows importation, must resolve several issues of concern to ensure that patients continue to receive safe and effective medications – and that they know how to use those medications. A new system must address the role of the FDA and the State Boards of Pharmacy in maintaining a safe drug supply, respect the patient-pharmacist-physician relationship, require valid prescriptions, assure consumer recourse for harm, prevent efforts to circumvent U.S. health care professionals, include measures to limit counterfeit and contaminated drugs, and address the differences between FDA-approved medications and foreign products. Even this long litany of issues is not an exhaustive list of what must be tackled when evaluating a system to protect the U.S. drug supply and American consumers.

Prescription drugs, unlike so many other products, are not just another commodity – we ingest them to affect our bodies. They are one of the most valuable weapons we have in our health care arsenal today and we must treat them as such. Pharmacists rely on the quality of the U.S. prescription drug supply to provide our patients with safe and effective treatments. As the FDA does when it evaluates a new prescription drug, we must look at both the risks and the benefits and determine if the benefits outweigh the risks.

Importation may provide the benefit of lower cost prescription drugs, but as currently practiced it appears that the benefits do not outweigh the potential risks. We caution against recommending importation as an alternative method of drug distribution without appropriate safeguards – both in statute or regulation and in enforcement. At a minimum, any legalization of importation should be limited to drug products approved by the Food and Drug Administration and assure coordination of care with the consumer’s doctor and pharmacist.

In conclusion, thank you for the opportunity to provide comments on this important issue. APhA appreciates the Committee’s commitment to examine the wide range of issues surrounding the prescription drug importation debate. We offer our assistance to the Committee as you continue your valuable work.



**TESTIMONY OF THE
BIOTECHNOLOGY INDUSTRY ORGANIZATION**

**BEFORE
THE JUDICIARY COMMITTEE
OF THE
UNITED STATES SENATE**

IMPORTATION OF PRESCRIPTION DRUGS

JULY 14, 2004

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The Biotechnology Industry Organization (BIO) appreciates the opportunity to present the views of the industry and our members on the issue of legalizing prescription drug importation. BIO represents more than 1,000 biotechnology companies, academic institutions, state biotechnology centers and related organizations in all 50 U.S. states. BIO members are involved in the research and development of health care, agricultural, industrial, and environmental biotechnology products. BIO looks forward to working with Congress to help patients access the prescription drugs they need – including the life-saving products developed by our members.

BIO supported expanding the Medicare program to include a prescription drug benefit and continues to believe that when the prescription drug benefit is fully implemented it will improve the lives of millions of Medicare beneficiaries. Should future program changes be warranted, BIO stands ready to assist Congress to develop these modifications. However, we do not agree that enacting legislation authorizing Medicare beneficiaries and other patients to import prescription drugs will create safe and effective access to our products.

Currently, patients feel secure when taking their medications because they know that this country has the highest safety standards in the world for drugs and biological products. The Food and Drug Administration's (FDA) approval of a new product signifies that the product meets the FDA's gold standard for safety and effectiveness. Legislative proposals that authorize prescription drug importation will place patients at risk of obtaining products that do not meet FDA's gold standard. The wholesale importation of prescription drugs across American borders will jeopardize all U.S. consumers, regardless of whether they have chosen to obtain their prescription drugs from a foreign source because of the commingling of foreign and domestic products that will result from importing drugs.

Moreover, drug importation will stifle innovation in the U.S. biotechnology industry by imposing price controls and jeopardizing intellectual property rights. Stifling innovation hurts patients who are counting on advances in research and medicine to treat debilitating and often life-threatening illnesses. Whether they support prescription drug importation or not, many members of Congress insist that they oppose price controls, because price controls do not work to lower prices and, when they have been tried, often have resulted in policies and business consequences that have been harmful over the long run. But allowing wholesale importing of prescription drugs is tantamount to imposing price controls because the underlying intention is to import foreign prices and, thus, the foreign government-imposed price controls. Not only will this do little to level drug costs over the long term, but it also will seriously threaten continued innovation in the U.S. biotechnology industry.

In addition, expanding prescription drug importation and the definitions of who may import a manufacturer's products legally has serious implications for protection of intellectual property. As this Committee is aware, international disagreements abound over the obligations of foreign governments to protect the intellectual property of drug and biological product manufacturers, and differences are rampant among countries about

the extent to which they are willing to allow the breach of these protections. Those differences of policy and practice have affected international trade negotiations, international policy on access to drug products for serious diseases, international trade and tariff policy, and other areas. For the U.S. Congress to sanction and, indeed, encourage the importation without consequence of foreign drug products that have not been directly associated with a "normal" FDA approval, by individuals or wholesalers who are not directly licensed by the product's manufacturer or owner, raises all of these issues in our own country and calls into question the U.S. policy regarding protection of intellectual property. It is tantamount to placing this country on a par with countries that routinely disregard patents and other intellectual property protections. If the United States makes this kind of choice for prescription drugs — that they are no longer entitled to be protected under the laws of our own country — the government will compromise its ability to contest violations of intellectual property in other arenas and for all of the other kinds of products about which this country and its manufacturers are concerned.

Prescription Drug Importation Is Unsafe

BIO strongly opposes the legalization of prescription drug importation, notwithstanding the exemption of many biological and biotechnology products. Legalized importation will open the floodgates to a variety of unsafe prescription products.

For example, the FDA has testified on multiple occasions that the U.S. prescription drug supply already is under attack from a variety of increasingly sophisticated threats. Opening our borders, the FDA has asserted, would enable unscrupulous entities to circumvent the agency's safety and effectiveness standards and peddle unapproved and perhaps dangerous products to U.S. consumers. Even if biologics and certain biotech products are exempt, counterfeiters and other criminals likely will find a way to ship dangerous versions of our products across the border.

Biological/Biotechnology Products Are Unique

Many biologics and other biotechnology-derived medicines are particularly susceptible to adulteration, degradation and virtually undetectable counterfeiting. Moreover, many of our products cannot be administered safely by a patient and require the intervention and/or supervision of a health-care provider. As a result, our products are often not available in the U.S. through outpatient prescriptions, nor available at the local pharmacy.

Yet patients and the FDA, through its sting operations, have been able to acquire biological and biotechnology products through Internet sites and through other questionable means. In many of these cases, the products were packaged improperly, maintained at temperatures that hastened their degradation or completely destroyed their effectiveness, or were diluted, concentrated or otherwise dangerously adulterated. Obviously, the illegality of the transactions did not prevent them from occurring. To legalize importation for virtually all prescription drugs will do little to protect against

further entry of unsafe medicines and likely will increase the availability of unsafe or, at the very least, ineffective biotechnology medicines.

Wholesale Importation Is Not Individual Importation

Questions about the safety and integrity of the prescription drug supply are real and valid. The Congressional Budget Office recently issued a report on prescription drug importation, noting, with respect to cost savings, that although one patient filling a prescription in a foreign pharmacy may realize savings, the same would not necessarily be true for the entire health-care system.

This finding also can be extrapolated to safety concerns. If an individual chooses to travel to a foreign country to fill a prescription or to order prescription drugs from an unknown source via an Internet site, that individual is making a decision to accept the risk associated with that transaction. But wholesale importation will result in an intermingling of foreign drug products with those that have been approved as safe and effective through the FDA's gold-standard approval process. This means that every person filling a prescription will face the possibility of receiving a "second class" drug. Whether a consumer chooses to take the risk of filling a prescription from a foreign source will be irrelevant: we all will be forced to take the risk that our prescriptions are second-tier medicines.

Legalizing Importation Devalues the FDA Approval System

Drug importation will call into question the value and the viability of the FDA approval process. Recently introduced importation legislation essentially deems that products are FDA approved, whether their sponsors actually have provided the data needed for a true FDA approval or not. For example, some legislative proposals would require prescription drug manufacturers with foreign-approved drugs to submit an FDA application for approval, stating the differences between the foreign-made product and any U.S. counterpart. Based on this scant information, FDA is expected to determine whether the product can receive agency approval. Technically, supporters argue, FDA can deny approval, but this is hardly a realistic expectation. The legislation's clear message is an expectation of FDA approval. Indeed, since FDA, when it receives such an "application," would be required to make it public, the same pressure driving this legislation will come to bear — making it extremely difficult to deny the presumptive "FDA approval." Patients deserve better than titular FDA approval, but under this system, that is what they will get. The FDA will be required essentially to approve drugs for distribution in the United States that have not undergone the same safety and efficacy tests as their U.S. counterparts. Importation legislation will allow foreign-approved drugs to circumvent the FDA approval process completely. The result will be that patients will no longer have confidence that the medicines are proved to be safe and effective prior to reaching the market.

Unrealistic Expectations for FDA Make Enforcement Impossible

Creating numerous new requirements and voluminous paperwork for FDA under a new importation program will not and cannot make an inherently bad system safe. It would be impossible for the FDA to register, monitor and regulate importers and exporters; ensure that all incoming drug products are in accord with proper prescriptions; and inspect parcels, products and facilities to ensure product safety with the intensity required under such a program. Small and legislatively limited user fees assessed from importers will be insufficient to ensure that FDA can enforce the myriad new requirements. The agency itself has testified to this effect, reminding Congress of the significant and continuing resources — including more than 1,500 new inspectors — it chose to appropriate to assure control of imported foods. Concerns about attacks on the nation's food supply led to a decision by Congress to increase FDA's authority.

Those who will benefit most from the unenforceability of drug importation requirements will be those who least intend to abide by them — criminals, counterfeiters, smugglers and others whose only goal is to make the most money in the easiest fashion without regard to whether the so-called prescription products they peddle are safe or effective.

Prescription Drug Importation Will Hurt the Economy and Biotechnology Innovation

In addition to threatening the safety and integrity of the U.S. prescription drug supply, there are also valid economic reasons to oppose drug importation.

The biotechnology industry is a growing creative force on the U.S. economic landscape. The industry provides many jobs and a thriving tax base for communities throughout the country. National and state policies that encourage biotechnology innovation and foster the growth of the industry will provide not only an economic boost but also fertile ground for the development of treatments and cures. Biotech innovation has led to the development and FDA approval of more than 190 products that have helped at least 325 million people worldwide. Policies and legislation that discourage innovation will slow or end this progress.

Importation Will Have a Negative Impact on Investment

Investment in the U.S. biotechnology industry is based on an expectation that a product's success will reap benefits not only for patients but also for future industry projects and investors. That expectation can be fulfilled if a successful product remains in a favorable competitive environment for a reasonable period of time. Investors will not look favorably on the possibility of imported products quickly becoming competitors of FDA-approved products, nor will they look favorably on what will become, essentially, a system of foreign-imposed price controls on FDA-approved products.

The vast majority of biotechnology companies across the United States are small companies with no products on the market and without significant revenue or profits. To fund costly and lengthy periods of research and development, biotechnology companies rely heavily on three primary sources of capital: (1) private (i.e., institutional or venture investors); (2) public (i.e., the stock markets — mutual fund investors and individual investors); and (3) capital obtained from partnerships with other companies.

The capital markets are acutely sensitive to factors that threaten to limit current or future profitability for any company or industry sector. We see examples of this on a daily basis: if a public company unexpectedly announces an event that could adversely impact future earnings, the stock price plummets, resulting in millions, sometimes billions, in lost market value. Frequently, depending on the nature of the event, an announcement by one company also will have a negative effect on other stocks in the same sector, because of the fear that something similar could happen to those companies. Broader pronouncements that threaten to limit the profitability of an entire sector have even greater significant adverse consequences.

To illustrate this phenomenon, one need only recall the early nineties, when the call for widespread health-care reform with government price controls caused a precipitous decline in health-care stocks, in aggregate valuations, and in the subsequent flow of investment capital into the health-care sector. It is worth remembering that this tide was reversed only when the threat of price controls subsided. Another example of the capital markets' quick response to a perceived threat to future profitability was the Clinton-Blair gene patent pronouncement, when a misstatement by a White House press secretary caused the immediate loss of billions of dollars in market value for the biotech industry. There was no policy change, yet the bottom fell out of the biotechnology market as stock prices plunged within a few hours.

Broadening legal prescription drug importation will have at least the same desultory impact and probably a greater one. The question is whether Congress and patients want to take the chance that prescription drug importation — which is arguably not even a long-term solution to the identified problem of escalating drug costs — will have an adverse impact on biopharmaceutical innovation. BIO is certain that it will affect biotechnology innovation in a way that could slow the development of new products, or perhaps stop such development in its tracks.

Biotechnology development is an extremely high-risk venture. Of the many wonderful ideas this creative industry generates, only a small handful result in FDA-approved new products. Our member companies are dedicated to finding the next biologically based treatment or cure. They are willing to devote enormous energy, creativity, and resources to this endeavor, even though they know success is difficult and elusive. This research and development cannot be undertaken without the commitment of substantial financial resources, most of which come from the highly sensitive capital market. Some may argue that the pro-forma (and we believe unenforceable) exemption of biotechnology products from importation legislative proposals will resolve these economic concerns.

However, it is important to remember that many BIO member companies use the fruits of biotechnology as part of their drug discovery and development efforts, although the products themselves may not be manufactured using biotechnology processes. Such companies would be severely adversely affected by the legalization of drug importation regardless of whether biological products are exempted.

The unrestricted importation of drugs that are sold to foreign suppliers under foreign government-imposed (or “negotiated”) price controls will reduce the profitability of the companies that developed the drugs. In fact, that is precisely the objective of importation advocates — to use importation as a mechanism to reduce prices for consumers artificially, and thereby reduce company profits as a result. The immediate and unavoidable impact of reducing economic profitability is a reduction in investment in an industry that requires capital to fund further innovation. Quite simply, reduced profits (via price controls or any other mechanism) mean less investment capital to support drug research and development.

De facto implementation of price controls via importation will not create a corresponding reduction in drug development costs. It will still cost the same to discover, test, validate through clinical trials, manufacture and ultimately sell a new product. The failure rates experienced during the product development process will still be the same. The costs and risks will remain the same, but the potential return will be greatly diminished. As a result, companies will have no choice but to limit their development efforts to only those drugs that have the highest potential profitability in the face of price controls. Drug candidates that could potentially help many patients and that were once considered viable opportunities under a free-market pricing system will be abandoned because they will no longer be sufficiently profitable in a world of de facto price controls.

Prescription Drug Importation Imports Foreign Government Price Controls

The importation issue is not just about the importation of drugs — it’s about the importation of price controls. Importation would not even be a topic of discussion today were it not for the fact that foreign governments have arbitrarily imposed pricing restrictions on companies that develop new, safer and innovative medicines. That is a global trade issue that must be addressed. Why should foreign countries be allowed to force U.S. consumers and companies to subsidize their health-care costs? Without the innovations provided by the U.S. biotechnology and pharmaceutical industry, their health-care costs would surely be far higher, and the quality of life experienced by many patients far less, than they are today.

The U.S. leads the way in biotechnology innovation. This country is without peer in terms of understanding disease and developing the most appropriate ways to treat disease. The reason we are so successful, and the reason our patients have the best chance at the latest and best medicine, is that our national policies foster innovation. We do not have prescription price controls because such controls hinder and discourage innovation. We do not have international parallel trade because those trade policies stifle innovation. We

have strong protections for intellectual property because such protections foster innovation. Biotechnology innovation will deliver on its promise if the country delivers on policies that allow it to thrive.

Importation Proposals Threaten Patent Law

Prescription drug importation legislation also erodes intellectual property rights. One bill that has been introduced would prevent United States manufacturers from enforcing their patents against foreign products that, if marketed in the U.S. under current law, would violate the patents on the U.S. products. In other words, even though a foreign product would be imported into the U.S. market in direct competition with a patented FDA-approved drug, the manufacturer would be denied any recourse under U.S. patent laws. The impact on the biotechnology industry of such a change to patent rights would be enormous. In many cases, companies in this industry own very little except their intellectual property. The entire value of the company may hinge on intellectual property rights to a material or a means to achieve specific activity from certain kinds of biological agents. The message of such legislation is loud and clear: the United States is not willing to protect patent rights associated with pharmaceutical innovation. This message alone is enough to discourage investment and smother innovation.

Every week, the public and the Congress hear about a policy debate during which the United States argues that intellectual property protection is critical and other countries argue that it is not. These debates occur during discussions of trade policy, treaties, international health policy and other issues. The United States often finds itself in the unenviable position of being right on a policy that some critics say hurts people in other countries. While this stance has made for negative headlines, it also has continued to reinforce U.S. policies that preserve and promote our country's preeminence in technology, and particularly in biological science, medicine and biotechnology. This promotion of policies that ensure our scientists and innovative manufacturers remain at the cutting edge of their fields benefits our citizens. The benefit is especially obvious in the case of pharmaceutical biotechnology innovation, the source of the next treatment or cure for a disease that today has no hope of cure. To allow intellectual property protection to erode, or deliberately to say that it is irrelevant, as some importation legislation advocates, is tantamount to saying "no" to patients. That is unacceptable policy.

Prescription Drug Importation Does Not Guarantee Cost Savings

Although prescription drug importation legislation is intended to lower prescription drug prices, the Congressional Budget Office and numerous other economists have challenged the assumptions of significant savings, noting both the unique features of the world pharmaceutical marketplace and the substantial costs that would be incurred by middlepersons in the import/export scheme — costs that certainly would be passed along to patients. Recently introduced bills would impose many additional requirements that were not even envisioned by the economists who looked at earlier legislation, so these

transaction costs would be significantly higher. Additionally, examination by economists of European parallel imports shows that the expected significant savings for consumers have not materialized, although tidy profits have been made by the traders. Finally, no proposal guarantees that the cost differential obtained by the importer/exporter is actually passed along to the consumer.

Conclusion

BIO strongly opposes legalized prescription drug importation. We believe existing proposals will harm both our industry and, more importantly, the patients we are dedicated to helping. No exemption is fail-safe and the ingenuity of criminals should not be underestimated. They will find ways around the myriad requirements proposed by these bills, and no on-paper "exemption" for biologics will stop them from dealing in whatever product they believe will be the most lucrative.

There can be no doubt that incursions into trade policy, intellectual property protection, and economic incentives for U.S. business — all of which are part of this legislation — will have unintended consequences. The benefits of a free-market economy for U.S. citizens and for this country's economic well-being are well-accepted. There will be harm when legislative policy attempts to distort the free market by imposing requirements and penalties designed to perturb what the market otherwise achieves on its own. This is particularly true when the incursions and perturbations are directed at one, and only one, industry and at one set of products.

BIO agrees with those who believe that patients need access to our life-saving and life-enhancing products. Health coverage helps this happen, and we encourage the Congress to take action to reduce the number of uninsured Americans and increase prescription purchasing assistance to those in need. We also support the new entitlement under Medicare, which will help all Medicare beneficiaries — most of whom are our senior citizens — with their prescription drug needs. Until that prescription benefit takes full effect, the Medicare discount card will help many. Whether one supports the new Medicare benefit or not, or believes the discount card is sufficient or not, both of these mechanisms at least do no harm to the future of innovation and the future possibility that treatments and cures will be available for those who need them. Legalizing prescription drug importation is not the answer to prescription drug access. Its promise is false and its dangers are real.

**Testimony of
Carmen A. Catizone, MS, RPh, DPh
Executive Director/Secretary
National Association of Boards of Pharmacy**

**Testimony before the Senate Committee on the Judiciary
July 14, 2004**

Examining the Implications of Drug Importation,

Mr. Chairman and Members of the Committee:

I am honored to submit information on the implications of the illegal importation of drugs into the United States on the public safety and state regulation of the practice of pharmacy.

The National Association of Boards of Pharmacy (NABP) was founded in 1904. Our members are the pharmacy regulatory and licensing jurisdictions in the United States, District of Columbia, Guam, Puerto Rico, and the Virgin Islands, eight provinces of Canada, two Australian States, New Zealand, and South Africa. Our purpose is to serve as the independent, international, and impartial Association that assists states and provinces in developing, implementing, and enforcing uniform standards for the purpose of protecting the public health.

NABP does not oppose importation if it can be implemented within the safe and secure regulatory framework of the Food and Drug Administration (FDA) and state boards of pharmacy. NABP does oppose the illegal importation of medications which is presently occurring and compromising the integrity of our medication system and state regulation of the practice of pharmacy. At our recently concluded Annual Meeting, which marked the 100th Anniversary of the founding of NABP, the member boards passed a resolution which resolved:

That NABP continue to oppose the illegal importation of medications and express to the Food and Drug Administration (FDA) the concerns of its member boards and strongly urge the FDA or appropriate legal authority to pursue actions against state and local governments for endorsing, promoting, or engaging in the illegal importation of medications.

Illegal Importation is a Real Threat to the Public Health and Safety

The illegal importation of drugs from Canada and other countries is one of the most complicated and frustrating issues confronting pharmacy regulators. It is an issue that has the potential of altering how medications are dispensed in the United States and how the practice of pharmacy is regulated. In fact, if the illegal importation of drugs into the US is allowed to continue, the impact on patient safety, pharmacy practice, and the regulation of pharmacy practice will be devastating. Patients illegally importing drugs are bypassing the drug approval process of the Food and Drug Administration (FDA) and the safety of licensed US pharmacies thus placing their health and well being in the hands of the country, territory, or back room with the seemingly lowest prices for pharmaceuticals.

At its worst, the illegal importation of drugs creates the opportunity for unknowing and unsuspecting patients to suffer harm, counterfeit and dangerous drugs to contaminate the US medication distribution system, and a thalidomide-like disaster to reoccur.

When the patient safety concerns of state boards of pharmacy, the FDA, and other regulatory agencies are ignored by patients, governors, mayors, and legislators with a chilling, "If the illegal importation of drugs is unsafe, then show us the bodies!" the situation becomes even more compelling. NABP cannot accept the premise that people must die from the illegal importation of drugs before the existing laws ensuring the safety of patients are complied with and enforced. The "show us the bodies" strategy proposed by some legislators, governors, mayors, and other public officials is irresponsible.

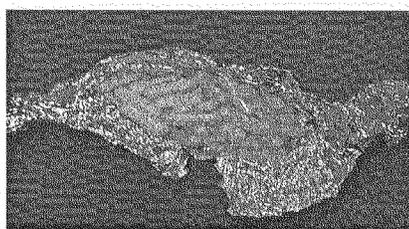
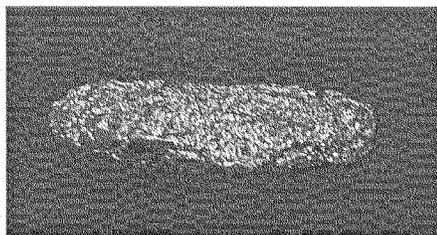
Critics of the regulatory actions of the FDA and state boards of pharmacy against entities distributing or assisting in the distribution of medications from other countries contend that there have been only a few reports of patient harm and injury. Although the number of reports may be low, the actual harm to patients is immeasurable and could be significant. NABP maintains that the number of reported patient injuries is low and immeasurable because patients may not be able to discern whether the drugs received from other countries are authentic or appropriate, injuries resulting from patients receiving wrong or counterfeit drugs may not manifest in the health care system until sometime later when the patient's condition worsens and requires emergency treatment or hospitalization, and consumers purchasing drugs from other countries are reluctant to report any adverse consequences because of the fear of prosecution for violating federal and state laws.

NABP's response to critics of the actions of the state boards of pharmacy to enforce existing state and federal laws protecting the public and prohibiting illegal importation is the presentation of reports from consumers describing real problems which are occurring with illegal importation. Some of the incidents reported to NABP include:

- A Wisconsin patient who ordered medications from a Canadian web site and suffered unexplained reactions after taking the medications received.
- Consumer complaints, totaling thousands of dollars, reporting that payment was made (credit cards charged) and no product received.

- Consumer complaints of counterfeit or inactive products:
 - *Ordered Acyclovir 400MG from this site received some other medication. Verified using imprint codes.*
 - *Product has no effect. Seems counterfeit.*
 - *The pills have no obvious effect.*
 - *I have taken pain medication before (prescribed by a local doctor). The effects of such meds are obvious. For one thing, the taste is bitter, bordering on awful. In contrast, the pills from MedPrescribe have no taste (I split one in half and tasted it). More importantly, the MedPrescribe pills have no effect (no benefit). In short, they do nothing to alleviate my pain. Nothing.*
 - *The item I received was very close to the shape and size of genuine Viagra. However, they bore no marking, logo, or insignia. Also the surface of the tablet was not as smooth and polished as real Viagra. The tablets were received sealed inside of a foil pouch with no indication of origin.*
 - *Order arrived with pills in a zip lock bag with drug name and dose on an adhesive label stuck on the bag. No return address on the mailing envelope and no receipt in the envelope.*
 - *I ordered "Tramadol" from this site, but what I received was not Tramadol. I contacted the poison control center, and they stated that they did not know what this medication was, nor did any local pharmacy know. I called [the site's] customer service number but they would not let me speak to the pharmacist that filled the script.*
- Consumer complaints regarding illegal and life-threatening access to addicting drugs,
 - *My wife is ordering drugs such as phendimetrazine and clonopin over the internet. They arrive by FedEx. Her charge card is charged because she gave the pharmacies her info. The pharmacies have some unknown drugs.*
 - *The header read, Vicodin, 24 Hour Sale Online - looks to be aimed at drug addicts. My son is a prescription drug addict (currently non-using), so the potential is very high.*

One of the most startling examples of the atrocities of illegal importation drugs is the receipt of drugs wrapped in tin foil void of any labeling, product identification, directions for use, warning labels, or protective container.



NABP has also learned that the purchase and import of drugs from other countries is gravely compromising state laws and regulations by granting the authority to practice medicine and prescribe medications to unqualified, unlicensed individuals and fueling the proliferation of solicitations for controlled substances:

- A US entity affiliated with a Canadian pharmacy operation is paying paramedics in the US to conduct the physical examination and diagnosis of patients. The paramedics' examinations and diagnosis are then forwarded to a Canadian pharmacy where prescriptions are issued by a Canadian doctor and drugs shipped to US patients. This activity contravenes US laws by allowing paramedics to practice medicine without appropriate education, training, and licensure.
- A certification/purchasing program is providing the means for psychologists to illegally order psychotropic drugs (e.g. barbiturates, Clozapine, haloperidol, etc.) for their patients through a Canadian pharmacy. Again, the opportunity to obtain prescription medications through foreign sources is directly abrogating the US regulatory system and allowing individuals to practice medicine without the appropriate education, training, and licensure.
- NABP continues to identify a staggering number of web sites brazenly offering controlled substances without a valid prescription (as required by federal and state laws) and a never before witnessed preponderance of spam emails offering unrestricted and illegal access to controlled substances.

The General Assembly of the State of Rhode Island passed legislation that will require the Rhode Island Department of Health to issue licenses to Canadian pharmacies. The legislation became law without the governor's signature in early July and distinguishes Rhode Island the first state to allow foreign pharmacies to obtain U.S. pharmacy licenses. The law's disregard of the existing state regulations and safeguards is particularly troubling to NABP in its mandate that "any pharmacy located in a province of Canada which maintains a valid, unexpired license, permit, or registration, to operate the pharmacy in compliance with the laws of said province shall be licensed in this state upon payment of a license fee ..."

The Food and Drug Administration directed a letter to Rhode Island Governor Carcieri warning him that federal law supersedes the new law and thus deems the state law unconstitutional. The FDA further noted to Governor Carcieri that the Rhode Island law will undermine the FDA's efforts to control drug quality.

The entire regulatory process for the practice of pharmacy could be decimated if other states follow the actions of Rhode Island and mandate the licensure of Canadian pharmacies with laws that are unconstitutional and completely compromise federal and state public protection safeguards. Comparable actions by other states could extend the distribution of drugs to US patients from outside of the US and Canada to countries or territories with laws and standards that differ markedly from the US. In doing so, such actions would eliminate the drug approval process of the FDA and replace state regulation with unknown and disparate regulatory processes and standards. No individual state would have control over the medications provided to its patients because the entire distribution system would be compromised by the state that allows for the purchase of drugs from the country with the lowest prices, regardless of what standards may exist in that country.

Importation Places Patients Outside of Regulatory Safeguards

NABP acknowledges that appropriate safeguards exist within Canada's federal and provincial regulatory systems to ensure that the dispensing of medications in Canada to Canadian patients is safe. Similarly, NABP attests that the dispensing of medications to US patients within the US regulated system is safe.

Unfortunately, the same safeguards do not exist for US patients purchasing and importing drugs from Canada and other countries. Information received by NABP indicates that although Health Canada prohibits the import of drugs outside of the Canadian approval system for dispensing to Canadian patients, it does not prohibit or regulate the import of such drugs for export to US patients. The regulatory void and breach of the safety net for US patients is significant and unknown to the overwhelming majority of patients ordering drugs from Canadian, or believed to be Canadian, pharmacies. NABP learned first-hand from the president of an Internet pharmacy corporation based in Canada that drugs shipped to US patients may not be approved by the Canadian drug approval process and may originate in New Zealand, Vietnam, Pakistan or any country in the world where prescription drug prices are lower than those in the US or Canada.

In fact, there are no limitations as to where drugs will originate from for delivery to US patients. Although NABP has information regarding the drug approval process and provincial regulatory system in Canada, related information from countries in Europe and other parts of the world is extremely limited. Each progression to extend the distribution source to unknown borders further away from the FDA drug approval process and state regulation of pharmacy practice makes the situation more dangerous. The extension of importation to countries lacking effective drug approval processes, regulatory systems, or practice standards, the further the erosion and destruction of the entire regulatory structure for the practice of pharmacy. The US system, based within the states and the FDA, has been exemplary in protecting the citizens of the various states and providing patients and health care practitioners with the assurances and confidence that the medications prescribed and dispensed are safe and effective products. The state based regulatory system successfully protects patients and is flexible enough to extend the regulatory framework and safety net across state borders and allow for the practices of telepharmacy and telemedicine to become realities.

The keys to this interstate regulatory framework have been uniform practice standards, state licensure of pharmacists and pharmacies, and licensure or registration of non-resident pharmacies. In fact, all but a handful of states require that non-resident or out of state pharmacies license or register with them and comply with their applicable laws and statutes. These laws and regulations have been in place in some states for almost 20 years, effectively protecting the citizens of the states and fostering cooperation among the states. The nonresident pharmacy laws and regulations protect the practices of pharmacy and medicine across state lines without unduly burdening interstate commerce and rightfully restricting the operation of illegal operations seeking to bypass the regulatory system of the states. State laws and regulations also allow for Internet pharmacies, the electronic transmission of prescriptions, shared data bases, electronic patient profiles, and other means for patients to receive pharmacist care and appropriately prescribed medications across state lines, through the Internet, or by the use of the mail. These laws and regulations transfer existing and accepted standards for patient care from traditional brick and mortar pharmacies to new, non-traditional Internet pharmacies and interstate practices. In order for importation to occur safely and appropriately, the same regulatory framework and safeguards must be in place across the borders of the US.

If the appropriate inter-border regulatory framework is not in place, then allowing for the purchase and import of drugs from pharmacies or foreign operations that do not comply with existing federal and state laws and regulations places US patients at risk. If the safeguards in place for the US drug approval system and state regulation of pharmacies and wholesale distributors are deliberately compromised, US patients will be subject to the dangers of a "buyers beware" environment and left unprotected to gamble with their health and safety.

Enforcement Workshop on Importation

NABP is not willing to accept a “buyers beware” environment for US patients and finds itself in the middle of a policy and political quagmire concerning access to medications and preservation of state regulation and patient safety standards. Until importation is legalized, NABP must stay the course of assisting its members in enforcing existing laws and regulations and prosecuting those entities involved in the illegal importation of drugs.

On June 21 and 22, representatives of the state boards of pharmacy and state attorney general offices participated in a special workshop to discuss the public health dangers of illegal importation and the successful prosecution of physicians, pharmacists, and pharmacies involved in this illegal activity. The workshop identified the legal basis and strategies for pursuing action against those entities involved in the illegal importation of drugs and allowed states to share their experiences in dealing with this complex and sometimes irresolvable problem.

As a result of the workshop, an enforcement template to guide state boards of pharmacy and the offices of the attorneys general in assembling the information needed to prosecute entities involved in the illegal importation of drugs will be distributed to all states. A strategic planning process was also initiated at the workshop and will be continued at an upcoming Fall Conference to help states manage a regulatory environment significantly impacted by efforts to bypass state laws and regulations and the ongoing globalization of the practices of pharmacy and medicine.

Legalized Importation Requires an Inter-border Regulatory Framework

NABP recognizes that a solution resolving the conflict of affordable access to medications versus safety concerns must be developed to address the needs of US patients and prevent irreparable damage to, if not the elimination of, the regulatory systems in the US. The first step of this process was the launching of the VIPPS program in Canada in November 2003 by NABP and the National Association of Pharmacy Regulatory Authorities (NAPRA) in Canada. The VIPPS Canada program mirrors NABP's VIPPS program¹ in the US and will identify for Canadian patients legal and safe Internet pharmacies accredited by a credible and valid system with standards that focus on the protection of the public health and patient safety.

¹ NABP's VIPPS program was introduced by NABP in 1999 and fashions traditional regulation and consumer empowerment into a thorough and successful verification and authentication system. The VIPPS process developed by NABP encompasses compliance with state and federal laws governing the practice of pharmacy and the direct verification of licensure of the Internet pharmacy with all states where licensure or registration is required. VIPPS certifies, through on-site inspections and the meticulous analysis of the site's operations and submitted written information, compliance with an 18-point criterion. The VIPPS Criteria combine current licensure requirements in all of the US states and territories with additional criterion that concentrate on the distinctions of Internet practice such as the transmission of prescription information and patient data, confidentiality of patient records, and quality improvement and monitoring of prescription processing and patient interactions.

NABP is also in discussions with a variety of regulatory agencies and affected stakeholders to develop the necessary regulatory framework to regulate the inter-border practice of pharmacy and dispensing of medications to patients in the US and Canada if legislation legalizing importation is enacted. The framework would provide similar protections as those afforded US patients who utilize pharmacies engaged in the interstate practice of pharmacy and would focus on identifying and monitoring the source of medications. The framework will coordinate the regulatory efforts and resources of the Canadian provinces and US state boards of pharmacy.

In closing, NABP respectfully requests that the Committee recognize that allowing and encouraging the purchase and importation of medications from other countries without the appropriate regulatory safeguards is a serious threat to our regulatory foundation and patient safety. NABP requests further, the Committee's assistance in preserving the sanctity of current regulations so as to prevent any patient from being seriously injured by the illegal importation of medications from other countries where US laws and regulations are being ignored or the laws of that country or territory do not equate to US laws and regulations. NABP does not believe that even one patient should suffer or be harmed as a consequence of disregarding federal and state laws that ensure the dispensing of safe and effective medications to US patients.

Thank you for the opportunity to address this important issue.



TESTIMONY BEFORE
THE COMMITTEE ON THE JUDICIARY
ON
PRESCRIPTION DRUG IMPORTATION

JULY 14, 2004

WASHINGTON, D. C.

WITNESS: JOANNE DISCH, Ph.D.
AARP BOARD MEMBER

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Mr. Chairman and members of the Committee, my name is Joanne Disch. I am a member of AARP's Board of Directors. On behalf of the organization and our over 35 million members, thank you for convening this hearing and for including AARP in your discussions about the need for safe importation of prescription drugs.

In November 2003, Congress enacted some sweeping changes to Medicare – including long-overdue prescription drug coverage. We believe that the new law lays the foundation for affordable Medicare prescription drug coverage upon which we will build over time. AARP will continue to work with Congress to strengthen and improve the drug benefit and the Medicare program.

The Need for Importation Legislation

The Medicare prescription drug benefit was an important first step. But now more needs to be done to control the rising costs of prescription drugs so that Americans of all ages can afford needed medications. Modern medicine increasingly relies on prescription drug therapies; yet the benefit of these therapies still eludes those Americans who cannot afford to pay escalating drug prices.

Prescription drug importation is not the sole solution to soaring drug prices in the United States. However, AARP believes that a system providing for the safe and legal importation of prescription drugs can serve to put downward pressure on drug prices and will permit consumers to realize some savings on the cost of their prescription drugs.

CMS estimates that, in 2003, per capita spending on prescription drugs rose approximately 12 percent, with a similar rate of growth expected for this year.¹ Much of the increase in drug spending is due to higher utilization and the shift from older, lower cost drugs to newer, higher cost drugs. However, rapidly increasing drug prices are a critical component.

A recent AARP study revealed that, on average, pharmaceutical manufacturer prices for the brand-name drugs most widely used by older Americans increased at more than double the rate of general inflation from 2000 through 2003.² The average annual increase in manufacturer prices charged to wholesalers for these drugs increased from 4.1 percent in 2000 to 6.9 percent in 2003. For the 155 brand-name drugs that were in the market for the entire four year period, this translates into a cumulative average price increase of over 25 percent.³ Last month, AARP released another study examining prescription drug prices for the 12 month period ending in March 2004. This study

¹ Data for 2003-2004 are projections from Table 11 Prescription Drug Expenditures; Aggregate and per Capita Amounts, Percent Distribution and Average Annual Percent Change by Source of Funds: Selected Calendar Years 1990-2013, <http://cms.hhs.gov/statistics/nhe/projections-2003/t11.asp>

² David J. Gross, Stephen W. Schondelmeyer, and Susan O. Raetzman, *Trends in Manufacturer Prices of Brand Name Prescription Drugs Used by Older Americans, 2000 Through 2003*, AARP Public Policy Institute Issue Paper #2004-06 (Washington, DC: AARP), May 2004.

³ David J. Gross, Stephen W. Schondelmeyer, and Susan O. Raetzman, *Trends in Manufacturer Prices of Brand Name Prescription Drugs Used by Older Americans, 2000 Through 2003*, AARP Public Policy Institute Issue Paper #2004-06 (Washington, DC: AARP), May 2004.

revealed that the prices charged by pharmaceutical manufacturers to wholesalers for these brand-name drugs increased faster than the previous years – by an average of 7.2 percent,⁴ a figure particularly troubling given that the average annual rate of general inflation actually fell during this same time period.⁵

High drug prices, combined with the surging growth of the older population, are also taking a toll on state budgets and private sector health insurance costs. Medicaid spending on prescription drugs increased at an average annual rate of nearly 20 percent between 1998 and 2001. Until lower priced drugs are available, pressures will continue to squeeze public programs at both the state and federal level. Pressure will continue on the private sector as well, possibly leading to elimination of, or reductions in, employer-provided drug benefits. Further, over 43 million Americans currently have no health insurance coverage. Without access to negotiated prices, these Americans pay among the highest prices for prescription drugs in the world or, worse yet, don't fill prescriptions because they cannot afford to pay for them.

AARP surveys demonstrate that our members consider drug prices exorbitant and the single most significant barrier to obtaining needed medications. Responses to an AARP *Bulletin* questionnaire last fall showed that our members split pills, skipped doses, asked doctors for free samples, and sold possessions because the costs of needed medications

⁴ David J. Gross, Stephen W. Schondelmeyer, and Susan O. Raetzman, *Trends in Manufacturer Prices of Brand Name Prescription Drugs Used by Older Americans--First Quarter 2004 Update*, AARP Public Policy Institute Issue Brief #IB69 (Washington, DC: AARP), June 2004.

⁵ David J. Gross, Stephen W. Schondelmeyer, and Susan O. Raetzman, *Trends in Manufacturer Prices of Brand Name Prescription Drugs Used by Older Americans--First Quarter 2004 Update*, AARP Public Policy Institute Issue Brief #IB69 (Washington, DC: AARP), June 2004.

were too expensive. One woman poignantly noted that she begged for the unfinished prescriptions of friends who had died, hoping their left-over drugs would meet her needs.

Americans of all ages need affordable prescription drugs now. Safe importation of prescription drugs from Canada is one way to begin to secure lower priced drugs. Our members question why drug prices in Canada can be lower, sometimes far lower, than prices in the U.S. It is a national embarrassment that people from all over the world come to the United States to access our advanced medical systems while many of our own citizens need to look outside our borders in order to afford their prescription drugs. But with the same drugs selling, in some cases, at 30 percent and even 50 percent less in Canada and overseas, it is hardly surprising that so many make that choice.

It is no longer a question of whether we should or should not allow the importation of drugs from abroad. The simple fact is that importation is already happening. Many Americans travel to Canada for less costly prescription drugs, or purchase their drugs through the Internet without any systematic U.S. oversight process in place to assure safety. Importation of drugs is likely to continue whether or not Congress acts. The trend is growing, and we have a responsibility to ensure that Americans can access lower cost drugs without putting their health at risk. We believe that Congress should enact legislation that provides appropriate safeguards and, at the same time, ensure a workable system.

AARP therefore supports S. 2328, the Dorgan-Snowe importation legislation, which would legalize importation of prescription drugs through a system designed to ensure safety and lower drug costs. We strongly urge you and your colleagues to take action that will lead to enactment of S. 2328. We believe the Dorgan-Snowe legislation meets the challenge of designing a prescription drug importation program that will ensure the integrity of pharmaceuticals and provide consumers access to lower cost prescription drugs.

A safe system of importation is paramount. The drafters of S. 2328 have worked with AARP and others to revise their legislation to include additional safety measures and consumer protections to ensure the integrity of pharmaceuticals entering into the United States from abroad.

Safety Issues

The health and safety of individuals is critical in any importation system and AARP supports the approach taken in S. 2328 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. We believe that drugs purchased from Canada can be as safe as drugs purchased in the United States.

FDA Certification

Congress has charged the Food and Drug Administration ("FDA") with ensuring the safety and effectiveness of U.S. pharmaceuticals. S. 2328 provides that only drugs that have been approved by the FDA may be imported. Drugs manufactured for distribution in other countries may differ slightly from drugs destined for the U.S. Some differences may be minimal and have little or no effect on the efficacy of the drug. Other differences may actually change the efficacy of the drug. In cases where pharmaceuticals significantly differ from its U.S. counterpart, S. 2328 requires that a supplemental application be filed and the FDA approves the application before the pharmaceutical may be imported.

In addition, the safety and authenticity of imported pharmaceuticals must be assured at each point along the stream of commerce, including regular inspection of the flow of prescription drugs to the ultimate point of dispensing. The Dorgan-Snowe legislation mandates that importers and exporters agree to allow inspection of their facilities by the FDA not less than once every three weeks.

Consumers purchasing prescription drugs should be provided with a list of FDA-approved entities that engage in importation. This is particularly important for consumers who purchase prescription drugs through Internet pharmacies. Many consumers fall victim to rogue Internet pharmacies due in part to the inability to distinguish between reputable and fly-by-night Internet pharmacies.

The Dorgan-Snowe legislation instructs the FDA to maintain, on its website, a list of approved pharmacies. Having the FDA web site 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.

Pedigree Requirements

One way of effectively ensuring the safety of pharmaceuticals is the institution of pedigree requirements – being able to trace a drug from the point of origin to the point of dispensing. In order to accomplish this task in an expanded international arena, we believe legislation must provide a way to trace pharmaceuticals back to the point of manufacture and enforce pedigree requirements. Each entity that handles prescription drugs should be required to maintain records as to the drug's pedigree. Furthermore, there should be no impediments to an entity's ability to receive records regarding a drug's pedigree.

The Dorgan-Snowe legislation includes mandatory pedigree requirements. Importers and exporters may only purchase pharmaceuticals from a manufacturer or entity that can establish a drug's pedigree, or chain of custody. 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.

Anti-tampering/Anti-counterfeiting Requirements

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 anti-counterfeiting technology on imported drugs.

Labeling

It is important that consumers have the necessary information included with the prescription drugs they purchase. Because pharmaceuticals may be manufactured in countries where English may not be the official language, the Dorgan-Snowe legislation provides that pharmaceutical labels and patient package inserts destined for the United States be written in English as well. In cases where a pharmaceutical's inactive ingredients differ from the active ingredients approved by the FDA, the drug's package must bear an advisory label indicating that fact for individuals with potential allergies.

Finally, S. 2328 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.

Funding

AARP believes that in order to ensure the integrity of an importation system the FDA will need appropriate authority and resources to effectively monitor and enforce these standards. The Dorgan-Snowe legislation provides for appropriate FDA funding through registration fees assessed to importers and exporters who wish to engage in the importation system as well as inspection fees capped at no more than 1 percent of the price of prescription drugs importers/exported. If the FDA requires additional financial resources in order to accomplish their goal of protecting the safety and efficacy of the U.S. prescription drug supply, then AARP would support this additional funding.

Anti-gaming

We recognize that some manufacturers are already curtailing their drug supply to Canada, which could lead to supply shortages. We share the concern of many who fear that legislation, absent some mechanism to prevent manufacturers from undermining the newly created importation system, will amount to nothing more than a false assurance in an individual's ability to engage in an importation system. Our members do not want

hollow promises of importation legislation – they want legislation passed that will allow them the opportunity to fill their prescription safely and at a lower cost.

AARP believes that a vital component of any importation legislation is anti-gaming provisions. The Dorgan-Snowe legislation seeks to prevent entities – particularly pharmaceutical manufactures – from eliminating or reducing drug supply to those who engage in importation of prescription drugs to the United States thereby ensuring that an importation system will work as effectively as Congress intended.

Related Issues

Beyond the creation of an importation system, there are additional issues that we urge Congress to consider. There remains a strong need to examine the safety of pharmaceuticals within the United States' drug supply in order to prevent counterfeit, diluted, or ineffective drugs. As Congress examines foreign pharmaceutical supply systems, there is also an opportunity to revisit the integrity of the U.S. pharmaceutical system – from point of manufacture to the ultimate consumer. The FDA should be required to submit reports to Congress, annually or as otherwise appropriate, to monitor the impact of regulated importation on the price, quality, and access to pharmaceuticals both in the U.S. and worldwide.

Conclusion

Our members want Congress to enact bipartisan legislation this year to allow for legal, safe 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 the issue of importation legislation. We understand the challenges Congress faces in designing a program that will not only ensure the integrity of pharmaceuticals, but also 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.

AARP appreciates the opportunity to testify and looks forward to working with the Committee to help our members afford the medications critical to their health and well-being.

Testimony of U.S. Senator Byron L. Dorgan
Senate Judiciary Committee Hearing on "Examining the Implications
Of Drug Importation"
July 14, 2004

Chairman Hatch, Ranking Member Leahy, and other Members of the Judiciary Committee, I want to thank you for having this hearing on the important issue of prescription drug importation and for granting me the courtesy of testifying before you today. This is an issue that I have been working on for quite some time. In fact, I introduced the very first prescription drug re-importation legislation in the Senate back in 1999.

More recently, I have introduced S. 2328, the Pharmaceutical Market Access and Drug Safety Act, the only bipartisan drug importation bill before the Senate. I am pleased to be joined in sponsoring this bill by Senators Snowe, Kennedy, McCain, Daschle, Lott, Stabenow and others, and I'm glad to note that many Members of the Judiciary Committee are cosponsors of this bipartisan legislation.

In short, my bipartisan bill would allow American consumers, pharmacies and drug wholesalers to import FDA-approved prescription drugs at the substantially lower prices available on the world market. Many studies have confirmed what millions of Americans already know – the same prescription drugs cost significantly less in Canada, Europe, and other developed countries than they do here in the United States. And in fact, the Congressional Budget Office has confirmed that brand-name drugs cost, on average, 35 to 55 percent less in other industrialized nations than they do in the United States.

American consumers are desperate for the lower-priced prescription drugs that the Pharmaceutical Market Access and Drug Safety Act would provide, and I intend to continue fighting for an opportunity to bring my legislation before the full Senate. I am very disappointed that I was not given an opportunity to offer my amendment on drug importation to the Class Action reform legislation when it was before the Senate last week. I was likewise very disappointed to read in yesterday's *Washington Post* that Majority Leader Frist said it is unlikely the Senate will consider drug importation legislation before adjourning this fall. That is unacceptable to me.

Having said that, I am encouraged to hear that HELP Committee Chairman Gregg plans to hold a mark-up on drug importation legislation next week.

Confronting the Safety Issues

I have worked very hard with Senators Snowe, Kennedy, McCain and others to assure the safety of drugs imported under our legislation.

Unfortunately, there exists in the United States a situation today whereby American citizens are resorting to potentially unsafe measures in order to afford their medicines – including cutting pills in half, skipping dosages, and ordering drugs from possibly rogue foreign and domestic Internet pharmacies. In fact, the amount of

potentially unsafe drugs coming into the country has exploded because people who can't afford high U.S. prices have been buying their medications over the Internet under a system that is virtually unregulated by the Food and Drug Administration (FDA).

Mr. Chairman, not acting on drug importation legislation is a far greater safety hazard than acting on this bill would be. The bipartisan bill will empower consumers to purchase safe, approved prescription medicines from Canadian pharmacies via mail-order or the Internet under a regulated program. Consumers who choose this option will be assured that they are dealing with a legitimate, licensed Canadian pharmacy that is registered and inspected by the FDA. The FDA will post the list of approved Canadian pharmacies on its website and through a toll-free number, so Americans can readily check to see if they are dealing with a legitimate pharmacy and not a rogue website.

My bipartisan bill also creates a closed system of commercial drug importation that ensures the safety of imported drugs from the point of manufacture to the drugstore shelf. Again, the bipartisan bill includes a range of safety features. First of all, only FDA-approved drugs made in FDA-inspected facilities can be imported under the Dorgan-Snowe bill. Moreover, commercial importation by pharmacists and wholesalers could only occur from a limited number of countries – Canada, Europe, Japan, Australia, New Zealand, and Switzerland – that have drug regulatory systems comparable to our own. And only U.S. licensed pharmacies and drug wholesalers that register with the FDA can import prescription drugs. Registered pharmacies and drug wholesalers would be subject to frequent, random FDA inspection and could have their registration suspended or terminated if they don't comply with the bill's requirements.

Perhaps most importantly, the bipartisan bill enables American consumers to stay at home and use their local pharmacy, while still benefiting from lower drug prices. This would ensure that pharmacists could coordinate their patients' pharmaceutical care and help to prevent adverse drug interactions.

Let me make one final point about safety: Some have suggested that we should rely on a requirement that the Health and Human Services Secretary should certify to the safety of imported medicines before drug importation legislation be implemented. As I mentioned earlier, we currently have an unsafe system whereby as many as 5 million packages containing drugs come into the United States with no regulation. We cannot allow this unsafe situation to continue, and that is what a Secretarial certification requirement would cause.

Closing Loopholes

It is also very important that drug importation legislation include provisions that would prevent drug companies from exploiting loopholes to shut down drug importation and prevent consumers from saving money. The Dorgan-Snowe bill includes a number of provisions that are not included in Senator Gregg's bill to close these loopholes.

The situation in Canada is evidence that the provisions in the bipartisan bill are vitally needed to ensure real savings for American consumers. The drug companies have

already demonstrated in Canada that, if they cannot shut down importation by lobbying Congress, they will take steps to do so by backdoor methods.

More specifically, the bipartisan bill:

- Prevents drug companies from taking actions, such as discriminating against a foreign pharmacy or wholesaler that exports drugs to the U.S. by shutting off their drug supply, that would thwart drug importation. Such an action would be an unfair and discriminatory practice, subject to treble economic damages.
- Prevents a drug manufacturer from blocking importation of drugs in more subtle ways, such as by changing the color, dosage form, or place of manufacture of the drug so that it is no longer FDA-approved. Drug manufacturers that make these kinds of changes would be required to notify the FDA, and the FDA would be given the authority to approve these changes, if approval is warranted.
- Protects pharmacies, wholesalers, and individuals from patent damages arising from the importation of drugs.

Opponents of drug importation have alleged that some of the provisions in the bipartisan bill may be unconstitutional. Regrettably, it is not terribly surprising that the drug industry would make this claim – the drug industry always argues that legislation to reduce the cost of medicines for consumers violates the Constitution. However, objective legal authorities tell me the bipartisan bill is constitutional.

Conclusion

In closing, the Senate must – and I hope will -- act promptly to pass the bipartisan Dorgan-Snowe bill. The House of Representatives has already passed strong bipartisan legislation, the Pharmaceutical Market Access Act, last summer by a wide bipartisan vote. Now it is our turn.



News From: _____

U.S. Senator Russ Feingold

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Statement of U.S. Senator Russ Feingold At the Senate Judiciary Committee Hearing on "Examining the Implications of Drug Importation"

July 14, 2004

Mr. Chairman, thank you for holding this hearing on a topic that is very important to the people of Wisconsin. Each year, I travel to all 72 counties in Wisconsin and hold a listening session in each one. And for the past twelve years, the high cost of health care, and specifically the skyrocketing prices of prescription drugs, has been one of the top issues raised at these meetings by my constituents all across Wisconsin.

I am a strong supporter of the bipartisan bill introduced by Senators Dorgan and Snowe that will help Americans purchase prescription drugs at reduced prices. Without it, Americans are at the mercy of the pharmaceutical companies, which are raising the prices of the most commonly prescribed brand name drugs at twice the rate of inflation. It is our duty in the Senate to provide some relief. People in the United States pay substantially more for prescription drugs than people in any other industrialized country.

I have long supported efforts to create a competitive marketplace for prescription drugs. Drug manufacturers are free to move their factories to countries that have cheaper labor or greater tax incentives and to buy supplies from countries with the lowest costs, but Americans cannot purchase the drugs they need that are offered at lower prices in other countries. That doesn't make sense.

A growing number of American seniors, including a growing number of Wisconsinites, are obtaining their prescription drugs from Canada, whether they cross the border in person, order their prescriptions online, or go to one of the Canadian-company storefronts that have opened in this country.

I have heard from senior groups in Wisconsin that are concerned about the announcements by certain pharmaceutical companies that they will discriminate against Canadian pharmacies that provide Americans the same discount that they provide to Canadians.

To address this issue, I have introduced S. 477, the Preserving Prescription Drug Discounts Act,

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along with Senators Leahy and Dayton, which would deny tax breaks to drug companies that limit supplies of prescription drugs to Canadian pharmacies that provide Americans with prescription drugs. If these drug companies actively discriminate against American seniors, we should no longer provide them with tax breaks.

At least six major pharmaceutical companies have announced that they are going to take steps to curb the reimportation of prescription drugs from Canada into the U.S. by limiting supplies provided to Canadian pharmacies. I am concerned that the drug companies are only starting with Canada, and will extend these discriminatory practices to other countries that Americans now, or in the future will, turn to for cheaper prescription drugs.

Seniors are forced to go to Canada because the price of prescription drugs in this country is out of control. The Congressional Budget Office estimates that brand-name drugs cost, on average, 35 to 55 percent less in other industrialized countries than they do in this country.

Drug companies say that they need to charge high prices to recover the enormous research costs involved in bringing new medicines to market. Yet that argument overlooks the fact that Americans already fund much of the research and development of prescription drugs through taxpayer-funded research conducted at the National Institutes of Health and through tax breaks to the drug industry.

It is simply unfair that some Americans cannot afford the prescription drugs that their tax dollars help develop, and when they try to go to obtain these drugs from Canada they are discriminated against by the drug companies. It is far past time for Congress to allow Americans access to safe prescription drugs at the prices that the rest of the industrialized world enjoys.

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July 14, 2004

The Honorable Orrin G. Hatch
Committee on the Judiciary
United States Senate
Washington, DC 20510-6275

Dear Chairman Hatch:

Thank you for inviting me to testify at your hearing on the issues associated with drug importation. This is an important public health and safety issue that I have been reviewing recently and I am concerned that those who are purchasing cheaper medicines in this manner are not fully aware of the risks associated with such a practice. I am pleased to share my views with you.

Please accept the enclosed submission of the interim findings of the review being conducted by Giuliani Partners, LLC, on behalf of the Pharmaceutical Research and Manufacturers of America (PhRMA), regarding prescription drug importation to the United States from foreign sources. These interim findings were also submitted to the United States Department of Health and Human Services Task Force on Drug Importation on May 11, 2004. The preliminary findings address the risks associated with drug importation through both the internet and commercial importation.

Thank you.

Respectfully submitted,

Rudolph W. Giuliani

Enclosure

**Giuliani Partners LLC
Examination and Assessment of
Prescription Drug Importation From Foreign Sources
To the United States**

**Interim Findings
May 11, 2004**

INTRODUCTION

The availability of safe, effective and reasonably priced medications for all Americans is at the center of an important, ongoing debate regarding our health care system. As the costs of medicines have increased, so has the focus of pricing on this debate. Individuals and even local and State governments have sought alternative means to obtain necessary medicines at lower costs, and these initiatives have further narrowed the debate to the value of importing Canadian or foreign medicines into the United States.

However, the safety and efficacy of these same imported medicines has received less attention and focus and is often overshadowed or even ignored by the pricing issue. From the outset, there is little dispute that the high price of many prescription medicines becomes an impediment to access. And while the price of today's medicines exist in part to provide for the development of tomorrow's cure, patient access should be expanded by exploring methods for lowering costs for those in need.

Giuliani Partners LLC has been retained by the Pharmaceutical Research and Manufacturers of America (PhRMA) to evaluate the risks, if any, associated with the importation of Canadian and foreign medicines.

In recognition of the public health implications associated with importation, and at the request of Congress, the United States Department of Health & Human Services has convened a Task Force on Drug Importation to examine these very concerns. Acknowledging the importance of this issue to the public, the Task Force is working with great alacrity to provide its recommendations to HHS. Giuliani Partners LLC will be providing the Task Force with a more detailed report encompassing our preliminary findings and conclusions as part of our effort to inform this critical debate and to assist the Task Force in its work. For now, we have made a series of interim findings that are worth discussing today to widen the lens through which the issue of the importation of drugs is viewed, and consequently address the equally important issues of safety and risk in the Task Force's assessment.

It is important to note from the outset that there appears to be a fundamental misunderstanding about the source of the less expensive drugs at the center of this discussion. Initially, this debate was framed around "re-importation" – in other words, the importation (from Canada) of medicines manufactured under U.S. Food and Drug Administration (FDA) oversight and now available at a lower cost via Canada. Under such a system, a patient could reasonably assume that the medicine

was safely and properly manufactured under FDA oversight without corruption in the supply chain. However, that is not necessarily what is occurring. Instead, U.S. patients are receiving medicines from foreign countries (albeit ordered through Canada or sources purporting to be Canadian based) that were manufactured or re-packaged without any oversight by the FDA or Health Canada (the Canadian FDA counterpart).

Indeed, several U.S. States that provide links to websites for their citizens to order "Canadian" drugs have graphic disclaimers disavowing any warranty about the product and relinquishing the state government from any legal liability with regard to the product or care from the on-line pharmacy. In some instances, the Canadian pharmacy website requires the patient to sign a waiver that denies the patient any legal recourse in the U.S. for harm caused by these imported drugs. The current U.S. regulatory process, while not perfect, protects patients seeking medicines from U.S. pharmacies. This raises an important question that must be reviewed when assessing the relative risks associated with obtaining imported medicines against the potential rewards of lower prices.

Product Quality: What Is In Our Medicine?

When a patient seeks to fill a particular prescription for a particular medicine, there is an assumption that the medicine is in the exact form, quality, potency and dosage as directed by the patient's physician. Anything less constitutes a risk to that patient's health and well-being.

Based upon our review to date, we have found that some patients who believe they are purchasing re-imported Canadian medicines are in fact receiving non-FDA approved drugs from foreign countries that are not at all what they claim to be. There is significant evidence that patients have received drugs through the internet that are past their expiration date, are sub-potent (or, in some cases, more potent than indicated), contain the wrong dose, are contaminated or clearly counterfeited, are not properly stored or shipped (i.e. medicines that require constant refrigeration or others that must be protected from freezing) among other problems. We have found that medicines ordered over the internet that purport to be manufactured under FDA oversight or delivered through Canadian pharmacies are in fact manufactured in countries such as Pakistan, China, Iran, Singapore and many others. The fundamental question of product quality and integrity must be at the center of this important discussion.

Set forth below is an outline of the review we have undertaken. Significant questions are raised regarding the level of safety for patients and indeed for our nation from the relaxation of importation controls. It is vital that the Task Force and others carefully and thoughtfully consider all of these legitimate concerns so that our health care system can be as safe, effective and accessible as possible.

SYSTEMIC ISSUES

The American system for manufacturing, distributing and selling prescription medicines is significantly regulated and often referred to as the "gold standard."

Notwithstanding this fact, however, there are identifiable weaknesses in this process that can compromise the quality and integrity of our medicine supply.

The Distribution Chain

On its face it appears that the distribution chain for prescription medicines in the United States is fairly straightforward – manufacturers sell their products to wholesalers, who in turn sell the products to retail pharmacies or stores, who in turn dispense medicines to patients with prescriptions. It is not until the system is studied in greater detail that one begins to appreciate both the complexities and the vulnerability of the distribution chain and the potential for exploitation or abuse.

Some contributing factors are as follows:

- Wholesalers or distributors are primarily regulated by the states with no uniform standards across state borders. States have a comparatively small number of investigators to monitor the licensed wholesalers; thus, given the sheer number of wholesalers, oversight is minimal.
- There are thousands of “secondary” pharmaceutical wholesalers in addition to McKesson, AmerisourceBergen and Cardinal Health (the “big three”) involved in the distribution of prescription medicines. As reported in The Washington Post, there are more than 6,500 small wholesalers nationwide.
- There is no uniform mechanism, i.e., a chain of custody or “pedigree,” to track the medicine from point of manufacture to point of sale; the FDA has not implemented the pedigree requirement that was mandated by law in 1988.
- Repackaging is a vulnerable point in the process and can provide an opportunity for counterfeit or non-FDA approved products to compromise the system.

Report of the Florida Grand Jury

Two years ago the State of Florida convened a statewide Grand Jury to examine the safety of prescription drugs in Florida and to analyze the sale and resale of prescription drugs in the wholesale market. The report, released in February 2003, found an overwhelming need for tighter regulation and oversight of the pharmaceutical distribution industry. Many of those interviewed by Giuliani Partners indicated that the problems identified in the Florida Grand Jury Report are pervasive throughout the United States. A summary of the Grand Jury’s findings follows.

- Oversight of the system is lax.
 - Minimal background checks are required for licensing wholesalers and warehouse operators were found to be uneducated amateurs, some with criminal records.
 - Corrupt wholesalers are neither investigated nor prosecuted.
 - Despite existing requirements, drugs are being distributed with either incomplete or, in many cases, non-existent pedigree papers to document the products’ supply chain history.

- Inspection of wholesaler operations by the appropriate authorities and oversight by responsible agencies is spotty at best.
- Funding for oversight agencies is inadequate.
 - The Florida Bureau of Statewide Pharmacy Services employs only nine field inspectors to inspect 422 wholesalers statewide.
- Product quality is compromised.
 - Widespread problems with the quality and integrity of the secondary wholesale drug supply were found to include:
 - expired drugs re-labeled with falsely extended dates
 - previously dispensed medicines
 - illegally imported drugs
 - sub-potent drugs
 - drugs that contained an entirely different substance from the one listed on the container's label
- Health risks are significant.
 - The mainstream market is compromised by corrupt, secondary wholesalers. Diverted drugs are often combined with counterfeit medicines or re-labeled or repackaged. Then, these compromised drugs enter the mainstream market through corrupt secondary wholesalers and are dispensed by legitimate pharmacies, hospitals or clinics. By way of example, a father in Michigan who thought he was injecting his son with a growth hormone later found that the vials actually contained insulin. These drugs were traced to a legitimate pharmacy in Orlando, Florida.
- Incentives for counterfeiting and diversion are considerable.
 - The huge profits derived from these activities rival those of illicit narcotics traffickers, while the penalties are minor by comparison.

Challenges to Oversight and Enforcement

There are challenges associated with the oversight and enforcement of our current laws with regard to ensuring that medicines being purchased or sold in this country are FDA-approved, safe and effective.

- The current volume of parcels of drugs coming into this country through the mail (it is estimated to be more than 10 million packages annually) and the increasing volume of internet purchases make meaningful inspection by the FDA almost impossible.
- The FDA has less than 100 investigators to deal with drug importation issues nationwide, and its investigative authority is limited relative to its ever-increasing law enforcement responsibilities. For example, the FDA has no administrative subpoena authority in order to facilitate the conduct of its investigations; thus it must either partner with another investigative agency or request subpoenas from the local United States Attorney's office.

- Investigating and prosecuting counterfeit drug cases or illegal internet sales cases are not, with few exceptions, a priority for the federal or state law enforcement agencies.
- The penalties are comparatively low for engaging in this kind of activity – the current penalties for FDA violations are approximately 3 years.
- The technologies being advanced as mechanisms to ensure an imported drug shipment is safe and effective are not foolproof, and, in some instances, not yet available.
 - Electronic Track and Trace – most agree that these technologies, e.g., using bar coding or radio frequency identification (RFID) chips that could track drug products in real time throughout the system and then provide an electronic pedigree, are still very costly when available.
 - Counterfeit resistant technologies that include covert and overt packaging and labeling techniques, such as holograms, watermarks, color shifting inks or fluorescent inks, as well as chemical agents, are widely used by the industry already. However, they can be easily duplicated and, therefore, must be changed on a periodic basis.
 - “Unit of Use” packaging, which is a container closure system designed to hold a specific quantity of drug product for a specific use and dispensed to a patient without any modification except for appropriate labeling, does eliminate the need for some repackaging; however, there are packaging and cost issues for the manufacturers, and some drugs do not lend themselves to such packaging.
 - Authentication testing, while not a technology *per se*, is also an option when determining the integrity of a pharmaceutical product. It is a complicated, time consuming and costly process, however, and can be performed only by the original manufacturer. There are no available tests that can be conducted “in the field” to ascertain whether a product is real or fake.

These factors, among others, make it a high profit, low risk business for the counterfeiters or those involved in circumventing the laws in supplying medicines outside the traditional distribution chain, and, therefore, it may be appealing to organized crime and terrorist organizations.

PRODUCT QUALITY

Weaknesses in the existing system already threaten the quality and integrity of the nation’s drug supply. Despite best efforts, the evidence we have seen thus far supports the notion that the drug supply is indeed vulnerable. Some examples are as follows:

Random Examinations Conducted by the FDA and U.S. Customs and Border Protection

The FDA and U.S Customs and Border Protection conducted a number of random inspections or “blitzes” at several mail ports in the fall and early winter of 2003.

- In the first inspection, 1,153 drug products were examined and 1,019 or 88% were not approved by the FDA; the drugs came from countries such as India, Thailand, and the Philippines.
- In the second exam, 1,982 parcels were examined and 1,728 or 87% were not approved; 16% of those shipments were from Mexico.
- Many of the drugs examined during these visits were non-FDA approved for many reasons, including:
 - improper labeling, e.g., there were no instructions for proper use;
 - the presence of controlled substances;
 - potentially recalled drugs, e.g., drugs that had been withdrawn from the market for safety reasons;
 - animal drugs not approved for human use;
 - drugs requiring risk management and/or restricted distribution (e.g., initial screening or periodic monitoring); drugs with clinically significant drug interactions; or drugs requiring careful dosing; and
 - required special storage conditions for certain drugs were violated.

Portal Visits

In order to gain an appreciation for the scope of the problem, United States mail facilities were visited to observe the volume and nature of the packages allegedly containing prescription drugs entering the United States. A number of the observations follow.

John F. Kennedy Airport Mail Facility

At the invitation of United States Senator Norm Coleman, former New York City Mayor Rudolph W. Giuliani and former New York City Police Commissioner, Bernard B. Kerik, accompanied the Senator on a visit in March, 2004 to the US Mail facility located at JFK Airport. Customs officials advised that approximately 40,000 packages of suspected drug shipments are received each day from the postal service for review and inspection. Based upon information, the FDA focuses on "countries of interest" and visually inspects 500 to 700 parcels per day. Thus, the majority of packages are sent on to the addressee uninspected. The following was learned:

- Drugs purported to be Xanax, Valium (Diazepam), Lorazepam, Vicodin (all controlled substances) and Lupron were observed; there were numerous packages from the Netherlands, Brazil, Pakistan, as well as other countries.
- Many of the drugs contained in the parcels were non-FDA approved because they were inappropriately packaged, expired, mislabeled or otherwise noncompliant.
- The sheer volume of shipments overwhelms Customs and FDA; FDA has only 6 staff members assigned to JFK.
- Although much of what is inspected is non-FDA approved, few parcels are actually detained. The processing requirements to detain a shipment are

cumbersome and time consuming. The rules require the FDA to send a notice to the addressee of the package. If the person does not respond or the response is insufficient, the package must then be returned to the sender (manufacturer). This process varies significantly from the way controlled substances or narcotics are handled. Such drugs can be destroyed without further processing.

Miami International Mail Branch Facility Visit in March 2003

Giuliani Partners was provided with a Congressional staff report regarding a similar review of the Miami facility in March 2003. The findings of the bipartisan Congressional report were consistent with the findings of this review:

- Congressional staff witnessed “thousands of shipments of foreign drugs” being processed; the packages were from countries such as Honduras, Costa Rica as well as Great Britain; and the packages purportedly contained “valium” (diazepam), Reteina (Ritalin), Zolipidem, and Ciprofloxacin.
- The volume of drugs coming through the mail facilities is too great to allow for any meaningful inspection.
- Parcels are only visually inspected; there is no testing as to the quality or integrity of the product.
- FDA and Customs detain very limited numbers of questionable drugs coming into the facility because of the cumbersome nature of the detention process.

The Increase in Counterfeit Drugs

- Most of those interviewed by Giuliani Partners agreed that:
 - The number of incidents involving counterfeit medicines is increasing;
 - The increased use of internet sale and purchase is exacerbating the problem;
 - The counterfeiting techniques are becoming more sophisticated and harder to detect;
 - There are vulnerabilities in the current distribution system that contribute to the problem; and
 - Opening the borders for wholesale importation will worsen the problem.
- The former Commissioner of the FDA, Dr. Mark McClellan, testified before the U.S. Senate Committee on Commerce, Science and Transportation on March 11, 2004 that the FDA has seen its number of counterfeit drug investigations increase four-fold since the late 1990’s. “Although counterfeiting was once a rare event, we are increasingly seeing large supplies of counterfeit versions of finished drugs being manufactured and distributed by well funded and elaborately organized networks.”
- On its website, the World Health Organization (WHO) states that while the true extent of the problem of counterfeit drugs is difficult to know or measure,

they have estimated that at least 8% – 10% of the world's total drug supply is counterfeit.

- An August 30, 2002 Washington Post story cites the Shenzhen Evening News in reporting that an estimated 192,000 people died in China in 2001 because of counterfeit drugs. Another news story reported that as much as 50% of China's drug supply is counterfeit (Investor's Business Daily dated October 20, 2003).

Reported Incidents of Adverse Effects

Without question, the most frequently asked question by proponents of importation is "who is really being harmed by the purchase of medicines from outside of the United States?" There appears to be no easy answer to the question. Because receipt of imported medicines is unregulated, there are no systems in place to effectively monitor whether injuries result from the taking of compromised medicines. When complications arise from taking imported medicines and a patient does consult with his or her doctor or reports to an emergency room, no one is asking the question "where do you purchase your prescription medicines?" Patients are also reluctant to report adverse reactions that may be attributable to medicines illegally purchased from outside the country.

Given these circumstances, coupled with the systemic challenges discussed earlier, it is difficult to ascertain the actual source of an imported drug. The following are some examples of actual incidents where people taking medicines with undocumented origins were adversely affected as a direct result of taking the prescription drugs. These cases represent the dangers of obtaining drugs from sources outside of the United States' closed system.

- In La Mesa, California, Ryan T. Haight, 18, died in his bedroom of an overdose after taking narcotics obtained on the internet. After his death, his parents found a bottle of the painkiller Vicodin in his room with a label from an out-of-state pharmacy. An investigation by federal drug agents showed that the teenager had been ordering addictive drugs online and paying with a debit card his parents gave him to buy baseball cards on eBay. (Washington Post, October 19, 2003)
- In Sacramento, California, James Lewis, 47, a former triathlete, shopped the world for painkillers that flowed unimpeded from pharmacies in South Africa, Thailand and Spain. His wife discovered him dead of an overdose on the living room couch. (Washington Post, October 19, 2003)
- A 15-year-old paraplegic boy went into convulsions and died after taking a non-FDA approved drug called Lincocin which had been smuggled in from Mexico. (Los Angeles Times, March 10, 2001)
- Juris Abolins, 43, used painkillers off and on for years to treat pain from kidney stones. His roommate found him slumped on his bedroom floor dead. An autopsy revealed the presence of controlled substances in his blood stream.

Relatives found a Federal Express slip for drugs purchased from a website in Tijuana, Mexico. (Washington Post, October 19, 2003)

THE INTERNET

Over the past several years, hundreds of websites have appeared on the internet selling prescription medicines. While some sites provide legitimate prescription services, many sites are illegitimate and pose significant risks to all patients who use them.

Private Investigation Regarding Internet Purchases

A security and investigative firm based out of New York City, Beau Dietl & Associates, conducted an investigation regarding the importation of foreign medicines and reported its findings in December 2003. The results were disturbing:

- More than 1400 websites were identified as selling prescription drugs.
- 352 of those sites did not require a prescription when ordering.
- 142 of 170 orders were placed without a prescription and at the time of the report, 79 orders were filled without a prescription.
- Many of the medicines received were not only shipped in improper packaging but came from foreign countries such as Pakistan.
- An order for Ciprofloxacin was placed, received and tested. It was determined to be only 65% potent.
- The investigation found that website operators were often difficult to identify and trace; and some of those identified were found to have questionable backgrounds:
 - One website owner/operator was a convicted felon;
 - Other website owners could not be traced because the registration information was false;
 - Many sites failed to comply with legal requirements – doctors wrote prescriptions without ever meeting the patient; and one internet doctor was a convicted sex offender.
- Websites were easily established with no minimum qualifications, standards, or oversight.
- Once the websites were established, emails were received from various suppliers offering to provide medications from “several countries,” or “bulk meds from Pakistan” for resale in the U.S. market.

The results of this investigation offer a troubling snapshot of the nature of the internet pharmaceutical business.

The CASA White Paper

The National Center on Addiction and Substance Abuse at Columbia University, under the direction of Joseph Califano, former Secretary of the Department of Health, Education and Welfare, the predecessor of the U.S. Department of Health and Human Services, released a study in February 2004 regarding the sale of controlled, dangerous and addictive prescription drugs in America. It looked particularly at internet sales and teamed with the same New York City investigative firm to conduct the review. CASA characterized its findings as “alarming.”

During a one-week period of observation, the firm identified a total of 495 web sites offering Schedules II through V controlled substance prescription drugs. Examples of the controlled substances available online included painkillers, stimulants, and nervous system depressants.

- Of the 157 sites selling controlled substance prescription drugs on the internet
 - 90% (141) did not require a prescription
 - 4% (7) required that a faxed prescription
 - 2% (3) required that a mailed prescription
 - 4% (6) made no mention of prescriptions
- Of the sites, 47% disclosed that the drugs would be coming from outside the United States; 28% stated the drugs would be shipped from a US pharmacy; and 25% gave no indication where the drugs would be coming from.
- The analysis determined that there were no mechanisms in place to block children from purchasing these drugs.

Canada – The Implications of Importation

It is generally agreed that prescription medicines purchased by Canadians in a Canadian drug store are safe and effective. Like the United States, Canada has a system of regulatory controls over its medicine supply. However, the same cannot be said for the drugs that are being imported to Canada and then exported. In fact, the Canadian government is not inspecting those medicines that are being imported to Canada and then exported to the United States. The Canadian government has clearly stated that it would not be responsible for the safety and quality of prescription drugs exported from Canada into the United States or any other country. Furthermore, the Canadian Food and Drug Act does not apply to any packaged food, drug, cosmetic or device not manufactured for consumption in Canada and not sold for consumption in Canada.

With respect to the question of drug supply capacity, it is undisputed that Canada does not have supply sufficient to provide for its residents and Americans as well. (In 2002, 3.1 billion prescriptions were filled in the U.S. compared to 335 million prescriptions filled in Canada.)

According to information provided by Industry Canada, a department of the Canadian Federal Government, from September 2002 to September 2003, there was a significant increase in drugs imported into Canada from the following countries:

- Singapore up 30%
- Ecuador up 198%
- China up 43%
- Iran up 2,753%
- Argentina up 221%
- South Africa up 84%
- Thailand up 52%

Prudential Financial, Inc. released similar findings, stating that Canadian internet pharmacies were increasingly obtaining their product from other countries such as Bulgaria (exports to Canada up 300%), Singapore (up 101%), Argentina (up 171%), South Africa (up 114%), Pakistan (up 196%), as well as others. Further, some Canadian pharmacies, such as Canadameds.com, have publicly indicated that because of the increasing demand from the United States, they are turning to Great Britain for prescription drugs.

**THE POTENTIAL FOR EXPLOITATION BY NARCOTICS TRAFFICKERS,
ORGANIZED CRIMINALS AND TERRORISTS**

The terrorist attacks of September 11, 2001 demonstrated how vulnerable this country is to those who have total disregard for human life or who mean us harm. Since that time, the United States has invested billions of dollars to protect our borders. Despite all that has been done, we have not focused on the vulnerability of the nation's medicine supply as a potential target. The present controlled system of importation and inspection is open to exploitation and abuse. Any further removal of controls, much less the total opening of the borders to foreign drugs, would create a situation that terrorists, drug dealers and organized criminals might well use to their advantage. It seems counter-intuitive to contemplate opening our borders with regard to our medicine supply when in all other aspects of border security and protection, we as a country are looking for ways to tighten security.

A July 22, 1998 story in Insurance Day, while reporting on pill piracy and the World Health Organization's efforts to confront pharmaceutical fraud, stated that "Interpol believes that this aspect of the drug trade is closely connected with the narcotics cartels and that the profits generated by it are in part used to finance international terrorism." The article further stated that Interpol had been following the global counterfeit drug racket for some time and based its belief on evidence uncovered by police in North America and Western Europe.

Further, in her book, Funding Evil, How Terrorism is Financed – and How to Stop It, Rachel Ehrenfeld makes numerous references to the fact that terrorists use counterfeiting activities as a means to fund their terrorist acts. While counterfeit prescription drugs are not specifically referenced, the use of illegal drugs to fund such activities is well documented.

GlobalOptions Inc. identified the potential terrorist threats to America's medical supply in its work, An Analysis of Terrorist Threats to America's Medicine Supply. In sum, it identified three potential threats. First, the "mere infiltration of terrorists in the counterfeit drug market poses a threat to the public." Terrorists could easily produce and sell harmful prescription drugs. Second, terrorist groups could use the profits raised through the sale of counterfeit or diverted drugs to fund their activities. And third, terrorists could use poisoned drugs as a method of attack or, worse, as a weapon of mass destruction.

This study cited numerous examples of links between counterfeiting activities of various types and terrorist groups, where such groups were using the proceeds from these sales to fund their terrorist activities. In particular, the authors pointed to the following:

- The activities of the Irish Republican Army in the early 1990's in Florida that included the manufacture of a counterfeit drug product used to treat livestock. Proceeds from this operation were used to purchase guns;
- An international drug ring raised millions of dollars for Hezbollah. The report states that the terrorist group's operatives legitimately purchased large quantities of pseudoephedrine in Canada, smuggled it into the United States, and produced "speed."

THE CONCLUSION

After conducting a preliminary, independent review of the issues associated with the wholesale importation of prescription medicines, it is evident that the existing pharmaceutical system is open to significant exploitation of counterfeit, diluted or adulterated drugs coming into the United States. The limitations of our system should be addressed before it is opened to wholesale importation.

The Health and Human Services Task Force on Drug Importation is currently considering all of these issues. The Task Force should be allowed to complete its mission as Congress directed before any major statutory changes are contemplated. Given the seriousness of this issue and its implications for the health and safety of Americans, a thorough and well-informed analysis is necessary.

Our interim findings can be summarized as follows:

- Although the current pharmaceutical manufacturing and distribution system is comprehensive and regulated, counterfeit or otherwise adulterated products still penetrate the market.
- There are serious questions as to the quality and safety of the medicine products coming into the United States from foreign sources.
- There are no minimum standards and little or no regulation regarding the operations of internet pharmacies.

- There are identifiable weaknesses in the current pharmaceutical distribution chain (e.g., the “secondary” wholesale distribution market and the lack of a drug pedigree)
- The agencies responsible for enforcing the existing laws and regulations are already overwhelmed with the current volume of non-FDA approved prescription medicines coming into the United States.
- The potential exists for the use of the nation’s medicine supply as a vehicle for terrorist activity.
- There are serious implications for Canadians with the current demand on their drug supply.

As noted previously, this review and these findings are preliminary. However, the issues discussed herein strongly suggest that no action be forced on the FDA or other government oversight agencies until the HHS Task Force has completed its analysis. In the meantime, the public should be made aware of the risks associated with importing medicines from outside the United States. As the importation debate continues, it is vital that all aspects of this important public health issue be carefully assessed. We should not minimize the potential risks surrounding importation.

Opening Statement by Senator Chuck Grassley
Judiciary Hearing titled "Examining the Implications of Drug Importation"
July 14, 2004

Chairman Hatch, Ranking Member Leahy and Members of the Senate Judiciary Committee, thank you for holding this important hearing today regarding the importation of prescription drugs. More and more we are hearing about unsafe drugs imported into the United States through rogue Internet pharmacies and personal importation. There have been several hearings on Capitol Hill regarding the illegal importation of prescription drugs, as well as newspaper articles detailing the pharmaceutical black market that has developed through foreign pharmacies, criminal profiteers and unscrupulous wholesalers. What once was boasted as the safest, most closely regulated pharmaceutical system in the world has turned into a broken system that allows illegal and counterfeit drugs into the United States.

On June 24, 2003, Elizabeth Durant, Director of Trade Programs for the Bureau of Customs and Border Protection (BCBP) testified before the House Committee on Energy and Commerce. In her testimony, Ms. Durant stated that, out of the millions of packages that come through international mail and express courier facilities every year, thousands of these packages are found to contain illegal and unapproved pharmaceuticals. Additionally, the BCBP estimates that about 10 million individuals cross the land border annually carrying the same unapproved products.

The Permanent Subcommittee on Investigations for the Senate Government Affairs Committee also conducted an investigation into current drug importation. They found that about 40,000 parcels containing prescription drugs come through the mail facility at JFK airport every single day of the year. In addition, the committee estimated that 30,000 packages of drugs are shipped into the U.S. through Miami and 20,000 packages are shipped through Chicago each day of the year. About 28 percent of these drugs are controlled substances.

Although the Federal Food, Drug and Cosmetic Act prohibits the importation of unapproved, misbranded, or adulterated drugs into the U.S., the fact is that thousands of counterfeit and unregulated drugs are seeping through our borders. John Taylor, Associate Commissioner of Regulatory Affairs for the Food and Drug Administration (FDA), in his testimony before the House Committee on Energy and Commerce in June 2003 stated that, "the growing volume of unapproved imported drugs, which often are generated from sales via the Internet, presents a formidable enforcement challenge."

Despite the hard work of both the FDA and BCBP to control our borders, the importation of illegal drugs has become an unenforceable problem. Increased funding by the Federal government to combat the influx of these drugs alone will not solve this problem. Rogue Internet pharmacies located outside and inside the United States can open and close at a moment's notice. Successfully identifying these rogue Internet pharmacies presents a daunting task for law enforcement and medical leaders alike.

Congress must act now on legislation that will not only shut down rogue Internet pharmacies selling unsafe drugs to consumers, but will also lower the cost of prescription drugs. Legalizing the importation of prescription drugs through a highly regulated system overseen by FDA will stem the tide of unregulated pharmaceuticals coming into the U.S. and create a safe and effective system for obtaining low-cost prescription drugs.

On April 8th, I introduced the Reliable Entry for Medicines at Everyday Discounts through Importation with Effective Safeguards (REMEDIES) Act of 2004. My legislation would provide legalized access to lower drug prices through importation. At the same time, my bill addresses the safety concerns associated with the importation of prescription drugs into the United States and would provide the FDA with the necessary resources and authority to implement a safe and effective program. I would like to take this opportunity to tell you about the specifics of my legislation.

If enacted, the REMEDIES Act would halt unsafe importation by allowing individuals to immediately obtain legal drugs from Canadian pharmacies during the 90 day interim period that the FDA would have to get the new drug importation system up and running. Under this new system, individuals, pharmacies, and drug wholesalers could purchase qualified drugs for import into the U.S. from foreign exporters that register with the FDA. To obtain registration, a foreign exporter would have to demonstrate compliance with safety measures, submit to jurisdiction of U.S. courts, and take other steps to assure safety of imported drugs. A user fee charged to registered exporters would provide the financing needed for FDA to register and oversee foreign drug exporters and ensure the safety of imported drugs.

Filling a prescription overseas would employ the same process as mail order pharmacies in the U.S. use today. Consumers that want to have their prescriptions filled at an overseas prescription drug exporter would be able to go to the FDA website and find a list of companies that have passed FDA's requirements to become a registered exporter. The patient would have to have a valid prescription written by a health care professional licensed in a state in the U.S. to prescribe drugs. The patient would then compare drug prices at the different registered exporters to find the best price available. To get the prescription filled, the patient would have to contact that exporter and either mail or fax the prescription to them. Alternatively, the registered exporter could call the patient's prescriber and get the prescription over the phone.

The prescription could only be filled according to the prescriber's instructions and with brand-name drugs approved by the FDA and manufactured by the same company as approved by the FDA for sale in the U.S. Individuals could also have a prescription filled that is technically not an FDA-approved drug, so long as the drug contains the same active ingredients, dosage form, strength, and route of administration as the FDA-approved drug, and is made by the same manufacturer as the FDA-approved drug.

It would be the responsibility of the registered exporter to verify that the drug can be traced back to the original manufacturer and that the drug has been stored and handled properly. The FDA, through onsite inspectors, would also verify that the prescription

drugs dispensed to patients meet FDA's criteria. Exporters would have to permit FDA inspectors to be present onsite on a continuous basis and the FDA would be required to have inspectors assigned to each exporter.

My legislation also includes methods to ensure that only qualified drugs are entering the United States. Once a prescription is filled, the registered exporter would place a counterfeit-resistant label or other marking on the package to identify the shipment as being in compliance with FDA's safety requirements. This marking would be designed by FDA and could include track-and-trace technologies. When the package enters the U.S., that marking would signify to Customs officials that the product was dispensed from a registered exporter and can therefore be permitted to enter the country. Packages with drugs that lack this marking would be automatically seized by Customs, which will ensure that products without FDA approval do not slip into the country through the mail.

For the first two years, my legislation would only allow importation of prescription drugs from Canada. In the second year of the importation program, the Department of Health and Human Services (HHS) would be required to submit a report to Congress on the safety of the program and its impact on trade and drug pricing. The program would then be expanded in its third year to include importation from the European Union, the European Free Trade Association, Japan, Australia and New Zealand. Other countries that meet specific statutory criteria may also be added to the list.

Finally, my legislation would offer both an incentive for drug makers to import prescription drugs and a penalty should they attempt to impede the importation of prescription drugs. Drug manufacturers may not want to see their lower priced products from other countries coming into the U.S.

Under my bill, drug makers that take steps to prevent importation of their products from FDA-approved drug exporters would lose their tax deduction for advertising costs. There are some drug makers who argue that lowering prices would take money from research and development. To combat these assertions, my bill also creates an incentive for companies that do not prevent importation by offering them a 20 percent increase in their R&D tax credit.

Now is the time for Congress to legalize the importation of prescription drugs from Canada and other developed countries. We cannot, however, assume that importing drugs from Canada and other developed nations is safe without further steps. We need legislation that includes specific safety standards to protect American consumers, such as my REMEDIES Act.

I believe that by utilizing available technology and with proper oversight of registered exporters, we can shut down rogue Internet pharmacies and achieve a safe and effective system for legalizing the importation of prescription drugs.

Statement of Sen. Orrin G. Hatch
before the Senate Judiciary Committee
“Drug Importation”
July 14, 2004

Many Americans -- especially senior citizens -- are understandably seeking more affordable prescription drugs and are wondering if drugs imported from Canada and other countries are the answer.

Several bills have been introduced on this topic, including those by, respectively Senator Grassley, Senator Gregg, and Senator Dorgan -- whom we will hear from shortly.

The purpose of today’s hearing is to begin the Judiciary Committee’s deliberation over the many issues related to drug importation that fall under the Committee jurisdiction. Today’s hearing will largely focus on whether amending the longstanding, carefully-crafted law, the Prescription Drug Marketing Act of 1988, that established a tightly-regulated, closed system of prescription drug distribution in our country will open the door to counterfeit and otherwise adulterated or misbranded drugs being widely distributed to an unwitting American public.

Representative John Dingell, the Dean of the House of Representatives and a prime sponsor of the 1988 PDMA law, succinctly summarized the problem: “the very existence of a market for reimported goods provides the perfect cover for foreign counterfeits.”

We will hear today from the FDA and the Bureau of Customs and Border Protection on the problem of counterfeit drugs. The FDA has documented many cases of what appeared to be FDA-approved imported drugs that, in fact, were contaminated or counterfeit, contained the wrong product or incorrect dose, were accompanied by inadequate directions, or had outlived their expiration date. Unfortunately, FDA has witnessed a sharp spike in such counterfeiting and their partners at Customs will tell us that this is not an easy crime to detect or prevent.

We will hear from Rudy Giuliani, a former tough-nosed prosecutor, who will tell us why we should think twice before we do away with the protections in current law.

I am mindful that on several occasions the Senate has adopted an amendment offered by Senator Cochran that requires the Secretary of Health and Human Services to certify the safety of imported drugs before they can enter the United States. Neither Secretary Shalala nor Secretary Thompson — one a Democrat, one a Republican — could make that simple but prudent certification with respect to the additional risk to public health

Given the testimony submitted by the agency today, it seems that the safety of imported drugs remains in doubt in the minds of the experts at FDA and a strong case can be made that Congress would be well advised to retain the protection afforded by the Cochran Safety

Amendment.

Frankly, it may be beneficial for Congress to receive the report from the Secretary's Task Force on drug importation before legislation is considered in this area. I recognize that the Report is not due until after the election and the strategy of some is to attempt to use Election Day politics as leverage for legislation and that sound policy will not win out.

We all want medicines to be safe and affordable, yet we do not want to take steps that stifle the innovation that has made the United States the world leader in pharmaceutical development. Importing drugs from other countries in order to take advantage of other countries' price controls has other potential repercussions, including the prospect of diminished research into future life-saving treatments. We need to think carefully about the long term effect of this trade-off.

In this regard, I commend the efforts of Senators Kyl and Thomas for a hearing they recently held in the Finance Committee that examined the critical, yet almost totally overlooked, question of whether U.S. trade policy can be used to see that the citizens of our trading partners are paying their fair share of pharmaceutical R&D. The fact is that American taxpayers are putting up \$28 billion of their hard-earned dollars this year for biomedical research at the National Institutes of Health while, year in and year out, many other countries essentially free-ride on U.S. research and development activities and then set price controls the approved drugs products that are the fruits of this U.S.-financed research. It is the American tax payer and consumer that is paying dearly.

Consideration of pharmaceutical importation raises many complex issues beyond the problem of counterfeiting. For example, concerns have been raised about the manner in which Senator Dorgan's bill, S. 2328, affects patent and antitrust law. The bill appears to alter current law with respect to domestic patent rights once overseas sales occur. One of the areas that this Committee should explore as this debate moves forward is how the Doctrine of International Exhaustion of patent rights might be altered by the Dorgan legislation.

I would note that last year this Committee played a constructive role in correcting the excesses in the proposed changes to patent damages by the Gregg-Kennedy-McCain-Schumer bill even after it passed the Senate by an overwhelming majority. It can take time to fully analyze and refine inherently intricate pharmaceutical-related statutes. For example, I think that most objective observers would now agree that last year's Senate-passed bill contained a blatantly unconstitutional provision relating to declaratory judgments that was corrected in large part by this Committee's involvement.

In short, as drug importation legislation is crafted and considered, this Committee must remain vigilant in examining not just the counterfeit problem, substantial as it is, but also patent issues and other matters under our jurisdiction such as any potential antitrust and Takings Clause issues. For example, the extent to which the Dorgan legislation appears to preclude

manufacturers from charging exporters market-based prices for drugs, if they are higher than the lowest price-controlled price of the exporting country, deserves the close scrutiny of our Committee. As a defender of, and believer in, property rights, including intellectual property rights, I am always leery of systems that impose government-mandated prices, sales or licenses.

Finally, I must note that I am far from certain that importation is the *magic bullet* that will -- instantly and without repercussions -- lead to lower drug prices. I am concerned that importation may eventually provide the bullet in a grand-scale game of pharmaceutical Russian roulette.

I am willing to continue to work with my colleagues on ways to make prescription drugs more affordable for the American public, and to devise ways to do so that do not jeopardize patient safety or undermine the incentives for the discovery of the next generation of therapies.



Healthcare Leadership Council
Statement for the record

United States Senate
Committee on the Judiciary

Hearing on
"Examining the Implications of Drug Importation"

July 14, 2004

The Healthcare Leadership Council (HLC) commends the members of the committee for devoting much-needed attention to the issue of drug importation and its potential harmful ramifications. While the idea of allowing wholesale prescription drug importation from foreign countries is an idea that has achieved a significant degree of popularity, it is critical that Congress fully investigate and understand the potential dangers of such a step before exposing American consumers to drugs that may be counterfeit, adulterated, or substandard.

On the subject of drug importation, the American public is being led to believe that significant cost savings can be had simply by opening our borders to an unimpeded flow of imported medicines. In fact, though, this committee will be doing a great public service by pointing out that the potential gains from importation are negligible while the risks are considerable.

We need to replace the current rhetoric regarding drug importation with the following facts:

Consumer savings from drug importation will be minimal, at best. The Congressional Budget Office has estimated that, even if the U.S. allows wholesale importation from a large number of industrialized countries, American consumers will only experience a one percent savings over the next decade. Our nation's leading health care distribution companies have underscored this finding by pointing out that costs for storage, inspections, relabeling, repackaging and liability insurance would absorb virtually all of the potential consumer savings. This Congress has taken steps to make prescription drugs more affordable for millions by passing a Medicare prescription drug benefit, including the currently-available drug discount cards that are saving seniors more than 20 percent, on average, at the pharmacy counter (according to a Lewin Group study). This policy direction – emphasizing coverage – achieves greater savings, and greater safety, than importation.

No one can completely assure the American public that imported drugs will be safe. There is a reason that commissioners of the Food and Drug Administration in both Democratic and Republican administrations have opposed the idea of drug importation. It is impossible for FDA officials to guarantee the sanctity of prescription medicines that are being imported from Canada. Transshipments – when a country imports drugs from a foreign source and then passes those drugs along to another trading partner – exacerbate the dilemma. Canada, for example, does not have the capability to meet the prescription drug needs of its own citizens as well as what would become a much larger U.S. demand, should importation legislation become law. Thus, Canada would have to do what it is already doing – importing drugs from other countries, including nations that have documented drug counterfeiting and tampering problems. This would put the safety of Americans at considerable risk.

Future medical breakthroughs will be undermined. For decades, medical innovation has thrived in the free marketplace. Today, Americans have healthier, longer lives, have fewer disabilities, and spend less time in the hospital because of a market environment that has encouraged pharmaceutical research and development. Importation legislation would, in effect, allow foreign governments to not only impose price controls upon their own countries, but upon ours as well. This would have a devastating effect on research that will lead to new cures. Importation would be a short-term political salve purchased at the expense of long-term health care gains.

No, it is not an acceptable situation when Americans pay significantly more for prescription medicines than citizens of other countries. Importation legislation, however, is not the answer. Rather, it should be a priority of future trade negotiations to insist that other nations pay their fair share for pharmaceutical innovation that benefits their citizenries as well as ours. HLC's top priority is to promote safest and highest quality health care possible. We believe the best way to achieve this goal is through competition, innovation, research and continuous quality improvement. Federal policy should support such innovation and protect the well-being of American health care consumers.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
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STATEMENT OF

WILLIAM K. HUBBARD
ASSOCIATE COMMISSIONER FOR
POLICY AND PLANNING
U.S. FOOD AND DRUG ADMINISTRATION

BEFORE THE
COMMITTEE ON THE JUDICIARY
UNITED STATES SENATE

JULY 14, 2004

Release Only Upon Delivery

INTRODUCTION

Mr. Chairman and Members of the Subcommittee, I am Mr. William K. Hubbard, Associate Commissioner for Policy and Planning at the U.S. Food and Drug Administration (FDA or the Agency). With me is John M. Taylor, Associate Commissioner for Regulatory Affairs at FDA. We appreciate having this opportunity to discuss with you the issues relating to the importation of prescription drugs into the United States and the use of the Internet to facilitate the sale of these 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 ensured that Americans can be confident that, when they use an FDA-approved drug, the medicine will be safe and effective and will work as intended in treating their illness and preventing complications. In carrying out this responsibility, FDA is working to do all we can under the law to make medicines accessible and help doctors and patients to use them as effectively as possible, through such steps as expanding access to generic medicines, reducing the time and cost of showing that new medicines are safe and effective, and providing up-to-date information for health professionals and patients to obtain the benefits and avoid the risks associated with powerful medicines. That is the primary mission of the thousands of dedicated staff, including leading health care experts, doctors, economists and scientists who work tirelessly at FDA in public service for the American people. FDA remains strongly concerned about counterfeit, and/or illegally imported pharmaceuticals whose safety and effectiveness cannot be assured because they are distributed outside the legal structure and regulatory resources provided by Congress.

IMPORTATION OF PRESCRIPTION DRUGS

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

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

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

SAFETY CONCERNS RELATING TO IMPORTATION

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

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

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

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

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

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

- Unapproved drugs such as 1) alti-azathioprine, an immunosuppressant drug that can cause severe bone marrow depression and can be associated with an increased

risk of infection and cancer development; and 2) human growth hormone, which can have serious side effects if used inappropriately or in excessive doses.

- Controlled substances – FDA and Customs found over 25 different controlled substances, including Diazepam; Xanax; Codeine; Valium, Lorazepam, Clonazepam and anabolic steroids.
- Drugs withdrawn from the U.S. market for safety reasons such as Buscapina, which appears to be the drug dipyrene, removed from the market in 1977 due to reports of association with agranulocytosis -- a sometimes-fatal blood disease.
- Improperly packaged drugs shipped loose in sandwich bags, tissue paper or envelopes.
- Animal drugs not approved for human use such as Clenbuterol, a drug approved for the treatment of horses but also known as a substance of abuse in the “body building” community and banned by the International Olympic Committee.
- Potentially recalled drugs -- Serevent Diskus and Flovent Diskus medicines from Canada for the treatment of asthma. Shortly after the blitz, certain lots of the Canadian versions of these drugs were recalled in Canada.
- Drugs requiring risk management and/or restricted distribution programs -- for example, Canadian-manufactured isotretinoin, which in the U.S. is subject to a stringent risk management plan, under which prescribers are required to screen, educate and monitor patients to avoid certain serious risks such as birth defects.
- Drugs with inadequate labeling such as those with missing dosage information or labeling that is not in English.

COUNTERFEIT DRUGS

Counterfeiting of prescription drugs is a growing global concern. In fact, counterfeiting of drugs is commonplace in many countries.

In the ongoing debate over drug importation, the term "counterfeit drug" has been widely used in different contexts to mean different things. Some use the term as a catch-all to refer to all unapproved new drugs that are imported into the US. Others use it to refer to so-called "foreign versions" of FDA-approved drugs (i.e., versions of FDA-approved drugs that are not approved in the U.S. but are approved in the foreign country in which they are sold).

In fact, the term "counterfeit drug" is defined in the FD&C Act, and it describes a narrow set of drugs. In section 201(g)(2) of the FD&C Act, "counterfeit drug" is defined as "a drug which, or the container or labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, or device, or any likeness

thereof, of a drug manufacturer, processor, packer, or distributor other than the person or persons who in fact manufactured, processed, packed, or distributed such drug and which thereby falsely purports or is represented to be the product of, or to have been packed or distributed by, such other drug manufacturer, processor, packer, or distributor.

Note that a key element in this definition is the idea of fraud or deceit. The provision is aimed at products that are labeled as something other than they are. Thus, any product that is labeled or embossed with a drug trade name must be the precise product so identified or it is a counterfeit. For example, an article labeled as Viagra that is not in fact the genuine Pfizer product is a counterfeit. It makes no difference whether the counterfeit drug is an effective, chemically indistinguishable version of Pfizer's. So long as the trade name is used on the label without authorization to suggest the product is something that it is not, the product is counterfeit.

In contrast, an unapproved new drug that is not falsely labeled is not counterfeit within the meaning of section 201(g) of the FD&C Act. This includes "foreign versions" of FDA-approved drugs that are labeled with their approved foreign labeling. Again, the key distinction is the element of fraud. Suppose, for example, that a Canadian pharmacy dispensed into the U.S. a Canadian version of Paxil called "Proxy," which was manufactured by the "ACME Company" and approved for sale in Canada but which was not FDA-approved for sale in the U.S. Whether that drug was also counterfeit within the meaning of section 201(g)(2) of the FD&C Act would depend on how it was labeled. If the pharmacy labeled the Proxy as "Paxil," which is the trade name of an FDA-approved drug manufactured by GlaxoSmithKline, then the drug would be a counterfeit because the unauthorized use of the trade name would falsely suggest to the consumer that the drug he or she received was in fact GSK's FDA-approved product. If, however, the drug were labeled as Proxy that was manufactured by ACME, the product would not be counterfeit because there would be no false indication that the drug at issue was in fact FDA-approved Paxil. Even though the US consumer might think of the product as Paxil-like, the fact that the product label did not misrepresent the product's true identity would keep it outside the technical definition of a counterfeit.

In sum, the term "counterfeit drug" has a precise legal definition. Virtually all drugs that are imported by individual consumers into the U.S. are illegal, but not all of them are counterfeit. To determine whether a drug is a "counterfeit," investigators look at the drug and at its label and packaging. If the drug is embossed or labeled with a trade name or identifying mark that suggests it is a genuine FDA-approved product, the drug itself is examined more closely. If the drug has not in fact been manufactured, packaged, processed, or distributed by the person(s) identified on the tablet or labeling, and thereby falsely represents that fact, then the drug is a counterfeit within the meaning of the Act.

In the U.S., Federal and state authorities have kept counterfeiting of drugs to a minimum because of our extensive system of laws, regulations and enforcement. As a result, Americans have a high degree of confidence in the drugs they obtain from their local pharmacy. In recent years, however, FDA has seen growing evidence of efforts by increasingly well-organized counterfeiters, backed by increasingly sophisticated

technologies and criminal operations, intent on profiting from drug counterfeiting at the expense of American patients. FDA has seen its counterfeit drug investigations increase to over 20 per year since 2000, after averaging only about five per year through the late 1990's. From October 1996 through June 2004, FDA's Office of Criminal Investigations (OCI) has opened approximately 113 counterfeit drugs cases. These investigations have so far netted 77 arrests and 42 convictions.

Although we believe domestic counterfeiting is not widespread, the Agency has seen both an increase in counterfeiting activities, and a more sophisticated ability to introduce finished dosage counterfeits into otherwise legitimate drug distribution channels. Much of this activity has targeted high volume, high cost drugs where counterfeiters attempt to obtain the highest return possible in a short time period. Many of these drugs are used for treating cancer and AIDS patients. FDA believes the increase and shift in this illicit activity has occurred for a number of reasons, including:

- Better counterfeiting technology, including improved technology to make labeling, packaging and products that appear real.
- Better organized, more effective criminal groups attracted by financial opportunities.
- The use of the Internet as a sales tool by unlicensed pharmacies and/or foreign websites.
- Opportunities for introducing foreign-made counterfeit and unapproved drugs into large and rapidly growing import flows.
- Weak spots in the domestic wholesale drug distribution chain, including some wholesalers who acquire most of their inventory from secondary sources, do not maintain effective due diligence efforts on these sources and ignore warning signs indicative of illegal or unethical behavior.

In July 2003, FDA began a major new initiative to better protect American consumers from drugs that have been counterfeited. FDA's initiative was designed to better identify the risks and threats from counterfeit drugs, coordinate public and private efforts to fight drug counterfeiting and distribution, and develop new tools to aid in identifying, deterring and combating counterfeiting. In addition, FDA is working to establish closer coordination with other Federal agencies and state and local governments that share the responsibilities for ensuring the safety of the U.S. drug supply and distribution system.

The initiative included the creation of an internal task force to explore modern technologies and other measures to make it more difficult for counterfeit drugs to be distributed with – or deliberately substituted for – safe and effective drugs. The information gathering process included a public hearing held in October 2003.

On February 18, 2004, FDA issued a final report that lays out specific steps the Agency is taking to keep the U.S. drug supply secure against the increasingly sophisticated criminal efforts to introduce counterfeit drugs. The comprehensive report highlights ways to assure that the nation's drug distribution system protects Americans from counterfeit drugs. These measures address six critical areas:

- Securing the actual drug product and its packaging;
- Securing the movement of the product as it travels through the U.S. drug distribution chain;
- Enhancing regulatory oversight and enforcement;
- Increasing penalties for counterfeiters;
- Heightening vigilance and awareness of counterfeit drugs; and
- Increasing international collaboration.

The report addresses the safety and security of the legal U.S. drug supply, over which the Agency has regulatory authority. It must be noted that the counterfeit initiative is not intended to assure the safety and efficacy of drugs purchased from other countries outside this legal drug distribution system, or from unregulated Internet sites that are not run by pharmacies licensed and regulated by states.

The report describes specific steps that can be taken now and in the future to protect consumers from counterfeit drugs and to secure the U.S. drug distribution system. These measures include:

- Implementation of new technologies to better protect legitimate drugs against tampering or replacement with counterfeits.
- Adoption of reliable modern track and trace technology, which the FDA has concluded is feasible by 2007, to accomplish and surpass the goals of the Prescription Drug Marketing Act.
- Adoption and enforcement of stronger anti-counterfeiting measures by the state regulators of drug wholesalers and distributors.
- Increased criminal penalties to deter counterfeiting and more adequately punish those convicted.
- Adoption of secure business practices by all participants in the drug supply chain.
- Development of a system that helps ensure timely and effective reporting of counterfeit drugs to the FDA, and that strengthens the ability of the FDA, other regulatory agencies, and the other participants in the drug distribution system to respond rapidly to such reports.
- Education of consumers and health professionals about the risks of counterfeit drugs and about how to respond if they encounter such products.
- Collaboration with foreign stakeholders to develop strategies to deter and detect counterfeit drugs globally.

Implementing these steps will:

- Help prevent the introduction of counterfeit drugs into the U.S. drug distribution chain;
- Facilitate the identification of counterfeit drugs;
- Minimize the risk and exposure of consumers to counterfeit drugs; and

- Avoid unnecessary additional costs in the prescription drug distribution system, and unnecessary restrictions on lower-cost sources of drugs.

The full Counterfeit Drug Task Force Final Report is available on FDA's website at www.fda.gov/oc/initiatives/counterfeit.

Reporting of Information on Counterfeit Drugs by Manufacturers

In another move to respond to the increase in counterfeit drug cases and to strengthen the Agency's and industry's collaboration in those situations where counterfeit drugs are suspected, on April 22, 2003, the Pharmaceutical Research and Manufacturers of America (PhRMA), which represents the country's major research-based pharmaceutical and biotechnology companies, announced the adoption of a voluntary program to report suspected instances of drug counterfeiting to FDA. The information provided by PhRMA members under this program will assist FDA in carrying out its responsibilities to protect the safety and integrity of the nation's drug supply. It will enhance the Agency's ability to detect quickly and remove counterfeit drugs from the marketplace.

Under this program, PhRMA member companies have agreed to notify OCI within five working days of determining that there is a reasonable basis to believe that a product has been counterfeited. The program also applies to counterfeits discovered in foreign countries if there is clear evidence that the counterfeits are intended for distribution in the U.S. Drug manufacturers already conduct their own investigations of suspected distribution of counterfeit drugs. This formal collaborative agreement will strengthen FDA's ability to assure the safety and effectiveness of drugs used by U.S. The reporting program went into effect on May 1, 2003 and has already led to some useful tips. To date, thirty-five (35) voluntary counterfeit reports have been submitted to the Agency since this agreement with PhRMA was put in place.

Recent Counterfeit and Unapproved Drug Cases

Counterfeit Viagra

On June 24, 2004 FDA's Office of Criminal Investigations (OCI) received a report of counterfeit Viagra from Pfizer after the company confirmed that the product had been dispensed by two pharmacies in California. Pfizer had received two complaints of suspicious Viagra from two different pharmacies in California and after testing was able to confirm that both the product and the packaging were counterfeit.

Counterfeit Viagra

On June 23, 2004 Khoa Twan Do, also known as Chris Do, pled guilty to charges of conspiracy, trafficking in counterfeit counterfeit goods, and a felony violation of the Federal Food, Drug and Cosmetic Act. In pleading guilty, the defendant admitted that he conspired with a manufacturer in Beijing to import thousands of counterfeit Viagra tablets into the United States that he would then resell. He had told his Beijing supplier

that the counterfeit tablets needed to "look like the real thing" because "I can find many customers who want the real thing." In January 2004, U.S. Immigration and Customs Enforcement and FDA intercepted a shipment of thousands of these counterfeit tablets destined for Do.

The defendant is scheduled for sentencing in September, 2004. He faces a maximum possible penalty of 18 years in federal prison and a fine of more than \$2 million.

David Palumbo

On June 16, 2004, an indictment was unsealed in San Diego, California that charged David Palumbo, a bodybuilder and editor-in-chief of Rx Muscle magazine, with conspiring to unlawfully distribute human growth hormone and traffic in counterfeit goods. According to the indictment, Palumbo obtained counterfeit Serostim and sold it to bodybuilders who did not possess lawful prescriptions for the drug. The indictment further alleged that Palumbo sent his payments in cash by commercial interstate carriers such as Federal Express, often contained within the pages of a copy of the bodybuilding magazine he edited. The source of the counterfeit Serostim for Palumbo proved to be Bill Young who pled guilty on February 19, 2003 to trafficking in counterfeit goods. The counterfeit Serostim produced by the defendants in this case was identified by the fact that the hologram on the box was a sticker, rather than an imprint on the box itself. Palumbo faces 5 years in prison and/or a \$250,000 fine.

Omega Pharmaceuticals

On June 9, 2004, Omega Pharmaceuticals of Daphne, Alabama pled guilty to selling and holding for sale counterfeit prescription drugs. In February 2003, OCI investigators executed a federal search warrant at the Daphne, Alabama offices of Omega, a wholesale distributor of prescription drugs. They seized multiple bottles of eleven types of purported brand-name prescription drugs: Viracept (Agouron Pharmaceuticals); Videx EC and Sustiva (Bristol-Meyers Squibb); Crixivan (Merck); Retrovir, Ziagen, and Trizivir (GlaxoSmithKline); Prilosec (Astra Zeneca); Zyprexa (Eli Lilly); and Kaletra and Norvir (Abbott Laboratories). Forensic analysis confirmed that the drugs seized from Omega were, in fact, counterfeit.

Records of Omega seized during the search of its office verified that the company was in the business of buying and selling prescription drugs throughout the country. As part of its plea agreement, Omega agreed to the destruction of all of the drugs seized by FDA. The company is scheduled to be sentenced in October, 2004, and faces a fine of up to \$200,000.

Steven Gabriel Moos

On June 3, 2004, the Department of Justice (DOJ) announced the indictment of Steven Gabriel Moos, an Oregon physician, on multiple criminal charges including the unlawful importation of misbranded drugs and human growth hormone; falsifying information

submitted to DEA; and unlawfully obtaining controlled substances. The indictment stemmed from a multi-Agency investigation which uncovered that Moos had allegedly attempted to import drugs from China which were labeled as vitamin supplements, prednisone or blood pressure medicine but were "misbranded" to appear to be Viagra. Moos also allegedly imported misbranded human growth hormone that was not legitimately manufactured or packaged. According to the indictment, neither of these products included necessary warnings on safe use or contraindications for use; and the lack of appropriate labeling posed significant patient safety concerns.

Moos had been placed on probation by the Oregon Board of Medical Examiners in March, 2000 due to his intended prescription practices. Moos allegedly later filed DEA registration forms misrepresenting his status to practice medicine. After the Board of Medical Examiners acted to further suspend Moos' license to practice medicine in January 2003, Moos allegedly misrepresented his status to drug manufacturers and wholesalers to unlawfully maintain his access to a supply of controlled substances. This investigation was conducted by OCI, FBI, DEA and HHS/OIG. The Oregon Board of Medical Examiners and the Oregon Department of Justice Medicaid Fraud Unit provided assistance.

Counterfeit Contraceptive Patches

On February 4, 2004, the FDA issued a press release warning the public about an Internet site selling contraceptive patches that contained no active ingredient, thereby providing no protection against pregnancy. The website's domain name, www.rxpharmacy.ws, is registered to American Style Products of New Delhi, India. That firm was also listed in the return address of mail parcels containing the bogus contraceptive patches. The website also sold other products that purported to be versions of FDA-approved drugs. FDA is currently analyzing these other products as well, and has urged consumers to treat any drugs purchased from this firm as being suspect. The FDA also sought and obtained the cooperation of the U.S. based Internet service provider (ISP) in discontinuing service to this website.

The bogus contraceptive patches were promoted on the website as Ortho Evra transdermal patches, which are FDA approved, and made by Johnson & Johnson's Ortho-McNeil Pharmaceutical, Inc. subsidiary. Instead of receiving the advertised Ortho Evra patches, customers received patches without the active ingredient necessary to make the patches effective. Moreover, the patches were sent in simple plastic zip-lock bags without identifying materials, lot numbers, expiration dating or any other labeling information needed to safely and effectively use this prescription product.

On February 12, 2004, FDA also obtained the cooperation of a U.S. based Internet Service Provider in discontinuing service for three additional foreign Internet sites associated with www.rxpharmacy.ws. The three newly discovered Internet sites involved were www.usarxstore.com, www.europeanrxpharmacy.com, and www.generic.com. These sites also sold other drugs that purported to be the same as FDA-approved drugs, but were in fact from unknown sources and of unknown safety and efficacy.

The FDA believes these four websites are indicative of the dangers consumers face when they purchase pharmaceuticals off the Internet. The content of each of these websites was written in perfect English, and to the average US consumer, these websites may appear to be of domestic origin. On closer inspection, none of the websites listed a physical address, telephone number or other identifiers. In fact, all four websites appear to be controlled by largely unknown business entities in various parts of the world, who sell questionable and dangerous products to unsuspecting consumers for pure profit motives.

FDA's Office of Criminal Investigation is working with Johnson & Johnson and the Department of Homeland Security's Bureau of Immigration and Customs Enforcement (ICE) to combat illegal/counterfeit drug imports, to include those facilitated by the Internet. These criminal investigations are ongoing.

Alliance Wholesale Distributors/Local Repack Inc./Phil & Kathy's

On September 15, 2003, FDA announced the seizure of all drug products labeled in a foreign language and/or labeled as repacked by Phil and Kathy's, Inc., d.b.a. Alliance Wholesale Distributor and/or Local Repack, Inc. of Richton Park, Ill.

FDA acted to prevent these drug products from entering the U.S. drug distribution system because there was no assurance that they were safe or effective. Many of the products received and repackaged at Local Repack were of unknown origin and their storage and handling was unverifiable. Local Repack repeatedly failed to comply with cGMP requirements.

FDA inspections conducted after an August 1999 Warning Letter to Local Repack revealed significant and continuing violations. A series of inspections and other recent evidence revealed numerous deficiencies including the failure to properly handle customer complaints, discrepancies surrounding the signatures of quality control employees, records indicating the review and approval of repackaging operations before the operations were completed, incomplete or missing repackaging records, duplicate and inconsistent repackaging records for the same batch, and unreliable receiving and distribution records for drugs.

The September seizure followed the July 9, 2003, seizure of more than 4,500 bottles of prescription drugs that were being repackaged by Local Repack stemming from an investigation of counterfeit Lipitor. Many of the products seized in July were marked with expiration dates to permit them to be sold after similar U.S.-approved drugs would have expired. For example, Portuguese-labeled product that Local Repack labeled as Lipitor had expiration dates well beyond the two-year limit that is based on stability studies performed under the new drug application (NDA) approved in the U.S. for Lipitor.

On April 8, 2004, Phil and Kathy's signed a consent decree agreeing to operate in full compliance with FDA's regulations. Under the consent decree, Phil and Kathy's is prohibited from manufacturing, labeling and distributing any article of drug until it meets certain conditions, the most important of which is the FDA's determination that the firm's repackaging operations comply with cGMPs. In addition, Phil and Kathy's agreed not to repackage any foreign-labeled drugs or drugs that are in any manner inconsistent with FDA's standards for approval.

INTERNET DRUG SALES

With greater and greater frequency, consumers are using the Internet to access health related information and products. Sales of consumer products over the Internet have grown rapidly, including the sale of drugs. The growth in online drug sales by reputable pharmacies has provided significant benefits to consumers. Many managed health care organizations are searching for ways to achieve cost savings and are turning to online prescription plans as a means of providing quality service at a lower cost.

A number of online drug websites, however, present risks to purchasers and unique challenges to regulators, law enforcement officials and policy makers. FDA is concerned about the public health implications of unlawful Internet drug sales, and we are responding to these concerns as we develop and implement risk-based strategies to protect the public health. FDA monitors the Internet to evaluate the quality of products and information being offered, and we encourage consumers to remain vigilant about their purchases and to rely on reputable Internet sites. But we remain concerned about consumers directly purchasing foreign unapproved drugs through the Internet, because of the Agency's continued concerns that there is not sufficient information or means to assure that these products are as safe and effective as products sold within the United States. Our challenge is to make sure that the protection for consumers who purchase prescription drugs in cyberspace is just as strong as the protection consumers enjoy when they purchase drugs at their corner pharmacy.

Prescription drug sales over the Internet can provide tremendous benefits to consumers. These benefits include:

- Access to drugs for the disabled or otherwise homebound, for whom a trip to the pharmacy can be difficult;
- The convenience of shopping 24 hours a day; and a wide selection of pharmaceutical products;
- Privacy for those who don't want to discuss their medical needs in a public place.

FDA is aware that many reputable Internet pharmacies provide consumers seeking prescription drugs with a measure of safety, privacy and convenience. They can provide detailed information on drug interactions, and may e-mail customers if the drug they ordered has been recalled, a cheaper generic version of the drug becomes available or to remind them of prescription renewals. Some also sell drugs for less than traditional "brick-and mortar" pharmacies. Hyperlinks and search programs provide online customers with written product information and references to other sources of health

information more easily than in the traditional storefront. Finally, as data sharing standards are developed and adopted to expand automated transmission of prescriptions from doctors to pharmacies, a reduction in prescription errors may be possible.

While online pharmaceutical sales are important for some customers, brick and mortar pharmacies can offer benefits and services that are often not available through the Internet, such as quick access to prescription drugs needed for immediate treatment. These pharmacies will undoubtedly remain an essential component in the delivery of effective health care.

As beneficial as this technology can be, the Internet also has created a marketplace for the sale of unapproved drugs, prescription drugs dispensed without a valid prescription, or products marketed with fraudulent health claims. Consumers may have difficulty identifying which sites sell legitimate products. As FDA considers the issues related to online drug sales, we recognize that there are various types of websites engaged in drug sales. Many sites focus on selling prescription drugs and are referred to by some as "Internet pharmacies." These sites offer for sale either FDA-approved prescription drug products, or in some cases, unapproved or illegal versions of prescription drugs. In many cases, FDA cannot provide consumers with assurance that drugs purchased over the Internet were manufactured under cGMP requirements, even if the website appears to be based in the U.S. While the increase in "Internet pharmacies" engaged in illegal sales is seen as a potent threat, FDA believes that some of the non-pharmacy sites are also harmful. We have moved aggressively against these types of sites that unlawfully offer unapproved drug products, products making fraudulent health claims, or drugs for recreational use.

Patients who buy prescription drugs from an illegitimate site are at risk of suffering adverse events, some of which can be life threatening. These risks include 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 purchase genuine product, others may unknowingly buy counterfeit copies that contain inert ingredients, legitimate drugs that are outdated and have been diverted to illegitimate resellers, or improperly manufactured sub-potent or super-potent products.

FDA is concerned about the proliferation of sites that substitute a simple online questionnaire for a face-to-face examination and patient supervision by a health care practitioner. According to the American Medical Association, a health care practitioner who offers a prescription for a patient he or she has never seen before, based solely on an online questionnaire, generally does not meet the appropriate medical standard of care. Four years ago, the Federation of State Medical Boards, Special Committee on Professional Conduct and Ethics found that "Prescribing of medications by physicians based solely on an electronic medical questionnaire clearly fails to meet an acceptable standard of care and is outside the bounds of professional conduct." This statement is especially important in light of the primary responsibility of states in regulating the practice of medicine.

The Agency is equally concerned that in some Internet transactions there is an apparent absence of any health professional/patient relationship. This is a particular concern where a patient may be using a prescription drug for the first time or where the patient may be taking other medications. FDA believes that the selection of prescription drug products or treatment regimens for a particular patient should be made with the advice of a licensed health care practitioner who is familiar with the patient's current health status and past medical history. In situations where a customary physician-patient relationship does not exist, the patient may be practicing what amounts to self-diagnosis. Consequently, the risk of negative outcomes such as harmful drug interactions, contraindications, allergic reactions or improper dosing is potentially magnified.

"Canadian Generics" Website

A recent example illustrates some of the dangers associated with the purchase of prescription drugs from rogue pharmacy sites. Within the last six months, FDA has examined two web sites having identical web pages headlined "Canadian Generics" which were identified through spam e-mails sent to consumers. FDA has purchased prescription drugs from both of these sites, and has found that these drugs and the manner in which they are sold pose potential threats to the health and safety of consumers.

There is at least one Canadian flag on every page of these sites, as well as the words "Canadian Generics." The web sites say, "Order Canadian to get the biggest discounts!" Both of the URLs from which the orders were placed suggest the sites are located in, and operated out of, Canada. Despite these representations, however, we determined there is no evidence that the dispensers of the drugs or the drugs themselves are Canadian. The registrants, technical contacts, and billing contacts for both web sites have addresses in China. The reordering website for both purchases and its registrant, technical contact, and billing contact have addresses in Belize. The drugs were shipped from Texas, with a customer service and return address in Florida.

FDA purchased drugs described by the website as generic Viagra, generic Lipitor, and generic Ambien. None of these products, however, has a generic version approved in the U.S. or Canada. Both times, to obtain the drugs, an FDA investigator posed as a consumer and filled out an on-line questionnaire. The investigator was never asked to provide a prescription. After each purchase, the drugs arrived packaged in heat-sealed plastic bags within a manila envelope.

Ambien is a controlled substance with a potential for addiction. In addition, for both purchases, FDA's "consumer" said in the on-line questionnaire that he is taking erythromycin. The use of Viagra with erythromycin is contraindicated and, more importantly, there is a warning on the approved labeling for Lipitor about concurrent administration of Lipitor with erythromycin. Despite these critical safety issues, the website operators sent the drugs anyway.

The drugs received from the second purchase were tested in an FDA laboratory. All three samples failed, using the brand-name manufacturer's methodology. While all three samples had some level of active ingredient, the "generic" Lipitor and Viagra were found to be subpotent, while the "generic" Ambien was found to be superpotent. Two of the three drugs failed the dissolution parameters of the brand-name drugs. The third drug passed the dissolution testing, but only because it was superpotent. Two of the three samples also failed purity testing, while all three samples failed the USP criteria for content uniformity.

Consumers can, and should, be cautious when purchasing drugs online. There are legitimate sites that dispense drugs based on valid prescriptions. Consumers should check with their State Board of Pharmacy or the National Association of Boards of Pharmacy to see if the online pharmacy possesses a valid pharmacy license and has met state quality standards.

One means that consumers have at their disposal to protect themselves is the Verified Internet Pharmacy Practice Sites, or VIPPS system, developed by the National Association of Boards of Pharmacy (NABP) in choosing online pharmacies with which to do business. This program, which verifies the legitimacy of Internet sites dispensing prescription drugs, provides a "seal of approval" to sites that apply and meet state licensure requirements and NABP's standards. Although participation in the VIPPS program is voluntary, the Agency believes this program is an example of one that is helpful in assuring consumers that the Internet site they are using is reputable.

USE OF THE INTERNET TO BYPASS REGULATION

The unique qualities of the Internet, including its broad reach, relative anonymity, and ease of creating new or removing old websites, pose new challenges for the enforcement of the FD&C Act and state laws regulating the practice of medicine and the practice of pharmacy. FDA has found that many Internet sites are actually comprised of multiple related sites and links, thereby making investigations much more complex and resource intensive. The global nature of the Internet creates special problems for effective law enforcement. Different approaches to drug approval and marketing in foreign countries further complicate law enforcement issues for U.S. officials. FDA and other U.S. government agencies must try to work with foreign governments to share information and to develop mechanisms for cooperative law enforcement, but this is a difficult task.

FDA Authority

The types of unlawful conduct that can occur when drugs are sold over the Internet are similar to unlawful activities that occur in other contexts. Under the FD&C Act, FDA has the legal authority to take action against:

- The sale, distribution or importation of an adulterated or misbranded drug;
- The sale, distribution or importation of an unapproved new drug;
- The sale or dispensing of a prescription drug without a valid prescription; and
- Counterfeit drugs.

When the Internet is used for an illegal sale, FDA, working with DOJ, must establish the grounds for a case, develop the same charges, and take the same actions as it would if another sales medium, such as a storefront or a magazine, had been used. FDA has investigated and referred numerous cases for criminal prosecution and initiated civil enforcement actions against online sellers of drugs and other FDA-regulated products, particularly sellers of drugs not approved by the Agency.

State Regulation of the Practice of Medicine and Pharmacy

The states have enacted laws regulating the practice of pharmacy and the practice of medicine to protect patients from harm resulting from the use of unsafe drugs, and the improper practice of medicine and pharmacy. Under many of these laws, to receive a prescription drug, a licensed health care practitioner who determines the appropriate treatment and issues a prescription for an FDA-approved drug generally must examine a patient. The prescription may also authorize refills. The patient then has the prescription filled by a registered pharmacist working in a licensed pharmacy that meets state standards.

Even with these Federal and state systems in place, the Internet provides ample opportunities for circumventing established safeguards. The speed, ease, and anonymity of ordering products on the Internet can attract unscrupulous sellers. Individuals not licensed to sell prescription drugs can easily create websites that appear to represent legitimate pharmacies. The fact that operators can quickly change the location and appearance of their Internet site makes enforcement all the more difficult.

Safeguards are not always maintained when drugs are purchased over the Internet. A health care practitioner may not examine the consumer prior to the purchase of drugs online. A patient-doctor relationship may not be established. Unfortunately, attempts to stop some U.S. doctors and online pharmacies from issuing online prescriptions without a physical examination have not always been successful. States face many obstacles when it comes to regulating online pharmacies. State pharmacy and medical boards have limited resources for enforcement and state regulations may not fully address the Internet context.

Jurisdictional Challenges

Online drug sales pose unique challenges for regulatory and law enforcement agencies at the state, Federal and international level. Internet technology can obscure the source of the product as well as provide a degree of anonymity to those responsible for selling and shipping the product. The parties to a transaction can be dispersed geographically and usually never meet. Thus, the regulatory and enforcement issues cross state, Federal, and international jurisdictional lines.

The sale of drugs to U.S. residents via foreign websites is an extremely challenging area. Medications sold on the Internet that may be legal in foreign countries may not be

approved for sale in the U.S. Products not approved for sale in the U.S. often do not conform to the cGMP and quality assurance requirements in U.S. laws and regulations, and it is illegal for a foreign pharmacy to ship such drugs into the U.S. Foreign sales pose the most difficult challenge for U.S. law enforcement because the seller is not within U.S. boundaries. Although FDA may have jurisdiction over a resident in a foreign country who sells in violation of the FD&C Act to a U.S. resident, from a practical standpoint, the Agency working with DOJ has a difficult time enforcing the law against foreign sellers, when they are hard to reach and outside our borders. As a result, the Agency's efforts typically focus on requesting the foreign government to take action against the seller of the product, or asking the CBP to stop the imported drug at a U.S. port-of-entry.

STATE-ENDORSED PHARMACY SITES

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

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

- 1) several pharmacies used unsupervised technicians, not trained pharmacists, to enter medication orders and to try to clarify prescription questions;
- 2) one pharmacy had its pharmacists review 100 new prescriptions or 300 refill prescriptions per hour, a volume so high that it would have been impossible to assure safety;
- 3) one pharmacy failed to label its products, instead it shipped the labels unattached in the same shipping container, even to patients who received multiple medications in one shipment; and
- 4) drugs requiring refrigeration were being shipped un-refrigerated with no evidence that the products would remain stable.

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

Similar problems have become evident in the operation of the state of Wisconsin's Prescription Drug Resource Center. In reviewing the reports submitted by the three Canadian pharmacies linked to the Wisconsin website, the Pharmacy Society of Wisconsin has identified serious breaches of the agreements under which the pharmacies participate in the state program. The Society found that of the 765 prescriptions dispensed by the pharmacies, 316 (over 41%) violated the state agreements. Specifically, 127 of the dispensed drugs were products not approved by FDA or available in the U.S., while 189 of the drugs were products not authorized by the state program. In six instances, the pharmacies improperly sent drugs requiring refrigeration through the mail. Additionally, one of the Canadian pharmacies advised the state that it intended to obtain drugs from a European supplier, even though that was specifically prohibited by its agreement. Responding to these reports, the Wisconsin Department of Health and Family Services sent letters to the three pharmacies on April 27, 2004 ordering them to cease these prohibited practices. In reaction to these reports, the executive director of the Wisconsin Pharmacy Society, which is the professional association representing licensed pharmacy practitioners in the state, concluded that "no one in Wisconsin has any real idea what these Canadian businesses are doing."

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

FDA ACTIONS TO PROTECT PUBLIC HEALTH

FDA has long been engaged in taking steps to minimize the dangers to public health posed by the sales of drugs on the Internet. In July 1999, FDA adopted, and has since been implementing, an Internet Drug Sales Action Plan, which includes five key areas of activity:

- Engaging in public outreach and education;
- Partnering with professional organizations;
- Coordinating action with state and other Federal agencies;
- Cooperating internationally; and
- Enhanced enforcement tailored to the Internet environment.

Coordination with State and Federal Agencies

Several Federal agencies, as well as the states, have the authority to regulate and/or enforce U.S. laws related to the sale of drug products online. Due to the growth of potential cases involving the Internet, there are instances when working with another agency or state yields a more effective enforcement result. Working closely with the states is essential to effectively regulate the sale of drugs, as well as the sale of prescription drugs without a valid prescription over the Internet. FDA has established partnership agreements with several state bodies, including the National Association of Boards of Pharmacies and the Federation of State Medical Boards, to coordinate Federal and state activities aimed at questionable practices associated with the selling and prescribing of prescription drugs over the Internet.

FDA has increased coordination with other governmental bodies and meets regularly with other Federal agencies and state officials to share information, discuss the roles and responsibilities of the parties regarding online drug sales and identify opportunities for partnering in enforcement actions. FDA maintains strong working relationships with DOJ, including the Drug Enforcement Administration (DEA) and Federal Bureau of Investigation (FBI), the U.S. Postal Inspection Service, CBP, the Office of National Drug Control and Policy (ONDCP) and other appropriate Federal and state agencies. FDA believes that cooperation among Federal agencies is particularly critical to address the sale of drugs to U.S. residents by foreign sellers.

FDA is also involved in the effort to combat an increase in the abuse of prescription drugs, which is evident in the increasing illegal sales of controlled substances on the Internet. In announcing the President's National Drug Control Strategy for 2004, ONDCP has brought together the efforts of FDA, Federal substance abuse prevention and treatment agencies, and law enforcement to bear on the factors contributing to rising prescription drug abuse. The Strategy incorporates education of medical professionals and consumers, outreach to businesses involved in Internet commerce, pharmaceutical manufacturers, and pharmacies. The new program includes a range of activities designed to reduce the abuse of prescription drugs, and includes the use of web crawler/data mining technology to identify, investigate and prosecute "pill mills" -- Internet pharmacies that provide controlled substances illegally.

In conjunction with DEA, FDA will implement additional investigative efforts and enforcement actions against the illegal sale, use, or diversion of controlled substances, including those occurring over the Internet. Many of these sellers are foreign-based and expose the purchaser to potentially counterfeit, contaminated, or adulterated products.

Enhanced Enforcement

Since 1999, FDA has aggressively expanded its investigation and enforcement activities relating to Internet drug sales because we believe that illegal online drug sales pose a significant public health risk. FDA has initially focused its enforcement activities in the following areas:

- Unapproved new drugs;
- Health fraud; and
- Prescription drugs sold without a valid prescription.

Through the use of various search tools and by upgrading its data handling capabilities, FDA has increased its capability to monitor the Internet and identify sites that potentially violate the FD&C Act. These actions help the Agency to better understand the type and extent of unlawful conduct on the Internet and to more accurately assess whether its enforcement efforts have had an impact on illegal behavior. FDA has reviewed thousands of websites and identified hundreds involved in the sale of drug products. But this remains a daunting task and each day new sites are identified.

Starting in 1999, FDA has reviewed potential enforcement actions and coordinated case assignments through the use of a case assessment or "triage" team with representatives from the Office of Enforcement and OCI within the Office of Regulatory Affairs (ORA), the Center for Drug Evaluation and Research (CDER), the Office of Chief Counsel (OCC) and the Office of Policy. Under the triage process, when FDA obtains leads on sites that potentially violate the FD&C Act from internal Internet monitoring activity, state, other Federal or foreign law enforcement agencies, consumers, Congress, or the press, the triage team evaluates leads and decides whether they should be pursued through a civil or criminal investigation. Priority is given to cases involving unapproved new drugs, health fraud, prescription drugs sold without a valid prescription, and products with the potential for causing serious or life-threatening reactions. The triage team makes referrals, when appropriate, to various offices within FDA for follow-up.

The triage process results in a better coordination of criminal and civil enforcement actions at the appropriate Agency components and reduces overlapping effort. This process helps to ensure that decisions are made in a timely way. The Agency seeks an appropriate balance in terms of achieving a maximum deterrent effect while taking action, if needed, to remove harmful products from the market. The team will continue to oversee Internet-related enforcement activities while they are being investigated, and will ensure that they are brought to appropriate conclusion.

OCI, working with OCC, is responsible for investigations of pharmacy sites and other Internet drug sites whose operations involve potential criminal activity. The Investigative Analysis Branch analyzes the information collected by OCI. After the suspect sites are researched, and possible violations are identified, the OCI field offices receive assignment for investigative work, which often includes undercover buys. Further investigation determines the bona fides of the pharmacy and doctor(s), and examines the relationship between the patient and doctor and the doctor and pharmacy. OCI has ongoing cooperative relationships with CBP, DEA, FBI, the Postal Inspection Service and appropriate state law enforcement and regulatory agencies, and this has enhanced their investigative capabilities with regard to Internet drug sales.

Recent Internet-Related Cases

The following examples of recent enforcement actions taken by FDA illustrate the serious risks to the public health posed by fraudulent or illegal drug sales utilizing the Internet.

NoPrescriptionpharmacy.com (Alden L. Sears)

The National Association of Boards of Pharmacy forwarded information to OCI that a website called NoPrescriptionpharmacy.com was offering for sale numerous controlled and non-controlled prescription drugs such as Clenbuterol, Clomid, Valium and Viagra without any apparent requirement for an online consultation or a doctor's prescription. Based upon this information, two separate undercover orders were made from the website. In both instances, although money orders were negotiated, no products were received despite numerous e-mail inquiries. In August 2003, search warrants were executed at the domain registrant's residence, during which time numerous anabolic steroids were seized. The domain registrant, Alden L. Spears, was arrested and charged with mail fraud. The defendant pled guilty and was sentenced on April 26, 2004. This case was investigated by both OCI and the U.S. Postal Inspection Service.

Genapharm.com

On March 9, 2004, Hadi M. Ghandour, owner of Genapharm, Inc. of Austin, Texas, pled guilty to four counts of conspiracy to introduce misbranded and unapproved new drugs into interstate commerce, counterfeiting human growth hormone, and possessing controlled drugs with intent to distribute. Ghandour admitted to engaging in a conspiracy to sell unapproved, misbranded, counterfeit and Schedule I controlled drugs from 1999 to 2001. Ghandour sold these drugs through Genapharm, Inc. and Biosculpt Technologies, Inc., and through an Internet website, www.genapharm.com.

The drugs included:

- 1,4 Butanediol, which converts into gamma hydroxybutyric acid or GHB, a Schedule I controlled substance, when metabolized by the human body;
- Counterfeit human growth hormone;
- 4 Bromo-2, 5-dimethoxyphenethylamine (2CB or Nexus), a Schedule I controlled substance;
- BZP, which if combined with 1-(3-trifluoromethylphenyl) piperazine (TFMPP), has stimulant and hallucinogenic effects similar to 3,4-methylenedioxymethamphetamine (MDMA), or ecstasy, a Schedule I controlled substance; and
- Tiratricol, tri-iodothyroacetic acid (TRIAC), a potent thyroid hormone.

Two other persons involved in these offenses were previously convicted and sentenced. Ghandour faces up to five years in prison and a fine of \$250,000 on each count. He had previously been convicted in 1998 of counterfeiting drug labels. The investigation was

conducted by FDA/OCI and the DEA, with assistance from the Dallas District Office of FDA and the Texas Department of Health.

Vinci-online.com

On August 5, 2003, Christian Frederic Finze pled guilty to charges relating to various counts of conspiracy, distribution, and importation of controlled substances as a result of a case initiated by OCI in July 2000 after Finze was identified as the principal for Vinci-online and CFF Pharma Consult. The website domain used by the defendant, Vinci-online.com, was found to be registered to CFF Pharma Consult, a German business established by the defendant to ship drugs from Germany to customers in the U.S. These shipments included 7,200 units of flunitrazepam, commonly known as Rohypnol or the "date rape drug." Flunitrazepam is not approved for manufacturing or distribution in the U.S. Vinci-online.com also offered other pharmaceutical drug products for sale via its website including controlled substances, antibiotics, anti-allergens, weight loss medications, steroids, and hormones. Several undercover purchases of prescription drugs were made from the website without providing prescriptions. These purchases were in response to instructions on the website that consumers should place orders via e-mail. Following the e-mail purchase request, an invoice was generated instructing the purchaser to send a money order or cashier's check to Vinci American Ltd. in Las Vegas, Nevada. The products that were received as a result of these on-line purchases were sent from Germany and displayed and contained German labeling. Moreover, the products were shipped from Germany into the U.S. through the use of forged and fraudulent documents designed to deceive employees of CBP and FDA. Finze is awaiting sentencing.

Joan Davis a.k.a. Joan Smith, a co-defendant in the case, pled guilty on September 17, 2003. She was sentenced on February 9, 2004 and received 37 months' confinement and 36 months' probation.

Rx Clinic

On December 3, 2003, a 108-count indictment charging ten individuals and three companies with illegally selling controlled substances and other prescription drugs over the Internet was unsealed. The indictment charges that the defendants used an "online ordering process" to allow consumers to order prescription controlled substances over the Internet, through such websites as www.get-it-on.com, without ever seeing a doctor. Defendants were charged with, among other things, conspiring to unlawfully distribute Schedule III and IV controlled substances (including weight-loss drugs Bontril, Ionamin, Phentermine, Adipex, and Meridia) without a legitimate medical purpose and outside the usual course of professional practice. Defendants include Vineet (Vincent) K. Chhabra of Florida, an owner, operator, and officer of the businesses, and Sabina S. Faruqui of Florida, an officer, manager, and operator of the businesses. Also indicted were five physicians, a pharmacist, and a partner of Chhabra's who co-owned and operated some of the websites. Various defendants are charged with money laundering, and the indictment

seeks forfeiture of \$125 million. Several defendants are charged with violating the FD&C Act by introducing into interstate commerce misbranded prescription drugs, including Bontril, Meridia, Xenical, and Viagra.

On December 19, Marvin Brown, a physician, and Luke Coukos, a pharmacist, entered guilty pleas to charges related to this case. Brown, a retired obstetrician-gynecologist, relinquished his DEA controlled substance registration, and turned in his licenses to practice medicine in Ohio and Massachusetts. Brown pled guilty to conspiracy to dispense and distribute controlled substances, and admitted that in the course of the conspiracy he authorized more than 22,056 prescriptions for Schedule III and IV controlled substance diet drugs. Coukos pled guilty to conspiracy to dispense and distribute controlled substances and to introduce into interstate commerce prescription drugs without the prescription of a practitioner licensed by law to administer prescription drugs. Coukos admitted that he personally dispensed at least 43,066 Schedule III and IV controlled substance prescriptions, and at least 9,055 prescriptions for non-controlled prescription drugs. Coukos was sentenced on March 12 to 60 months' incarceration and a \$140,318 fine. Between April and July, three other physicians and one other pharmacist charged in the Indictment pled guilty to conspiracy to distribute and dispense controlled substances, and await sentencing.

Storefront Pharmacies

FDA has taken recent actions against so-called "storefront pharmacies," which are generally walk-in businesses, sometimes associated with Internet sites, which assist U.S. consumers in ordering prescription drugs from Canadian or other foreign pharmacies and facilitate the filling of these orders. FDA is concerned about these domestic operations that are not properly licensed under state pharmacy laws, and expose consumers to a number of potential risks. As of November 2003, twenty-two states have taken, or are prepared to take, regulatory actions against storefront pharmacies that facilitate illegal imports of prescription drugs from Canada.

Rx Depot Inc.

DOJ and FDA filed an injunction on September 11, 2003, to stop Rx Depot Inc. from causing the importation of prescription drugs from Canada in violation of U.S. law. The Agency brought the suit because the storefront chain posed a risk to public health by importing unapproved prescription drugs and drugs that may only be imported by the U.S. manufacturer. Earlier in the year, FDA issued a warning letter to Rx Depot in conjunction with the Arkansas State Board of Pharmacy, but the company's response was inadequate. These drugs posed a public health risk because they do not have the same assurance of safety and efficacy as drugs regulated by FDA. Rx Depot and similar companies have incorrectly stated that FDA condones their activities and that their prescription medications are "FDA approved."

On November 6, 2003, Federal District Court Judge Claire V. Eagan, U.S. District Court for the Northern District of Oklahoma, granted a preliminary injunction to immediately

prevent the defendants from importing prescription drugs from Canada, because the importation of such unapproved drugs was a clear violation of the FD&C Act. In addition to its unequivocal findings of law, the court found that these companies could not assure the safety of the drugs they have been importing and, as a result, in violating the law, have put Americans at risk. The court stated that “unapproved prescription drugs and drugs imported from foreign countries by someone other than the U.S. manufacturer do not have the same assurance of safety and efficacy as drugs regulated by the Food and Drug Administration.” The court continued, “Because the drugs are not subject to FDA oversight and are not continuously under the custody of a U.S. manufacturer or authorized distributor, their quality is less predictable than drugs obtained in the United States.”

CanaRx

On September 16, 2003, FDA issued a warning letter to CanaRx notifying the firm of our concerns about supplying prescription drugs from unregulated sources and making unwarranted claims about these products. Specifically, FDA’s warning letter stated that CanaRx runs an Internet website and mail operation that illegally causes the shipment of prescription drugs from a Canadian pharmacy into the U.S., thereby exposing U.S. consumers to risky imported drug products. This potential risk is compounded by the fact that CanaRx makes misleading assurances to consumers about the safety of its drugs.

An FDA investigation of this firm showed that CanaRx operates a drug purchasing arrangement that channels drugs through companies that are not U.S. licensed pharmacies and does not consistently use shipping practices necessary to ensure its drugs are safe and effective. For example, FDA has evidence demonstrating that CanaRx shipped insulin, a product that should be stored under refrigeration, in a manner that did not satisfy the storage conditions specified in FDA approved labeling, and which could potentially compromise the safety and effectiveness of the insulin. CanaRx’s response to the Agency’s warning letter was inadequate, and on November 6, 2003, FDA sent a second letter reiterating our concerns about the potential safety of the product, and the firm’s business practices. The investigation is ongoing.

Expedite-Rx, SPC Global Technologies, and Employer Health Options

On January 22, 2004, FDA issued a warning letter to Expedite-Rx, a technological interface, SPC Global Technologies, Ltd., a pharmacy benefits manager, and Employer Health Options, Inc., a pharmacy benefits manager, all of Temple, Texas, notifying them that it considers their drug import program to be illegal and a risk to public health. The letter accuses the firms of facilitating illegal imports of prescription drugs from Canada and misleading the public about the drugs’ safety. Expedite-Rx, which does not hold a Texas Pharmacy license, was directed by the Texas State Board of Pharmacy last July to “immediately discontinue receiving/processing prescription drug orders.” FDA is reviewing information received from the three firms in response to the Warning Letter.

As these actions indicate, FDA will continue to work closely with its partners in the individual states in support of their efforts to curtail illegal and potentially dangerous operations, especially when they involve misleading claims about drug safety. FDA has been working closely with states and private sector entities like the online search engines to address the problem of illegal Internet pharmacy issues over the past four years to protect the public health.

MEDICARE IMPORTATION STUDY AND TASK FORCE

Last year, when Congress enacted the Medicare Modernization Act, it recognized these safety issues and included language that authorizing a program of drug importation, but only if the Secretary of Health and Human Services could certify that implementation of the program would not compromise the safety of the U.S. prescription drug supply. At the same time, Congress directed the Secretary to conduct a comprehensive study and prepare a report to Congress on whether and how importation could be accomplished in a manner that assures safety. The Department of HHS is currently working on that analysis and the Secretary has created an intergovernmental task force to steer this effort to completion.

The taskforce includes representatives from FDA, the Centers for Medicare and Medicaid Services, CBP, and DEA. The taskforce has brought together a wide variety of stakeholders to discuss the risks, benefits and other key implications of importing drugs into the U.S., and to offer findings to the Secretary on how to best address this issue in order to advance the public health. The statutory language and the conference report provide detailed, comprehensive requirements for the importation study. As an integral part of the study process, the task force held a series of six meetings to gather information and viewpoints from consumer groups, health care professionals, health care purchasers, industry representatives and international trade experts, and a public docket for comments was opened as well.

CONCLUSION

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. The employees of FDA constantly strive to maintain these high standards. However, a growing number of Americans are obtaining prescription medications from foreign sources. U.S. consumers often seek out Canadian suppliers, sources that purport to be Canadian, or other foreign sources that they believe to be reliable. Often, the imported drugs arriving through the mail, through private express couriers, or by passengers arriving at ports-of-entry are unapproved drugs that may not be subject to any reliable regulatory oversight. FDA cannot assure the safety of drugs purchased from such sources.

The vigilance of FDA and CBP inspectors is an important tool in detecting imported products that violate the FD&C Act. Given the available resources and competing priorities facing these agencies, however, experience shows that inspectors are unable to visually examine many of the parcels containing prescription drug products that arrive

through the mail and private courier services each day. The growing volume of unapproved imported drugs, which often are generated from sales via the Internet, presents a formidable challenge.

The nature of Internet technology presents law enforcement and policy makers with unique challenges. FDA is grappling with these challenges, and we must strive to carefully balance consumer access to information and products with protecting the public health. We are aggressively using our existing educational, compliance and enforcement tools to combat the proliferation of unsafe or fraudulent pharmaceuticals on the Internet, and we will continue to evaluate what changes in our procedures, regulations, or the law might be appropriate to enhance our efforts. Our goal is to ensure that the protections afforded to consumers who purchase drugs from their corner drugstore also extend to consumers in the electronic marketplace.

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

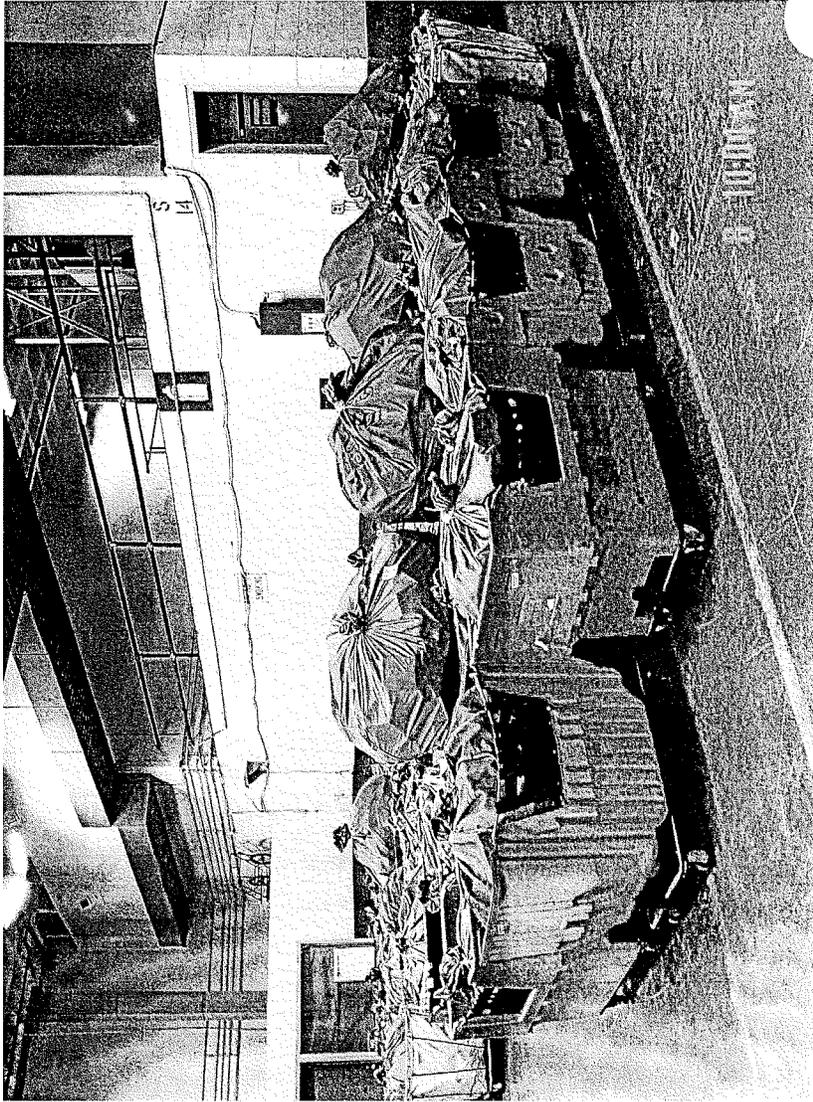
**Senate Judiciary
Committee Hearing**

July 14, 2004
FDA Exhibits









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Where is CVS.com?

Where do they
say they are?

Woonsocket, RI

Who is the registrant?

Amy St. Angelo,
CVS Contact
(401) 770-4301

Where is Amy
St. Angelo?

Woonsocket, RI

Internet Pharmacy Data

- Survey of 1,009 sites that appeared to be Canadian
- Analyzed random sample of 106 sites:
 - 47 sold Controlled Substances
 - 77 sold Restricted Distribution Drugs
 - 42 contained “FDA-approved” language
 - 94 had Liability Disclaimers

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Sample Price Comparison

Drug Name	Qty	Leading US Price	Our Price	You Save (%)
Lipitor 20 mg tabs	100	\$308.63	\$214.47	30.0%
Celebrex 100 mg caps	100	\$144.98	\$78.32	45.3%
Vioxx 25 mg tabs	100	\$248.00	\$132.84	47.4%

3 Easy Steps to Order

- 1 Search for a drug
- 2 Fill out the order form
- 3 Fax or Mail us your Prescription

In the News:

- Appalachian Pharmacies Become Fortresses
AP - Mon, July 05, 10:35 AM PT
- Clinical Trials Update: July 2, 2004
Healthday - Fri, July 2, 11:48 PM ET
- Origon Voters on Easing Medicinal Marijuana Use
Rundell - Fri, July 2, 6:59 PM ET
- Clinical Trials Update: July 1, 2004
Healthday - Thurs, July 1, 11:48 PM ET
- AARP: Drug Prices Jumped in 2004
AP - Thurs, July 1, 3:15 PM ET
- Clinical Trials Update: June 30, 2004
Healthday - Wed, June 30, 11:47 PM ET

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Where do
they say they are?

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British Columbia

Who is the
registrant?

Anton Dvorak

Where is Anton Dvorak?

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Vrbno pod Prededem
CZ
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Who is the registrant?

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Thuy

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The Path of the Canadian Generics Drugs

Where are they registered?	Dandong, China
Where was the post-mark address?	Dallas, TX
Where was the return address?	Miami, FL
Where was the credit card billed?	St. Kitts
Where was the listed phone number?	Belize

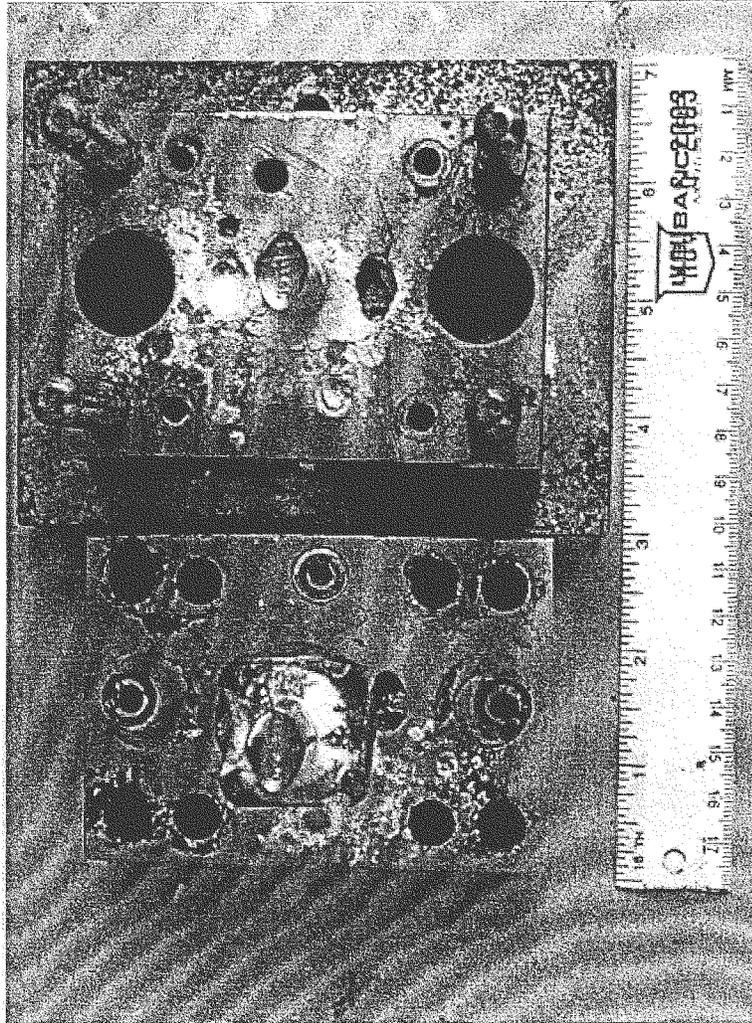
Laboratory Analysis of "Canadian Generics"

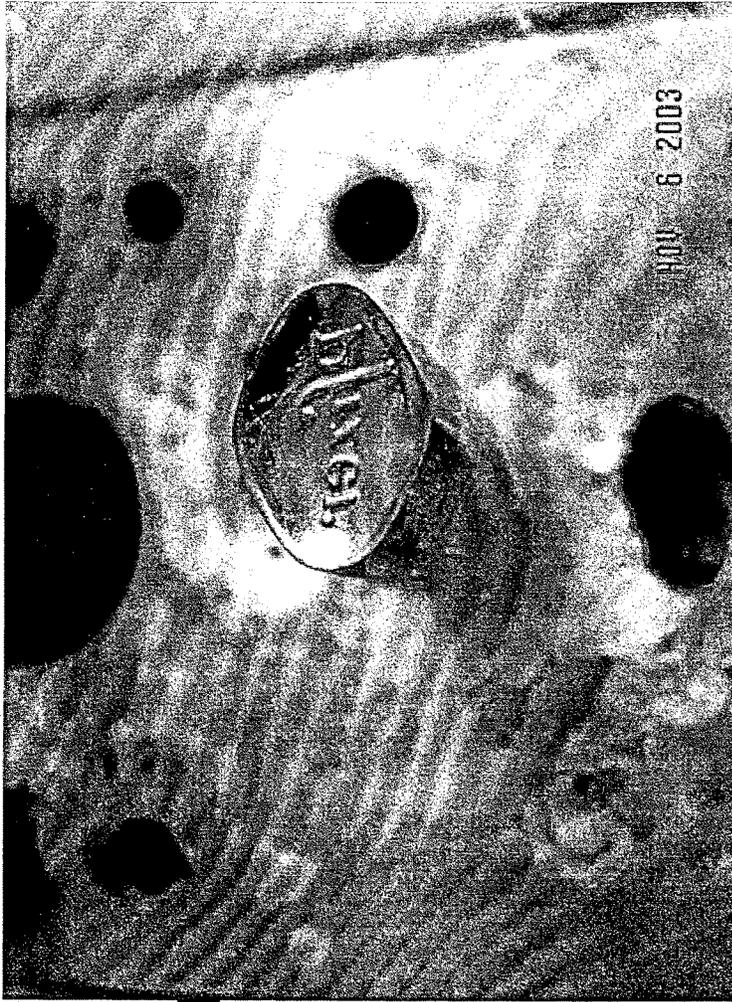
	<u>"Lipitor"</u> (20 mg)	<u>"Viagra"</u> (100 mg)	<u>"Ambien"</u> (10 mg)
Identification	Drug present	Drug present	Drug present
Potency Test (Amount)	Fail (81%)	Fail (65%)	Fail (140%)
Dissolution Test (Bioavailability)	Fail (55%)	Fail (67%)	Pass (128%)
Impurities Test (Amount)	Fail	Fail	Pass

Undissolved Calcium Tablets



Source: University of Maryland School of Pharmacy







**Testimony to the
Senate Judiciary Committee
July 14, 2004**

**EXAMINING THE IMPLICATIONS OF DRUG
IMPORTATION**

**Kathleen D. Jaeger
President & CEO**

2300 Clarendon Boulevard Arlington, VA 22201
Ph. 703-647-2480 f. 703-647-2481
www.gphaonline.org

GPhA Testimony: Senate Judiciary Committee Hearing on Drug Importation

July 14, 2004
Testimony of Kathleen Jaeger
President & CEO
Generic Pharmaceutical Association

Mr. Chairman, I am Kathleen Jaeger and I serve as President and CEO of the Generic Pharmaceutical Association. On behalf of GPHA and its members, I thank you for the opportunity to testify on the issue of drug importation.

GPHA represents manufacturers and distributors of finished generic pharmaceutical products, manufacturers and distributors of bulk active pharmaceutical chemicals, and suppliers of other goods and services to the generic pharmaceutical industry. Our products are used to fill more than one billion prescriptions every year, producing countless billions of dollars in savings for consumers, businesses, and government. Patients rely on generics to improve their lives, and the nation relies on generics to help keep U.S. healthcare affordable.

I. INTRODUCTION

For more than two decades, FDA-approved generic pharmaceuticals have played a critical role in the effort to contain rising prescription drug costs. In the early 1980's, when you and Congressman Waxman wrote the Hatch-Waxman reforms, the nation faced a health care cost crisis similar to the one it faces today. Since that time, with your help, the generic pharmaceutical industry has matured and has provided tens of billions of dollars in savings each year, while improving the health of millions of Americans.

Mr. Chairman, GPhA and all of our members are proud of our commitment to—and our success at—helping Americans access less expensive, high quality medications. Today, FDA-approved generics account for more than 51 percent of all prescriptions filled in the United States. Yet, generics represent less than eight cents of every dollar consumers spend on prescription drugs. Clearly, the existence of a healthy generic drug industry has enhanced access to affordable medications – something all purchasers should want to continue to encourage.

Nonetheless, we well understand the frustration that consumers, businesses, and health plans have with ever-increasing drug costs. As Members of Congress struggle to respond to this frustration, it is critical to make certain that any policy option considered does not inadvertently undermine incentives for generic competition OR sacrifice safety or quality of our medicines. Unfortunately, as currently drafted, we believe that the legislation before Congress on reimportation has the potential for these unintended consequences.

Many of the Members of Congress we have worked most closely with in assuring greater access to more affordable generics are now seeking to develop a workable approach to import less expensive prescription drugs from abroad. We have great respect for this bipartisan effort – whether it be initiatives drafted by Senators Dorgan, Snowe, Kennedy and McCain, by Chairman Gregg of the HELP Committee, or by Chairman Grassley of the Finance Committee.

II. RECOMMENDATIONS

However, as I will describe in my testimony, GPhA has concerns about safety, and the impact of drug importation on maintaining and assuring the continuation of: a safe and secure drug supply system; a healthy generic drug industry; and the availability of affordable generics. Because of these concerns that have not yet been addressed, GPhA has taken a position opposing reimportation. However, if Congress believes it is necessary to pursue legislation in this area, we believe the following issues need to be addressed to limit unintended and negative impacts the proposals would have on cost and quality:

First and foremost, the Food and Drug Administration (FDA) must be provided with adequate resources to ensure the safety of this nation's drug supply. GPhA would recommend that oversight of safety issues related to importing drugs should be the responsibility of the FDA, and that Congress should ensure that any importation bill is accompanied by the necessary agency funding to do this effectively. Without adequate resources and the time to train the requisite number of specialists to oversee such a critical program, the agency will be hard pressed to implement the necessary safeguards, provide the requisite oversight, and take appropriate enforcement actions to ensure that this nation's drug supply system remains secure. Consumers should be confident that the same strict standards that the regulators require for domestic brand and generic drugs will be in place for imported drugs as well. We believe that FDA must have sufficient oversight over all drug importations in order to prevent this nation's drug supply chain being vulnerable to an influx of inferior and/or potentially dangerous medicines. Adequate patient safeguards therefore must first be in place to assure that unregulated imported products meet all applicable U.S. standards as a prerequisite of importation.

In testimony before the HHS Task Force on Drug Importation earlier this year, several panelists reviewed the severity of the prescription drug counterfeit issue facing multinational brand manufacturers. Counterfeiting is not a problem found only in developing countries; it has become a growing problem all over the world. Counterfeit prescription drugs have been repackaged and reformulated in foreign countries and then introduced into legitimate distribution channels. Counterfeiting activities are well-orchestrated business enterprises, with the intention of diverting products for *robust* markets, such as the United States and Australia.¹ Given the gravity and breadth of the worldwide counterfeiting epidemic that plagues the pharmaceutical industry even under the current system, adequate safeguards must at a minimum, remain intact.

Secondly, GPhA would recommend that the importation program should be limited to those drugs that will actually provide cost savings to health care consumers—brand drugs with no

¹ John Theriault, Testimony before the HHS Task Force on Drug Importation, April 5, 2004.

generic competition. Permitting the importation of generic drugs has great potential to be counter-productive. U.S. generic drugs are not only cheaper than potential imported brand drugs, but as several reports suggest, U.S. generic drugs are generally more affordable than generics in Canada and other industrialized countries.² Thus, it seems counterintuitive to permit entry of branded and generic imports if there is a less expensive generic already available to consumers here at home. Accordingly, any proposal to loosen the restrictions on imports should take into consideration the cost savings already available through U.S. generic drugs. Additionally, the resources given to the FDA to inspect and regulate imported drugs would better utilized on a limited sample of the drug market to minimize safety concerns and administrative burdens. If we permit the importation of generic drugs and their brand counterparts, we will in effect, be encouraging the use of prescription drugs which may be more costly than the generic drugs available in this country while substantially adding to the burden placed on FDA by importation.

Thirdly, while we would prefer that the imported drugs be required to be therapeutically equivalent, we strongly recommend that if an imported drug is therapeutically inequivalent to the FDA-approved domestic brand drug, consumers should be made aware of the difference through product labeling. To be therapeutically equivalent, the drug must not only have the same active ingredient or ingredients, route of administration, dosage form, and strength as its counterpart, it must also be bioequivalent. Generic drugs are required to be therapeutically equivalent to the referenced brand drug before they can be considered by FDA to be interchangeable for their FDA-approved domestic brand counterparts. Being therapeutically equivalent allows the generic to be substituted with the brand without any adverse effects to the patient. Thus, if an imported brand is not considered to be therapeutically equivalent to its domestic alternative, FDA should be provided the authority to label drug products accordingly to ensure that health care professionals and consumers are empowered to make well-informed decision before switching between medication products.

Lastly, any importation program should protect the important balance between innovation and access to generics by prohibiting importation during the 180-day exclusivity period for generic companies. By allowing importation during this vital period, current importation proposals could undermine the well-crafted compromise that provides the critical incentive for generic companies to challenge invalid patents and bring affordable medicines to the market years ahead of the expiration date of the invalid patent. The 180-day period has been an extremely important reason why the generic industry has thrived over the past 20 years by bringing consumers accelerated access to affordable medicines. Changes enacted under last year's Medicare Modernization Act were designed to restore its original value and effectiveness. Through patent challenges, generic drugs have bought billions of dollars of savings to consumers. For example, in just one case, Prozac, a challenge brought generic competition to the market three years early, saving \$2.5 billion on that drug alone. However, if the importation of foreign drugs (which may not be therapeutically equivalent) is permitted during the 180-day

² Palmer D'Angelo Consulting Inc. Report Series, "Generic Drug Prices: A Canada-US Comparison," August 2002
John R. Graham and Beverly A. Robson, The Fraser Institute, "Prescription Drug Prices in Canada and the United States - Part I: A Comparative Survey," Public Policy Sources, No. 42 (2000) pp. 3-5

period, it will undo the carefully crafted balance between innovation and access that Congress has worked so hard to achieve.

III. IMMEDIATE AND AVAILABLE SOLUTIONS FOR LOWERING PRESCRIPTION DRUG COSTS

Although the debate about importation continues, there are steps that can be taken now to immediately reduce prescription drug costs. Generic pharmaceuticals are a safe, reliable solution to the problem of increased costs of prescription drugs. Increasing access to and utilization of generic drugs would benefit all consumers, businesses, and government purchasers, through lower out-of-pocket and insurance costs.

The tools to immediately increase generic drug utilization and the savings it provides include, but are not limited to: (1) solidifying a definitive, efficient pathway for affordable biopharmaceuticals; (2) mandating the use of therapeutically equivalent generics in all federal and state programs; (3) removing all needless generic substitution carve outs in federal and state programs; (4) having generic approvals be an Administration priority, which provide for agency consults, legal and scientific issues resolved in a timely fashion; (5) conducting scientific research to support the approval of nonsystematic generic medicines; (6) substantially improve the funding for and staffing of the FDA's office of generic drugs; and (7) educating consumers of the value of generic medicines.

FDA plays an important role in ensuring that American consumers have access to generics through its generic drug review and approval process. Yet, the Office of Generic Drugs, which is responsible for the approval of generic medicines, does not receive adequate funding. This is significant given that the number of generic drug applications continues to rise significantly, while the number of new drug applications is declining. Equally important is the fact that the review and approval of generic applications currently takes longer, on average, than the approval of new drugs, potentially delaying consumer access and savings. We urge the Senate to include a similar increase in funding for the OGD that was included by Representative Emerson in the House Agriculture appropriations bill. Congress and the Administration need to address the issues of increasing the resources necessary to approve generic drugs more efficiently, and of making generic approvals a priority, rather than creating an expensive new regulatory mechanism to monitor the importation of unregulated drugs.

Additionally, as Senator Hatch and the Senate Judiciary Committee recognized last month when discussing generic biopharmaceuticals, Congress and the Administration must focus attention on establishing a definitive process pursuant to which generic versions of expensive biopharmaceuticals can receive FDA approval. Last year, biopharmaceuticals cost payers more than \$21 billion. Generic versions of these important, but expensive drugs would contribute additional billions of dollars a year in prescription drug savings.

Lastly, the Administration and states also could work together to ensure that aggressive generic substitution tools are employed in state Medicaid programs. States could garner

additional savings by implementing aggressive generic substitution tools to other state senior supplemental programs and employee health programs.

IV. AUTHORIZED GENERICS

Finally, Congress and the Administration need to address the issue of "authorized generics" because they undermine the 180-day generic exclusivity period which encourages generic manufacturers to challenge weak and questionable patents. Successful patent challenges significantly accelerate consumer access to affordable medicines. The practice of "authorized generics" involves brand companies licensing the distribution rights of their product, which has been the subject of a patent challenge, to generic companies that then can market the product during a 180-day generic exclusivity period that has been won by the first generic company challenging the patent. This could effectively remove the economic incentive for the company undertaking the patent challenge. GPhA urges Congress to explore and consider this issue.

V. INTERNATIONAL TRADE AGREEMENTS

GPhA is committed to a balance between innovation and access. To that end, we are committed to innovation in medicines and the preservation of intellectual property protections both in the United States and abroad. With this fragile balance as our main concern, we strongly believe that it is essential that new trade agreements take into consideration existing U.S. measures relating to the accessibility of affordable pharmaceuticals. New trade agreements, such as the one currently being considered with Australia, could potentially affect American consumers' access to affordable drugs as well as the business interests of the U.S. generic pharmaceutical industry. As evidence to support our concern, we need only look at the fall-out of the harmonization efforts relating to TRIPS. A study conducted by University of Minnesota Professor Stephen Schondelmeyer concluded that the cost of the TRIPS harmonization efforts would "exceed six billion over the next two decades." The study also suggested that "[t]he annual generic savings lost by American consumers due to delayed generic entry [as a result of TRIPS] will range from \$200 million in some years to over \$500 million in other years."³ Accordingly, if trade agreements contain certain provisions that promote innovation, yet are devoid of other essential provisions that foster access to generics, or contain export prohibitions that restrict access to bulk pharmaceuticals and other materials used to manufacture U.S. generic pharmaceutical products, American's access to affordable medicines could be severely harmed as a result of future harmonization measures.

VI. SUMMARY

In summary, GPhA believes that the debate around reimportation legislation is the logical conclusion of a continued frustration with rising brand name drug prices and utilization in this

³ S. Schondelmeyer, "Economic Impact of GATT Patent Extension on Currently Marketed Drugs," PRIME Institute, University of Minnesota, March 1995.

country. We question whether pursuing such a policy would most effectively address the underlying problems the nation faces in this area. We believe there are a number of policies worthy of Congressional and Administration consideration, including policies that incentivize generic utilization, which would make a substantial contribution to our shared goal of assuring affordable quality medications for the American consumer. If Congress is to pursue reimportation legislation, however, we strongly believe that it must address some of the flaws of the current pending bills. We look forward to working with you and all interested Members from both parties in this regard.

STATEMENT OF SENATOR EDWARD M. KENNEDY
IMPORTATION OF SAFE AND EFFECTIVE PRESCRIPTION DRUGS
July 14, 2004

I thank the Chairman for holding a hearing on this important issue.

The current rules on importation or reimportation of FDA-approved drugs manufactured in FDA-approved plants are indefensible and unsustainable. They prohibit anyone except a drug manufacturer from importing drugs into the United States. They create a shameful double standard under which Canadians, Europeans and other foreign patients can buy American drugs at affordable prices, while drug companies charge exorbitant prices to American patients.

The central issue is fairness for millions of Americans struggling to afford the soaring cost of prescription drugs. Americans understand fairness. They know it's wrong when American patients buy the same prescription drug and pay sixty percent more than the British or Swiss, two-thirds more than Canadians, 75% more than Germans, and more than twice as much as Italians.

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

The Pharmaceutical Market Access and Drug Safety Act—S. 2328—will give American patients a fair deal at long last. Our proposal will legalize imports of safe U.S.-approved drugs manufactured in U.S.-approved plants. It will enable U.S. consumers to buy FDA-approved drugs at the same fair prices as they are sold abroad.

The drug companies and the Bush Administration argue that imported drugs threaten the health of American consumers because of the possibility of counterfeiting or adulteration. We are likely to hear some of these same arguments made at this hearing. But under our legislative proposal, that argument isn't credible. Our program will actually provide American patients stronger protections against counterfeit drugs than they have today.

Our legislation sets up iron-clad safety procedures to guarantee that every drug imported legally into the United States is the same FDA-approved drug originally manufactured in an FDA-approved plant—whether the drug is manufactured abroad and shipped to the U.S., or whether it is manufactured in the United States, shipped abroad and then imported back into the United States.

Compare our rigorous requirements with what happens today. Fraudulent dealers throughout the world can set up web sites or otherwise advertise low cost drugs and claim to be Canadian pharmacies. Individuals have no way of knowing whether they are purchasing safe or unsafe drugs or whether the seller is legitimate or not. All sales are equally illegal, and the only rule is let the buyer beware.

The FDA will testify today, as they have in the past, to the Wild West dangers that American consumers face every day under the current rules. As long as it is illegal to buy safe drugs at low prices, the trade in unsafe drugs will flourish. As long as we bury our heads in the sand and fail to act to guarantee the availability of safe and legal imported drugs, millions of American patients will continue to risk their health on potentially unsafe, unapproved, and counterfeit drugs. Our bipartisan legislation not only gives consumers access to drugs at prices they can afford, it protects them against the danger of the essentially uncontrolled and uncontrollable counterfeit drugs they face today.

It is because of the rigorous safeguards in our bill that Dr. David Kessler, who served under both Republican and Democratic Presidents as Commissioner of the Food and Drugs has stated that our amendment “provides a sound framework for assuring that imported drugs are safe and effective.”

It is because of these provisions that Dr. Philip Lee, one of the nation’s leading authorities on prescription drugs, a physician who has served as the Assistant Secretary of Health under two Presidents, and a former Chancellor of the University of California at San Francisco, has stated, “I conclude that [the bipartisan legislation] will reduce rather than increase the likelihood of counterfeit drugs entering the U.S. supply chain from abroad and that drugs imported under the program will meet FDA standards for safety and effectiveness.”

When it comes to imported drugs, safety is the first responsibility—and it is a responsibility that our bipartisan amendment fulfills. But legalizing safe drugs imports is only half the battle to bring fairness to the prices that consumers pay. Legalization is meaningless unless it is backed by strong measures to prevent drug manufacturers from manipulating the market to subvert the law.

Already, large American drug companies are retaliating against imports from Canada by limiting the amount of drugs they will sell to Canada and denying drugs to pharmacies that re-sell them to American patients. A few weeks ago, a group of senior citizens was forced to cancel a bus trip to Canada because the Canadian pharmacies they relied on for affordable drugs were effectively shut down by the big U.S. drug companies.

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

Any proposal that does not include comparable protections is a fig leaf, not a solution.

Year in and year out, drug industry profits are the highest of any industry in the United States.

Yet year in and year out, patients are denied life-saving drugs because those astronomical profits are possible only with astronomical prices—prices that drug companies can’t charge anywhere else in the world because no other country in the world would let them.

A broad coalition of groups representing senior citizens and consumers have endorsed our bipartisan proposal. It's time to end the shameful price gouging. It's time for basic fairness. It's time for this Congress to pass a real drug import bill.

Statement
United States Senate Committee on the Judiciary
Examining the Implications of Drug Importation
 July 14, 2004

The Honorable Patrick Leahy
 United States Senator, Vermont

“Examining the Implications of Drug Importation”
 Senate Judiciary Committee
 July 14, 2004

Mr. Chairman, I agree that this is an issue with profound implications for the American public. Vermonters were among the first to throw a spotlight on the issue of prescription drug importation, and we have followed this issue closely for many years and have pushed for consumer-friendly solutions. I am pleased that now, we in this Committee, have the opportunity to restate the very compelling case for the establishment of a safe, legal system to import affordable drugs into the United States. I regret that the Senate Republican leadership has obstructed the path to a solution for so long.

A Lifeline, Not A Luxury

Americans pay some of the highest prices for prescription drugs of any country in the world – despite the fact that many of these drugs are made right here, and they are often made with the benefit of taxpayer supported research. Prescription drugs are a lifeline, not a luxury. Faced with this dilemma, and with Washington’s unwillingness to help, many Vermonters and other Northern Border citizens were among the first to take matters into their own hands. On buses, Congressman Sanders started leading trips to Canada five years ago to let Vermonters safely buy affordable medicines on the other side of the border, where struggling seniors are able to find savings of anywhere from 50 percent to 70 percent. Buses like this were powerful early symbols in opening this debate. And they have been effective, much like Senator Dorgan’s use of his famous orange rubber pylon in demonstrating the lack of security along the Northern Border.

Voting With Their Bus Tickets

American consumers didn’t take long to figure out that the deck is heavily stacked against them, and they have found ways like this to vote with their pocketbooks and with their bus tickets. Meanwhile, the White House, big drug companies and many in Congress have done all they can to thwart each consumer breakthrough.

Those trips worked for awhile, but for seniors who couldn’t easily make the trek across the border, there had to be another option. That is where mail order entered this equation, and by now mail order has drastically transformed the importation of medicine, and it has also become a powerful new catalyst for reform. The fact is a bus trip across the border is not the way Americans should have to get affordable medicine prescribed by their doctors. And the fact that American consumers have had to resort to creative solutions like this long ago should have shamed Congress and the White House into action.

In my home state of Vermont, our Republican Governor, our Democratic Attorney General and the Mayor of our largest city have all spoken out on the unmet needs of the people of our state, and to offer their help to the federal government in designing workable systems for prescription drug

http://judiciary.senate.gov/print_member_statement.cfm?id=1264&wit_id=2629

8/15/2008

importation. But their pleas, and those of state and local government officials all across the country, have been met with obstinate resistance.

Raw Deals, Life-And-Death Choices

At the same time, American consumers are moving ahead with or without us. They know when they have been dealt a raw deal. They see this raw deal in black and white each month when they sit down at their kitchen tables to pay the bills. The issue boils down to access: A prescription drug is neither safe nor effective if you cannot afford to buy it.

We have to recognize that this imposes real dangers on American consumers when they cannot follow their doctor's treatment plan because they can't afford their medicine. While we must do more to bring affordable healthcare to the millions of Americans who are currently uninsured or who do not have good coverage, we cannot continue to deny them this immediate market-based solution.

For many Vermonters, purchasing drugs from Canada literally means the difference between following their doctors' orders or having to throw the dice with their health and sometimes even with their lives by doing without their prescription medicines. It makes the difference for the woman who has maxed out her health plan's annual prescription drug benefit only three months into the year and is then faced with purchasing the other nine months worth of medicine at U.S. prices on her own. It makes the difference for the elderly man on a fixed income who is unable to afford both the heart medicine he needs to live, and the gas bill he needs to keep warm. As regulators and policymakers sit idly by in Washington, the pharmaceutical industry is moving to cut off supplies to Canadian pharmacies in order to prevent Americans from purchasing their drugs at affordable prices. Are we prepared to tell those in dire need that they must go back to choosing between paying gas, food, and heating bills, or their medicine?

We owe it to American consumers to stop asking whether we can set up a system to provide safe and affordable prescription drugs from Canada and to promptly devise a system that answers the question of how we do that. Fortunately, we can do it and we have a bill before us that will do it. It comes down to a matter of political will. American consumers were ahead of their Government. They have already proven that importation works. We should be coming together without further delay to establish a self-financed system that will give FDA and Customs the resources they need to afford Vermonters and all Americans access to legally imported safe, FDA-approved prescription drugs from Canada.

We in Congress have put our stamp of approval on allowing American consumers to purchase prescription drugs from Canada three times over the past four years and yet each time those efforts have come up short because of the objections by many in the Executive Branch and their friends in the drug industry. I am hopeful that this hearing and the long awaited markup before the Senate HELP Committee scheduled for next week will finally move us toward a workable solution.

Leverage For Average Consumers

At every turn, American consumers are finding that the big pharmaceutical firms have all the leverage. The Bush Administration fought every effort we made during debate on the Medicare prescription drug bill to give some leverage to consumers and taxpayers. And the critical issues of safe and reasonable drug importation are not being played out just at the FDA and in Congress. Now the White House's trade negotiators have become involved, and I am concerned that they have not acted to improve the situation.

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8/15/2008

New Trouble In A Trade Agreement

In the last few days, some very troubling – and unpublicized – provisions in the proposed free trade agreement with Australia have come to light. That agreement, as negotiated by the Administration, seems to pose real threats to drug importation. It contains new provisions, not found in earlier agreements with other countries, that would appear to give new rights to pharmaceutical companies at the expense of American families. It may also allow for the creation of new barriers to the importation of low-cost prescription drugs. And it gives giant drug companies the opportunity to delay the availability of generic alternatives to their patented products. These provisions raise serious concerns, and they threaten new and more dangerous precedents for subsequent trade agreements regarding prescription drugs being negotiated by this Administration. On behalf of America's consumers, we need to fight for the availability of low-cost generic drugs and for the importation of low-cost prescription drugs -- in the Senate, before administrative agencies and in this Administration's trade negotiations.

We have a number of capable witnesses this morning. I welcome Senator Dorgan and Senator Breaux. We appreciate your leadership Senator Dorgan on this issue and the work you have done with Senator Stabenow, and we are always delighted to hear from the senior Senator from Louisiana. It should be no surprise that I am a cosponsor of Senator Dorgan's legislation on drug importation, as are a number of this Committee's members and, I believe, a large portion of the Senate. I look forward to hearing from a leader on this important issue in the House of Representatives, the distinguished Congressman from the State of Vermont, my friend Bernie Sanders. Those of you on the Committee who have not had the pleasure of working with Congressman Sanders are in for a treat.

Mr. Hubbard, Mr. Taylor, and Ms. Durant, thank you for coming up to the Hill today. Mr. Mayor, welcome, it is good to see you again. I also look forward to hearing from Mr. Catizone and Ms. Jaeger and I am pleased that Ms. Disch of AARP and Professor Schondelmeyer could be here with us this morning as well.

Finally, I want to extend a particularly warm welcome to a fellow Vermonter who is here to testify on our third panel. Dr. Elizabeth Wennar is the CEO and Executive Director of United Health Alliance of Bennington, Vermont. Her organization, which is made up of community physicians, a rural hospital, a nursing home and a home health agency in Southwestern Vermont, was a pioneer in importing prescription drugs from Canada by mail. She has also done extensive research on prescription drug importation and has previously testified before Congress on this issue. Dr. Wennar, I appreciate your coming to Washington today to share your considerable expertise.

Testimony of Representative Bernard Sanders
Before the Senate Committee on the Judiciary
Wednesday, July 14, 2004

Mr. Chairman, thank you for welcoming me to address this very timely and important hearing. As the first member of Congress to take constituents over the Canadian border to purchase prescription drugs at a fraction of the price charged in the U.S. and as the Representative of a state in which large numbers of seniors regularly purchase prescription drugs from Canada, this issue is obviously of huge importance to me. This issue is not just about whether Americans will be forced to pay the highest prices in the world for prescription drugs - it is about whether Congress will turn its back on tens of millions of Americans who desperately need lower prices for the medicines they rely on each day to survive and instead succumb to the hundreds of millions of dollars spent by the industry on campaign contributions, political advertising and relentless lobbying.

This is not just a health issue - it is one about whether Congress represents the interests of the people of this country. The pharmaceutical industry year after year is the most profitable industry in the world - by far - and has paid its CEOs as much as \$150 million in a given year. And, year after year, our people are forced to pay two and three and sometimes even ten times what Canadians are charged for the exact same prescription drugs. I will not ever forget the trip I took to Montreal in 1999, where women who were struggling with breast cancer were able to buy Tamoxifen, a widely prescribed breast cancer drug, at one tenth the price they were forced to pay at home. This, Mr. Chairman, is nothing short of a moral outrage and if the industry had any shame whatsoever it would have discontinued such egregious price-gouging on its own years ago.

Yet it hasn't - and it is the responsibility of Congress to reign in the insatiable greed that consumes this runaway industry. American prescription drug prices - already outrageous - rise at roughly fifteen percent every year and, without action from us, there is no end in sight. Meanwhile, according to a Kaiser Family Foundation report, almost twenty-five percent of seniors do not fill or skip doses of their prescription drugs in order to make their medicines last longer, and, for those without drug coverage, that number goes up to over thirty-three percent.

The simple truth is that the pharmaceutical industry lies a lot. They set up phony seniors' organizations and they have over 800 well-padded lobbyists from both parties who are prepared to descend on Congress at any given hour to protect the profits of the drug giants. The two big issues they repeatedly harp on in opposition to drug importation are the supposed safety threat presented by a reimportation system and the threat such a system would pose to the research and development of new prescription drugs. Let me briefly respond to both of these common charges.

Last year, William Hubbard, a senior official with the FDA and one of the leading critics of reimportation, testified before a Government Reform subcommittee on which I

serve. When asked if he could cite one example of an American consumer who had been harmed by a prescription drug purchased on the Canadian market, he responded, and I quote, "I know of none." Then, as now, the industry and, pathetically, the FDA, were spending huge amounts of money talking about safety threats while they could not even name one individual who had been harmed by such purchases – despite that more than one million Americans are regularly buying on the Canadian market. Some safety threat.

Also last year, I requested a report from CRS that confirmed that the drug markets in the United States and Canada are regulated in virtually identical ways from manufacturing and importation to labeling, distribution and sales. Every prescription drug manufacturer, wholesaler, and distributor in Canada must be licensed by the federal government, and every pharmacy and pharmacist must be licensed by their provincial government. All Canadian prescription drug manufacturing facilities and distribution facilities must meet strict Good Manufacturing Practices and Canada maintains strict chain of custody requirements. All prescription drugs on the Canadian market must be approved for sale to Canadian consumers and must include contact information of every company that has handled the product along the chain of distribution. Again, I say some safety threat!

Reimportation or its equivalent, "parallel trade" in pharmaceuticals, has taken place regularly in Europe and many other parts of the industrialized world for over 25 years with none of the problems conjured up in the scare campaign of the industry. Further, I would simply add the safety argument represents the ultimate in hypocrisy. Only in an institution so thoroughly corrupted and dominated by big money interests could those who swear on the altar of free trade tell us regularly how great it is that we can safely purchase fruits and vegetables from tens of thousands of farmers in dozens of countries and safely purchase beef and pork and poultry from farms all over the world, while simultaneously maintaining that the FDA cannot effectively regulate the flow of drugs from a handful of well-regulated pharmaceutical markets in the developed world. Nobody seriously believes this transparent pharmaceutical industry lie, Mr. Chairman, and I urge your committee to reject it.

In terms of the "threat to research and development" argument, the industry is lying once again. The taxpayers of this country regularly fund the most fruitful pharmaceutical research and development in the world and simply hand it over to the drug giants for free. Our taxpayers directly fund nearly all R&D conducted in the U.S., both through our financing of the National Institutes of Health as well as through generous tax breaks given to the industry for the research it conducts on its own. In return, the industry charges these very taxpayers anything they will please for desperately needed life-saving drugs.

The industry often claims that it costs an average of \$800 million to bring a product to market, though they refuse to produce documentation of such expenses. Others who watch the industry closely estimate that the true cost is closer to \$200 million. Why must our citizens be gouged at every turn when this same industry manages to turn sufficient enough profit in European countries - where governments put

reasonable limits on drug prices - to continue to conduct significant levels of research and development there? This industry refuses to make clear to Congress or anyone else how much they really spend on research and development for drugs we need for cancer and heart disease and high blood pressure. Yet the suspicion is that much of their so-called R&D dollars go to developing "me-too" drugs that make minor changes – often merely cosmetic changes – to existing drugs in order solely to give one drug maker or another a bigger share of the market.

In short, I hope the Senate will reject the scare tactics of the pharmaceutical industry and instead stand up for the interest of regular Americans who are struggling to afford their medicines. Let the United States Congress have the courage to do what the rest of the industrialized world has done and tell the industry that they may no longer corner our sick and dying into an isolated, monopolized market and force them to pay "whatever the market will bear" for medicines they need to simply survive.

Mr. Chairman, thank you again for this opportunity to share my views.

**Testimony of
Dr. Elizabeth A. Wennar,
President and CEO, United Health Alliance
Bennington, Vermont
and
Principle, Health/nova,
Manchester, Vermont
Testimony
Before the Committee on the Judiciary
United States Senate
Hearing on
(Re)importation of Prescription Drugs
July 14, 2004**

Mr. Chairman, and Members of the Committee:

Thank you for inviting me to discuss (re)importation of prescription drugs.

Today's healthcare market presents many challenges. None is more controversial than that of technology in the form of a "pill". Pharmaceutical spending has almost doubled in less than a decade. More often than ever, our policymakers and physician providers are being queried as to why it is that Americans must pay many times more for their medications than their counterparts in other countries? As you know, over the past few years many of your constituents have been purchasing their medications from Canada. For these individuals, these medications are now affordable and even more importantly safe. From a pure medical standpoint, the most important part of a treatment plan that is intended to produce the best possible outcome for a patient, is the patients ability to comply with what 's prescribed by their provider/physician. Any medication, as part of a prescribed treatment plan, that is not affordable and therefore not accessible, is neither safe nor effective.

Quality and Compliance

Many of the recent conversations around (re)importation have focused on quality and safety issues. As providers of care, no one knows better than physicians and pharmacists how important quality is in the process of providing care. Quality can be defined in many ways, in this instance I want to discuss the importance of compliance for an individual/patient. When a physician/provider prescribes a medication as part of a treatment plan, they assume that the individual will have access. Many do so because they [the provider] have used samples provided to them at no costs to give to their patients. So, when they have a patient that responds well to a particular medication provided as a sample, they do naturally what comes next in the process...write a prescription

for the medication. Unfortunately, medications supplied as samples, in general, are the very ones that are not affordable.

Clearly as a provider network, our major concern is the ability of patients to comply with a given treatment plan. When a patient cannot afford their medications it is costly for all of us. Are physicians concerned about quality? Absolutely. And there is a quality issue and exist on this side of the border. When a patient cannot take their medications, they most definitely will consume services elsewhere in our system, such as the emergency room or by being admitted to the hospital. That simply is not rational. This is not about people that won't comply with a treatment plan, this about individuals that can't afford to purchase prescription drugs in the country they live in. Also, let's keep in mind that we are talking about Canada not some third world country. Having said this, these individuals are willing to take the risk associated with accessing their medications across the border. Many of them have told us that there is certainly no more risk in doing this than they are at by not taking their medications as prescribed or not at all.

Let's talk about quality and safety. I would ask you to reflect on when the last time was that you witnessed an armored vehicle delivering medications from manufacturer to the community pharmacy in this country. This is an extreme example, but I would like to make a point about safety under the guise of quality. Much propaganda has surfaced over (re)importation of medications from other countries, particularly Canada. This attempt to frighten individuals that are already terrified of compromising their health by not being able to take their medications, creates a form of terrorism that is inexcusable. Some would have you believe that Canada's pharmaceutical supply is unsafe and of inferior quality. Ads placing pills side by side and questioning which one is the counterfeit drug and poisonous snakes around medication bottles, is a poor use of valuable resources and intended to produce fear (**Exhibit A,B, C**). It does nothing to help address the problems associated with access.

Facts/Observations:

- ✓ Parallel trade has existed safely in the EU for years. There is no evidence that parallel trade promotes counterfeiting when the appropriate controls and regulatory processes are established. (**Exhibit D**)
- ✓ (Re)importation from Canada exist. The U.S. consumer has taken upon themselves to demonstrate it works. Millions are currently utilizing as a means to comply with their treatment plans. (**See Map displayed during testimony**)
- ✓ The Canadian system is well regulated and safe (**Exhibits E,F,G**)
- ✓ Canada (as does) other countries) has the equivalent of the FDA with regard to oversight
- ✓ Customer satisfaction and compliance for those using (re)importation from Canada appears high
- ✓ Physicians engaged in the process. Compliance results in better outcomes and potentially lower costs to the overall system.

- ✓ Guidelines and standards can be [and have been] established for the oversight of mail-order. Accreditation process must be much broader than just the marketing via the internet (**Exhibit H**)
- ✓ U.S. Consumer created the mail-order industry in Canada. Legitimate mail-order in Canada welcomes standards and the regulatory process needed to provide safety controls for U.S. citizens protection from unscrupulous providers via mail-order. Particularly for "lifestyle, me-too" medications and controlled substances (**Exhibit I**)
- ✓ The community-based pharmacists must be re-integrated into the health management plan (mail-order has carved the community-based pharmacist out as a provider of quality oversight)
- ✓ Recent reports surface that make reasonable arguments for legislation to be passed (**Exhibit J,K,I GAO,AARP and Sagar**)
- ✓ Legislation is necessary to provide standards and oversight for what already exist

Background on United Health Alliance

United Health Alliance is a nonprofit physician-health system organization located in Southwestern Vermont. Our partners include a rural hospital, nursing home, home health agency and just over one hundred (120) community physicians. We serve residents of Vermont, New York and Massachusetts. Our mission is to promote a physician-driven organization whose principle services are to provide advocacy and leadership in the areas of care management, contracting, performance improvement and educational programs to maximize value for our physician-hospital membership and customers [patients]. Although we have committed to ten (10) guiding principles, none is more important to us than assisting the communities we serve at becoming the healthiest in the nation. Several years ago we found that although admirable, this objective was going to be very difficult to achieve given the circumstances that existed for some of our elderly and uninsured/underinsured. Very simply, they did not have access to affordable prescription drugs, therefore they were not able to comply with the treatment plans prescribed by their physicians. Although we had individuals that were seeking affordable medications via bus trips to Canada, we knew that this was not an option for the majority of the communities we serve by virtue of their medical condition and/or their limited resources. One of our physicians came to us and requested our assistance at investigating how we could help a patient of his with breast cancer from Massachusetts access her medications from Canada without having to get on a bus. Today that patient takes her medications because she can afford them. It cost her ninety (90) percent less in Canada. We compared the costs for 145 seniors for the first six months to see if what we had heard about the differences in pricing was in fact true. While these individuals would have had to pay just over \$81,000 in the U.S., they paid approximately \$22,000 for their medications in Canada (**see Exhibit M**). Our

understanding is that there were no substitutions for the medications they were currently on. All medications accessed were for the treatment of chronic diseases such as diabetes, heart disease and cancer. A price comparison of some of the more commonly prescribed medications for the treatment of these diseases has been provided along with this testimony. Although there is minor variation with some pricing in Canada, the savings are still significant and have been reported anywhere from thirty (30%) to (95%) percent (**see Exhibit N**) [**Note: These prices have changed since supply has been cut to some pharmacies and wholesalers**]. Although the majority of the individuals that accessed their medication from Canada were the elderly on fixed incomes, with no prescription coverage, many individuals that have depleted their pharmacy benefits also are now accessing their medications from Canada. As we have conversations with employers located in the communities we serve about benefits and coverage for their employees we find many are concerned about how to continue the level of coverage they currently provide, particularly with the growth in their expenditures for prescription drugs. The implications are frightening for all of us.

Compliance: Physicians assume that when they prescribe a medication (write a script) that the patient will take their medication as prescribed. They don't have any interest in where you get it filled. This is not to say that they would not be concerned if they thought there was a safety or cost issue. They are concerned about compliance with regard to a prescribed treatment plan.

FDA Site Visit: The FDA completed a site visit/audit of the UHA initiative on July 22, 2002. No notice to cease and desist was issued. Additional information can be provided to the Committee upon request.

Conclusion/Recommendations

Personal re-importation has for all intensive purposes, been implemented by the American consumer. It may or may not be a long-term solution, but it does provide an option until we can provide appropriate levels of coverage (access). Long-term viability will depend on the development of a program that can be implemented not just signed into law [as evidenced by MEDSA 2000].

Barriers to access are unacceptable. (Re)importation of prescription drugs is working as a mechanism for access of affordable prescription drugs. Should the current process be improved upon ...absolutely! Should there be controls in place to monitor quality of those involved...absolutely!

Clearly, there is no simple answer with regard to the issues we are discussing. Barring any type of regulation of the pharmaceutical industry on this side of the border, personal (re)importation from Canada under controlled circumstances can provide an interim solution for those in need of access to affordable prescription drugs.

The passage of S2328 (The Pharmaceutical Market Access and Safety Act of 2004) with the incorporation of standards requirements for participation is essential to protect what has already been established by the U.S. consumer. I believe that all the intent of S2464 (Internet Pharmacy Consumer Protection Act) can be achieved by including language on standards requirements. The marriage of these two pieces of legislation is essential to the establishment of a "good health policy".

Epilogue

FDA Oversight

From the perspective of safety and oversight clearly the FDA [and other agencies] must be concerned as to how any initiative that would involve re-importation of prescription drugs would be maintained under their current charge. Although challenging, it can be done. With regard to Canada it would not be that difficult to do. The following could/should be considered:

1. In order to maintain and provide an efficient means of oversight by the FDA, all participating pharmacies would be registered with the FDA. In order to do so, they would have to be accredited, much the same as the Joint Commission (JCAHO) accredits hospitals and other health institutions here in the United States. After meeting a set of quality standards the mail-order pharmacy would be awarded accreditation and allowed to register with the FDA. They would then be listed as approved as foreign participating mail-order. Once all requirements are met, the FDA or another entity, would issue non-counterfeitable seals/emblems for these pharmacies to use when shipping packages into the US (through Custom). No seal, no entry in to the U.S. (suggest the system currently used by the U>S. Treasury to protect U.S. currency)

Note: Flex Products is a world leader in the development of optically variable technology for counterfeit deterrence. Their Optically Variable Pigment (OVP) security technology is currently utilized by over 87 countries, including the US and the newly designed \$10, \$20, \$50 and \$100 bills.

2. With regard to monitoring of the quality of drugs being shipped, a proxy with the country (Canada) could be established. There is no reason that we can not accept the standards that are equal or higher established by another country. No country should be allowed to participate that does

not have at the very least a set of standards equal to ours regulatory agency [FDA]. Additionally provider whether mail-order or wholesale should be able to meet standards of U.S.-based oversight organizations similar to JCAHO (The Joint Commission on Accreditation of Healthcare Organizations)

3. The role of US and Canadian physicians and pharmacists could/should be worked out through the development of a cross-border professional associations association (licensure/registration and protocol development).
4. Private/Public partnerships should be developed in order to reduce the costs at the Federal level [while maintaining the oversight and input of the FDA].

Major/Potential Barriers to Access from Canada:

1. Major pharmaceutical manufacturers recent actions to discontinue supplies to wholesalers and pharmacists in Canada for export. Although they accuse others of breaking the law, what they are doing although legal, is very unethical. Many individuals have complying with their treatment plans for almost three years and now they propose to take away their medications. All in the name of quality and safety...their answer... a prescription drug benefit under Medicare. With no costs controls put in place on the front end.
2. No one central clearinghouse to manage the process on this side of the border exists currently. His should be the FDA's responsibility.
3. Personal (re)importation is still considered illegal and therefore puts agencies such as the FDA in a very awkward position [actually impossible position until the law is changed and implemented]. They are charged with enforcing what currently exists and it's almost impossible to do so. Their recent threats to prosecute those of us that aid and that we may "be found civilly and criminally liable" was expected at some point, but is such an incredible waste of time and resources. This will serve to accomplish only one thing and that to hurt the very individuals that we profess to serve. Those individuals that are currently complying with their treatment plans. All of this in the name of quality and safety. [a drug that is not accessible because it is not affordable is neither safe or effective]

Final Note:

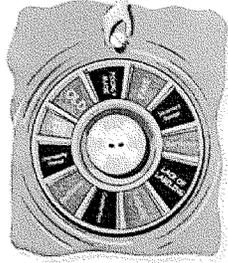
In reality the economic model regarding sales for the pharmaceutical industry actually improves: 1) they now get inconsistent sales (unstable purchasing currently exist). Although the new sales would be a lower price, it would result in stability of purchasing and consistent compliance would result, which according to their own mission is their objective. 2) data reported by the Canadian pharmacies to the FDA could be very beneficial to research and development efforts and the development of a meaningful Medicare prescription drug benefit.

This concludes my prepared remarks. Thank you again for this opportunity and I would be happy to try to address your questions.

Respectfully submitted,

Elizabeth A. Wennar, M.P.H., D.H.A.

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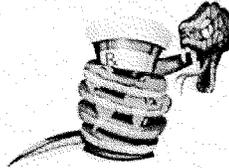


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 • Be contaminated
 • Contain the wrong or no active ingredients

DO NOT BUY FROM:

- Mail-order sites by purchasing direct from U.S. foreign-based pharmacies.
- Selling the Web by purchase from the site or a salesperson's demonstration of your samples at your store. Check with your state board of pharmacy.

OK, look to this site:

Look for the eagle on the seal of the United States Pharmacy Practice Exam (USPPE) Accreditation Program for a list of sites with the USPPE Seal. Visit www.fda.gov/usppe/counterfeit/05_05_04.pdf

If you suspect you have purchased a counterfeit drug because you are experiencing unexpected side effects or notice something different in how your medicine, contact your pharmacist or doctor.

To learn more about counterfeit drugs, visit FDA's Web Counterfeit website at www.fda.gov/counterfeit

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PRESS STATEMENTS 08.07.2004
PARALLEL TRADE REMAINS SAFE DESPITE INDUSTRY-SPONSORED SMEARS

After several decades of manufacturers repeating myths about parallel trade themselves, in a vain attempt to boost their profits further by eliminating this legal and beneficial activity, an even more disturbing new strategy is emerging. 'Think tanks', academics or other apparently independent bodies, all in receipt of pharmaceutical company funding, are almost simultaneously announcing research that purports to show parallel trade poses a risk to patient safety. In fact, such research is almost non-existent. It is primarily based on anecdotes, and highly selective ones at that. Any calculations are of the 'back-of-the-envelope' variety. Attempts are made to link parallel trade to areas of genuine concern without a shred of connecting evidence. 'Reports' turn out to be little more than press releases, devoid of any methodology to allow examination of their sensationalist claims. 'That a self-styled ethical industry that prides itself in scientific rigour and the evidence-based approach should sponsor such activities is most distressing', EAEPIC President Hans Bøgh-Sørensen says. 'We urge action be taken against companies who directly or indirectly disparage without proper evidence the business of our members', he adds.

Consider the facts, based on 30 years experience:

- Parallel trade is thoroughly regulated, by both national and EU regulatory authorities. Every parallel traded product has in fact been approved twice over; it has a full marketing authorisation, and an abbreviated marketing authorisation as parallel trade. Any company that repackages or re-labels parallel trade has a manufacturing authorisation, employs an EU Qualified Person, and is subject to GMP and periodic inspection.
- As well as regulatory review of all their packaging and patient package inserts, parallel importers are required to make available on request to the original manufacturer a complete product sample before marketing takes place.
- No case of damage to patient health from medicines merely because they were in parallel trade form has ever been reported.
- Not one single case of a counterfeit medicine reaching a patient as parallel trade has ever been confirmed. In the case of Germany, this was verified last year in a written parliamentary answer by the Federal Ministry of Health.
- All parallel importers have regulatory authority-approved standard operating procedures in place in the event of a product recall. When a recall has proven necessary, parallel importers have shown they can conduct this just as efficiently, promptly and comprehensively as any other pharmaceutical distributor.



Health
Canada

Santé
Canada

Health Products
and Food Branch

Direction générale des produits
de santé et des aliments

Tunney's Pasture
Address Locator # 0701A1
Ottawa, Ontario
K1A 0L2

JUN 01 2004

04-110133-635

Richard H. Carmona, M.D., M.P.H., F.A.C.S.
VADM, USPHS
United States Surgeon General
Chairman, Secretary's Task Force on Importation
5600 Fishers Lane, Room 18-67
Rockville, MD 20857

Dear Dr. Carmona:

Please find attached Health Canada's input to the Public Docket for the Health and Human Services Task Force on Drug Importation (docket number and title: 2004N-0115 - Prescription Drug Importation; Public Meeting). I trust that you will find this information helpful.

Yours sincerely,

Diane C. Gorman
Assistant Deputy Minister

Enclosure: (1)

Canada

May 31, 2004

**Input from Health Canada to the
Public Docket for the United States Department of Health and Human Services
Task Force on Drug Importation**

I welcome the opportunity to provide the Health and Human Services' Task Force on Drug Importation with information pertaining to the regulatory mandate of Health Canada in relation to drugs, medical devices, and other therapeutic products in Canada. Health Canada trusts that this information will be helpful to the Task Force's deliberations.

Health Canada is the federal department responsible for helping the people of Canada maintain and improve their health. Health Canada regulates therapeutic products in accordance with Canada's *Food and Drugs Act* and its *Regulations*, and does so based on the premise that each country is responsible for the safety of products made available to its citizens.

Health Canada has a rigorous system for the regulation of therapeutic products comprised of three main components: pre-market review to determine if the product meets the legislative and regulatory requirements; post-market surveillance to monitor the safety and therapeutic effectiveness of the product; and inspection to verify compliance with the *Food and Drugs Act* and its *Regulations*. Drugs imported for sale in Canada, or for subsequent export, must first be approved by Health Canada and meet the requirements of Canada's *Food and Drugs Act* and *Regulations*. Through these activities, Health Canada ensures the products intended for Canadians are safe, efficacious and of high quality.

Health Canada works with a number of partners in protecting the health and safety of Canadians, including the provincial and territorial regulatory authorities for the practice of pharmacy and medicine, the Royal Canadian Mounted Police, and the Canada Border Services Agency (with respect to imports). Health Canada also works closely with foreign regulatory authorities, including the United States Food and Drug Administration, on shared public health and regulatory issues. This information-sharing and collaboration allows Canada and its regulatory partners to benefit from respective areas of expertise and knowledge, share information pertinent to regulatory issues such as product review, safety monitoring and compliance, and ensure that our respective regulatory practices are consistent with international norms.

Health Canada's Regulatory Responsibilities for Drugs and Other Therapeutic Products
The *Food and Drugs Act* and *Regulations* prohibit the sale of a drug unless it has been subject to pre-market safety, efficacy and quality review. In drug submissions, a manufacturer must present substantive scientific evidence supporting the information submitted to Health Canada as required by the *Food and Drugs Act* and *Regulations*. Pre-market submissions are reviewed by scientists at Health Canada to determine if the benefits outweigh the risks and the risks can be

1

May 31, 2004

mitigated. If the evidence shows the product meets the requirements stated in the *Act*, the product is issued a market authorization, and if applicable, a Notice of Compliance (NOC), which permit the sponsor to market the drug in Canada. In addition, the fabrication, packaging/labelling, importation, distribution, wholesaling and testing of such products are also monitored following the product's approval through an Establishment License framework.

Once a product is on the market in Canada, it is monitored for safety as well as its therapeutic effectiveness. Post-marketing activities include monitoring and collecting adverse reaction and medication incident data; reviewing and analysing marketed health product safety data; conducting risk/benefit assessments of marketed health products; and communicating product related risks to health care professionals and the public.

Establishment Licences are required for all Canadian businesses engaged in the fabrication, packaging/labelling, importation, distribution, wholesaling and testing of drugs in Canada. Before granting an Establishment Licence, Health Canada conducts an inspection to assess an establishment's compliance with the regulatory requirements applicable to the establishments' activity including those relating to Good Manufacturing Practices (GMPs). An Establishment Licence is granted only if the establishment complies with the requirements of the *Food and Drugs Act* and *Regulations*. Establishment Licences, issued by Health Canada, are renewed on a yearly basis. Establishment licence holders are inspected every three years.

Canada's *Food and Drug Regulations* also require that certain drugs, listed in a schedule to the *Regulations*, only be sold to a patient when a supporting prescription has been issued by a practitioner licensed to practice in a province of Canada. In Canada, provincial and territorial governments license and regulate doctors and pharmacists practising medicine and pharmacy through provincial colleges or registrars of physicians and pharmacists.

Importing Drugs and other Therapeutic Products into Canada

Drugs imported for sale in Canada, or for subsequent export, must first be approved by Health Canada and meet the requirements of Canada's *Food and Drugs Act* and *Regulations*. Such drugs must, for example be properly labelled with a valid Drug Identification Number (DIN) and be fabricated at a site compliant with Canada's GMP regulatory requirements. Health Canada, in partnership with Canada Border Services Agency, enforces the requirements that only drugs approved for use in Canada enter Canada. Establishments importing drugs for sale in Canada or for further export are also required to hold an Establishment Licence authorizing such import activities.

To determine whether drugs being brought into the country meet Canada's GMP regulatory requirements under the *Food and Drugs Act*, Health Canada uses reports from its own inspectors or from recognized partner countries under the terms of Mutual Recognition Agreements (MRAs) and the Pharmaceutical Inspection Cooperation Scheme (PIC/S). Health Canada also

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uses inspection reports from the United States Food and Drug Administration. The use of inspection reports from recognized partner countries through MRAs or PIC/S is based on a rigorous process that has established equivalency of both GMP standards and compliance inspection procedures and reports between Canada and the partner country.

Canada has determined, through evaluation and experience, that MRA and PIC/S countries provide indication of GMP compliance equivalency that warrant their use. Canada has established MRAs with Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Liechtenstein, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland, and the United Kingdom. An MRA is also being finalized with Australia. The Pharmaceutical Inspection Cooperation Scheme members include the MRA countries listed above, as well as: Czech Republic, Hungary, Malaysia, Romania, Singapore, Slovak Republic and Latvia.

Exporting Drugs and other Therapeutic Products from Canada

Canada's *Food and Drugs Act* and *Regulations* operate to prohibit the export of drugs that are not approved for sale in Canada, as they do not distinguish between domestic and export sales. An exemption is, however, available to drug manufacturers who fabricate in Canada and sell a drug solely for export, who certify under oath that a product being exported complies with the laws of the country of import. This exemption avoids unnecessarily subjecting exporting manufacturers in Canada to Canada's *Food and Drugs Act* and *Regulations* when they have already complied with the laws of the importing country. It is important to reiterate that the exemption can only be used by drug manufacturers in Canada for drugs fabricated in Canada solely for export. This exemption cannot be used by pharmacists, other establishments, or individuals.

Compliance and Enforcement

Health Canada's Health Products and Food Branch has an Inspectorate which is tasked with verifying compliance with the *Food and Drugs Act* and *Regulations* and, where necessary, taking steps to enforce the prohibitions outlined in these laws.

Pursuant to their authority under the *Food and Drugs Act*, inspectors can enter and inspect places where therapeutic products are manufactured, prepared, preserved, packaged or stored in order to verify/monitor that Canada's food and drug laws are being complied with. If any non-compliance with federal laws is found, appropriate compliance and enforcement actions are taken.

Health Canada compliance and enforcement activities, with respect to therapeutic products, are conducted in concordance with the *Compliance and Enforcement Policy* of the Health Products and Food Branch. This policy stipulates that compliance and enforcement activities will be

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guided by the level of risk to the health of Canadians and will be directed at the earliest point of distribution to achieve the greatest impact and efficiency. Compliance will normally be achieved through a cooperative approach between the regulated party and the Health Products and Food Branch Inspectorate and other relevant organisations within Health Canada. However, when this is not possible, a number of enforcement options may be used in an escalating fashion, including warning letters, seizures and detentions, formal hearings, or prosecution.

Conclusion

The regulation of drug safety worldwide is based on the premise that each country is responsible for the safety of products made available to its citizens. Health Canada contributes to maintaining and improving the health of Canadians by ensuring that drugs and other therapeutic products sold in Canada are safe, of high quality and therapeutically effective in accordance with their labelling, and with partners and stakeholders, are appropriately used and accessible in a timely and cost-effective fashion.

Diane C. Gorman
Assistant Deputy Minister
Health Products and Food Branch
Health Canada

31 mai 2004

Données de Santé Canada**pour le dossier public à l'intention du *Task Force on Drug Importation*
du *Department of Health and Human Services* des États-Unis**

C'est avec plaisir que je présente au *Task Force on Drug Importation* (groupe de travail sur l'importation des drogues) du *Department of Health and Human Services* (département de la Santé et des Services humanitaires) des renseignements que Santé Canada a obtenus dans le cadre de son mandat en matière de réglementation des drogues, des instruments médicaux et d'autres produits thérapeutiques utilisés au Canada. Santé Canada espère que cette information sera utile au groupe de travail lorsqu'il entreprendra ses délibérations.

Santé Canada est le ministère fédéral chargé d'aider les gens du pays à maintenir et à améliorer leur état de santé. Le Ministère réglemente les produits thérapeutiques en vertu de la *Loi sur les aliments et drogues* du Canada et de son *Règlement* d'application; il le fait en se fondant sur le principe selon lequel chaque pays est responsable de l'innocuité des produits offerts aux citoyens.

Santé Canada a établi un système rigoureux de réglementation des produits thérapeutiques, dont les trois principaux éléments sont les suivants : examen préalable à la mise en marché, afin de déterminer si le produit satisfait aux exigences législatives et réglementaires; surveillance après la mise en marché, de façon à garantir l'innocuité et l'efficacité thérapeutique du produit; inspection visant à vérifier la conformité avec la *Loi sur les aliments et drogues* et son *Règlement* d'application. Les drogues importées au Canada pour y être vendues ou être exportées ailleurs doivent être approuvées par Santé Canada et satisfaire aux exigences précitées. Grâce à ces activités, le Ministère s'assure que les produits destinés aux Canadiens sont sûrs, efficaces et de qualité.

Santé Canada travaille avec un certain nombre de partenaires afin de protéger la santé des Canadiens et de garantir leur sécurité; parmi ces partenaires, mentionnons les suivants : les autorités réglementaires provinciales et territoriales dans le domaine de la pharmacologie et de la médecine, la Gendarmerie Royale du Canada et l'Agence des services frontaliers du Canada (dans le cas des importations). Santé Canada collabore de plus avec des autorités réglementaires d'autres pays, dont la *Food and Drug Administration* (administration des aliments et drogues) des États-Unis à des dossiers communs concernant la santé publique et la réglementation. Partager de l'information et collaborer permet au Canada et à ses partenaires de la réglementation de profiter des domaines d'expertise et de connaissance de chacun, de partager des renseignements utiles sur des questions réglementaires comme l'examen des produits, la surveillance de l'innocuité et la conformité, et de faire en sorte que nos pratiques réglementaires respectives soient conformes aux normes internationales.

Exhibit

Dr. Elizabeth Wennar, Testimony -July 2004

The cross border sale of drugs to the United States has become an important business in Canada because many Americans are taking advantage of lower Canadian patented drug prices and are purchasing their drugs from Canada. Neither Canada's international trade obligations nor our domestic laws prohibit these exports.

-- The Government of Canada ensures that Canadians have access to high quality, safe and reasonably priced drugs. Canada's regulatory requirements for the approval of drugs are governed by the Food and Drugs Act and Regulations monitored by Health Canada. Canada has one of the most rigorous drug approval systems in the world and one of the best safety records.

-- Canada's Food and Drugs Regulations stipulates that only a licensed practitioner (a doctor or a dentist) can legally write a prescription. Only a registered pharmacist may dispense a drug to the holder of a prescription. Without a signed prescription, drugs cannot be provided to individual consumers.

-- All pharmacies in Canada must comply with Canadian laws. The provinces and territories are responsible for regulating the practice of medicine and pharmacy, often through their Colleges or Registrars of Physicians and/or Pharmacists. They also have a responsibility for providing health care services to Canadians.

-- The U.S. Food and Drug Administration is responsible for ensuring that drugs entering the U.S. meet the requirements of the Food, Drug and Cosmetics Act.

-- Price differentials in pharmaceutical products between different countries exist due to a combination of factors, including regulatory and legislative systems, currency, patent status, prescription requirements, and approaches to reimbursement.

-- While prices for patented drug products in Canada are, on average, lower than those in the U.S., they are in line with the six other industrialized countries in Europe, that are used for price comparison purposes. These countries all have publicly-funded health care systems and use a variety of measures to control the prices of drugs or profits of manufacturers and overall expenditures on drugs. Other market-place dynamics also influence prices.

-- Canada's Patented Medicine Prices Review Board (PMPRB) was created in 1987 under the Patent Act to protect consumer interests and contribute to Canadian health care by ensuring that prices charged by manufacturers of patented medicines are not excessive. The PMPRB's jurisdiction extends to manufacturer prices of patented medicines approved for sale in Canada. More specifically, the PMPRB regulates the first price at which the drug product is sold by the manufacturer - regardless of the purchaser, whether it be the wholesaler, pharmacy, hospital, or other.

-- Canada's drug price regime is based on factors established in the Patent Act. For new drugs, prices are limited to prices of other drugs used to treat the same disease; and to prices at which the drug is sold in seven comparator countries (France, Germany, Italy, Sweden, Switzerland, U.K., U.S.) As for existing drugs, the price increases are limited to changes in the Consumer Price Index.

HEALTH CANADA

Testimony- Dr. Elizabeth Wennar, July 2004**Exhibit 2****Statement by the Canadian Embassy in Washington, D.C. to Giuliani Partners LLC**

2. P. 12 of Giuliani Partners LLC's submission (Interim Report) reads:

"According to information provided by Industry Canada, a department of the Canadian Federal Government, from September 2002 to September 2003, there was a significant increase in drugs imported into Canada from the following countries:

- Singapore up 30%
- Ecuador up 198%
- China up 43%
- Iran up 2,753%
- Argentina up 221%
- South Africa up 84%
- Thailand up 52%

Prudential Financial, Inc. released similar findings, stating that Canadian internet pharmacies were increasingly obtaining their product from other countries such as Bulgaria (exports to Canada up 300%), Singapore (up 101%), Argentina (up 171%), South Africa (up 114%), Pakistan (up 196%), as well as others."

Prudential Securities' Oct. 8, 2003, report relies on Canadian data using the North American Industry Classification System statistics for Pharmaceutical and Medicine Manufacturing (NAICS 32541), assembled by Canada's Statistical Agency- 'Statistics Canada'.

NAICS 32541 cannot be used to demonstrate the occurrence of imports of unapproved drugs into Canada-- from any country. This is because prescription drugs are but one item covered under NAICS 32541, the category itself is extremely broad and not available for disaggregation. For example, NAICS 32541 includes products such as contact lens solution, botanical products, vitamins, feed additives, herb grindings, and water purification tables, to name but a few (see below for complete list).

More to the point, these imports are registered by Statistics Canada based on the filing of proper permits with Canadian customs official at Canadian borders points. If there were drugs coming from unapproved sources, they would not be allowed into the country. And certainly, they would not be registered into our official statistics.

I hope this information is of assistance to you. We would be grateful if Giuliani Partners LLC could incorporate it into any further reporting on this topic. Please do not hesitate to email or call me at (202)682-7758 if you have any questions.

DH

The official definition of 32541 is: "This industry comprises establishments primarily engaged in manufacturing drugs, medicines and related products for human or animal use.

Establishments in this industry may undertake one or more of several processes, including basic processes, such as chemical synthesis, fermentation, distillation and solvent extraction; grading, grinding and milling; and packaging in forms suitable for internal and external use, such as tablets, vials, ampoules and ointments.

Anesthetics, manufacturing
Antibiotics (including veterinary), manufacturing
Antiseptics, medicinal, manufacturing
Blood derivatives, for human or veterinary use, manufacturing
Botanical products, medicinal, ground, graded and milled, manufacturing
Contraceptive preparations, manufacturing
Contact lens solutions, manufacturing
Cough medicines, manufacturing
Diagnostic agents, biological, manufacturing
Endocrine products, manufacturing
Feed additives, manufacturing
Herb grinding, grading and milling, manufacturing
Hormones and derivatives, manufacturing
Vaccines, manufacturing
Veterinary pharmaceutical preparations, manufacturing
Vitamins, manufacturing
Water decontamination or purification tablets, manufacturing"

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Guidelines for obtaining prescriptions through mail-order pharmacies via the Internet

While there are hundreds of Internet-based pharmacies in operation today, only a small group of them (mainly Canadian) can offer the deep discounts. The problem is how to distinguish the quality mail-order providers from the unscrupulous ones. Considering the risk involved in purchasing drugs over the Internet, asking a few key questions before you order is critical. Besides the 30-80% savings on prescriptions that most of the Canadian sources offer, there should be evidence of the additional layer of quality assurance. There are very specific requirements one should look for when considering the purchase of medications over the internet:

- The pharmacy should require the patient to complete a medical questionnaire signed by their physician and obtain an annual exam from their personal doctor. Beware of pharmacies that say you don't need your personal physician involved or nor prescription needed.
- Is there evidence that the pharmacy has been accredited by a US body (such as iMPAC, www.impac.org or JCAHO, www.jcaho.org). Be able to identify what the standards are that have been met. Confirmation should be available that a site visit completed as part of the accreditation process.
- The pharmacy should require a written prescription from the patient's doctor and a listing of all medications that the individual is currently taking, including over-the-counter and herbals.
- The pharmacy must be show evidence of licensing, certification/credentials of professionals and any accreditation on their website.
- A physical location for he pharmacy should be listed with all contact information
- The patient or their physician should be able to contact/speak directly with the staff pharmacist and/or physician.
- There should be a dedicated customer service department available to answer your questions and track your orders.
- All prescriptions must be provided in the manufacturer's original sealed container.
- The pharmacy should provide clearly stated privacy and security policies to protect the patient's personal information.

- **Shipping and handling prices should be a pass through with no add-on fees.**
- **Stay clear of internet mail-order that promote "Me too and lifestyle drugs"**

If the Internet or mail order pharmacy you are considering doesn't have every one of these in place, steer clear and find one that you can trust.

Sagar (www.healthreformprogram.org) - Do Drug Makers Lose Money on Canadian Imports? 15 April, 2004)

For full report, see www.healthreformprogram.org - [Do Drug Makers Lose Money on Canadian Imports? 15 April 2004](#).

Do Drug Makers Lose Money on Canadian Imports?

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Data Brief No. 6

15 April 2004

Summary

Drug makers and others persistently assert that importing prescription drugs from Canada would damage drug makers' profits and their capacity to finance research. This view is widely accepted. Importing proponents have not generally questioned this view but instead focus attention on the clinical and financial benefits of lower drug prices.

But what if importing drugs from Canada does not harm drug makers' profits? This data brief questions and explores the premise that importing necessarily means lower profits. Lower Canadian prices let some Americans fill prescriptions that otherwise go unfilled. We find that if new prescriptions' share of imports is 44.53 percent or more, importing actually increases drug makers' profits. This is the point at which the profit lost by drug makers when patients fill existing prescriptions at lower Canadian prices is exactly offset by the profit drug makers gain by selling new prescriptions through Canada. That share is not yet known empirically, but should be ascertained. New prescriptions' share of imports may be high enough today to prevent a loss of profits owing to importation.

This finding offers reason to hope that a combination of lower drug prices and higher volumes could address patients' and payers' needs for affordable prescription drugs while satisfying drug makers' needs for adequate profits and research financing.

For full report, see www.healthreformprogram.org - or use this direct link: [Do Drug Makers Lose Money on Canadian Imports? 15 April 2004](#).

Disclaimer: As always, we write only for ourselves, not on behalf of Boston University or any of its components.

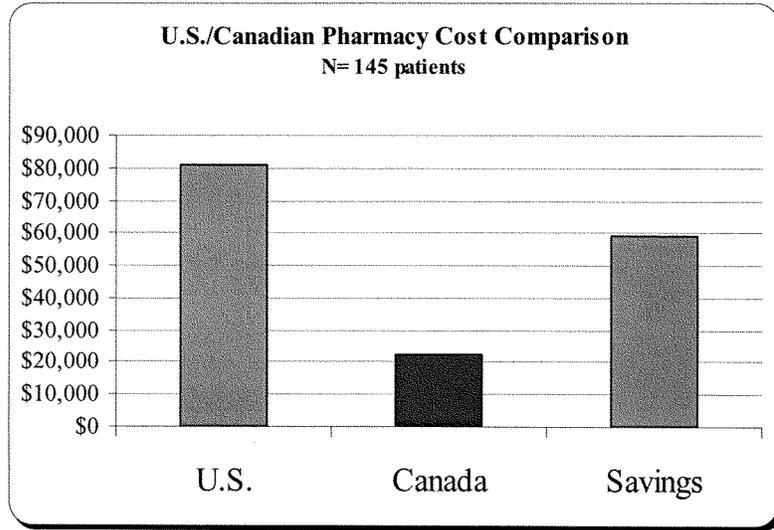
AARP (www.AARP.org) - Trends in Manufacturers Drug Prices of Brand Name Drugs) Note: Since AARP is testifying, I assume they will provide the Committee with the entire report.

**GAO Report Issued June 17, 2004 on Internet Pharmacies
(www.gao.gov/cgi-bin/getrpt?gao-04-888T)**

UHA Savings Analyses

Six-month Summary Analysis

Time Frame: July – December 2000
 Number of patients participating: 145
 Number of physicians participating: 19
 Number of drug names ordered: 106



Total cost of prescriptions in U.S.	\$81,006.17
Total cost of prescriptions in Canada	\$22,361.53
Total savings:	\$58,963.84
Percent savings:	72.8%
Overall average savings:	68.4%
Range of savings by drug:	28% - 97%

Source: United Health Alliance 2000

Note: U.S. prices are based on AWP plus 30%. The actual cost of U.S. prescriptions will vary based on geographic area and by individual pharmacies.

Sample Drug Pricing

Drug	Number of Tabs	Canada	U.S.	Savings
Tamoxifen 10 mg	60	\$7.05	\$142.44	95%
Lipitor 10 mg	90	\$106.33	\$230.58	54%
Plaxil 10 mg	30	\$33.01	\$94.57	60%
Prozac 10 mg	100	\$115.93	\$361.28	68%
Coumadin 5 mg	100	\$25.52	\$90.07	72%
Glucophage 500mg	100	\$15.70	\$86.26	82%
Prilosec 10 mg	30	\$33.88	\$144.62	77%
Fosamax 10 mg	30	\$36.40	\$85.99	58%

Note: U.S. prices are based on AWP plus 30%. The actual cost of U.S. prescriptions will vary based on geographic area and by individual pharmacies. All dollar figures are reflected in U.S. Currency