

**EXAMINING PRESCRIPTION DRUG IMPORTATION:
A REVIEW OF A PROPOSAL TO ALLOW THIRD
PARTIES TO REIMPORT PRESCRIPTION DRUGS**

HEARING
BEFORE THE
SUBCOMMITTEE ON HEALTH
OF THE
COMMITTEE ON ENERGY AND
COMMERCE
HOUSE OF REPRESENTATIVES

ONE HUNDRED SEVENTH CONGRESS

SECOND SESSION

—————
JULY 25, 2002
—————

Serial No. 107-135

Printed for the use of the Committee on Energy and Commerce



Available via the World Wide Web: <http://www.access.gpo.gov/congress/house>

U.S. GOVERNMENT PRINTING OFFICE

81-494CC

WASHINGTON : 2002

For sale by the Superintendent of Documents, U.S. Government Printing Office
Internet: bookstore.gpo.gov Phone: toll free (866) 512-1800; DC area (202) 512-1800
Fax: (202) 512-2250 Mail: Stop SSOP, Washington, DC 20402-0001

COMMITTEE ON ENERGY AND COMMERCE

W.J. "BILLY" TAUZIN, Louisiana, *Chairman*

MICHAEL BILIRAKIS, Florida	JOHN D. DINGELL, Michigan
JOE BARTON, Texas	HENRY A. WAXMAN, California
FRED UPTON, Michigan	EDWARD J. MARKEY, Massachusetts
CLIFF STEARNS, Florida	RALPH M. HALL, Texas
PAUL E. GILLMOR, Ohio	RICK BOUCHER, Virginia
JAMES C. GREENWOOD, Pennsylvania	EDOLPHUS TOWNS, New York
CHRISTOPHER COX, California	FRANK PALLONE, Jr., New Jersey
NATHAN DEAL, Georgia	SHERROD BROWN, Ohio
RICHARD BURR, North Carolina	BART GORDON, Tennessee
ED WHITFIELD, Kentucky	PETER DEUTSCH, Florida
GREG GANSKE, Iowa	BOBBY L. RUSH, Illinois
CHARLIE NORWOOD, Georgia	ANNA G. ESHOO, California
BARBARA CUBIN, Wyoming	BART STUPAK, Michigan
JOHN SHIMKUS, Illinois	ELIOT L. ENGEL, New York
HEATHER WILSON, New Mexico	TOM SAWYER, Ohio
JOHN B. SHADEGG, Arizona	ALBERT R. WYNN, Maryland
CHARLES "CHIP" PICKERING, Mississippi	GENE GREEN, Texas
VITO FOSSELLA, New York	KAREN McCARTHY, Missouri
ROY BLUNT, Missouri	TED STRICKLAND, Ohio
TOM DAVIS, Virginia	DIANA DEGETTE, Colorado
ED BRYANT, Tennessee	THOMAS M. BARRETT, Wisconsin
ROBERT L. EHRLICH, Jr., Maryland	BILL LUTHER, Minnesota
STEVE BUYER, Indiana	LOIS CAPPS, California
GEORGE RADANOVICH, California	MICHAEL F. DOYLE, Pennsylvania
CHARLES F. BASS, New Hampshire	CHRISTOPHER JOHN, Louisiana
JOSEPH R. PITTS, Pennsylvania	JANE HARMAN, California
MARY BONO, California	
GREG WALDEN, Oregon	
LEE TERRY, Nebraska	
ERNIE FLETCHER, Kentucky	

DAVID V. MARVENTANO, *Staff Director*

JAMES D. BARNETTE, *General Counsel*

REID P.F. STUNTZ, *Minority Staff Director and Chief Counsel*

SUBCOMMITTEE ON HEALTH

MICHAEL BILIRAKIS, Florida, *Chairman*

JOE BARTON, Texas	SHERROD BROWN, Ohio
FRED UPTON, Michigan	HENRY A. WAXMAN, California
JAMES C. GREENWOOD, Pennsylvania	TED STRICKLAND, Ohio
NATHAN DEAL, Georgia	THOMAS M. BARRETT, Wisconsin
RICHARD BURR, North Carolina	LOIS CAPPS, California
ED WHITFIELD, Kentucky	RALPH M. HALL, Texas
GREG GANSKE, Iowa	EDOLPHUS TOWNS, New York
CHARLIE NORWOOD, Georgia	FRANK PALLONE, Jr., New Jersey
<i>Vice Chairman</i>	PETER DEUTSCH, Florida
BARBARA CUBIN, Wyoming	ANNA G. ESHOO, California
HEATHER WILSON, New Mexico	BART STUPAK, Michigan
JOHN B. SHADEGG, Arizona	ELIOT L. ENGEL, New York
CHARLES "CHIP" PICKERING, Mississippi	ALBERT R. WYNN, Maryland
ED BRYANT, Tennessee	GENE GREEN, Texas
ROBERT L. EHRLICH, Jr., Maryland	JOHN D. DINGELL, Michigan,
STEVE BUYER, Indiana	(Ex Officio)
JOSEPH R. PITTS, Pennsylvania	
W.J. "BILLY" TAUZIN, Louisiana	
(Ex Officio)	

CONTENTS

	Page
Testimony of:	
Copeland, Don, President and CEO, Associated Pharmacies, Inc	80
Hubbard, William K., Senior Associate Commissioner, Office of Policy, Planning and Legislation, accompanied by John Taylor, Director, Office of Enforcement; and David Horowitz, Director, Office of Compliance, Food and Drug Administration	19
Hutt, Peter Barton, Covington & Burling, on behalf of PhRMA	70
Shepherd, Marv, College of Pharmacy, University of Texas at Austin	59
Wennar, Elizabeth A., President, United Health Alliance	63
Material submitted for the record by:	
Streck, Ronald J., President and CEO, Healthcare Distribution Manage- ment Association, prepared statement of	109

(III)

EXAMINING PRESCRIPTION DRUG IMPORTATION: A REVIEW OF A PROPOSAL TO ALLOW THIRD PARTIES TO REIMPORT PRESCRIPTION DRUGS

THURSDAY, JULY 25, 2002

HOUSE OF REPRESENTATIVES,
COMMITTEE ON ENERGY AND COMMERCE,
SUBCOMMITTEE ON HEALTH,
Washington, DC.

The subcommittee met, pursuant to notice, at 2:50 p.m. , in room 2123, Rayburn House Office Building, Hon. Michael Bilirakis (chairman) presiding.

Members present: Representatives Bilirakis, Greenwood, Burr, Whitfield, Norwood, Bryant, Buyer, Pitts, Tauzin (ex officio), Brown, Waxman, Strickland, Barrett, Capps, Towns, Pallone, Stupak, Wynn, and Green.

Also present: Representatives Kingston, Gutknecht, Thune, and Sanders.

Staff present: Brent Del Monte, majority counsel; Steven Tilton, health policy coordinator; Eugenia Edwards, legislative clerk; Benjamin Beaton, policy analyst; Patrick Morrissey, deputy staff director; Chris Knauer, minority investigator; David Nelson, minority investigator; and Jessica McNiece, minority staff assistant.

Mr. BILIRAKIS. I call this hearing to order. I would like to start by welcoming our witnesses and all of the subcommittee members, though there are not many here at this point.

The issue we will be discussing this afternoon is reimportation of prescription drugs. Like many issues our subcommittee deals with, today's topic is a complicated, politically charged issue that engenders strong feelings among members of the subcommittee and of the Congress.

The goal of many members is to legalize reimportation of drug products, which in turn may provide many Americans with cheaper medicines. Conversely, if this practice is permitted without adequate safety controls, reimportation could place our constituents in grave danger.

The high cost of prescription medicine is a monumental concern for all of us. About a month ago, our committee worked all night and favorably reported legislation, which passed the House. The House bill would provide lower-cost medicines to seniors. Unfortunately, the Senate has not been able to muster the necessary votes to pass a bill. We all hope, I like to think, that the Senate acts soon

to pass a prescription drug benefit; but if they do not, our committee will act responsibly to find creative solutions for Americans.

In 1988 the Democratically-controlled House of Representatives passed the Prescription Drug Marketing Act, which made reimportation of prescription drugs by anyone other than the original manufacturer illegal. The driver for this legislation was this committee's finding that reimporting drugs placed Americans in danger.

Despite the illegality of personally importing prescription drugs, we have all heard of the bus trips to Canada to purchase cheaper drugs. In fact, some members of our subcommittee have organized these types of trips. If this practice is illegal, I guess one question should be: Why doesn't the FDA, the Food and Drug Administration, prevent these types of actions? I am very interested in why the FDA chooses to use its discretion and allow for personal import. Specifically, I would like to ask if the Agency has quantified the risk that is involved in this type of reimportation.

I look forward to the testimony today, and hope we all keep an open mind and political rhetoric to a minimum, which I doubt is going to happen. We need to carefully examine the pros and cons of this major policy shift and avoid grandstanding for political points. Reimporting drugs is a serious issue. If we pursue legislation, we must be certain that in fact it will help to lower the cost of prescription medicines without compromising the health of Americans.

Once again, I would like to offer a warm welcome to all of our panelists and thank them for their time and effort in joining us today.

Now I am pleased to recognize the ranking member, Mr. Brown, for his opening statement.

[The prepared statement of Hon. Michael Bilirakis follows:]

PREPARED STATEMENT OF HON. MICHAEL BILIRAKIS, CHAIRMAN, SUBCOMMITTEE ON HEALTH

I now call to order this hearing of the Health Subcommittee. I would like to start by welcoming our witnesses and all of the Subcommittee members.

The issue we will be discussing this afternoon is reimportation of prescription drugs. Like many issues our Subcommittee deals with, today's topic is a complicated politically charged issue that engenders strong feelings among Members of the Subcommittee and the Congress. The goal of many Members is to legalize reimportation of drug products, which in turn may provide many Americans with cheaper medicines. Conversely, if this practice is permitted without adequate safety controls reimportation could place our constituents in grave danger.

The high cost of prescription medicine is a monumental concern for all of us. About a month ago our Committee worked all night and favorably reported legislation, which passed the House, that would provide lower cost medicines to seniors. The Medicare Modernization and Prescription Drug Act of 2002 creates a voluntary prescription drug benefit for seniors and utilizes strong tools to ensure that seniors will receive the lowest prices available. Unfortunately, the Senate has not been able to muster the necessary votes to pass a bill. I hope that the Senate acts soon to pass a prescription drug benefit, but, if they do not, our Committee will act responsibly to find creative solutions for Americans.

In 1988, the Democratic controlled House of Representatives passed the Prescription Drug Marketing Act, which made reimportation of prescription drugs by anyone other than the original manufacturer illegal. The driver for this legislation was this Committee's finding that reimporting drugs placed Americans in danger.

Despite the illegality of personally importing prescription drugs, we have all heard of the bus trips to Canada to purchase cheaper drugs. In fact, some Members of our Subcommittee have organized these types of trips. If this practice is illegal,

why doesn't the Food and Drug Administration (FDA) prevent these types of actions? I am very interested in why the FDA chooses to use its discretion and allow for personal importation. Specifically, I would like to know if the agency has quantified the risk that is involved in this type of reimportation.

I look forward to the testimony today and hope that we all keep an open mind and political rhetoric to a minimum. We need to carefully examine the pros and cons of this major policy shift and avoid grandstanding for political points. Reimporting drugs is a serious issue, and if we pursue legislation we must be certain that it lowers the cost of prescription medicines without compromising the health of Americans.

Once again, I would like to offer a warm welcome to all of our panelists and thank them for their time and effort in joining us today. I now recognize the Ranking Member, Mr. Brown, for an opening statement.

Mr. BROWN. I thank the chairman.

Ruth Tubbs is an engaging and articulate 70-year-old woman from Bristol, Connecticut. Ruth has Medicare but no drug coverage. She receives Social Security, and her husband works part-time. In the United States, Ruth pays \$1,200 every 3 months for her prescriptions. In Canada, she pays \$350. In 1 year, by going to Canada, she saves \$3,700. These savings amount to 6 months' worth of Social Security for her.

Ruth should be testifying this afternoon. Instead, she was earlier in the audience, and then caught a train back to Connecticut. My Republican colleagues did not want a consumer witness, but a representative from the drug industry will join us today to testify. After all, reimportation would reduce the industry's revenues, and drug makers only earned \$300 billion last year.

It is crucial that we discuss reimportation in the context of its impact on the drug industry. The fact that seniors throughout this country are able to fill their prescriptions only by purchasing them from other countries, that fact is messy, it is emotional, and should be ignored.

To whom do Members of Congress report? I thought we reported to our constituents. I thought their concerns were important. I thought we reported to people like Ruth Tubbs. If we ignore Ruth Tubbs, it becomes so easy to ignore the fact that the risk to a senior of forsaking their medicine may far outweigh the risks of reimporting those medicines.

It becomes too easy to ignore the fact that reimportation is one of this Nation's only means of protecting U.S. consumers, U.S. companies, and U.S. tax dollars from grossly inflated drug prices.

I don't know any American, as I have taken people on buses to Canada, who want to travel to another country solely for the purpose of purchasing affordable medicine, or who thinks the Internet and commercial reimportation are a step up from the way medicines typically are distributed in this country. But I do know Americans, as we all do, who cannot afford to fill their prescriptions at U.S. prices, who need to pay for food and shelter, so they can't afford to fill those prescriptions.

Reimportation is a symptom, not the problem. It is a symptom of the fact that 12 million seniors lack drug coverage, and millions more are underinsured. It is a symptom of the fact that health care inflation, fueled by spiraling drug costs, is jeopardizing access to health care coverage and health care for every American.

It is a symptom of the fact that Americans pay two and three and four times more than consumers in any other country for drugs

manufactured by the same company, in the same facilities, in the same packaging, in the same dosage, the exact same drugs.

It is a symptom of the fact that while this administration and this Congress hang on every word when multibillion-dollar drug companies spew their self-serving rhetoric, attacking reimportation or attacking any other attempt to get a fair deal for American consumers, while this administration and this Congress permit the drug industry to subject American consumers to what amounts to blackmail for saying to seniors on fixed incomes, if you want new medicine, you are going to pay your share of our enormous profits, plus compensate for the profits we can't earn in other countries around the world; while this administration and this Congress permit the drug industry to push our health care financing system into crisis, this administration and this Congress stall and hem and haw and patronize and outright ignore seniors who depend on purchasing their drugs in Canada.

FDA, like the drug industry witness—and, unfortunately, more and more these days we simply can't tell them apart—will warn us that reimportation is dangerous. The Agency may even recommend cutting off all mail order imports into this country. But FDA has not conducted a study of the actual dangers to prove to seniors that the risks of taking imported drugs are greater than the risks of not taking anything at all. Somehow it is okay to recommend taking away the only option that many seniors have for affordable drugs without proving to them it is necessary.

FDA has taken to stopping mail order shipments from Canada at the border. I have been on the phone time after time after time with them when they hold drugs at the border, not because the Agency is concerned about safety, because they know they are safe when they come from certain pharmacies in Canada, but because the Agency is concerned that these shipments may be commercial in nature, and we know whom that bothers.

Is it more important to protect the drug industry from commercial reimportation than to make sure that seniors who purchased insulin or medicine to control the symptoms of Parkinson's, or medicines to forestall another stroke, that they receive that medicine? Apparently the FDA thinks so.

I have great respect for Bill Hubbard, who is testifying on behalf of FDA this morning—or this afternoon—but the Agency he represents is falling into the same trap as this Congress. Their role is to ensure the safety and efficacy of prescription drug products. Their role is not to protect drug industry revenues, and not to brag about U.S. drug company market share in the world.

Brand name drug companies should make a profit. They invest heavily in research, they take on substantial financial risks, they produce life-saving products. For that we are grateful. If commercial reimportation would jeopardize this important industry, we need to know that.

But American consumers should not pay the highest price in the world for brand name drugs. Seniors should not have to go to Canada. And, with all due respect to the drug industry, the welfare of seniors is more important than their profit performance, something this Congress should understand, something the FDA should understand.

Mr. Chairman, it is a proconsumer safety bill, a pro-consumer access bill, and a bill the drug industry will no doubt demonize. I only hope this administration and this Congress can disentangle itself from the drug industry and consider this legislation on its merits.

Mr. BILIRAKIS. The Chair recognizes the chairman of the full committee, Mr. Tauzin, for his statement.

Chairman TAUZIN. Thank you, Mr. Chairman.

First of all, we all know Americans deserve access to affordable prescription drugs. We believe that is particularly true for our seniors. Just less than a month ago, this committee worked through the night, 30 long hours, to produce a drug benefit bill under Medicare. We hope, obviously, to see that enacted into law very soon.

But until then, we have to continue to see what we can do to get safe and effective, affordable drugs in the hands of our seniors. Corporate America, by the way, is beginning to feel the crunch of rising drug costs and is asking us, too, to help them make sure they can keep people employed under health plans that cover them for prescription drugs.

Today we consider a proposal which attempts to do this by legalizing the personal reimportation of drugs from other countries. I want to commend you, Mr. Chairman, and our friend, Jack Kingston, for his interest in this important subject.

By and large, drugs do cost less in Canada and in Mexico, largely because of price controls. We have all heard of the bus trips when seniors cross into Canada to purchase these cheaper prescription drugs. While these trips provide seniors with access to cheaper drugs, they also provide seniors with access to drugs which may or may not be safe or as effective as drugs that have been approved by the FDA.

Our Nation today has the safest drug supply in the world. The FDA's safety regimen is commonly referred to as the "gold standard." I look forward to learning from FDA today precisely whether they have quantified the risk posed by personal reimportation. Is the risk posed by personal reimportation not so high, given that the FDA exercises its enforcement discretion and generally does not stop these drugs from entering the country? Or are there other factors preventing FDA from stopping the flow of reimported drugs into the United States?

Does the FDA have data which shows that a percentage of drugs being brought into our country, which have in fact been adulterated or unsafe, or are subpotent? And if not, why not? Why don't we have that data?

As many know, our country technically has a law on its books pertaining to reimportation. The law was passed in the 106th Congress. It permits reimportation by pharmacists and wholesalers, but only if the Secretary of Health and Human Services certified that the practice would ensure cost savings and would provide safe drugs for Americans.

Now, the fact, Mr. Brown, is that neither the Clinton Administration nor the Bush administration was able to certify those facts. Is the Clinton Administration in the pockets of the drug companies? Was Donna Shalala in the pockets of the drug companies?

All Donna Shalala had to do was say, we can certify, it is safe to do so. She could not do it. That ought to be troublesome to all seniors. It ought to be troublesome to any one of us who is worried about this issue. We ought to get an answer to it. We ought to know. We ought to know facts before we commit anyone to damaging the safest drug regimen in the world.

As a result of neither the Clinton Administration nor the Bush Administration apparently being able to certify that reimportation is safe, the practice remains illegal, as it has been since this committee passed the Prescription Drug Marketing Act under John Dingell's leadership in 1988.

So the legislation before the committee today would change that act and would say that pharmacists are allowed to reimport drugs from anywhere in the world, as long as the drugs do not appear to be adulterated, counterfeited, or misbranded. There is no requirement that they certify that reimportation will ensure safe drugs; and further, unlike any proposals which we have seen, this bill does not limit reimportation to any specific country or list of countries, and it does not require that reimported drugs be tested by anyone.

The Secretary has already told us that legislation with these protections is not enough to protect the public health—if you don't have these protections in it, rather. So we are interested in learning from the FDA what protections are necessary to protect the public health if we change the law and allow reimportation.

I appreciate Jack Kingston's bringing this to the committee's attention, and we will learn whether reimportation could be done safely, and if so, what protections ought to be put into the law to get it done right.

It is my intent, Mr. Chairman, that our committee move on this issue before the end of September, and the witnesses you assembled today are vital to helping us get it right.

Thank you, Mr. Chairman.

[The prepared statement of Hon. W.J. "Billy" Tauzin follows:]

PREPARED STATEMENT OF HON. W.J. "BILLY" TAUZIN, CHAIRMAN, COMMITTEE ON ENERGY AND COMMERCE

Mr. Chairman: We all agree that all Americans deserve access to affordable prescription drugs, particularly our seniors. Just less than one month ago this Committee worked through the night to make good on the promise of an affordable drug benefit under Medicare, and I look forward to seeing that a drug benefit is enacted soon. Until then, however, we must continue to explore what can be done to get safe, effective, and affordable drugs in the hands of our seniors. Today, we will consider a proposal which attempts to do this by legalizing the personal importation and reimportation of drugs from other countries. I commend you, Chairman Bilirakis, for calling this hearing to examine this issue, and I commend our colleague, Jack Kingston for his interest in this important subject.

By and large, drugs cost less in both Canada and Mexico, largely due to price controls. We have all heard of the bus trips where seniors cross into Canada in order to purchase cheaper prescription drugs.

While these trips provide seniors with access to cheaper drugs, they also provide seniors with access to drugs which may not be as safe and as effective as drugs approved by the FDA. Our nation has the safest drug supply in the world, and the FDA's safety regime is commonly referred to as the "gold standard." I look forward to learning from FDA precisely whether they've quantified the risk posed by personal importation. Is the risk posed by personal importation not so high, given that FDA exercises its enforcement discretion and does not stop these drugs from entering the country? Are there other factors preventing FDA from stopping the flow of reimported drugs into the U.S.?

Does FDA have data showing the percentage of drugs being brought in to our country which are adulterated, unsafe, or subpotent? If not, why hasn't this data been collected?

As many of you know, our country technically has a law on the books pertaining to reimportation. This law, which passed in 106th Congress, would permit reimportation by pharmacists and wholesalers, but only if the Secretary of Health and Human Services certified that the practice would ensure cost savings and safe drugs for Americans. Neither the Clinton nor the Bush Administration could certify those things. As a result, reimportation by third parties remains illegal, as it has been since this Committee passed the Prescription Drug Marketing Act under Mr. Dingell's leadership in 1988.

The legislation before the Committee today would change this by allowing pharmacists to reimport drugs from any nation in the world, as long as the drugs do not appear to be adulterated, misbranded or unapproved. There is no requirement in the bill that the Secretary of Health and Human Services certify that reimportation will ensure safe drugs for Americans. Further, unlike other proposals which I've seen, the bill before us today does not limit reimportation to a specific country or list of countries, and it doesn't require the reimported drugs to be tested. The Secretary has already told us that legislation with these protections is not enough to protect the public health. I'm interested in hearing from FDA what protections are necessary to protect the public health.

I appreciate Jack Kingston bringing this matter to the Committee's attention. I want to work with him, as well as all concerned Members of the Committee, to learn whether reimportation can be done safely and, if so, what protections must be placed into the law for it to be done right. It is my intent to continue to examine this issue thoroughly and then move legislation through our Committee before the end of September. I look forward to hearing from the witnesses.

Mr. BILIRAKIS. I thank the gentleman.

Mr. Pallone for 3 minutes.

Mr. PALLONE. Thank you, Mr. Chairman. I have a great deal of respect for our full committee chairman, but I am listening to what he says, and of course, his emphasis has been on the safety aspect with regard to reimportation.

I would venture to say that I think that is sort of spinning it in a direction that maybe is convenient for the Republican leadership but does not tell the true story about what is going on with reimportation. Reimportation and the need for it right now directly relates to price, and the issue of price and price discrimination is the issue that the Republican leadership in this committee and in the House as a whole do not want to address.

That is why they didn't include it in the prescription drug bill that they passed. That is why they would not allow Ms. Tubbs, a consumer witness, to testify today, because she was going to testify about the issue of price. That is what seniors face. They face tremendous price discrimination. The price and the inability to access drugs because of the price is the main reason why we need a Medicare prescription drug benefit.

The bill that we should pass in the House—not the Republican bill but the Democratic alternative that we tried to get up on the floor and could not because the Republicans would not allow it—directly addresses the issue of price by requiring that the Secretary of Health and Human Services negotiate price reductions. The Republican bill says the opposite: There can be no interference with price, no negotiations, no price structure. There is a specific clause in the bill that says that.

I want to say—I was going to address it, but now they left—we had three of our Republican colleagues here who are sort of heroes on this issue: Mr. Gutknecht, who takes to the floor from time to time; Mr. Kingston; and Mr. Thune. I maybe should not talk about

them because they did leave the room, but I am only saying good things, so I think it is okay.

The bottom line is that this is a very—there is a political reason for this hearing today. That is, that there are members of the Republican Party—and Mr. Gutknecht is one of them—who were supportive of the Democratic alternative because it addressed the issue of price.

Now, they were basically told, I am sure, well, you know, we can't get to it in the bill that passes the floor, but maybe we will have some hearings on it, so we can give you an opportunity to say that we are trying to do something about reimportation, we are trying to do something about price.

You are not trying to do it after the fact. You already passed the bill. What is this hearing for today? Is it simply for show, to try to give the impression to these guys who wanted to be helpful that somehow we were going to address the issue?

We are not addressing it today. This is a sham. The fact of the matter is that the Republicans do not want to address the issue of reimportation, other than talk about the safety aspect. They are not going to allow an amendment or any kind of legislation that would allow reimportation or expand reimportation. They are not going to address any issue that relates to price, because PhRMA and the pharmaceutical industry does not want the issue of price addressed. We have a PhRMA witness, but we don't have a consumer witness for that very reason.

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

Mr. Burr for 3 minutes.

Mr. BURR. Mr. Chairman, I must admit I tried desperately not to listen, but some of it did seep through.

You know, on this day, Mr. Chairman, where we in a bipartisan way will take up homeland security for one very specific reason, to say to the American people that the current threat that we have on terrorism, we will try to eliminate as much of it here at home as we possibly can. And we are here today to debate a similar thing as it relates to the possibility of whether we are going to lower the gold standard that we have set for the American people about the safety and the efficacy of the pharmaceutical products that they take, without question of how they were made or where they were made or whether they work.

I want to take this opportunity also to highlight Mr. Kingston and Mr. Gutknecht and Mr. Thune and Mrs. Emerson, who have been passionate about this issue. They are a lot of the reason that we are here today.

But the fact is that I also want to make some remarks on an editorial I read this week. It was an editorial written by Anthony Daniels, and for the purpose of my colleagues on the other side of the aisle, he is not an industry rep, he is not a policymaker, he is an FBI agent, retired.

He said, "Legislation allowing reimportation of U.S.-made drugs from abroad could open the door, the floodgates, to adulterated and often dangerous counterfeit drugs from unscrupulous profiteers, deranged individuals, and even terrorists. Not even trained professionals can spot the negligible differences between many of today's counterfeit and real things."

It goes on in that editorial to quote another individual who is a policymaker. That quote is: "Without our domestic safety net to ensure the integrity of these pharmaceuticals, consumers simply do not know what medicines they are buying." That quote was the observation of Senator John Breaux.

Mr. Daniels goes on to sum up in his editorial. He says this: "my advice to 100 Members of the U.S. Senate and to 435 Members of the House of Representatives on allowing reimported drugs is pretty straightforward: Don't risk it. Don't risk it."

Some say they are here today because their stand is for the health of the senior population. I would tell you that the reason we are here is to ensure the safety of the pharmaceutical inventory for the entire American population.

Mr. Chairman, I hope on this that we will have a healthy debate, and at the end of the day, the decision will be to protect this very valuable tool that we have in our health care arsenal, just like we intend today to protect this country from terrorists.

Mr. BILIRAKIS. I thank the gentleman.

Mrs. Capps.

Mrs. CAPPS. Thank you, Mr. Chairman. I am pleased we are holding this hearing on the reimportation of prescription drugs. The issues relating to reimportation, such as safety, such as medication prices, are very critical to my constituents.

In my time in Congress, I have been a supporter of proposals to bring U.S.-made prescription drugs back into this country. It has been the only way I could find on our agenda to help my constituents get access to affordable prescriptions.

Many have raised questions about the safety of reimportation. As a public health nurse, I want answers to these questions. But frankly, it is so appalling that we even need to look at these issues and that we are having this hearing today.

Why—and I hope this question is addressed by members of our panel—why are Americans feeling driven to seek their medications overseas or across the border? It is a cost and time to them to do this. Why are there not affordable alternatives here at home?

Our taxes fund billions of dollars in research and development at the National Institutes of Health. Our taxes subsidize the research that our American corporations enjoy, but the fruits of these public investments remain far out of reach to so many of our citizens, especially those on fixed incomes, our seniors.

Over the last decade, as new miracle drugs have come on the market, their prices have skyrocketed way above the cost-of-living increases, and as a result of that, many Americans have no choice but to turn to foreign markets to find affordable medications. Everywhere I go in my district, my constituents tell me about the problems they face because of the high price of drugs, prescription drugs; not just seniors, either, but working men and women struggling to support their families. They need help as well.

Nothing happens, however, to bring the prices down or to help people with their costs. We still have not enacted a prescription drug benefit under Medicare, and the proposal passed by the House will not help, particularly Ms. Tubbs who wanted to testify today, whose medication she pays out of pocket amounts to about \$4,000 a year. She would have to incur costs of up to \$2,000 additional a

year before the benefit that was passed out of the House would come into play.

Prescription drug companies insist that if we do anything to cut their exorbitant profits, it will prevent them from developing new drugs. When we suggest that maybe they can afford to do testing to make sure their products are safe and effective for children, they demand patent extensions. Yet they still have millions of dollars to pay for expensive advertising to induce people to buy their products, whether they need them or not, and to lobby against prescription drug proposals here in Congress.

Some of these companies do offer discount cards, but these discounts are usually nothing more than an illusion. They often provide limited savings that are wrung out of community pharmacists and do nothing to reduce the overall costs of medications. So I think we need to seriously examine the cost of prescription drugs in this country.

A debate about the safety of reimportation medications should be part of that evaluation, but it is not the entire question. It is only a symptom of a much larger crisis. I look forward to hearing from our witnesses.

Mr. BILIRAKIS. I yield 3 minutes to Dr. Norwood.

Mr. NORWOOD. Thank you, Mr. Chairman. Every time I open a paper, it seems like I see an article about seniors loading onto buses heading into Canada or Mexico to buy cheaper prescription drugs. While I admit I am encouraged by their ingenuity, I continue to have concerns about their safety as they try to meet their financial bottom line.

When I am back in Georgia, I hear from scores of constituents concerned about their rising prescription drug costs. We worked hard to address this issue in passing a Medicare prescription drug bill for seniors. There is no question in my mind that implementing a comprehensive prescription drug bill for seniors actually will bring down prices, and we do need to continue to talk about the cost of drugs.

We are going to talk about generic drug competition in September. I am very interested in some possible Hatch-Waxman reforms. I have also made no secret of my interest in examining the consequences of direct consumer advertising on drug costs.

But Mr. Chairman, I want to commend you. This whole series of hearings about prescription drugs have been, in my mind, divided correctly. This is about safety, that is what this hearing is about; the next hearings will be about cost. Even though you would not let me have my consumer advocate here, I am delighted that you held Mr. Brown to the same rules where he could not have his consumer advocate at this hearing about safety, and should have them next month at the cost hearing. So I commend you and thank you for that.

I will not continue on. I will put the rest of my statement in the record.

It appeared to me that the chairman copied my statement, anyway. My remarks were very similar to his, and I don't know that they need to be repeated. But I want us to keep in mind why we are here. We are here about the safety and efficiency of the medica-

tions that people in this country take. We had better take a very close look at that, or either we don't need an FDA.

I don't know anybody who is ready to vote the FDA out of business, but if you think they are important for our drug manufacturers in America, they have to be even twice as important for the drug manufacturers in China.

I hope we will be very careful, other than just talking about yes, they are too high; yes, it is a concern; and yes, we are going to try to look at that. But let us not do something stupid at this point by allowing drugs to come into this country that actually not only do not work, but potentially could kill people.

With that, Mr. Chairman, I yield back.

Mr. BILIRAKIS. The Chair thanks the gentleman.

Mr. Green for 3 minutes.

Mr. GREEN. Thank you, Mr. Chairman. Thank you for holding this hearing on reimportation of prescription drugs.

As a member representing Houston, Texas, I know from first-hand experience that many of my constituents travel south to Laredo, Brownsville, McAllen, and other border crossing sites to purchase their medicine. It is no wonder that they do. Prescription drugs in Mexico are significantly less expensive than they are in the United States. But as many critics of reimportation point out, there is understandable concern about the safety, potency, quality, and even authenticity of the drugs.

Unfortunately, gaping holes in our data prevent us from really knowing what the true scope of the problem is. We do know that we do not know how many people reimport drugs, what percentage are adulterated, counterfeited, or tampered with, and what the impact is on the individuals who take them. There is no doubt that this problem should be addressed. In all honesty, I have had the honor and privilege of buying pharmaceuticals in Mexico myself.

But I think the biggest problem is what drives individuals to cross the border in the first place: the skyrocketing prices of prescription drugs here in the United States. According to the National Institute for Health Care Management, expenditures for prescription drugs in the United States continue to be the fastest growing component of health care, increasing by an average of 15 percent per year over the past 5 years.

Even more troubling, American consumers are consistently paying higher prices than not only our neighbors, the Canadians, or citizens of Mexico, but also individuals in Europe, Japan, and other industrialized countries.

This huge problem for people who do not have prescription drug coverage, the low-income, the uninsured, and our seniors—I don't think a single member of this panel, whether we support reimportation or not, believes that it is the answer to our prescription drug woes. We need a national health care system that takes care of people so they do not have to drive across the border to access their medicines.

We need a meaningful and comprehensive, affordable Medicare prescription drug benefit. We need to expand Medicaid, S-CHIP, to help those individuals without health insurance get access to the health care system. Unfortunately, Congress continues to grapple with the issues year after year, and seniors must continue to do

what they need to do, and that is including taking bus trips to Mexico or Canada.

They don't want to go on the bus and drive 5 hours to the Rio Grande Valley; they would much rather drive 5 minutes down to their local drugstore. But we are not giving them any choice. If you live near a border, you will go get your pharmaceuticals if you can physically do it.

But until we solve the problem of drug coverage in our country, we really do not have a solution. As long as they are doing that, we need to make sure of the safety of those drugs, and make sure that our constituents know those risks.

Mr. BILIRAKIS. The Chair thanks the gentleman.

Mr. Bryant for 3 minutes.

Mr. BRYANT. Thank you, Mr. Chairman. I will try to be brief. I think just about everything that can be said has already been said, and we are not even halfway through the opening statements.

I do thank you for holding this hearing. It is an important issue. It is an issue today since we are discussing the reimportation issue and certainly the safety factors.

I understand that it is an election year, but I really think this is not a Republican or Democrat issue. I think what we want are affordable drugs for senior citizens that are safe. And to blow off safety is just a political issue. I do not understand that.

I know I have heard a couple of comments about that today, that we are just talking about safety and that is not really the real issue here; it is the cost of drugs, is what I am hearing. Mr. Green did not say that. And I would affirm what he said, that safety is a major, major reason. We can have all the drugs in the world at as cheap a price as possible, but if they are not safe, and we are not sure they are safe—again, we all know what can happen overseas. Even now, post 9/11, the possibilities are unimaginable what can be done.

But we have the FDA for a purpose. We need safe drugs. Certainly they need to be affordable. I hope this panel can work and learn something today that will help us along those lines. But ultimately, we are going to have to be concerned with the safety of these drugs, and ultimately that is the problem out there when we start talking about reimporting drugs. We just cannot be sure.

There are risks involved here, and certainly the people that go over there now assume those risks, and willingly do so. They are informed and they understand they are taking a risk. But certainly if they are going to bring them over here and sell them to unsuspecting people who are not willing to assume those risks, that is where I see a great problem here.

But indeed, this is a very complicated issue. I hope we can keep politics out of this, because certainly the administration prior to this administration, I do not think they were able to certify the safety of reimported drugs, either.

So it is not Republicans, and it is not Democrats. Let us look at this in seriousness, with the idea of trying to find some reasonable compromises and reasonable solutions here.

I want to thank my three colleagues, Mr. Kingston, Mr. Gutknecht, and John Thune, for the great work they have done on this.

I yield back my time.

Mr. BILIRAKIS. The Chair thanks the gentleman.

Mr. Strickland.

Mr. STRICKLAND. Mr. Chairman, I have a statement that I would like to put in the record.

Mr. BILIRAKIS. Unanimous consent is granted that statements of all members of the subcommittee be made part of the record.

Mr. STRICKLAND. Having just said that, I will just take 30 seconds to say that the problem that we are trying to deal with is this cost issue. There may be several ways to approach that, but I think many of us are desperately trying to find something that is going to work. This is one approach that I certainly am willing to look at, but I agree with those who have said that if we have a comprehensive, affordable drug program available within this country, this reimportation issue would go away.

I yield back the balance of my time and I look forward to hearing the witnesses.

Mr. Whitfield, 3 minutes, please.

Mr. WHITFIELD. Thank you, Mr. Chairman.

Of course, all of us do want affordable prescription drugs. That is why we in this committee and in the House passed a meaningful prescription drug benefit for our senior citizens, so that those at the 150 percent of poverty level and below would receive free prescription drugs.

It is not the Cadillac program that all of us would like, but I think it is an important first step and a meaningful first step to provide affordable prescription drugs for seniors.

I am disappointed that some of our friends on the opposite side of the aisle, when they realize that we do not agree with them on every issue, refer to our arguments as a spin, as a sham, as a show. I think the concerns that we have on safety are real concerns.

I was reading an article in the Associated Press on August 17 that said a man who rode a U.S. Senate candidate's Rx Express to Canada to buy prescription drugs says he was sickened by some of the medications he received. A gentleman from St. Cloud "was rushed to the hospital Tuesday after his heart slowed and he passed out. The emergency room doctor who treated him blamed it on the Canadian-purchased medication. While he purchased the correct drug, it was not in the time release capsule form that he usually received in the United States."

So I think these are real concerns, and I would also point out that there is no effective way under some of these drug importation bills to prevent the transshipments of drugs, legitimate or not, from Third World countries into Canada and then into the United States, because Canadian law explicitly exempts pharmaceuticals intended for export from any regulatory oversight whatsoever.

So I think we do have a legitimate concern here on safety, and I think that every senior citizen in America wants a safe drug; not only an inexpensive drug, but a safe drug. I think that is the goal of all of us to guarantee that.

So the fact that we are raising questions about reimportation certainly should not reflect or indicate that we are not interested in providing affordable drugs, safe drugs for our senior citizens. So

this is not a clear-cut issue, and I am delighted that the chairman is having this hearing and will have more on this subject.

Mr. Waxman is recognized for 3 minutes.

Mr. WAXMAN. Thank you very much, Mr. Chairman. The gentleman who preceded me says that this is not a clear-cut issue. There is something that is very clear-cut about this issue. That is the fact that the prices for drugs are too expensive. Seniors don't have coverage. They are being discriminated against. Costs are being shifted onto them, so our American seniors, often elderly women, are finding themselves gouged by the pharmaceutical industry and being charged the highest possible prices.

What we need to solve this problem is a defined, dependable, comprehensive Medicare prescription drug benefit. We need to use the strength of the purchasing power of America's seniors to secure better prices as other countries do. Instead, today these seniors don't have coverage. They pay out of pocket for their drugs. They are the victims of unconscionable discriminatory pricing by the drug companies.

We need not spend time asking why our seniors want to be able to buy drugs from Canada. The answer is obvious: They don't have Medicare coverage. They can't afford the high cost of drugs here, and they can buy those drugs at a cheaper price in Canada.

One response to price discrimination is to legalize reimportation of American drugs into the United States. How can we say no to seniors who cross the border into Canada because they can't afford their medications at U.S. prices? But reimportation schemes are usually complex. They raise difficult questions about whether the reimported drugs will be safe and will actually save consumers money. Some of them do not help all seniors.

So let us be completely clear about this. The pharmaceutical industry could make this problem disappear tomorrow without any of the legislative interference that they dread so much. We would not need to consider relaxing the rules on reimportation if they would voluntarily stop discriminatory pricing against American seniors.

I am proud to be a sponsor of the Allen bill that would stop this discriminatory pricing and put a limit on what can be charged our seniors, consistent with what seniors in other countries are paying for the very same drugs.

Of course I want, first and foremost, a strong prescription drug benefit in Medicare, but the majority of this committee seems to want to change the subject. They want to concentrate on the criticisms of reimportation bills instead of focusing on the reasons seniors have to go to Canada to get better prices in the first place.

Let us address the problems of the high price of drugs, respond to the abuses of the Hatch-Waxman legislation that is keeping generics from the market, let us proceed with a hearing on that subject, and let us give seniors real coverage in Medicare. That is the way to address this problem.

[The prepared statement of Hon. Henry A. Waxman follows:]

PREPARED STATEMENT OF HON. HENRY A. WAXMAN, A REPRESENTATIVE IN CONGRESS
FROM THE STATE OF CALIFORNIA

We are here today for one reason. That reason is price discrimination.

We are here because pharmaceutical companies charge America's seniors far more for prescription drugs than they do any other buyers. They charge seniors more than they charge other Americans with market power, and more than they charge seniors in other countries. And they have singled out some of the most vulnerable members of our society, most of them elderly women, for this price-gouging.

What we need to solve that problem is a defined, dependable comprehensive Medicare prescription drug benefit. We need to use the strength of the purchasing power of America's seniors to secure better prices, as other countries do.

Instead, today, those seniors don't have coverage. They pay out of pocket for their drugs. And they are the victims of unconscionable discriminatory pricing by drug companies.

Studies conducted by my staff on the Government Reform Committee show that, for the very same drug, our seniors pay, on average, more than twice what "preferred customers"—such as HMOs and the federal government—pay. For some drugs, seniors are paying more than 15 times the price paid by other favored customers.

Our studies also show that our seniors are charged at least twice and sometimes three times what seniors in Canada, France, Germany, Italy, Japan, and the United Kingdom pay for the same drugs.

We needn't spend time asking why our seniors want to be able to buy drugs from Canada. The answer is they need Medicare coverage. And they need an end to price discrimination by the pharmaceutical industry.

One response to price discrimination is to legalize reimportation of American drugs from Canada into the U.S. How can we say "no" to seniors who cross the border into Canada because they cannot afford their medications at U.S. prices? But reimportation schemes are usually complex, they raise difficult questions about whether the reimported drugs will be safe or will actually save consumers money, and some of them do not help all seniors.

Let's be completely clear about this: the pharmaceutical industry could make this problem disappear tomorrow, without any of the legislative interference they dread so much. We wouldn't need to consider relaxing the rules on reimportation if they would voluntarily stop discriminatory pricing against American seniors.

I have been proud to be a sponsor of the Allen bill which has been so effective in focusing attention on the practice of discriminatory pricing and the advantage citizens in other countries have over Americans in accessing more affordable drugs. It remains an effective response to these discriminatory pricing practices, and so long as these practices continue, we'll continue to pursue it.

Of course, I want first and foremost a strong prescription drug benefit in Medicare. That is what seniors want too. If this Subcommittee had allowed our beneficiary witness to testify today, that is what we would have heard.

But the majority on this Committee seems to want to change the subject. They want to concentrate on the criticisms of reimportation bills instead of focusing on the reason seniors have to go to Canada to get better prices in the first place.

Let's look at the real issue. Let's end price discrimination.

Let's address the problem of the high price of drugs, and respond to the abuses of the Hatch Waxman legislation that are keeping generics from the market. Let's proceed with a hearing on that.

And let's give seniors real coverage in Medicare. That's the way to address the problem.

Mr. BILIRAKIS. Mr. Pitts is recognized for an opening statement.

Mr. PITTS. Thank you, Mr. Chairman. Thank you for holding the hearing. I think it is important for us all to hear from the witnesses and have the opportunity to ask questions about drug importation and reimportation.

I personally have some concerns about the safety of imported or reimported drugs, which I'm sure will be discussed today. The Food, Drug, and Cosmetics Act requires the FDA to prevent the importation of any drug which appears to be adulterated, misbranded, or unapproved. The approval requirements in the act require that every new drug sold in the U.S. be approved in advance by the FDA based upon safety and effectiveness.

Mr. Chairman, a drug made outside the United States will be unapproved, and therefore, illegal, if it is made in a different plant or through a different process than what FDA approved for U.S.

use. This legislation allows for personal reimportation of prescription drugs, and also allows pharmacists to reimport prescription drugs, thus overriding the prohibition established on reimportation.

I understand my colleagues' concerns about the costs of prescription drugs. However, I am interested to hear in the hearing today whether this legislation will indeed reduce the cost of prescription drugs. Would the potential savings from this legislation be passed on to the American consumers? Mr. Chairman, is it possible for us to certify that reimported drugs are safe?

Opening our borders to this would increase the likelihood that we would expose ourselves to counterfeit drugs, cheap foreign copies of FDA-approved drugs, expired drugs, contaminated drugs, and drugs stored in unsafe conditions.

Further, border inspectors cannot be expected to examine imported drugs and accurately determine the identity of such drugs for the risk they pose to patients who need them.

So I will submit my entire statement for the record, but Mr. Chairman, I think we must be very careful on how we proceed on this very important issue.

[The prepared statement of Hon. Joe Pitts follows:]

PREPARED STATEMENT OF HON. JOE PITTS, A REPRESENTATIVE IN CONGRESS FROM
THE STATE OF PENNSYLVANIA

Mr. Chairman, thank you for holding this hearing today. I think it is important for us all to hear from the witnesses and have the opportunity to ask questions about drug importation and reimportation.

I personally have some concerns about the safety of imported or reimported drugs, which I am sure will be discussed today.

The Food Drug and Cosmetic Act requires the FDA to prevent the importation of any drug which appears to be adulterated, misbranded or unapproved.

The approval requirements in the Act require that every new drug sold in the United States be approved in advance by the FDA based upon safety and effectiveness.

Mr. Chairman, a drug made outside of the United States will be unapproved, and therefore illegal if it is made in a different plant or through a different process than what FDA approved for US use.

This legislation allows for personal importation of prescription drugs, and also allows pharmacists to reimport prescription drugs—blatantly overriding the prohibition on reimportation established by the Prescription Drug Marketing Act.

Mr. Chairman, I am concerned that this legislation has no requirement that the bill would not compromise health, or reduce costs, to become effective.

I understand my colleagues' concern about the cost of prescription drugs. However, I am interested to hear in this hearing today whether this legislation will indeed reduce the cost of drugs. Would the potential savings from this legislation be passed on to American consumers?

Mr. Chairman, it is impossible for us to certify that reimported drugs are safe. Opening our borders to this would increase the likelihood that we would expose ourselves to counterfeit drugs, cheap foreign copies of FDA-approved drugs, expired drugs, contaminated drugs, and drugs stored in unsafe conditions.

Further, border inspectors cannot be expected to examine imported drugs and accurately determine the identity of such drugs or the risk they pose to patients who need them.

The Administration as well as OMB, HHS, FDA, DEA, and CMS—all have released statements in opposition to reimportation. In fact, the Administration announced on June 27, 2001, that :

“The Administration would oppose any amendments . . . that could result in unsafe, unapproved, or counterfeit drugs being imported into the United States.”

And Secretary Thompson has expressed his strong disapproval and admitted that he cannot certify that imported drugs are safe. I quote:

“ . . . the law requires us to certify as Secretary that we know that these drugs are safe. It's impossible for us to certify that these drugs are safe.” (during testimony before the Senate Budget Committee on February 14, 2002.)

Mr. Chairman, we must be very careful on how we proceed on this issue. The Prescription drug Marketing Act was enacted for a reason—to ensure US public health is protected. The ramifications of this legislation could be dire.

I fear that this legislation would make it virtually impossible for FDA to conduct meaningful enforcement.

I yield back.

Mr. BILIRAKIS. The Chair thanks the gentleman.

Mr. Wynn, 3 minutes.

Mr. WYNN. Thank you, Mr. Chairman. I appreciate your calling this very important hearing.

I would only comment very briefly that the fact that we are having this hearing and this discussion today is a terrible indictment of America's health care system.

I would concur with the comments of my colleague, Mr. Waxman. The fact that we have to discuss reimportation of drugs suggests that we have failed. We have failed to provide an adequate prescription drug benefit under Medicare that makes prescription drugs, which are essential in our modern age, available at a reasonable price.

This has led to the creation of this issue, where people are willing to take the risks—that my other colleague on the Republican side of the aisle just described—from a health standpoint in order to get access at reasonable costs to drugs that they believe are either life-saving, or certainly life-enhancing.

So the real point is we ought to have the witnesses' testimonies and we ought to consider ways to do this, to allow people to gain access to these drugs, but we really ought to keep in mind the fact that the business of Congress this year ought to be passing a viable prescription drug plan that can reduce costs for our seniors.

Mr. Chairman, I yield back the balance of my time.

[The prepared statement of Hon. Albert R. Wynn follows:]

PREPARED STATEMENT OF HON. ALBERT R. WYNN, A REPRESENTATIVE IN CONGRESS
FROM THE STATE OF MARYLAND

Mr. Chairman, thank you for holding this important hearing to address the issue of drug reimportation. I look forward to hearing from our witnesses about the safety of drugs reimported from Canada, Mexico and all over the world.

The increasing costs of prescription drugs in the United States has forced many Americans, particularly the 35 percent of seniors who are uninsured, to travel to Canada and Mexico for less expensive prescription drugs. The problem, however, is that these reimported drugs are not inspected by the FDA and may pose a possible risk to patients. I hope that today's hearing will shed some light on the possible risks associated with drug reimportation.

However, while the safety of reimported drugs is important, it is an issue which we should not even have to address. Had Congress passed an adequate prescription drug benefit, the reimportation of drugs would not even be a salient issue. Unfortunately, the House has not yet passed legislation that would sufficiently provide affordable prescription drugs in the United States for seniors.

While I am interested in hearing from today's witnesses about the safety issues surrounding the reimportation of drugs, it is unfortunate that the House of Representatives has not passed a prescription drug benefit that will help all seniors in need of assistance.

Mr. BILIRAKIS. The Chair thanks the gentleman.

I believe that completes the opening statements. We will go on into the hearing—the appalling hearing, as some have referred to it as.

[Additional statements submitted for the record follow:]

PREPARED STATEMENT OF HON. JOE BARTON, A REPRESENTATIVE IN CONGRESS FROM
THE STATE OF TEXAS

Thank you Mr. Chairman for holding this important hearing. The issue of drug pricing is one on which all Members are focused. In particular, much has been made regarding the difference in prices between the United States and other countries.

Congress annually votes on measures to allow the reimportation of prescription drugs into this country. I was in Congress in 1988 when we passed the Prescription Drug Marketing Act. We included in this Act a provision which limits the reimportation of pharmaceuticals to the manufacturer of the product. This provision was designed to address the safety risks associated with drugs entering into the country which were sub-potent or adulterated.

In 2000, Congress passed legislation which allows third party reimportation of prescription drugs; however the legislation included a provision that prohibits implementation until the Secretary of Health and Human Services certifies that there would be no adverse effects on health and the provision would significantly reduce costs. Both Secretary Shalala of the Clinton Administration and Secretary Thompson of the Bush Administration have concluded that they can not guarantee the safety and efficacy of third party reimported pharmaceuticals.

I have supported, and voted for, allowing individuals to import prescription drugs for personal use. If a person knows the risk that a drug from another country may be adulterated, and they assume that risk, then that is their decision. However, if a senior from Grand Prairie, Texas walks into a pharmacy to pick up her heart medication, there should be zero risk that she will take home medication that does not work, or will have adverse health affects.

I come to this hearing with two questions: Can we allow third party reimportation in a manner that ensures the drugs coming into this country will be safe and effective? Will allowing third party reimportation lead to a price reduction in what our seniors are paying for prescription drugs? If the answer to both of these questions is yes, then we must reexamine our policies. If the answers are no, then we must take care in rushing ahead to implement policies which could endanger the public's health.

I look forward to learning the answers to these questions, and again I thank Chairman Bilirakis for holding this hearing.

PREPARED STATEMENT OF HON. FRED UPTON, A REPRESENTATIVE IN CONGRESS FROM
THE STATE OF MICHIGAN

Mr. Chairman, thank you for holding today's hearing on the issue of prescription drug reimportation. At every town meeting I hold in Southwest Michigan, the high cost of prescription drugs is one of the top issues raised. We all want to do something about this issue, and lifting the current-law ban on third-party reimportation of U.S. manufactured drugs sold in Canada, Mexico, or other countries at substantially lower prices than in the U.S. seems to many of our constituents and to many in Congress one easy, immediate way to accomplish this goal. But we need to move carefully and measure the perceived benefits of reimportation against the very real risks that could result.

In the last Congress, as chairman of the Oversight and Investigations Subcommittee, I presided over an ongoing investigation of the importation of bulk chemicals used in the manufacture of prescription drugs. While this is not the same issue as reimportation, what we learned about the sophistication of counterfeiters and the porousness of our borders should give us great cause for concern.

Here's a case in point. Several years ago, 89 Haitian children tragically died after taking cough medicine made with contaminated glycerin traced to China. We may think that tragic events like this can't happen here, with its sophisticated regulatory system. But it almost did. Some of that same batch of contaminated glycerin made it into our country. Fortunately, it was found before it could be used to manufacture cough medicine or other medications here. We got lucky that time.

Here's another case in point. The Subcommittee's investigation revealed that the FDA had linked the adverse reactions of 155 American patients to gentamycin sulfate made by a Chinese drug company. Despite FDA inspections and quality control by U.S. drug companies that used this material, this bulk drug still infiltrated our healthcare system without detection.

Let's not forget that it was this committee that wrote the 1988 Prescription Drug Marketing Act banning third party reimportation, and with very good reason. The Oversight and Investigations Subcommittee—then under the leadership of John Dingell—investigated drug reimportation in the 1980s and found that nearly \$10 billion worth of drugs manufactured in the U.S. and exported were re-entering the

U.S. marked as American Goods Returned. Some had been mishandled, become sub-potent, or were labeled improperly.

Even if we were able to put in place a reimportation policy that would protect us against the threat of counterfeit, sub-potent, misbranded, or adulterated drugs from entering this country—and I think this would be difficult if not impossible to do—I am not convinced that we would see any significant lowering in the cost of drugs to consumers. Remember, neither Secretary Shalala nor Secretary Thompson could certify to this or to the fact that reimports would not pose a public health risk when we tried this approach in the last Congress.

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

Mr. Chairman, most Americans understand there is a price to be paid for living in a country with arguably the most advanced medicine in the world. The research, development, innovation and manpower does not come cheap.

What concerns me is whether or not that price has become too high for too many. Prescription drug costs in this country are rising, and they affect each one of us differently—based on our stage in life, our walk of life, and our quality of life.

Senior citizens especially are struggling to afford the most basic of medications. These same individuals are making lengthy road trips to Canada and Mexico to buy their medications at a lower price. That is a very sobering thought, and one to which we must pay attention.

Technically, those seniors crossing the border to buy their prescription drugs are violating the law. Our system is very closed in that sense, but with good reason.

The law ensures a built in safety mechanism for consumers in how drugs are packaged, labeled, and tested.

Because of that, I have peace of mind knowing that the prescription medication I gave my child or my mother was proven safe. Do I want to compromise that? Absolutely not.

We need to find common, reasonable ground on this issue.

I am not about to compromise safety but, by the same token, prescription drugs serve no purpose if they are too expensive to access.

The legislative proposal before us today, the Drug Importation Act of 2002, attempts to find this common ground, but I do have safety concerns about that provision in the bill dealing with pharmacists.

If pharmacists can import drugs from anywhere in the world, like the legislation proposes, how can HHS conceivably follow the chain of distribution of a drug outside the United States? That seems problematic to me, in terms of the overall safety of the drug.

I would like Mr. Hubbard with the FDA to follow up on that if he might. In fact, I would like all of our witnesses today to comment on that.

Realizing we do have some work to do on this issue, I am certainly ready to do my part, and look forward to the discussion today.

With that, Mr. Chairman, I yield back my time.

Mr. BILIRAKIS. The first panel consists of Mr. William Hubbard, Senior Associate Commissioner for the Office of Policy, Planning, and Legislation of the Food and Drug Administration.

Mr. Hubbard, obviously your written statement is part of the record. Hopefully you will complement and supplement it as you will.

**STATEMENT OF WILLIAM K. HUBBARD, SENIOR ASSOCIATE
COMMISSIONER, OFFICE OF POLICY, PLANNING AND LEGIS-
LATION, FOOD AND DRUG ADMINISTRATION; ACCOMPANIED
BY JOHN TAYLOR, DIRECTOR, OFFICE OF ENFORCEMENT;
AND DAVID HOROWITZ, DIRECTOR, OFFICE OF COMPLIANCE**

Mr. HUBBARD. Thank you, Mr. Chairman. This is Mr. John Taylor, head of the Office of Enforcement, and Mr. David Horowitz from the Office of Drug Compliance in FDA.

As you said, Mr. Chairman, I do have written testimony, but I will include a few things orally.

First of all, on the drug pricing issue, personally I can relate to that as I have an 89-year-old mother myself who cannot afford her prescription medications.

But as an FDA official, I cannot really speak to that issue. That is not within FDA's mandate. All I can do today is talk about safety. I apologize that I can't do that balancing act that so many of you wish to have.

But we do have some things to say about safety, if I may. First of all, I will start with the concept or the problem of counterfeiting. We are all familiar with counterfeit handbags and watches and clothing and those sorts of things. That has been fairly commonplace. It certainly has an economic impact.

But we believe that pharmaceuticals are a much bigger potential problem because consumers not only risk their pocketbook with a counterfeit drug; they also risk their health, and even their life. Consumers cannot discern the difference between a counterfeit drug or a good drug.

This is a counterfeit watch. This is a counterfeit \$900 watch. It happened to cost \$9. A jeweler could tell the difference; a consumer could even perhaps tell the difference if they looked closely enough and feel how much lighter it was than the real thing. But these are counterfeit drugs; these are real drugs that FDA found recently. One is counterfeit and one is real. They are indistinguishable. No one in FDA can tell the difference. Even people in the company cannot tell the difference without doing testing.

I will pass these up to the table for them to be passed out. No pharmacist or physician could tell visually whether those drugs are good or not. Not only is the fact that they cannot be distinguished a problem, but these sorts of counterfeit drugs pose real health problems.

As we have said, counterfeits can be drugs that are subpotent, superpotent, a sugar pill, a powder, or anything else. This is a counterfeit drug that was a fertility drug. It is indistinguishable from the real thing. The actual drug is about 80 percent potent. If a woman took this, she would get a real drug. The problem is, to make this drug, the two vials, you pull a liquid solution called a diluent into a syringe and then shoot it into the other vial where the powdered drug is, and shake it up to dissolve it. Then you pull the reconstituted drug back into the syringe and inject it into the patient's arm.

The problem is, this was made in the back of a warehouse. It has bacteria in the diluent, in the saline solution. When you are injecting that into the patient, you would be injecting essentially blood poisoning into the patient, even though she would be getting some semblance of a real drug.

So we believe that sort of thing is a real concern, particularly since no one can tell at the time they administer it—the nurse administering that would not be able to tell, nor could the physician.

Since 1998, FDA has opened 55 counterfeit drug cases resulting in 26 arrests and convictions, but we are worried that this problem is growing fairly fast. We are seeing a gradual increase in counterfeit drug activity. In 1999, we opened 6 cases of counterfeiting; in 2000, 10 cases; in 2001, 23 cases; and so far in 2002, 16 cases, for

a rate of 30 for the year if that keeps up, which is a fivefold increase in 4 years. That does concern us.

We are also seeing counterfeit drugs being smuggled, which is a somewhat new thing. We are all familiar with narcotics being smuggled, and the Customs Service has been dealing with that for years, but we are seeing things like these. These are stuffed animals from an Asian company. The drugs are in here, the counterfeit drugs. These are not narcotic drugs but prescription drugs which are in this bear. Here is a little car which we found recently. These are prescription drugs in there. These are not narcotics, this is not cocaine, these are prescription drugs. This particular product, they took the motor out and put the drugs in where the motor would have been. Those drugs are counterfeit as well.

Of course, American citizens are clamoring for foreign drugs. They are seeking relief from the high cost of pharmaceuticals. As I said, we can understand that, but that is not our job.

As a result of the consumer demand, mail and Internet drug purchases are increasing steadily for these products. We and the Customs Service cannot adequately screen these drugs for authenticity or safety. Despite almost 400 investigations of these Internet drug sites that sell these drugs, and many, many convictions and arrests, we are still seeing a rapid increase of drugs coming in in little packages like this that we have shown you in the past. This is an injectable drug. It poses some of the same sorts of concerns we have mentioned earlier.

Here we have Viagra and antibiotics. Someone ordered them over the Internet. Of course, antibiotics are particularly a problem to come in over the Internet because we have an antibiotic resistance problem in this country.

Of course, we see these ads over the Internet that say "No physician examination needed, no prescription needed, just send us your credit card number and check off the drug you want, and it will be on its way."

So we are very concerned that despite an effort to enforce against these drugs, we are actually seeing an increase in this Internet purchase. Also, our criminal investigators are seeing counterfeit drugs coming from anywhere and everywhere.

These are just some recent ones. Here is one from Spain, one from France, Switzerland, Mexico, Germany. These are coming in every day, so we know the counterfeiters are out there. That is why we keep raising this issue of opening the borders up to these sorts of drugs. It is, from FDA's point of view—notwithstanding the price issue that, of course, you are all concerned about—we are very concerned about that as a trend.

Of course, the latest trend is to go to Canada. There has been legislation introduced and considered by Congress to legitimize that practice. Ads are running in newspapers around the country: "you can get your drugs from Canada, a big price savings. Just fill out this form and the drugs will be on the way."

We understand the consumer demand for these products, but we are concerned that if a Canadian system is set up, that Canada, which now probably has one of the more secure systems for assuring the safety of pharmaceuticals, could become a place where the drug supply is far different than it is today, and that it could be

a transshipment point for all of these folks who are making these counterfeit drugs in various parts of the world.

With that, Mr. Chairman, I will end my opening remarks and be glad to take questions.

[The prepared statement of William K. Hubbard follows:]

PREPARED STATEMENT OF WILLIAM K. HUBBARD, SENIOR ASSOCIATE COMMISSIONER
FOR POLICY, PLANNING AND LEGISLATION, FOOD AND DRUG ADMINISTRATION

INTRODUCTION

Mr. Chairman and Members of the Committee, I am William K. Hubbard, Senior Associate Commissioner for Policy, Planning and Legislation at the U.S. Food and Drug Administration (FDA or the Agency). I appreciate the opportunity to discuss our mutual concerns related to the importation of drugs into the United States. This topic encompasses a range of issues, including the importation by individuals of prescription drugs through the mail or in person; the purchase of drugs from foreign sources over the Internet; and the potential introduction of counterfeit drugs into the U.S. drug supply.

FDA is also concerned about legislative initiatives that, while intended to provide drug price relief to consumers, would severely damage the system of drug regulation that has come to be known as the "gold standard" for drug safety throughout the world. Last month, speaking at a biotechnology summit in Canada, Secretary Thompson said "Opening our borders to reimported drugs potentially could increase the flow of counterfeit drugs, cheap foreign copies of FDA-approved drugs, expired and contaminated drugs, and drugs stored under inappropriate and unsafe conditions. In light of the anthrax attacks of last fall, that's a risk we simply cannot take."

PERSONAL IMPORTATION OF DRUGS THROUGH THE MAIL

Under the Federal Food, Drug, and Cosmetic (FD&C) Act, unapproved, misbranded, and adulterated drugs are prohibited from importation into the United States. In general, all drugs imported by individuals fall into one of these prohibited categories. This includes drugs that are foreign versions of FDA-approved medications, and drugs that are dispensed without a prescription. In addition, under the Act, FDA-approved drugs that are manufactured in the U.S. and exported may not be reimported by anyone other than the manufacturer.

The volume of prescription drugs for personal use imported through the mail has increased dramatically in recent years. According to testimony by the U.S. Customs Service (Customs) before the House Government Reform Committee in May 2000, seizures of parcels containing scheduled or controlled substances at international mail facilities increased by 450 percent in FY 1999, primarily due to drug sales over the Internet. FDA estimates that approximately two million parcels containing FDA-regulated products for personal use enter the U.S. each year through international mail facilities. This estimate is based on an extrapolation of data obtained during a pilot project conducted at the international mail facility in Carson, California, which is discussed in more detail below.

At mail facilities, Customs officials identify parcels that may violate the FD&C Act for FDA examination. FDA inspectors then determine if these products should or should not be permitted to enter the country. If detained, FDA must issue a notice to the addressee describing the potential Federal violation and provide the individual with an opportunity to respond and provide reasons why the drug parcel should be allowed entry. If the addressee does not respond or provides an inadequate response, FDA will give the parcel back to Customs to have it returned to the exporter. Due to the requirements for notice and an opportunity to respond, the detention and further processing of mail parcels consumes large amounts of FDA resources. In addition, considerable storage space is needed to hold the large number of detained parcels until replies are received from the addressees.

Recent advertisements in U.S. newspapers and magazines claim that Congress has made the personal importation of drugs a legal practice. Other advertisements and certain Internet sites state that personal importation of up to a 90-day supply of prescription medications is legal. Neither of these claims is true. As we will discuss in more detail below, we are seeing an increasing number of Canadian pharmacies and U.S. intermediaries marketing prescription drug products directly to U.S. citizens, in violation of state pharmacy laws and the FD&C Act.

From a public health standpoint, importing prescription drugs for personal use is a potentially dangerous practice. FDA and the public have no assurance that unap-

proved products are effective or safe, or have been produced under U.S. good manufacturing practices. FDA cannot assure the public that re-imported drugs made in the U.S. have been stored under proper conditions or that they are even the real product, because the Agency does not regulate foreign distributors or pharmacies. Therefore, unapproved drugs and re-imported approved medications may be contaminated, subpotent, superpotent, or counterfeit. In addition, some websites based outside the U.S. offer to dispense prescription drugs without a prescription by a licensed practitioner or a physical examination, bypassing the traditional doctor-patient relationship. As a result, patients may receive inappropriate medications due to misdiagnoses, they may fail to receive appropriate medications or other medical care, or they may take a product that could be harmful, or fatal, if taken in combination with other medicines they might be taking.

Personal Importation Policy

Under FDA's personal importation policy, as described in guidance to the Agency's field personnel, FDA inspectors may exercise enforcement discretion in limited circumstances to permit the importation of certain unapproved prescription medication for personal use.

First adopted in 1954, the policy was last modified in 1988 in response to concerns that certain potentially effective treatments for AIDS patients were not available in the U.S. but were available in other countries. The Agency expanded the guidance for humanitarian purposes to allow individuals suffering from serious medical conditions to acquire medical treatments legally available in foreign countries but not approved in the U.S.

The policy is articulated in guidance to FDA field personnel and is not a license for individuals to import unapproved, and therefore illegal, drugs for personal use into the United States. Because the policy does not apply to medications that are already available in the U.S., even if sold under the same name, only a very few drug products available from foreign sources, especially Canada and Mexico, meet the personal importation criteria.

The current personal importation policy permits the exercise of enforcement discretion to allow entry of an unapproved prescription drug only if the intended use is for a serious condition for which effective treatment may not be available domestically; the product is considered not to represent an unreasonable risk; the product is for personal use; there is no known commercialization or promotion to U.S. residents by those involved in the distribution of the product; and the individual seeking to import the product affirms in writing that it is for the patient's own use and provides the name and address of the U.S. licensed doctor 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.

FDA's personal importation policy, as written, is difficult to implement with respect to mail shipments of drugs. This is due, at least in part, to the difficulty faced by Customs or FDA inspectors, or even health care practitioners, in identifying a medicine simply by its appearance or its labeling, which may falsely identify a product. From a practical standpoint, FDA inspectors cannot visually examine drug products contained in a mailed parcel and accurately determine their identity or the degree of risk posed to the individual who will receive these drugs. Also, largely due to the advent of Internet sites selling prescription drugs from all points around the globe, the volume of parcels containing prescription drugs has increased dramatically, beyond the ability of Customs and FDA staff to efficiently process.

Due to the huge volume of drug parcels entering the U.S. through the international mail and courier services, the requirements for notice and hearing, and our limited resources, it is difficult for FDA to detain and refuse mail imports for personal use. As a consequence, tens of thousands of parcels that FDA does not review are eventually released by Customs and sent on to their addressees, even though the products contained in these parcels may violate the FD&C Act and pose a health risk to consumers. We do not believe this is an acceptable public health outcome.

CARSON MAIL FACILITY PILOT

In early 2001, FDA and Customs conducted a survey of imported drug products entering the U.S. through the Carson City, California, mail facility (the Carson pilot). The purpose of the Carson pilot was to provide a means for examining incoming mail shipments of pharmaceutical products over a specified time frame to identify both the volume and the types of drug products entering the U.S. We also wanted to better assess the level of effort and human resources required to handle drug importations at a mail facility, and to better understand the public health implications these importations may have for U.S. consumers.

The Carson pilot ran for a five-week period, with FDA inspectors present for 40 hours per week, a much higher staffing level than is normally possible. Although Customs took a baseline sample which indicated they could have set aside for FDA review an estimated total of 16,500 international packages (650 packages per day), FDA was able to examine only 1,908 packages during the five-week pilot, or an average of 381 packages per week. Unexamined packages were sent on to the addressees. Of the 1,908 packages examined by FDA, 721 parcels originating in 19 countries were detained and the addressees notified that the products appeared to be unapproved for use in the U.S., misbranded and/or a drug requiring a doctor's prescription.

Analysis of the Carson Pilot Drug Parcels

FDA's Center for Drug Evaluation and Research (CDER) reviewed listings of the products detained during the Carson pilot to define better the nature of the risk to public health from the types of products coming into the U.S. through personal importation. CDER's review demonstrates that there are serious public health risks associated with many of the 721 drug shipments (composed of 197 different drugs) detained at Carson. There are primarily two types of risks that consumers of these drugs would face. The first risk arises when consumers take drugs of unknown origin or quality. Second is the very significant risk associated with taking many of these drugs without first obtaining a physician's prescription and without the continued oversight of the physician.

In general, FDA has no information to establish where these drugs were actually manufactured and whether current Good Manufacturing Practice requirements were followed. There is also no assurance that the drugs were packaged and stored under appropriate conditions to avoid degradation or contamination. Approximately eight percent of the shipments contained drugs that could not be identified because they contained no labeling; some of these contain only foreign language labeling. Most of these drug shipments were contained in plastic bags; one shipment contained drugs taped between magazine pages.

Several drugs do not appear to correspond with any FDA-approved drugs and the risks are therefore difficult to assess. One drug had been reviewed for FDA approval but was denied approval due to cardiac abnormalities and because its efficacy could not be demonstrated. Several shipments contained three drugs that were once approved by FDA but have been withdrawn from the market based on serious safety concerns.

The vast majority of the shipments were identified as containing prescription drugs, which by definition have a degree of toxicity and/or risk associated with them such that they are not safe for use except under the supervision of a licensed health care practitioner (Title 21, U.S.C. section 353(b)). We believe that very few foreign Internet sellers require a prescription from a practitioner licensed in the U.S. before dispensing drugs to U.S. residents. Moreover, after detention notices were issued to the intended recipients of the 721 drug shipments, fewer than four percent responded with evidence of prescriptions or that a physician would provide oversight of the use of the drugs purchased from abroad.

A number of controlled substances were identified, including lorazepam, codeine sulfate, loperamide, chlordiazepoxide, chloral hydrate, and diphenoxylate. These drugs have the potential for abuse, addiction or life-threatening overdose. A physician's prescription and oversight are essential for managing these risks. Additionally, drugs having potentially serious adverse side effects including diabetes, hypertension and serious infection were included in the Carson shipments, as were many drugs with serious contraindications and/or possible drug or food interactions for which physician oversight is essential.

Many of the drugs identified in the Carson pilot are intended to treat conditions that only physicians can properly diagnose. Consumers who bypass physician diagnosis and prescribing may be exposing themselves to risks and toxicities that cannot be justified by offsetting benefits. For example, almost ten percent of the shipments were for antibiotics, despite the fact that consumers are generally not able to diagnose whether their symptoms are caused by bacterial or viral infections. Several drugs listed are potent steroids, which are generally prescribed for conditions that are not self-diagnosable.

Based on these observations, FDA believes that the type of drugs that are coming into the country for personal use, as demonstrated by the Carson pilot, pose substantial risks to the public health.

INTERNET DRUG SALES

Based on a survey conducted in early 2000 by FDA's Office of Criminal Investigations (OCI) and a subsequent study by the General Accounting Office, there appears

to be roughly 300 to 400 Internet sites selling prescription drugs to consumers, with approximately half located domestically and half located outside the U.S. FDA has long taken the position that consumers are exposed to a number of risks when they purchase drugs from Internet sites that are not operated by pharmacies licensed and operating within state pharmacy law or sites that dispense foreign drugs. 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. FDA cannot provide consumers with any assurance that these products were manufactured under current good manufacturing practice standards. Taking an unsafe or inappropriate medication puts consumers at risk for dangerous drug interactions and other serious health consequences.

Internet sites that provide prescription drugs by having consumers fill out a questionnaire rather than seeing a doctor can pose serious health risks. A questionnaire generally does not provide sufficient information for a healthcare professional to determine if that drug is appropriate or safe to use, if another treatment is more appropriate, or if the consumer has an underlying medical condition where using that drug may be harmful. Finally, it must be noted that in the case of foreign based web sites, if consumers have an adverse drug reaction or any other problem they have little or no recourse because the physical location or operator of the "pharmacy" often is not known or the seller is beyond the consumers' reach. FDA has no ability to take effective action against these foreign operators on behalf of U.S. citizens.

Over the last twelve to eighteen months, FDA has noticed a proliferation of websites that offer drugs purportedly from Canada directly to U.S. consumers. As noted earlier, a number of these websites claim that drug sales from Canadian pharmacies directly to U.S. consumers are legal. This is false. Some websites purport to offer "U.S. approved" drugs, however, it is highly unlikely that the drugs are in fact approved by FDA. Some web sites are actually ordering services that take orders from consumers that are then fulfilled by supposed Canadian pharmacies. However, under state law, these ordering services are likely participating in the practice of pharmacy without a license to do so.

A number of Canadian drug websites and U.S. ordering services indicate that the Canadian drugs are dispensed pursuant to existing prescriptions that are rewritten by a Canadian doctor in order to comply with Canadian law. However, the dispensing of medication on a prescription written by a physician who has not seen the patient or conducted a physical exam is generally contrary to state medical practice standards. Additionally, Dr. Henry Haddad of the Canadian Medical Association has said that under the Canadian Code of Ethics, physicians have a responsibility to do a history, physical exam and discuss the risks and benefits of the medication with the patient. He went on to say that the approval of prescriptions for patients they have not seen "Is something Canadian physicians should not be doing" (Associated Press, 6/26/02).

Some of these sellers have become so emboldened that they have solicited state Medicaid programs to import drugs from Canada. One Canadian pharmacy recently sent packages of prescription drugs to more than 500 U.S. consumers in a single shipment. Another boasted that since it added Internet sales to its local pharmacy a year ago, the store has gained about 100,000 U.S. customers. An ordering service based in Florida has announced plans to open 500 storefront shops nationwide within three years (Orlando Sentinel, 6/3/02).

Some recent criminal cases indicate the seriousness of the risks to public health that confront regulators with regard to Internet drug sales, but also illustrate the progress that is beginning to be made in combating this problem.

NORFOLK MEN'S CLINIC

On February 16, 2002, a federal jury in Alabama convicted Anton Pusztai and Anita Yates of charges arising out of the operation of the online pharmacy that illegally sold prescription drugs over the Internet to consumers. On June 18, Pusztai and Yates were sentenced respectively to over 15 years and 6.5 years of incarceration. Pusztai, an Australian citizen, and Yates, a resident of Clanton, Alabama, were convicted of conspiracy to commit violations of the FD&C Act, conspiracy to commit money laundering, mail fraud, dispensing misbranded drugs, and operating a drug repackaging facility not registered with FDA. From fall 1998 to the summer of 2000, the defendants operated a website called Viagra.au.com, also known as Norfolk Men's Clinic, and related sites, that sold Viagra, Xenical, Celebrex, Propecia, and Claritin-D to consumers.

In September 1999, OCI received information regarding the Norfolk Men's Clinic and the website. Based on this information, several covert purchases were made via

the Internet. Search warrants were executed in October 1999 that resulted in the seizure of prescription drugs along with numerous business records. Additional covert purchases were made from part of the Internet operation in West Virginia. Based on these purchases and numerous interviews, several individuals were indicted. In addition to defendants Pusztai and Yates, the president of a prescription drug wholesaler located in Miami, Florida, and the company itself, pled guilty to distributing midbranded drugs and to obstruction of justice. In conjunction with the indictment, a second search warrant was executed in Clanton, Alabama along with two search warrants in West Virginia. While most of the drugs sold in this operation were domestic product, some appeared to have originated in New Zealand.

MEDICATIONS EXPRESS

On June 7, 2001, Gerald Bevins was convicted in U.S. District Court for the Southern District of California of conspiracy to defraud the U.S. and commit offenses against the U.S. by introducing misbranded drugs into interstate commerce and smuggling. On September 4, 2001, Bevins was sentenced to serve twenty-four months in prison. The case was initiated on information received from Customs concerning an Internet web site called Medications Express. Bevins sold Mexican prescription pharmaceuticals from this website and claimed that no doctor's prescription was necessary. He continued to sell Mexican prescription pharmaceuticals through the mail from Sun City, California, even after discontinuing the Medications Express web site. Bevins, his wife and daughter, would receive orders via mail, travel to Tijuana, Mexico to purchase the pharmaceuticals, and smuggle them back into the U.S. The three packaged the pharmaceuticals into commercial courier boxes and shipped them to customers around the U.S. The drugs supplied by Bevins were labeled in Spanish and included Ritalin, Valium, Rivotril, and steroids.

CANADIAN DRUG STORE, INC.

On May 14 of this year, the Ontario College of Pharmacists, a Canadian government agency, filed charges under Ontario law against The Canadian Drug Store Inc. for unlawfully operating an unlicensed pharmacy and using an un-registered pharmacist in filling prescriptions for U.S. residents. The College also filed charges against a licensed pharmacist, pharmacy, and physician in Ontario for helping to facilitate the delivery of prescription and non-prescription drugs to U.S. residents. A drug wholesaler was charged with supplying medications to a non-licensed pharmacy.

According to a statement released by the College, "There are many websites selling prescription and non-prescription medicines that have not been accredited as legitimate pharmacies by pharmacy regulators in either Canada or the U.S. The public needs to know that some websites presenting themselves as online "pharmacies" or "drugstores" may be operating without a pharmacy license and dispensing prescriptions without the oversight of a licensed pharmacist."

TOTAL REMEDY / PRESCRIPTION CENTER II

According to news accounts, a Los Angeles pharmacy and two pharmacists were assessed penalties of almost \$90 million in a state Board of Pharmacy proceeding this past May for filling more than 3,500 illegal prescriptions over the Internet. The case was under a new law enacted in 2001 that creates a requirement in California to fill prescription pursuant to a "good-faith medical examination." The Internet site concentrated on filling prescriptions for "lifestyle" drugs such as Viagra and Propecia (Associated Press, 5/29/02).

Pillbox Pharmacy

In March of this year, a Texas pharmacist, three doctors, two corporations and an individual were charged in a federal indictment alleging that they conspired to illegally dispense drugs in connection with an Internet pharmacy operation. The indictment charged one pharmacist, three physicians and two corporations, the S&H Script Shop and the Pillbox Medical Center, with conspiring to illegally dispense controlled substances and commit money laundering. According to the indictment, between January 1, 2000, and June 12, 2001, the defendants grossed more than \$7.7 million from the Internet sales of just two drugs alone. The indictment alleges the doctors would issue prescriptions without establishing a patient history, performing a mental or physical exam, using appropriate diagnostic or laboratory testing, or providing any means to monitor medication response. The charges were the result of an 18-month investigation by FDA, the DEA and the Internal Revenue Service, working with the U.S. attorney's office. In April, the pharmacist and two

corporations pled guilty to illegally dispensing controlled substances, and agreed to forfeit \$1 million.

Other Enforcement Activity

To date, OCI has initiated 296 Internet drug investigations with each case involving a variable number of websites from one to 25 or more. These cases originated from multiple sources including interception at mail facilities, web based research, consumer complaints, and a variety of others. OCI has effected 112 Internet-related drug arrests and obtained 72 convictions. OCI currently has 101 open Internet drug investigations.

Currently, FDA has 90 sites under active review for possible regulatory or civil action. Warning letters have been sent to 55 domestic online sellers. Additionally, FDA has sent 137 "cyber letters" to operators of Internet sites in many countries, including Canada, that offer to sell online prescription drugs or unapproved drugs. These sites may be engaged in illegal activity such as offering to sell prescription drugs to U.S. citizens without valid (or in some cases without any) prescriptions. Cyber letters are sent over the Internet to the suspect websites to warn the operators that they may be engaged in illegal activities, and inform them of the laws that govern prescription drug sales in the U.S. Cyber letters have a deterrent effect and FDA has seen positive results from using them. FDA also sends copies of its cyber letters to the home governments of targeted websites when the locations can be identified. Follow-up depends on the ability and willingness of the foreign regulatory bodies to investigate and take actions against website operators who are illegally shipping drugs to other countries.

In cooperation with the Department of Justice (DOJ), FDA has obtained five preliminary injunctions against the sale of illegal products, including one product marketed as a weight-loss aid containing a potent thyroid hormone which could cause heart attacks or strokes, and an unapproved cancer therapy. Additionally, 15 product seizures, 11 product recalls, and the voluntary destruction of 18 violative products have been achieved, generally pertaining to unapproved new drug products including gamma hydroxybutyric acid, gamma butyrolactone, Triax, 1,4 butanediol, and laetrile. Forty-five foreign shippers have been placed on Detention Without Physical Examination and added to Import Alert 66-57 for targeting sales of unapproved new drug products to the U.S.

IMPORTATION AT LAND BORDERS

FDA is aware that a number of U.S. citizens travel to other countries to purchase medications at a lower cost. However, many prescription drugs available from foreign sources are either unapproved foreign versions of FDA-approved drugs or products for which there is no U.S. approved counterpart. In either case, these products are unapproved drugs prohibited from importation by section 505 of the FD&C Act. In FDA's experience, many drugs obtained from foreign sources that purport to be the same as U.S. approved prescription drugs are of unknown quality. FDA cannot provide adequate assurance to the American public that the drug products they purchase in other countries are the same products approved by FDA.

FDA is developing a program to better warn U.S. citizens about these dangers and the potential risks to their health when purchasing such drugs. We have begun to provide brochures to consumers crossing U.S. borders to make such purchases and are installing posters at borders stations warning of the dangers inherent in purchasing drugs outside the U.S.

Within the last two years, FDA has conducted three surveys at U.S. borders to gather data on drug products carried by individuals entering the U.S. While these border surveys involve land traffic rather than mail importation, the results show some similarities to the findings from the Carson mail pilot, but also some significant differences.

Southwest Border Survey (August 2000)

A survey of prescription drugs being brought by pedestrians into the U.S. at eight ports of entry along the 2,000 mile border with Mexico was conducted by FDA's Southwest Import District (SWID) with the assistance of other agencies. The survey looked at activity during four hours on a Saturday (August 12, 2000) at eight border ports in California, Arizona, and Texas. The purpose of the survey was to determine what specific types of products are being imported, and who is importing these products. The data collected from over 600 interviews indicated that the most common importers of prescription drugs were older male Caucasians with prescriptions from the U.S., bringing back primarily antibiotics or pain relievers for their own use. Prescriptions were held by 63 percent of the persons interviewed (59 percent U.S. prescriptions and 41 percent Mexican). The most common drugs and their indications

that were purchased in Mexico during the survey were as follows: Amoxicillin (antibiotic), Glucophage (diabetes), Premarin (estrogen), Dolo Neurobion (vitamin supplement), Vioxx (inflammation), Retin-A (acne), Tafil (anxiety), Celebrex (arthritis), Penicillin (antibiotic), Viagra (impotence), and Carisoprodol (analgesic). While many of these products are already available as FDA-approved drugs in the U.S., some are unapproved for sale in this country.

Canadian Border Survey

On January 6, 2001, in cooperation with Customs, FDA conducted a survey to obtain a snapshot of prescription drug products being brought into the U.S. from Canada via passenger vehicles. During the eight-hour survey at three ports of entry in New York, Michigan and Washington, a total of 10,374 passenger vehicles and 58 buses crossed into the U.S. Of these, 33 passenger vehicles (35 individuals) were referred by Customs to be interviewed. These individuals brought in a total of 47 containers of drug products from Canada. The types of products included pain medicines—primarily A-222 (a combination of acetaminophen, caffeine, and codeine) or similar products. The indicated reason for import was that the products were available over-the-counter (OTC) in Canada and cost less than in the U.S. The next largest group of products was herbal products, with the reason for importation being that the products were not available in the U.S. Other products included Tobradex (antibiotic/ steroid ophthalmic for individuals having laser eye surgery); Claritin and Allegra (allergies) purchased OTC in Canada; Sibelium capsules (calcium channel blocker); and a variety of OTC products sold in Canada and not available in the U.S.

Some of these drugs are unapproved foreign versions of FDA-approved drugs, although some approved for sale as prescription drugs in the U.S. are sold as over-the-counter medications in Canada.

Southwest Border Survey (April 2001)

On April 11, 2001, FDA, Customs, and other agencies conducted a survey of prescription drugs being brought into the U.S. at seven ports of entry along the U.S./Mexican border. This survey coincided with both Easter vacations, college spring break and the end of the snowbird season, when tourists from Northern states visiting along the Southern border return home. During the four hour survey, a total of 586 persons brought in a total of 1,120 drugs. Approximately 56 percent had a prescription for the medicines (61 percent were U.S. prescriptions, 39 percent were Mexican). The most common drugs purchased in Mexico were: Amoxicillin (antibiotic), Premarin (estrogen), Claritine (allergy), Terramicinia (antibiotic), Ampicillin (antibiotic), Ibuprofen (analgesic), Penicillin (antibiotic), Vioxx (inflammation), Tafil (anxiety), Dolo Neurobion (vitamin supplement), Glucophage (diabetes), Celebrex (arthritis), Naproxen (analgesic), Retin-A (acne), Ventolin (pulmonary disease), and Valium (controlled substance/ nervous system depressant). As in the earlier survey, many of these products are already available as FDA-approved drugs in the U.S., while some are unapproved for sale in this country.

Controlled Substances

Although we do not know, nor is it possible to clearly determine, the amount of controlled substances brought into the U.S. purportedly for personal use, it is likely that such medicines are frequently imported for resale and pose a public health risk. The Agency has been working with both Customs and DEA to streamline and clarify Federal import policies specifically related to the importation of controlled substances.

COUNTERFEIT DRUGS

FDA continues to believe that the quality of drugs in this country is high, and that the public can continue to have confidence that the drugs sold in the U.S. market are authentic. The Agency, however, takes very seriously any allegations or information regarding the counterfeiting or adulteration of drug products. As the drug manufacturing and distribution system has become more global in nature, the challenge of protecting against counterfeit, adulterated or substandard drugs has become more difficult. We are concerned about a spate of drug counterfeiting and tampering cases that have occurred in recent months, and we believe these incidents caution against any weakening of the current regulatory system.

The manner in which FDA handles these types of counterfeit and tampering incidents are driven by two primary goals that are often, but not always, complementary. First and foremost, FDA works with consumers, manufacturers, wholesalers, distributors, state agencies and others in order to determine the composition of the unsuitable product and the extent to which it has been introduced into the distribution chain, and we use this information do whatever is necessary to protect the pub-

lic health. Second, OCI, with the support and cooperation of other FDA components and other law enforcement agencies, attempts to bring the perpetrators of criminal acts to justice. It must be noted, however, that the need to publicize the existence of a counterfeit or adulterated product in order to alert professionals and the public to potential dangers may compromise the successful conduct of criminal investigations.

Regular FDA district field investigators often work closely with OCI special agents in these cases. They follow up at specific wholesalers, distributors, hospitals or pharmacies identified as having received counterfeit product to conduct tracebacks on particular lots and to determine sources, quantities involved and the distribution of product to retail outlets. The FDA's Forensic Chemistry Center (FCC) and/or the drug and biologic review divisions provide field personnel with the labeling and packaging of authentic product for comparison with counterfeit product. FDA also posts information to its MedWatch site to inform consumers and health care professionals about safety concerns related to counterfeited or tampered products.

OCI opened 55 counterfeit drug cases from October 1998 through June 2002. During that time we have made 26 arrests with 20 convictions. We have seen a gradual increase in the incidence of finished dosage form counterfeit activity over the last few years. So far this year we have 16 cases opened, 12 arrests, and seven convictions. Eight of these arrests and five convictions are attributable to the latest eight counterfeit drug appearances.

The current focus on drug counterfeiting and the public perception of a more dramatic increase in counterfeit drug activity is due to the fact that the latest several counterfeits have appeared in the wholesale market and received wider distribution than has been the case historically. This is due to the existence of an illicit wholesale drug diversion network that has grown up around tiered pricing and economic fraud.

This system consists of criminal middlemen who knowingly solicit closed door pharmacies, such as a hospital or nursing home supplier, to over-order certain drugs based on fraudulent demand. The drugs are then sold into the wholesale drug diversion network. The diverter typically offers a 25 percent kickback to the closed door pharmacy and diverts the excess drugs into the illicit wholesale diversion system. This system depends on the diverter maintaining confidentiality for the closed door pharmacy since the pharmacy would lose its preferred pricing should the manufacturer discover the fraudulent arrangement. False pedigrees are the hallmark of the system as each wholesaler passing the drugs on to the next faces being "cut out" if the subsequent buyer knows the identity of his supplier's source. It is easy to see how this system of "willful blindness" facilitates the entry of counterfeit and otherwise unsafe drugs into the marketplace. Unfortunately these illegal schemes net huge profits. From October 1998 to June 2002, OCI opened 255 Prescription Drug Marketing Act diversion cases, executing 464 arrests and resulting in 337 convictions, with fines and forfeitures totaling approximately \$32 million.

The following examples of counterfeit drug products and tampering incidents may help to illustrate the types of activity we have recently encountered.

Serostim (somatropin (rDNA origin) for injection), Serono Laboratories

In late 2000 and early 2001, FDA became aware of consumer complaints about adverse effects and a recall at the distributor level of Serostim. FDA enforcement personnel and criminal investigators became involved and engaged FDA field offices nationwide, which included investigative follow-up at other distributors and the manufacturer. In January 2001, Serono issued a press release regarding the apparent counterfeiting of one particular lot. An additional press release and Dear Health Care Professional letter were issued by the company in May 2001, regarding a second lot.

In May 2002, Serono became aware that counterfeit Serostim displaying a fake lot number had been distributed. Preliminary information indicates that the counterfeit product may have been distributed via the Internet. Laboratory analysis by FDA shows that the product contains no active ingredient, and it has been determined that the product did not originate from Serono.

On May 16, Serono issued a letter advising Serostim handlers to be aware of the counterfeit lot even though it has not shown up in normal distribution channels.

Neupogen (filgrastim), Amgen, Inc.

In the spring of 2001, based on observations by a distributor about product appearance, Amgen analyzed a suspect lot and determined that the vials contained only saline solution. Investigation by the company and FDA revealed that the lot did not display a legitimate Neupogen lot number, but one that had been assigned

to a lot of Epogen, another Amgen product. The FCC performed additional analysis. In May 2001, Amgen issued 17,000 Dear Health Care Professional letters nationwide informing patients, physicians, pharmacies and wholesalers about the counterfeiting of Neupogen. Later that month, Amgen reported to FDA on product with four lot additional numbers having wrong expiration dates, indicating either counterfeit lot numbers or that expiration dates were changed to make them more saleable by extending dates. In June, Amgen updated its Dear Health Care Professional letter with information on additional confirmed and suspected counterfeit lots.

Epogen (epoetin alfa), Amgen, Inc.

In May 2002, FDA, state regulators and Amgen became aware that potential counterfeit Epogen may be in commerce. Amgen analysis indicated that a counterfeit product labeled as Epogen 40,000 U/ml vials with a particular lot number contained a clear liquid having active ingredient approximately 20 times lower than expected. Samples of the authentic product as well as the counterfeit product were sent to FCC for analysis. On May 8, Amgen issued a letter advising health care professionals about the counterfeit Epogen and describing the differences between authentic and counterfeit packaging so that physicians can identify the authentic product. Further investigation revealed that a major wholesale distributor was holding approximately 1,600 cartons of counterfeit product. The majority of this counterfeit product was tracked back to a wholesaler located in the western U.S. On May 24, Amgen issued a second advisory letter to warn health care professionals that two additional counterfeit lots of Epogen were discovered.

Combivir (lamivudine plus zidovudine), GlaxoSmithKline

In the spring of 2002, GlaxoSmithKline (GSK) received four complaints that bottles containing 60 tablets of Combivir were being replaced with Ziagen tablets. In addition, the firm determined that counterfeit Combivir labels were placed on authentic bottles of Ziagen tablets. Both medicines are used as part of a combination regimen to treat HIV infection. A GSK health hazard evaluation of this situation determined that if an individual takes the wrong tablet and is sensitive to abacavir sulfate (Ziagen), a potentially life threatening hypersensitivity reaction could occur. GSK has stated that the incidents appear to be isolated and limited in scope, and no injuries or adverse reactions have been reported. However, in May, distributors were advised to initiate recall to their customers. GSK also issued a press release to alert patients, pharmacists and physicians to watch for third party tampering that incorrectly labels Ziagen as Combivir.

Zyprexa (olanzapine), Eli Lilly & Co.

In the winter and spring of 2002, Eli Lilly received complaints from four pharmacies in four states that the product Zyprexa had been removed and replaced with white tablets labeled as aspirin. Zyprexa is indicated for the treatment of schizophrenia and acute bipolar mania. The tampering situations occurred in two strengths and in three different lots. The company determined that the tablets from two of the complainants were non-Lilly tablets and looked the same in both complaints. FDA has determined the manufacturing source of the white tablet marked as aspirin and is continuing to investigate. On May 4, Lilly issued a press release and Dear Health Care Professional letter concerning the tampering situation. The company stated in their press release that these incidents appeared to be isolated and limited in scope.

Procrit (epoetin alfa), Amgen/Ortho Biotech

In May 2002, based on requests from state health authorities, Amgen obtained and analyzed samples of 40K vials of Procrit from a certain wholesale distributor. The analysis indicated that a counterfeit drug product labeled as Procrit 40,000 U/ml vials with a certain lot number contains a clear liquid having active ingredients approximately 20 times lower than expected. Samples of the authentic product as well as the counterfeit product were sent to FCC for further analysis. Investigators are continuing following up at wholesalers and distributors identified as receiving the counterfeit product. One major wholesale distributor was found to be holding approximately 339 cartons of counterfeit product. In June, Ortho Biotech issued a Dear Health Care Professional letter and press release which details the differences between authentic and counterfeit packaging so that physicians can be certain they have the authentic product.

In addition to the above cases, OCI has made a number of recent arrests relating to counterfeit AIDS and cancer drugs, as described below.

Serostim, (somatropin (rDNA origin) for injection), Serono Laboratories

In November 2000, Nicholas Hanson was arrested by a task force of OCI, U.S. Postal Inspection Service, and Iowa State Police on charges of conducting an ongoing criminal enterprise. Hanson was the leader of a small group that counterfeited Serostim. He imported the human growth hormone through the Internet from China, via Express Mail. At the same time, Jeremy Gansen was arrested by the same task force and charged with conducting an ongoing criminal enterprise related to the misbranding and distribution of human growth hormone and steroids. Gansen assisted Nicholas Hanson in the counterfeiting of Serostim.

Nutropin AQ (somatropin (rDNA origin) for injection), Genentech

In July 2001, an individual was arrested in Texas by OCI and subsequently indicted in August 2001 by a Federal Grand Jury. He was charged with counterfeiting Nutropin, trafficking in counterfeit goods and controlled substances violations. He subsequently plead guilty to counterfeiting Nutropin and distributing controlled substances. In December 2001, a second individual was indicted by a Federal Grand Jury in Texas for counterfeiting the above Nutropin, conspiracy to defraud the FDA, aiding and abetting and controlled substances violations. He is a fugitive and a provisional international arrest warrant is being sought for his arrest. He will be extradited to the U.S. In April 2002, two additional individuals involved in the distribution of counterfeit Nutropin were arrested by OCI and DEA for selling heroin to an undercover agent. Finally, in May 2002, a fifth individual was arrested by OCI for selling counterfeit Nutropin, and he subsequently plead guilty to the charge.

FDA remains strongly concerned about any possibility that counterfeit or otherwise unsafe drugs may find their way into the American drug supply. We will remain vigilant as we refine and improve the programs and procedures that we use to ensure the availability of safe medications for consumers. We also believe that proposals that have been put forth in Congress to allow either the reimportation of drugs by persons other than the original manufacturer, or to allow consumers to import drugs for their own personal use, will provide additional avenues for unscrupulous individuals to place counterfeit, substandard or otherwise dangerous drug products into U.S. commerce and into citizens' medicine cabinets, as discussed below.

DRUG IMPORTATION LEGISLATION

Currently, new drugs marketed in the United States must be approved by FDA based on demonstrated safety and efficacy; they must be produced in manufacturing plants inspected and operated in conformance with FDA's current Good Manufacturing Practice (GMP) requirements; and their shipment and storage must be properly documented and subject to inspection. This "closed" regulatory system has been very successful in preventing unapproved, adulterated or misbranded drug products from entering the U.S. stream of commerce. Legislation that would establish other distribution routes for drug products, particularly where those routes routinely transverse a U.S. border, creates a wide inlet for counterfeit drugs and other dangerous products that can be injurious to the public health and a threat to the security of our nation's drug supply.

Although a number of bills have been introduced that would facilitate the importation of foreign drugs, FDA has looked most closely at S. 2244, which has been the subject of recent activity on the floor of the U.S. Senate. This bill, introduced by Senator Dorgan and others, and its companion bill in the House, H.R. 4616, introduced by Rep. Sanders, would create two new pathways for drugs to enter the U.S. outside of the current drug regulation system that, while not perfect, has a remarkable record of protecting the public from contaminated, ineffective, or counterfeit drugs. Of particular concern are the provisions for allowing individuals to import drugs directly from Canadian pharmacies. This would greatly exacerbate the growing problem of the hundreds of websites purporting to sell legitimate medications that are in fact selling unapproved or otherwise dangerous drugs to Americans. These personal importation provisions are so broad that they will over-ride existing statutes that allow FDA to refuse entry to prescription drugs from Canada if they are believed to be unsafe, ineffective, adulterated, contaminated or counterfeit.

Throwing the door open to drugs purchased by individuals directly from Canadian sellers will encourage unscrupulous individuals to devise schemes using Canada as a transshipment point for dangerous products from all points around the globe. Web sites touting the availability of supposedly legal drugs from Canada will spring up in large numbers, duping consumers that will have no way of knowing that the drugs may be illegal, counterfeit or contaminated.

S. 2244 and H.R. 4616 would create a second route for transporting drugs into the U.S. outside of the existing regulatory system. The bill would allow pharmacists

and wholesalers to purchase drugs from Canadian sellers over which U.S. authorities (FDA or others) have no jurisdiction or control. Because the bill requires that the drugs comply with sections 501, 502 and 505 of the Act, it may be found, in practice, that for the bill to have its intended effect, U.S. manufacturers would have to sell drug products manufactured, labeled and intended solely for the U.S. market to Canadian distributors, specifically for re-sale to the U.S. As a practical matter, meeting these requirements would be very difficult, and it is unlikely that Canadian sellers and U.S. importers would be willing to endure them. Additionally, it is not clear as to how FDA could ensure that drugs reimported under this proposal would in fact comply with those sections of the Act, because the Agency has no practical ability to regulate or inspect Canadian facilities.

The bill attempts to ensure the safety of the drugs under 804(b) by requiring testing for authenticity. Unfortunately, authenticity can rarely be established solely through chemical analysis. That can only be assured by the multiple layers of safeguards that are built into the FDA's oversight system in which drug approval, regulation, inspections and surveillance tracks drugs over their entire life cycle. The testing required by the bill would not protect against the threat of counterfeit drugs because no random sampling plan can protect against such criminal conduct. The threat of counterfeits does not depend on the integrity of the product itself, but on the integrity of those handling it. Since counterfeits can easily be commingled with authentic product, either by the case, by the bottle, or by the pill, there is no sampling or testing protocol sufficient to protect against the grave public harm they pose.

In addition, the bill would require drug manufacturers to disseminate their drug formulations and chemical fingerprints to potentially thousands of pharmacies and wholesalers. This information, currently protected as trade secret, could be worth millions of dollars, per drug, on the black market. Counterfeiters could obtain drug formulations and learn how to make their fake drugs look real and survive chemical analysis. Notwithstanding these very real safety concerns, it is questionable as to whether the bill would achieve the goal of bringing cheaper pharmaceutical products to U.S. consumers. Any cost savings that might be generated may well be absorbed by the fees charged by exporters, wholesalers, pharmacists and testing labs.

We would also like to recognize that the Administration is continuing to review this legislation and may have further comments. Finally, FDA notes that we will continue to offer our expertise and advice to the Congress, as we have in the past, in exploring any additional proposals which may be offered to address the drug pricing issue, including those involving reimportation.

CONCLUSION

Mr. Chairman, FDA remains concerned about any possibility that unsafe drugs may find their way into the American drug supply. We will remain vigilant as we refine and improve the programs and procedures that we use to ensure the availability of safe medications for consumers. We appreciate the Committee's interest in assuring that the American public has access to safe and affordable medicines and we look forward to working with you in furtherance of this goal. Thank you again for the opportunity to participate in today's hearing. I will be happy to answer any questions.

Mr. BILIRAKIS. Thank you very much, Mr. Hubbard. There certainly will be many questions.

Mr. Hubbard, how long have you been with the FDA?

Mr. HUBBARD. I will have 30 years in September with the Department of Health and Human Services, 26 of those with the FDA.

Mr. BILIRAKIS. So you are certainly far from a political appointment, are you not?

Mr. HUBBARD. One could say that, yes.

Mr. BILIRAKIS. Were you faced with this problem—for how long, now? Is this a new problem? Is this a very recent problem?

Mr. HUBBARD. We have seen isolated examples of counterfeiting going back at least 15 or 20 years, and probably further than that, but they were very isolated. Our concern is that, as with some of the statistics I gave you, we are seeing a ramping up of that right

now. It does concern us that the counterfeiters are increasingly anxious to get their products into this country.

Mr. BILIRAKIS. How about the reimportation?

Mr. HUBBARD. On the reimportation via the mail, the growth of the Internet has been a big cause of a spurt there. There were always catalogs around that people could order drugs from Germany or wherever, but that was a very low-level activity. Now, with the growth of the World Wide Web, it is fairly easy to go buy these drugs, and we are seeing—we don't have any firm data, but it is probably an exponential increase in the last 4 or 5 years.

Mr. BILIRAKIS. Mr. Hubbard, under present law, the FDA can prevent the reimportation of a drug which appears to be unapproved, adulterated, or misbranded. The Kingston legislation prohibits the FDA, as I understand it, from preventing importation if the drug appears to be approved.

I wonder if you could address the "appears to be approved," if you will. What does that mean, really? Can a drug appear to be approved and still be unsafe?

Mr. HUBBARD. Well, this is one of the drugs that we found in the mail. This appears to be approved. It says "Viagra," and gives the name of the manufacturer. We have no idea where it was made.

Mr. BILIRAKIS. What do you mean, it appears to be approved?

Mr. HUBBARD. It has the brand name of an approved drug, and it has the name of a manufacturer, and it has labeling that looks like the approved labeling. I have no idea whether this is a safe and effective drug or not, but it appears to be approved.

Mr. BILIRAKIS. So by changing the current standard whereby under the legislation it would meet the "appears to be approved" standard, if you will—

Mr. HUBBARD. I believe that is correct, Mr. Chairman. I believe this drug, if it arrived under Mr. Kingston's bill, would in fact be allowed in because it appears to be approved.

Mr. BILIRAKIS. You couldn't stop it?

Mr. HUBBARD. It appears to be approved. If that is what the standard would be, then we would not be able to stop it. I suppose if we had some—I believe the bill would allow—if we had evidence that a drug was unsafe, we could then stop it, but in most cases we would not know that.

Mr. BILIRAKIS. Under the legislation, could you stop it if you had concrete evidence that—

Mr. HUBBARD. My understanding—and I would want to consult with counsel—but I believe if we had concrete evidence that it was not approved or was somehow unsafe, that would indeed allow us to say it is misbranded or otherwise illegal.

Mr. BILIRAKIS. The FDA has analyzed a number of reimportation proposals and consistently told Congress that they would jeopardize public health. All of these proposals have contained various protections intended to safeguard the American consumer, and yet the FDA has said that they are all—they do not do enough to ensure safety.

Do you have any recommendations in terms of protections that might be necessary to allow reimportation to work?

We have all acknowledged the high cost of drugs, and many here have already harped on that, and the rhetoric, the political rhet-

oric, and all that. We all acknowledge that it is the high cost of drugs that is resulting in this reimportation. Mr. Brown indicated reimportation is due to the system of high drug costs. I don't think anybody would disagree with that. But until or unless something is done toward that end, we are faced with reimportation.

Do you have any suggestions on the part of the FDA, sir?

Mr. HUBBARD. We could give the Congress a list of things that might ameliorate the safety issues; things like assuring the pedigree of the product, testing the product, licensing the importer, limiting the people and places it can come into, and many other things.

You could tick off a lot of things that would be expensive for the FDA or the taxpayer to do that would hopefully make things better, but I don't believe that anything that we have been able to think of could create a system that duplicates the current safe system.

The current system is fairly closed. It is difficult for unsafe and ineffective drugs to get into the market in this country, so our fear is that anything that opens that up, even with some protections built in, would not be adequate for us to be able to say that the drugs are as safe as they are now.

Mr. BILIRAKIS. Thank you, Mr. Hubbard.

Mr. BROWN.

Mr. BROWN. Thank you, Mr. Hubbard. If prices were lower in the United States, would there be as many prescription drugs smuggled in and toy trucks and fluffy bears from China, or whatever you held up? Would we see as much of that?

Mr. HUBBARD. I actually think we might still see a fair amount, because many of the drugs, they are so-called lifestyle drugs: Viagra for sexual potency and propecia for hair growth. There are certainly consumers and patients out there who would still be seeking drugs, we believe, because it would be the kind of situation where they would not want to consult with a physician, or they might think they are doing something not totally legal.

But certainly for those who are seeking drugs because they cannot afford their current prescription, then that could be the case.

Mr. BROWN. So you had talked about drugs being smuggled in, and you mentioned three countries. You mentioned others, but three jumped out at me: Switzerland, Spain, and France.

It is curious that drugs in those three countries, all three, particularly Switzerland and France, wealthy countries but countries where drug prices—and Tamoxifen is one—it is one-fifth or one-eighth the cost as it is in the United States.

If we were to do some of the things that other countries did, compulsory licensing, bringing in competition into the marketplace, some sort of negotiations like Canada does with the drug companies, something direct like that, you would not—you would see very few drugs that seniors now can't afford that you mentioned, you would see very few of those smuggled in from Switzerland and France and Spain, presumably. Correct?

Mr. HUBBARD. I would defer to your judgment as to whether those sorts of controls had that effect. I would note that these are not real drugs, they are counterfeit, so you would be buying a fake

drug. You would be wasting your money. You would be getting a worse deal than you get by paying a high price in this country.

Mr. BROWN. I would submit that the number of counterfeit drugs is directly proportionate to the demand for them, and the demand for them is higher because prices are so high.

Let me go a different direction. Has FDA looked closely at Canada's drug regulatory system?

Mr. HUBBARD. I talked to the Canadian FDA the week before last, at some length, and asked them a lot of questions about their system. We obviously know some things about their system, because they are a neighboring country, and sometimes the two FDAs collaborate on things. But they have their own separate system.

They make two important points to us. One is that they have a law, just as we do, that exempts them from being concerned about the safety of a product for export. So just as a drug that can be brought in this country and sent to another country is not one that FDA looks at, they do the same thing.

So if an importer from Canada brings a drug in strictly to export to the United States, the Canadian FDA could care less. That is not even under their jurisdiction.

Mr. BROWN. You would assume, if they imported it from the United States, it would be safe, though?

Mr. HUBBARD. One would hope so.

Mr. BROWN. And most of these drugs that my constituents bring back and that the lady, Mrs. Tubbs, that refused to sit at the table on the next panel, a consumer representative, a consumer herself, that the drugs she buys are from the United States, sold to Canada and at a much lower price.

Is there evidence that the Canadian system is less rigorous than the U.S. system? Do you have any evidence of that?

Mr. HUBBARD. They did explain a concern that they didn't have as many inspectors as we did. They have about 90 to 100 inspectors for a very large country.

Mr. BROWN. Well, for a very small country.

Mr. HUBBARD. A very large country in size, I think.

Mr. BROWN. Well, I don't think drugs are bought by acres; they are bought by human beings. I mean, we are talking—the number of people is a lot more important than, you know, the size of Siberia.

Is the FDA—okay, this is through a couple of conversations you have had recently with—

Mr. HUBBARD. Right.

Mr. BROWN. Has the FDA looked at how Canadian provinces license their pharmacies?

Mr. HUBBARD. We have asked; it is similar to our system. The Canadian system is similar in that there is a Federal authority that oversees the safety and efficacy of drugs; and then the practice of medicine and the practice of pharmacy are regulated at the provincial level, which is analogous to the State level of the United States.

Mr. BROWN. Are the standards, in your view, more lax than those applying to U.S. pharmacies—to your knowledge, Canadian pharmacies?

Mr. HUBBARD. I couldn't qualitatively judge their standards. They appear to be analogous, at least in the way they are described. But I don't know the specific standards, I don't know the frequency of inspection, and I don't know the rigor of the regulatory authority.

I can only describe what they say, which is similar to ours.

Mr. BROWN. Okay. So you don't know their standards. You don't have evidence that they might be lax, more lax, less lax, the same. You don't know about the—if there is evidence, you don't have evidence that they are less rigorous than the U.S. regulatory system.

You have had a couple of conversations—almost the way you relate them, they sound kind of informal—fairly recently. Yet you make decisions to hold drugs at the border that American seniors have wanted to buy. You are making decisions where some of those seniors may not get their prescriptions at all because they can't afford them. So you have made the choice, it sounds like, at the FDA, based on no real evidence except a few conversations that you are admitting, you are saying, don't tell you a lot of information—you are making decisions that really do deny access to prescriptions, that a lot of American seniors and others want, based on no real evidence.

I mean, shouldn't the FDA be looking and really making and learning more about this and understanding what this is about, so you can make a decision on whether or not those drugs should be held at the border, whether we should be allowed to have—they should have access to them.

Mr. HUBBARD. Well, if I may respond, the law says they should not come in, none of them. We should be letting none of these products in.

But we tend to prioritize because of resource limitations and have been focusing on larger, so-called "commercial shipments." So, you know, Canadian pharmacies that send in hundreds of prescriptions, large, large bulk packages, Customs sees those. They call us, and we say, don't let them in.

The individual little packages that citizens mail tend not to be caught. It is not that we wouldn't like to turn them back, but we can't. We have to, as you know, go through a notice system to turn those back, so they do tend to come in.

Mr. NORWOOD. Thank you very much, Mr. Hubbard.

Mr. BROWN. I have one more question.

Mr. NORWOOD. The chairman is next. You are considerably over, Mr. Brown.

Mr. Chairman, you are now recognized for whatever time you would like.

Chairman TAUZIN. Thank you, Mr. Chairman.

Let me ask you a couple of questions directly from your testimony, sir. You pointed out in the testimony that the FDA does not have the ability to reach into another country, even Canada, to protect U.S. citizens from drugs that may have been sent to them that are harmful or dangerous, adulterated, or possibly just they were cheated because they were noneffective drugs; is that correct?

Mr. HUBBARD. That is correct, Mr. Chairman.

Chairman TAUZIN. You can take action here in the United States, though, against people who do that to our citizens, right?

Mr. HUBBARD. That is correct, Mr. Chairman.

Chairman TAUZIN. In the United States you don't authorize—as I understand it, the FDA has never authorized a drug until it is properly tested, until you know it is safe and effective; is that right?

Mr. HUBBARD. That is correct, Mr. Chairman.

Chairman TAUZIN. If we passed a law that said FDA from now on could authorize drugs for American seniors that simply appear to be safe and effective, would that destroy the gold standard?

Mr. HUBBARD. Well, it would certainly undermine it very substantially. I suppose the word “destroy” would be a good word for that.

Chairman TAUZIN. Yeah. I mean, if I were a drug manufacturer and I brought you a drug and I said, you know, look at it, does it appear to be safe and effective; and that is all you had to do—you didn't have to go through protocols and test it thoroughly to make sure it didn't have side effects; that it was the right potency; it was properly designed so that it didn't have damaging effects on citizens; that it really did what it was intended to and did it well; if you didn't go through that rigorous testing procedure, if all you were required to do was say, it appears to be safe and effective, that would destroy the safest drug system this world has ever seen, would it not?

Mr. HUBBARD. I think you make a strong case for that, Mr. Chairman.

Chairman TAUZIN. I am certain it would.

In your testimony you do talk about Canada. You give us some pretty good information. You tell us FDA has noticed a proliferation of Web sites that offer drugs purportedly from Canada directly to U.S. customers; is that right?

Mr. HUBBARD. Yes, Mr. Chairman.

Chairman TAUZIN. You make it clear that those Web sites are illegal, that ordering shops like that today take orders from consumers and probably violate the laws against practicing pharmacy without a license; is that right?

Mr. HUBBARD. Yes, Mr. Chairman.

Chairman TAUZIN. Are you shutting down those Web sites?

Mr. HUBBARD. Well, no. We have no authority to. We do write them and ask them to cease doing this.

Chairman TAUZIN. You don't have authority to shut them down even?

Mr. HUBBARD. And only a few have even bothered to write us back.

Chairman TAUZIN. Yeah, but I mean, they don't even get back in touch with you; We have got a real problem.

You also point out that in Canada, the Canadian code of ethics requires physicians to do a history, physical exam, and discuss the risk and benefits of medication with the patient; is that correct?

Mr. HUBBARD. I understand there is such a—

Chairman TAUZIN. And yet these shops are getting Canadian physicians to simply rewrite the prescriptions in order to comply with Canadian law; is that right?

Mr. HUBBARD. Yes.

Chairman TAUZIN. Without ever seeing a patient, without ever doing a history, without ever doing an examination to make sure this patient can take the drugs in the quantity or the way in which they are being presented to them from these shops; is that right?

Mr. HUBBARD. That appears to be the fact pattern.

Chairman TAUZIN. Is that not a risk to American seniors and people taking drugs in this country?

Mr. HUBBARD. And that is true not only with Canada, but with all Internet sales.

Chairman TAUZIN. I would think it would be.

I asked some questions when I gave you the opening statement, and I am going to ask you perhaps to do something you feel uncomfortable doing, but I am going to ask you to do it anyhow.

There is an awful lot of pressure on the Congress just to say, go ahead, let people buy drugs from anywhere they want to buy them, because drugs do cost an awful lot; and until drugs are faced with real competition, with generic varieties, you know, a patent protects drugs, and they are very expensive when they have to be tested. The rigorous testing standards we have in this country are pretty expensive to go through, all that testing and research and development, and they end up costing us a lot.

But that is part of our gold standard. We need to remember that.

But if this Congress were pressured to pass a bill that allowed importation, we could do several things. We could say, look, we are not worried about safety. We are not worried about whether physicians really see patients or whether drugs just appear to be safe. We are not worried about it anymore. It is okay. Send it in, if it appears to be safe, doctors, go ahead and sign prescriptions even though you don't know the patients, never saw them, never did a history, don't know whether they should be taking these drugs, go ahead and send it on in.

We could take that view. We are not worried about safety; we are just worried about costs, so send it on in. But if we took that view, and we were worried about making sure that people who bought drugs from another country were as protected as they are when they buy drugs under our gold standard here in America, from cheaters and people that might hurt them with adulterated and unsafe drugs, what reasonable, cost-effective measures would you recommend to us to ensure to the best practical extent, recognizing that we could not have as good a gold standard on imported drugs as we have on protecting citizens with drugs manufactured in this country and sold in this country, what would that list be?

Now, I am not asking for it today. But we are going to be back here in September having more hearings. We are going to be asked to report something to the House so the House can look at a bill. And I want to do the best job I can, and I know Mr. Bilirakis wants to do the best job he can.

And if we have to include protections, I really want you to work hard at this and send us your best recommendations on what the most cost-effective, most reasonable protections would be and still tell us what the—at that point, even what risk we have to accept, because if we in Congress really want to do this, we ought to know the risk we are taking not just for ourselves, but for the folks who

sent us up here to try to make sure we had a good, safe drug system.

One final question, Mr. Chairman, and I will yield.

We just got through passing a bioterrorism bill in the face of this war against terrorism we are engaged in. We were appalled to know how little we inspect food and drugs at the border. And I have read your importation policy, where you do allow people to come in with some drugs under certain circumstances.

And I read about your complaints, about your inability to do a real good job because of mail orders and inspections at the border and how weak that can be. We just went through an effort of trying to beef that up, because we were deeply concerned about people sending things in, like guys who mail anthrax letters to people around this city, deeply concerned about them using an importation policy we might pass to suddenly begin hurting citizens of this country by sending in drugs that may be laced with products like that that would harm them.

Can you give us any assurance that after having passed this bioterrorism bill, if we pass a drug importation bill, we will not have complicated the efforts of those at the border whom we are trying to energize into protecting Americans against people who intentionally would adulterate drugs not just to make us sick, but to kill us.

Mr. HUBBARD. It would certainly undermine the effort that Congress just passed in instructing us to be more careful at the border, because it would have more of these products coming in, more likely to have problems. And then we would be diverting resources, to look at these away, from sort of the terrorist thing that Congress ordered us to do; and the whole system would presumably get weaker.

Chairman TAUZIN. Thank you, Mr. Chairman.

Mr. NORWOOD [presiding]. Thank you, Mr. Chairman.

Mr. Stupak, you are now recognized for 5 minutes.

Mr. STUPAK. Thank you, Mr. Chairman. And let me thank Mr. Pallone. I have a 3 hearing that I have to get up to, and he let me go before him; so I appreciate his willingness to do that.

Mr. Hubbard, you know, the chairman talked about the gold standard our FDA has, and all that, and what reasonable protections can we have and what is the risk; and I thought those were good questions. But these are questions we asked you back in June of 2001, and I think we are still waiting for some answers. If people really knew that the drugs are, flowing into this country, whether it is Carson City—that is a Los Angeles mail facility—or the one right here in Washington, DC, you would have millions and millions of this stuff coming in every year.

And we had a hearing last year where people have died because they had taken drugs that—they thought it was something that they needed, and in fact, it was something that they did not need, and actually it was counterproductive to their health.

So I guess my question is that it has been more than a year ago when we had this hearing on the issue of reimportation—it was June of last year—and you testified that because these drugs represent a serious threat to public health that the FDA was recom-

mending to the Secretary of HHS that FDA stop allowing the importation of such drugs through the mail. Is that correct?

Mr. HUBBARD. That is correct.

Mr. STUPAK. So what have you done on that to make sure that we stop this importation of drugs through the mail?

Mr. HUBBARD. Well, we have met with HHS Secretary Tommy Thompson and gained his understanding of the issue and, I think, his concurrence that we have a problem and it needs to be addressed along the lines of what we recommended. And I believe Secretary Thompson discussed that with this committee at his March 13 hearing.

And so we stand by that recommendation and believe that we should work with the Congress to develop legislation that would indeed give FDA the ability to screen these drugs and turn them back.

Mr. STUPAK. All right. Mr. Hubbard you have met. You made the Secretary understand. You recognize there is a problem.

But my question is, what have you done? It has been 13 months. What have you done?

Mr. HUBBARD. Well, I believe—I understand we have given some draft language to the staff, but there has not been a formal administration position on that coming forward.

But I think we still stand by our position, and I think the Secretary still stands by what he said in March.

Mr. STUPAK. Well, it sounds like—if you are standing by your position, it sounds like your position is nothing because nothing has been done in over 13 months. And you promised us last time that there would be legislative language.

We haven't seen anything, and the frustration we are seeing up here, whether it is a little teddy bear or whatever they are coming in through—it is really obscene, if you go down to the mail house down here and see this stuff coming in here.

Mr. HUBBARD. Well, as I said, we will be very happy to sit down with the committee right away and—

Mr. STUPAK. Can you tell us when?

Mr. HUBBARD. Tomorrow. And present language and work with you to get it enacted.

Mr. STUPAK. You will have language ready tomorrow?

Mr. HUBBARD. Absolutely.

Mr. STUPAK. Why don't we have any formal language now signed off by the Secretary or else the acting Commissioner?

Mr. HUBBARD. Well, I think the process is just a cumbersome one.

I believe he has concurred, as he said on March 13, but he is going to have to go through a larger administration process, and it is a slow cumbersome process.

Mr. STUPAK. Slow. Okay. It really is slow and cumbersome. I mean, 13 months. You know, this stuff that comes in here through the mail, there are five requirements that have to be on that package before it can be accepted in the United States through the Postal Service, isn't it?

Five requirements? That is what you testified to 13 months ago. Certain requirements on the package had to have the prescription—the doctors script on it, return address, forwarding address,

a number of things; had to indicate what it was, what the drug was—all that had to be on the package, right?

Mr. HUBBARD. Well, no. Actually none of these drugs should be coming in. There is no requirement to let them in, because they are all illegal.

Mr. STUPAK. Right. So if they are coming in, they don't meet the requirements, they are all illegal, why doesn't the FDA say, Postal Service, turn them around?

Mr. HUBBARD. Well, again, that gets back to the problem. Under the current law, the Postal Service and Customs Service says to FDA, give us the authority to turn them around. And for us to do that, we have to have the authority. But our law was written to—

Mr. STUPAK. And they have been asking you now for well over 13 months, correct?

Mr. HUBBARD. And they are correct to ask. And our law says, we have to first send a letter to the intended recipient, give them notice of an opportunity for a hearing before the FDA to explain whether the drug is legal or not; and that is what we would like to dispense with is that notice and opportunity for a hearing.

Mr. STUPAK. Why won't the FDA just say, Postal Service, you have certain requirements a package has to meet before it comes into this country; if it doesn't meet that requirement, send it back?

Mr. HUBBARD. I understand. We do not have the authority to ask them to do that.

Mr. STUPAK. Why don't you have that authority? Did you ever ask for that authority? Have you ever come to Congress and asked for the authority?

This is the same question I asked you 13 months ago.

Mr. HUBBARD. That is what we would like to work with the committee and draft the language on.

Mr. STUPAK. It is going take you 13 more months to draft the language to ask this committee to give you the authority to tell the Postal Service to send it back because it hasn't met the requirements of the U.S. Postal Service and it could be illegal drugs.

I don't think it should take another 13 months. That would be 26 months and, you know, our patience up here isn't probably going to wait that long.

Mr. HUBBARD. I understand. As I said, Mr. Stupak, we will be glad to sit with you tomorrow on that, if that would be helpful, on such language.

Mr. STUPAK. Well, I think maybe at least Chris Knauer on the minority staff will probably help you with that language, since it has taken 13 months to draft.

I am sure we could get that to you, right, Chris? Thank you.

Mr. NORWOOD. Thank you very much, Mr. Stupak. And I believe it is my turn for questioning, but let me get the chairman back in the chair.

Thank you very much, Mr. Chairman. And I did think of staying in that chair where I could take all the time I needed, but believe it or not I think I am going to be fairly brief.

Mr. Hubbard, how many employees at the FDA?

Mr. HUBBARD. I believe there are around 9,500.

Mr. NORWOOD. How many of them are devoted in their daily work to stopping counterfeit prescription drugs coming into this country?

Mr. HUBBARD. Well, we have an Office of Criminal Investigations, and they spend about 65 percent of their time on drug safety issues, a substantial part of that on counterfeit drugs, so a rough estimate would be 40 or 50 people per year.

Mr. NORWOOD. Forty or 50 people. Is the counterfeit drug problem larger than that?

Mr. HUBBARD. I certainly think, if you asked them if they could use more resources to catch more counterfeiters and track down more, the answer would be yes.

Mr. NORWOOD. How many would it take to stop the business of counterfeit drugs, which I think is horrendous, but coming into this country. How many folks would it take?

Mr. HUBBARD. Well, that is sort of like asking how many it would take to stop narcotic drugs. We don't know. But it would certainly be more than we have.

Mr. NORWOOD. Give me a little better answer.

Mr. HUBBARD. I am sorry, Mr. Norwood. I think we will just have to get that for the record, if I may. I would be hard-pressed for a guess. Perhaps one of my colleagues would make a guess.

Mr. TAYLOR. I mean, part of the problem in answering that question is that we are still trying to quantify, quite frankly, the size of the problem. There are wide-ranging—

Mr. BILIRAKIS. The mike, please.

Mr. NORWOOD. Oky. Look, because of time limitations you don't know the answer, and I don't fault you for that. We do know that they have to be at every airline terminal in the country and every port in the country, and et cetera, et cetera. What we do know is that to stop counterfeit drugs it would take a tremendous increase in personnel to do so.

Mr. TAYLOR. That is correct.

Mr. NORWOOD. Now, that is—one part of our problem is not the counterfeit drugs that are coming in. The other part of our problem is perhaps legitimate drugs that are being sold through the Web sites. They may actually not be counterfeit, or I guess they would be counterfeit, but they may actually work is what I am saying.

Mr. HUBBARD. That is correct, Mr. Norwood.

Mr. NORWOOD. And that is illegal to do that.

Mr. HUBBARD. Absolutely.

Mr. NORWOOD. And that would take how many people to bring that to an end if it were humanly possible?

Mr. HUBBARD. Well, that is an even tougher question because not only would we have to have the resources but we would have to have more authority. Many of these Web sites are in other countries and we can't reach them anyway.

Mr. NORWOOD. Well let's presume the authorities—I am trying to—we have a bill before us that says besides counterfeit drugs, besides the Web site, let's make it legal for the importation of drugs from around the world to come into America, and I am trying to—and let's say Congress says, yeah, we need to do this. Let's say we pass this bill, but we add a little amendment to it saying we will agree to this as long as the FDA can assure us that these drugs

are safe and effective. Now, if we don't add the "safe and effective," what we are basically doing is telling all of our constituents, "Good luck, do the best you can. We hope to hell it doesn't kill you."

Mr. HUBBARD. That is right, Mr. Norwood.

Mr. NORWOOD. And so I can't really imagine a reimportation bill that doesn't include some "safe and effective." So if it does that now, how many more people do we have to hire at the FDA to make sure now that reimportation of drugs coming from everywhere in the globe, which this is a pretty neat market, you know, folks are going to let it rip. How big will this agency have to be to—for us to assure our constituents that when they go buy a prescription drug, it will be exactly what they think they are buying and what their doctor ordered. How big must you become?

Mr. HUBBARD. Again, we will have to get back to you. But we will do that if you like, Mr. Norwood.

Mr. NORWOOD. It might be cheaper for us to just give everybody money to buy their drugs.

Mr. TAYLOR. I mean, there would obviously still need to be an increase in our resources because the very nature or the very—probably the amount of imports would go up, and so there would have to be a corresponding need once again to ensure that the products that are coming over are safe and effective, so there will be a corresponding need for additional resources on the borders as well as probably a corresponding need for resources domestically. In those instances where we find out that a product that was claimed to be safe and effective is not, we will need to figure out domestically where that product has gone. We will need to do a recall. We need to ensure that if that product is in the domestic marketplace that we can get it back. So the answer is that indeed even in the scenario that you just painted, there would still be a significant need for increased resources to ensure that the—

Mr. NORWOOD. Well, some of us have visited Dulles and we have seen some of the stuff that is coming in. And bless your heart, you can't even stop what is coming in now, much less us passing a law making it legal for it to come in from everywhere in the globe.

Mr. Chairman, I submit that we are going to have to do one of two things. If we want to reimport drugs, we are going to have to be prepared to either make sure that the FDA can assure us that they are safe, or we are going to have to tell our constituents, okay. If the only thing here that matters is what they cost, you are on your own, and when you take it you can do a little prayer and hope first that it works, that it is efficient, or is it efficient enough; second, hopefully it is actually anything; and third, hope it doesn't kill you.

I mean, we are all concerned with the cost. But a fast, quick answer like this is very, very dangerous. And many of the team who want to solve the cost problem are good friends of mine and they are good people, but we need to be very concerned on the safety part of this, and that is what has held me up on this all along.

Probably that visit, Mr. Chairman, to Dulles Airport did as much to get my attention as anything I know. I mean, I would like to let's start, and you assure me, or Congress help you make sure we just stop the counterfeit stuff. Let's just start with that.

Time is up. Thank you, Mr. Chairman.

Mr. BILIRAKIS. Mr. Pallone, to inquire.

Mr. PALLONE. Thank you, Mr. Chairman. You know, I have listened to you, Mr. Hubbard, and I understand where—you know, your concern. But I guess you know you started off by saying that you can't talk about price, and it seems to me that that is the whole problem here. I am sort of following up on what Mr. Norwood said. I mean we have desperate people. We have people who are going to Canada, for example, because they don't have—they can't afford to buy the drugs.

And so for me, price is the issue. And I mean, the bottom line is that these people that are going on these buses to Canada are basically—I am sure that to some extent they may think in their minds that there is some risk, because they are going, you know, across the border, but they don't really have a choice. It is a question of their—you know, they are either going to buy the drugs and they are going to use it and hope that it works—and most of the time it probably does—or they are going to have no drugs and die or have other consequences from it.

So I guess I am very much in favor of what Mr. Kingston and Mr. Gutknecht are doing, because I think they—and I realize there may be some risk. But it is probably worth the risk, and that is what I wanted to discuss with you. In other words, let's assume, you know, I am a senior with a life-threatening disease that requires certain prescription drugs for treatment. You know, I can't afford to buy in the United States and so, you know, I go over to Canada. And maybe there is a slight risk but. If you were such a person and you were taking—had the option of taking a bus over to some pharmacy in Canada as opposed to not getting the prescription drug that you need to be alive, what would you do?

Mr. HUBBARD. Well, let me first apologize to you and Mr. Pallone and Mr. Kingston and Mr. Gutknecht, that we understand your motivation about the price issue. What we are saying is that we can't make those value judgments.

Mr. PALLONE. Oky. Well, if you can't make it, let me move on.

Mr. HUBBARD. I mean, it is just not what we do.

Mr. PALLONE. I understand that. But this is what it is all about. I mean, I don't see bodies piling up in the streets from taking drugs from Mexico or these bus trips to Canada. You know, millions of people are using prescription drugs that come from Canada, Mexico, the Internet. Wouldn't we begin to see thousands and thousands of adverse effects, particularly given the volumes of drugs now entering from these sources, if there was a serious risk and there was a widespread problem? It seems to me the problem is not that severe, given your alternative.

Answer it that way. Why aren't we seeing all these adverse effects if it is such a huge problem?

Mr. HUBBARD. That is a good question. I will answer it in two ways:

First, our concern is that if you institutionalize this process and open up the system that way, that the bad guys will have a better entree to the U.S. market and you could increase risk that way.

The other possibility is—and we have seen some evidence of this—people that buy these drugs this way when they have a problem tend not to tell anyone, particularly those who buy drugs over

the Internet. We have actually gone around to some of the folks who have bought these, because we have their addresses on these packages. And while we don't threaten any sort of enforcement action, we ask them why are you doing this? And they all say, well, I knew I shouldn't be doing this, and then they—the feeling is if they are injured by it, they won't tell anyone.

Mr. PALLONE. Okay, but let me ask you this. A lot of these bus trips go specifically to a pharmacy. You know, they set up something to go to Pharmacy X outside of Montreal or whatever. I mean, if you know you are going to a particular pharmacy, which is what is usually the case, is there any risk at all really of doing that. Going from Maine to, you know, Sherbrooke at the Quebec—you know, I love Quebec pharmacy—what is the danger?

Mr. HUBBARD. I have said that if I were in Canada as a tourist and fell ill and went to a Canadian doctor and got a prescription and went to a Canadian pharmacist and got it filled, I would have a relatively high confidence level that I should take that drug, especially if I had a serious illness. But the FDA still can't assure any safety of that product. And then, again, once you open the system up—

Mr. PALLONE. No, I understand that. But you know, maybe then the answer is to tailor the bill so it is more specific as to where you are going and how you are going there. But I mean, these guys, my colleagues on the other side, are making an honest effort to try to come up with something that is necessary, because frankly the Republican leadership won't pass a bill that addresses price. So I mean, it seems to me that rather than—and I am not trying to be difficult with you. I mean, rather than just holding on and saying we have got these counterfeit products, let's try to figure out a way that they can do the reimportation in a relatively safe way, because frankly it is not much of a risk if you know where you are going and it is a particular pharmacy on the other side of the border. That is what most of the cases are now, at least with the bus trips.

And maybe you have some suggestions about how to change the bill to provide that kind of protection. If you know where you are going and you are going to a specific place, I mean, give us some ideas to help us, rather than just say we have got all these counterfeit things and we have a huge problem. If you can either today or in writing, I don't know.

Mr. HUBBARD. Well, as I said to Mr. Bilirakis, we will be glad to provide whatever help we can to the community. But in the end, we are not going to be able to say that the drugs will be safe as they are now.

Mr. PALLONE. I know it is not foolproof, but nothing is. That is not what we are doing.

Mr. BILIRAKIS. Right. And Mr. Stupak went into that particular area, that promises were made, what, 13 months ago or whatever it was, and, you know, we are opening up the door to ask for your help in trying to do what is right here from the standpoint of safety, and you have got to do your share, though, and certainly you are.

Mr. HUBBARD. Well, we will help any way we can, Mr. Chairman and Mr. Pallone.

Mr. BILIRAKIS. Mr. Pitts, to inquire.

Mr. PITTS. Thank you Mr. Chairman.

Commissioner Hubbard, plasma therapies are life-saving medicines used to treat serious diseases such as bleeding disorders, immune deficiencies, alpha one burns, and shock. The safety and advocacy of these important therapies depend on assuring an appropriate chain of custody and proper storage and handling conditions, unlike traditional pharmaceuticals. These therapies must be treated carefully and maintained in tightly controlled environmental conditions.

Does reimportation, either personal reimportation or commercial reimportation, present any special threats to the safety and efficacy of these products? Put another way, is there any way to guarantee to the patients who rely on these medicines for their lives that plasma therapies imported from foreign countries are safe and effective?

Mr. HUBBARD. Without question, Mr. Pitts, some products are much more susceptible to risk depending on how they are handled, the length that they have moved around, the places they have been, the temperature extremes they have been under, the ways they have been stored, and many many other factors. And so the type of property that you are talking about would be exceptionally vulnerable to that. And so absolutely, that sort of chain of custody would be a critical issue for a product like that, and there are many other drugs for which that same issue would exist.

Mr. PITTS. I understand the FDA is presently considering requiring FDA-approved drugs to be labeled with bar codes. If reimportation were allowed, could this technology be used to prevent counterfeit drugs from entering the country?

Mr. HUBBARD. It might be a technology that could be helpful. We are having a public meeting tomorrow on bar coding. It is some years away from effectuation, but clearly there would be opportunities for greater inventory control. But having said that, if you can counterfeit a label, you can counterfeit a bar code.

Mr. PITTS. Is it possible for an Internet site to act as an ordering service and still comply with U.S. law; that is, is there any way a service can call a Canadian pharmacy to have scrips filled for U.S. patients?

Mr. HUBBARD. Well, theoretically a domestic site that only dealt within the United States could serve as an intermediary like that to link a patient with the physician and the pharmacy. But you would still have the State requirements of valid prescription and a valid doctor-patient relationship and then, of course, a licensed pharmacy, and these Internet sites tend not to have that in many cases.

Mr. PITTS. Can you definitely state that allowing for reimportation will increase the likelihood of counterfeit drugs making their way into the country? Would limiting reimportation to foreign pharmacies which, for instance, register with FDA, address these concerns? And how would you expect those drugs to be relabeled?

Mr. HUBBARD. Well, registration might be helpful, and you know who is there. But you don't really know what is behind that registration. The ultimate goal of any system is to assure that the registrant and/or the manufacturer is properly manufacturing and storing and holding a product, and registration alone would not get

you that. It would only get you some information about who the person is. Then, of course, lying about a registration would be fairly easy for a foreign firm.

Mr. PITTS. I understand Europe allows for parallel trade of pharmaceuticals wherein drugs freely proceed from country to country. Are you aware of whether this activity has increased counterfeiting in Europe?

Mr. HUBBARD. I don't know whether that particular activity has. We know that Europe is—that counterfeits are seen in Europe with some frequency.

Mr. PITTS. Thank you, Mr. Chairman.

Mr. BILIRAKIS. Mr. Green, to inquire.

Mr. GREEN. Thank you, Mr. Chairman. And Mr. Hubbard, again, after you heard all of our opening statements—how could you not, they were so long. But my concern is our southern border and the residents, because we don't go to Canada. We do go to Mexico. And can you assure us that for an individual has a life-threatening disease and required certain pharmaceuticals for that treatment, probability-wise is it a greater risk that they can't afford their pharmaceuticals here because of the high cost, would they be better going across the border and being able to purchase whatever that pharmaceutical may be called there? Oftentimes I am not familiar with the quality of what may be in all the pharmacies in Mexico, and I have been to a number of them, in fact, taking physicians with me, and said, okay, look at the array that they have. If you were to evaluate that risk, would it be better not to take the medication for a life-threatening disease here if you can't afford it or to go to Mexico?

Mr. HUBBARD. Well, I think Mr. Pallone asked a similar question. So if you go to Mexico and get the real thing and it is cheaper, then, that is a good thing. If you go to Mexico and get a fake drug and it doesn't do anything, whatever you spend is a bad deal not only for your pocketbook but for your health. But ultimately Congress has to decide what level of safety it wants for drugs. FDA can only say we do safety, and we are telling you that sort of thing is not safe.

Mr. GREEN. Well—and I have some other questions. But I know we have—we import lots of foodstuffs, and I know FDA—and I don't know if this has been touched on—but we bring in lots of cattle, lots of vegetables, lots of everything from Latin America, for example. Does the FDA inspect or have requirements on those various ranches or farms that ship into the United States?

Mr. HUBBARD. Well, for meat, the Department of Agriculture has very strict requirements that the meat be slaughtered in the other country under strict U.S. standards and then—

Mr. GREEN. And they inspect—

Mr. HUBBARD. And then often reinspect. They are inspected in the foreign country and then they reinspect when the product arrives at the border. Now, for the non-meat products, the fruits and vegetables, FDA has certain standards. For instance, you can't use an illegal pesticide. And we do random sampling to determine that, and if we find a particular grower, importer from a foreign country is using an illegal pesticide, we will prevent them from bringing that product in in the future.

Mr. GREEN. What if there was a pharmaceutical company in Renoso or Matamoros? Could the FDA, if we gave the authority and the funding, inspect that particular pharmaceutical specifically for reimportation, not unlike maybe what the Department of Ag does for meat?

Mr. HUBBARD. Well, if you gave us that authority and the Mexican Government gave us that authority, sure. But then, of course, we would want to be inspecting against an approval, so we would want it to be an FDA-approved drug that we would go there to inspect.

Mr. GREEN. Oh, sure. It would be something that would be approved in the United States because I know, in fact, our next panel has a witness from Texas who talks about you can go to Mexico and buy lots of things that you can't buy off the shelf or you can't even get in the United States. But I am talking about seniors who need the medications and could utilize that and, again, with some cost savings; we hope, in fact, a great deal.

Let me talk about the domestic actions that the FDA has done. In the Carson City Pilot, you found a high number of illegal or unsafe medications. How did this compare to domestic mail orders, because it seems like today so many of our pharmaceutical plans, you know, we get all our pharmaceuticals or so much of our pharmaceuticals by mail. And how does the FDA regulate domestic mail order services, and why can't these mechanisms work with selected international mail order services?

Mr. HUBBARD. I will ask Mr. Horowitz to answer that if he has an answer.

Mr. HOROWITZ. I am not aware of any data that compares the domestic mail order operations to the international operations. We did see a pretty high number of antibiotics that were coming into the country through the Carson mail facility. We saw a number of hormone products and potent steroid products. But I am not aware of the comparison to how domestic mail order drugs would relate.

Mr. GREEN. Okay. In your testimony—and I share the concern about the problems guaranteeing that drugs are packaged and stored correctly. What would the FDA need to guarantee this, and how do we guarantee this for domestic packages? Again, I think I receive my pharmaceuticals by mail because of our—how do we do that on domestic, and how could we set up a procedure to do it internationally?

Mr. HUBBARD. Well, we certainly have pervasive authority over domestic manufacture of drugs. The drug must be approved after adequate testing, and then it must be packaged properly, manufactured properly, have proper labeling and other things. And we inspect those facilities that do that. And then at the dispensing level, the States license pharmacies who actually dispense the drug, so you have another layer of regulation at the State level to ensure the drug is properly held and dispensed by a licensed pharmacist, for to do similar things in a foreign country would require a very substantial reach of FDA's regulatory authority across the foreign border, which is—would be an unusual thing, I believe.

Mr. TAYLOR. Just to follow up on that point, I mean the key here is domestically we obviously have a jurisdictional strength that we don't possess in terms of dealing with foreign manufacturers or for-

eign purveyors of these products. I mean, domestically we can go into the district court and we can take certain actions. We can avail ourselves of certain investigatory tools that allow us to follow up on those instances where we realize that a product is crossing interstate borders domestically.

Those same tools don't apply in the context, for example, of a foreign Web site, which is often why we need to work with the foreign government and solicit their help and solicit their assistance in dealing with the site, because our jurisdictional reach does not extend that far.

Mr. GREEN. Mr. Chairman, I know my time is up but sometime along the way, how do you regulate foreign Internet which is concerned? Because I have constituents who drive to Mexico. No telling how many we have who buy their pharmaceuticals through the Internet, and that might be something that the committee—

Mr. BILIRAKIS. Do you have a brief answer to that? We are well over time, but I think it is worthwhile.

Mr. HUBBARD. We don't regulate Internet sales. We would like to. And the way we would deal with Internet sales is to try to stop these mail shipments, because people order over the Internet but it arrives by mail, and so our proposal to you is to help us find legislation to stop the mail importation which deals with the Internet.

Mr. TAYLOR. Right. But in those instances where we do suspect that a product is coming from a certain country, what we will often do is we will try and stop the product at the border but, in addition, will notify the foreign government and seek their assistance in dealing with the product within their borders. And we have had some good cooperation with several countries including Germany, England, The Netherlands and some other countries.

Mr. GREEN. Well, Mr. Chairman, just briefly, it seems like you have become postal inspectors, instead of FDA making sure the pharmaceutical is correct, that it is legal, and that is the concern.

Mr. BILIRAKIS. Certainly. That is a good point.

Mr. GREEN. Thank you.

Mr. BILIRAKIS. Mr. Buyer, to inquire.

Mr. BUYER. Thank you. I would just like to pick up a little bit from where Mr. Green left off. Which countries are the largest importer of the counterfeit drugs? Do you know?

Mr. TAYLOR. No, I don't think I can answer that question.

Mr. BUYER. Would you answer that for the record, then, please?

Mr. TAYLOR. Sure. Yes, indeed we will get it.

Mr. BUYER. All right. With regard to our pharmacists, how would a pharmacist know whether the drug that he is dispensing to the customer is safe, whether it is FDA—or if that pharmacist somehow is going to get a reimported drug? How does he know?

Mr. HUBBARD. He wouldn't. Earlier we passed around a sample of a counterfeit and real drug that no patient, physician, or pharmacist could tell by visual examination that one was counterfeit and one was the real thing. In fact, companies have told us that even when they see the counterfeits it takes substantial analysis by the company to determine the counterfeit from the real one. And these are the people that actually make the drug. They ought to know that—if they don't know what their drug is, no one would know.

Mr. BUYER. I am challenged on this issue even from a philosophical standpoint. Having defended the quasi-private health system that we have in our society—quasi, because we have got Medicaid, Medicare, VA and the military health delivery system, and then we have got the uninsured that we end up dealing with through our Medicaid and other types of State systems, and the rest we do private pay, and then we use private pay to push the bounds of science. And then the same advocates, some of my own colleagues within the advocates of the private pay system are going, well, I tell you what; why don't you run off to a couple of those social systems and then you can get a cut-rate deal?

I don't understand. So I guess going back to philosophy, you guys are in charge of a closed system, because the closed system is what we recognize and have endorsed that provides great assurances, security assurances and safety into the American people. When it gets your stamp of approval, it gets a lot of comfort by the consumer, right? So I am challenged. So even though we have had these ideas about—I am a lawyer, chain of custody, chain of distribution, if we can counterfeit the bottle and counterfeit the label, can they counterfeit even chains of distribution? Or how would we know?

Mr. HUBBARD. Well, they can counterfeit the documentation that would show the chain of distribution. So in fact, yes, they would be counterfeiting that as well. In fact, they do. We see it all the time.

Mr. BUYER. Give me some examples.

Mr. HUBBARD. Well, if you go to a firm and ask them to show us, let's say, a counterfeit drug or where it has been, they can pull out records: Oh, we get it from this guy who got it from the manufacturer. It is all legal. And, of course, if we trace it back to the manufacturer and he checks lot numbers or something and he says, oh, I didn't sell that, it is obviously fake paperwork and we see that.

Mr. BILIRAKIS. Would the gentleman yield?

So what you are saying is in a corner drugstore, at a corner drugstore, a chain drug or whatever it might be, that there would be counterfeit drugs.

Mr. HUBBARD. Well, currently, very rarely, Mr. Bilirakis. And that is one of our points, is we don't see a lot of counterfeiting in this country because the system is so relatively closed. But when we have seen counterfeiting, we see related counterfeit documents because the counterfeiter wants to try to show a total picture of a good drug to the best he can.

Mr. BILIRAKIS. But is it conceivable that a drugstore might find in its supply of drugs a counterfeit drug that has been reimported from another country?

Mr. HUBBARD. Absolutely. As a matter of fact, the——

Mr. BILIRAKIS. It is not conceivable, it is definite. Is that what you are saying?

Mr. HUBBARD. The counterfeiting that this committee discovered in the late eighties that led to the Prescription Drug Marketing Act was a counterfeit birth control pill, and a pharmacist happened to notice, if I recall, zero was slightly different on the label than on the real thing. And this incredibly sharp-eyed pharmacist, I believe

in Indiana, found that and called the company and read the lot number and the company said there is no such lot number.

Mr. BUYER. So the challenge you are going to have if we open up the system to reimportation is even in the chain of distribution because you are finding that occurring along with the bottle.

Mr. HUBBARD. Yes, that would be what we would expect to find. A good counterfeiter is going to do it all. He is going to know how to fake it all.

Mr. BUYER. I yield back, Mr. Chairman.

Mr. BILIRAKIS. All right. Thank you.

Mr. Strickland.

Mr. STRICKLAND. Thank you, Mr. Chairman. I am sitting here listening to this, and I am feeling like Mr. Hubbard in his operation is just completely overrun and out of control, and I am wondering if anybody can guarantee any of us safety. You know, the mail order, the Internet operation, it seems to me like there is no effective way to deal with that, or that you can tell us that, in answer to Doctor Norwood's question. You seem to be unable—and I understand the difficulty in telling us how many personnel you are going to need if you are going to deal with this. Do you need more money?

Mr. HUBBARD. I think regulatory agencies would always like to increase their funding. But let me say that today if you go to an American physician and go down to your corner drugstore to get the prescription filled, you have an incredibly high likelihood that you are getting a safe and effective drug. Almost certainty. But if you do you buy it over the Internet or go to another country and buy it, that certainty is not there, and I couldn't give you a percentage, but it is a much less reliable source of a drug.

Mr. STRICKLAND. Okay. That leads me to a question that last year Doctor Shepherd, who is with us today, testified before the Oversight Subcommittee that perhaps as many as 30 to 40 percent of the travelers that enter Mexico return to the U.S. with a pharmaceutical product. Do you have any idea how many people visit Mexico from our country a year?

Mr. HUBBARD. No.

Mr. STRICKLAND. It could be millions.

Mr. HUBBARD. Could be.

Mr. STRICKLAND. Let's assume it is millions. I think it probably is. Doesn't that mean that it is likely that millions are bringing into the U.S. prescription drugs for personal use consumption?

Mr. HUBBARD. I will say—and you can certainly ask Dr. Shepherd—I believe that data shows, though, that many of the drugs people are bringing in from Mexico are things like narcotics and, you know, painkillers and antibiotics and not the sort of things that censors are so much worried about. And we also believe that drugs purchased in Canada tend to be different; that it tends to be more of these sorts of things.

Mr. STRICKLAND. You think Canadian drugs would likely be likely to be more safe than drugs purchased in Mexico?

Mr. HUBBARD. Well, I would rather not put—you know.

Mr. STRICKLAND. I am just asking for your opinion.

Mr. HUBBARD. Well, I think given that the Mexican system doesn't require a prescription for many of their drugs would, for in-

stance, give me more hesitancy, because many drugs in Mexico are sold over the counter, such as antibiotics, and you don't need a prescription there. And so that would be a less strict regulatory system, and therefore, sure, I would probably have a little bit less assurance there.

Mr. STRICKLAND. Okay. Since FDA is allowing many of these drugs to enter the U.S. in rather massive quantities under the so-called personal use policies, has your Agency done any systematic studies to analyze the contents of these many drugs that you are allowing seniors and others to bring into the U.S.? And if not, why not?

Mr. HUBBARD. Let me say that while we argue that a lot of these drugs are coming in, that there are 4 billion prescriptions written in the United States each year for prescription drugs, and if there are 2 million of these Internet boxes coming in, that is a lot; but it is still nowhere near the number of total prescriptions being written.

Mr. STRICKLAND. Do you not agree with me that it would be helpful, if not obligatory, for the FDA to carry out the studies so that we can have some more accurate data to work with in terms of what the situation is?

Mr. HUBBARD. I think Mr. Bilirakis asked us that last week, and I believe we said that this better data will help us. We would be glad to work with the subcommittee on a study. We feel that we have enough information to know that there are problematic drugs out there that make us raise these alarms we are raising today.

Mr. STRICKLAND. Do you have any idea what such a study may cost?

Mr. HUBBARD. I asked our economists that after Mr. Bilirakis asked us, and we think between \$500,000 and \$1 million would probably get you a reasonable data set that the Congress could use to make some policy decisions.

Mr. STRICKLAND. In your judgment, would that be a rather wise expenditure of funds?

Mr. HUBBARD. Well, as we told Mr. Bilirakis, sure, if Congress wants that data we would be glad to help them do that.

Mr. STRICKLAND. And I would encourage, if we can get such data, Mr. Chairman, I would suggest that we get it for both Canada and Mexico.

Mr. Chairman, I have one further question.

Mr. BILIRAKIS. Well, why don't you ask the question very briefly and we will request a brief answer?

Mr. STRICKLAND. Okay. We have all these drugs coming in but we don't have bodies piling up in the streets from taking Mexican or Canadian drugs, do we? If millions are using these drugs that come from these countries and from the Internet, wouldn't we begin to see thousands and thousands of diverse events, particularly given the volume? Does it surprise you that apparently we aren't seeing these adverse consequences?

Mr. HUBBARD. Well, one answer is that we believe that people that purchase these products in such surreptitious ways tend not to want to report them if they do have a problem. And to be quite honest, there could be lots of people out there whose blood pressure is not being controlled or whose infections are not being adequately

treated or otherwise are not getting adequate treatment, and they are slowly—their health is slowly deteriorating. But we wouldn't know that, because they were unhealthy to begin with.

Mr. STRICKLAND. Okay. Thank you, sir. Thank you, Mr. Chairman.

Mr. BILIRAKIS. I thank the gentleman. The Chair would recognize Messrs. Kingston and Gutknecht for 3 minutes each to inquire. Please stay within that 3 minutes.

Mr. KINGSTON. Thank you very much, Mr. Chairman. We certainly appreciate all the hard work this committee is doing. And Mr. Hubbard, I am going to make a deal with you. I get 90 seconds and I am going to give you 90 seconds. And my first question to you is—I am a member of the Agriculture Appropriations FDA Committee. You had actually 2 years since we had a bill in our appropriations committee in which we gave \$25 million. In all fairness, I think it was to HHS; I am not sure. But this committee has given you 13 months to come up with recommendations, and in our hearings we never have heard from FDA that, hey, we need more money because this is a growing issue.

The reason why that is important is because you have said you don't really care about price, which is fair. Your issue is safety. Well, doggone it, people are doing it now, and you are not coming to my appropriations committee and saying, you know, "We need money because we have got 45 to 50 people doing this now. We have made some commitments to the Energy and Commerce Committee, and we need to address this." And so if safety is your only concern, why aren't you addressing that?

Mr. HUBBARD. Well, when the bill that you are talking about was enacted, we certainly did put together a cost estimate of implementation. And you are right. The committee did appropriate that \$25 million, and we were prepared to go implement that. And, of course, it ramped up over several years. But Secretary Shalala then sort of refused to certify that it could be done safely, so we never got the money because the way that the law was written, we didn't get the money unless Secretary Shalala certified it could be done and then instructed us to do it. And then Secretary Thompson further certified when he came in that this couldn't be done. So we have gotten most of that funding.

Mr. KINGSTON. Okay. Let me ask you this now. Actually we do have reimportation now. The U.S. pharmaceutical companies can reimport, correct?

Mr. HUBBARD. That is correct. The company can bring back their own products.

Mr. KINGSTON. And I am just going to infer that you are saying that that is okay because it is a better chain of custody.

Mr. HUBBARD. Well, the way Congress set it up in 1988, it said American goods could not come back in if they had left the custody of the manufacturer, but if they had stayed in the custody of the manufacturer they could come back.

Mr. KINGSTON. And is that the way it happens?

Mr. HUBBARD. Well, I assume—

Mr. KINGSTON. I mean, I assume you guard those pretty closely. Armored cars, maybe?

Mr. HUBBARD. Well, the company is the one that is maintaining custody, not—FDA doesn't hold the drug.

Mr. KINGSTON. It is okay for the pharmaceutical companies who have the high price to reimport it, but it is not okay for Ruth Tubbs to do it, because she is at risk; but the companies can do it? I mean, I want you to think about that policy as a government that—what we have.

Mr. HUBBARD. You understand, this was an explicit policy of the Congress, adopted in 1988, and the feeling was if a company sold more of its product, say, in England than could really be sold, they should be able to bring that back.

Mr. KINGSTON. Well, I just want to make sure for the record we are reimporting now, it is just that we are only allowing the drug companies to do it, not the Ruth Tubbses to do it. And they are the people who need it.

Now, in the case of Ruth Tubbs—nd getting back to Mr. Pallone's question—if she knows the Canadian pharmacist she is dealing with, and if she feels comfortable about that, she is buying drugs from them now, what are we doing to make sure that that is a safe relationship because, of course, that is going on with hundreds of people, thousands?

Mr. BILIRAKIS. The gentleman's time has expired. You will respond in a brief manner.

Mr. HUBBARD. What we are doing—and we will pass it to the committee—you will see on these easels brochures that we are going to be passing out at the border, beginning this month, that advise people such as Ruth Tubbs what they are doing, that they may be taking some risk. And it says things like, make sure you tell your doctor you are doing this so he can monitor you, or your pharmacist in the United States. This is not a, quote, regulatory warning. It is not saying you are doing anything wrong. It simply says, be careful and talk to your doctor.

Mr. BILIRAKIS. So as these buses arrive at the border coming going north, someone will be handing these out?

Mr. HUBBARD. Right. These brochures will be given to the patients who purchase drugs, correct.

Mr. BILIRAKIS. All right. Thank you.

Mr. Gutknecht for 3 minutes.

Mr. GUTKNECHT. Well, I thank the chairman. I thank you for this hearing. I think it is historic. We are finally—Congress is taking seriously the matter of importation and reimportation. The fact that we are having a hearing, I think, is very refreshing and I hope that the FDA will work with us. I have attempted in the past not to beat up on the pharmaceutical industry because they do some wonderful things. It is not their fault that we have given them this market opportunity; and it is not shame on them, it is shame on us. And frankly, we need to do some things on the price side of the equation, because no one has refuted the charge that I use in terms of the difference between what Americans pay and consumers around the rest of the industrialized world pay for the same drugs.

But my question is for you, Mr. Hubbard, and I think the real ultimate question is how safe is safer? You know, I have a professor, Doctor Steve Shandelmeir, who is head of the pharmacology department at the University of Minnesota, and he has a great

quote. He said that a drug that you cannot afford is neither safe nor effective. And so if people can't take the drugs they need, all of the safety barrage that we put in front of them makes no sense.

And I think that I would hope that you would work with us to come up with some kind of a program using bar coding technology. I think my colleague asked the question; it is a good one. You know, what do the pharmaceutical companies do? How do drugs—how are they delivered to a local pharmacy? Is it by armored car? No, it is by regular truck. When they bring it into the country, it is by Evergreen containers. The idea that they have some kind of super-safe system that will guarantee that nothing can happen is really not true, and you know that, don't you?

And let me come back to the other issue about safety. Well, no, I want to change subjects slightly. It is the Food and Drug Administration, isn't it?

Mr. HUBBARD. Correct.

Mr. GUTKNECHT. Do you know how much pork comes into this country every year?

Mr. HUBBARD. Pork?

Mr. GUTKNECHT. Pork.

Mr. HUBBARD. I have no idea. We don't regulate pork.

Mr. GUTKNECHT. Well. You do regulate food, and it ultimately comes in as a food item.

Mr. HUBBARD. No, we don't regulate meat, unfortunately. The Department of Agriculture does.

Mr. GUTKNECHT. All right. But the point is, we bring into this country 500,000 tons of pork. And you can get salmonella, you can get trichinosis. As a matter of fact, a lot of people get sick from eating bad pork. The same is true with fruit and vegetables. By your own studies, the FDA's own studies, 2 percent of the fruit and vegetables that come into this country are contaminated with some kind of food-borne pathogen.

I guess the point, and Mr. Pallone asked it, you know, how safe is safe? It seems to me we ought to be able to come up with a regimen that would work to guarantee as much safety from Geneva Pharmaceutical Supply as we get from our local pharmacies, because we know one of the worst examples where drugs were actually contaminated occurred with a local pharmacist in New York City. Is that true?

Mr. HUBBARD. That is true. That was a pharmacist basically diluting a drug.

Mr. GUTKNECHT. Most of the counterfeit drugs you showed us today originated here in the United States?

Mr. HUBBARD. Many do, yes.

Mr. GUTKNECHT. The other point I want to make is that every month approximately \$21 million worth of cocaine is imported into the United States through Miami alone. Yet the whole idea that somehow we can stop this and make it completely safe I think really tests credulity.

I think we have to come up with a system and regimen, because my sense is this is going to happen regardless of whether this bill passes. We are going to have importation. We are going to have reimportation. It is just a matter of whether or not people—my 85-

year-old father—is going to be treated like a common criminal. I don't think he should be.

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

The Chair would yield, as soon as he gets settled, 3 minutes to inquire of Mr. Sanders.

Mr. SANDERS. Mr. Speaker, I thank the chairman very much for allowing me to barge right in here and ask a few questions.

As somebody who lives near the Canadian border and was one of the first persons to take people over the border to get Canadian drugs, needless to say, all of this concerns me very, very much.

A brief history: We took a number of women over the Canadian border. They purchased the widely prescribed breast cancer drug, Tamoxifen. Do you know what the differential was, sir?

Mr. HUBBARD. Probably substantial.

Mr. SANDERS. It was like one-tenth. Women in the United States of America who are fighting for their lives are paying 10 times more for the exact same drug as they are an hour away from where I live. If I may be allowed to editorialize, I think that is an outrage, and I think that is a disgrace.

Let me ask you this question. The pharmaceutical industry, I am sure they are probably headed here in droves, has 600 lobbyists on Capitol Hill, and has spent \$200 million in the last few years on campaign contributions, on lobbying, and on advertising.

Do you think that it is any coincidence that the most powerful lobby in this country, which spends such a huge amount of money influencing public opinion, that as a result of that—do you think it is any coincidence that our people pay, by far, the highest prices in the world for prescription drugs?

Mr. HUBBARD. I really can't answer your specific question. I think that to some extent American patients do pay higher prices because other countries do put price controls on, so Americans have—you know, in some sense we are subsidizing other countries' patients.

Mr. SANDERS. I don't think we are subsidizing. The pharmaceutical industry, based on my knowledge, makes money in Canada, they make money in Europe. Yet maybe you can tell us, help me out on this one: Year after year, the pharmaceutical industry earns higher profits than any other industry in America. Yet millions and millions of Americans are unable to afford the prescription drugs they need.

Can you tell me why the administration is not moving forward vigorously in terms of reimportation or other approaches to substantially lower the prescription drug costs in America?

Let me pick up on the point Mr. Gutknecht made, because it has to be made over and over again. You could have the best drug in the world, but if a person cannot afford it, it does not exist. It is no good.

Why are we the only country in the world that does not, in any substantial way, fight to lower the cost of prescription drugs? Why are our people forced to pay in some cases 10 times more for the same exact medicine?

Mr. HUBBARD. You are getting into questions that are beyond my scope. I have simply said that if the drug is—if the drug purchased overseas is not the real drug, it does not matter if it only costs you

\$1. If you are getting nothing from it, you are not getting treatment and you are still wasting that dollar.

Mr. BILIRAKIS. The gentleman's time has expired. He can make his point.

Mr. SANDERS. Explain to me and the American people how we can—

Mr. BILIRAKIS. That is not your point, with all due respect.

Mr. SANDERS. How do we import lettuce, tomatoes, beef, poultry, pork, you name it, from all over the world, how are we able to do that and yet we cannot regulate a few warehouses and a few companies to make sure, with FDA supervision, the product coming back into this country is not safe?

Mr. HUBBARD. We regulate food in a much different way; and second, there is no such thing as a counterfeit head of lettuce. It is really sort of a, no pun intended, an apples and oranges issue.

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

Mr. BILIRAKIS. You are welcome.

Mr. Burr, to inquire.

Mr. BURR. Thank you, Mr. Chairman. I will be brief.

Having heard some of the things that were covered and knowing some of the items in Mr. Kingston's bill that empower pharmacists to make some determination about the possible adulteration or counterfeit status of a product that might be reimported, given what you know and what the agency's position is on pharmaceuticals, and the degree of sophistication now with counterfeiting that we find, is there any possible way for a pharmacist to truly determine, if they are not 100 percent confident of the source from which they purchased the drugs, that that drug is not counterfeit or adulterated?

Mr. HUBBARD. We don't believe so, Mr. Burr. I could slip this package into a drugstore without notice, and the pharmacist would not know it. I even could ask a pharmacist, I could say, this is counterfeit. Tell me the difference. He could not tell me, nor could a physician. These counterfeits are perfect copies. A drug is a molecule. You only know if it is real if you put it in your body and if it treats a disease or does not.

Mr. BURR. Is it not therefore important that the chain of custody of that product be something that is impeccable as it relates to the FDA's records?

Mr. HUBBARD. That is correct.

Mr. BURR. Thank you. I thank the Chair.

Mr. BILIRAKIS. I thank the gentleman. I believe that completes, finally, the inquiry.

Mr. Hubbard, you have always been available every time we have called upon you. We appreciate it. We have learned a lot. That is what these hearings should be all about, and that is a learning process. If we come in here and basically know it all, then what is the sense? We are wasting time. Then it would be appalling, I think.

There will be questions submitted to you, as per usual, but also there have been requests for some of the language that has been promised quite some time ago. Do yourselves a favor, help us to help you, so to speak, to be able to do a better job with the concerns of Mr. Sanders and those so many others have raised.

Thank you very much.

Mr. HUBBARD. Thank you for having me, Mr. Chairman.

Mr. BILIRAKIS. The next panel consists of Dr. Marv Shepherd, with the University of Texas in Austin, College of Pharmacy; Dr. Elizabeth Wennar, President of the United Health Alliance, from Bennington, Vermont; Mr. Peter Barton Hutt, Covington & Burling, on behalf of PhRMA here in Washington; and Mr. Don Copeland, President and CEO of Associated Pharmacies, from Scottsboro, Alabama.

Before I open up your testimony, I just wanted to make a comment regarding the panel and the comments made by Mr. Brown and others when we started.

The staff has worked to put together a balanced panel that will present expert testimony from both sides of this issue. Two witnesses will outline the pros of reimportation, as I understand it, and how we may be able to set up a system to allow this practice in a safe manner, and the other two witnesses will outline some of the potential dangers of reimportation. This balanced panel will afford us the opportunity to gain valuable insight that we can use as we develop any legislation in this arena.

Again, this hearing was put together to help us come to some solutions on reimportation. I think we have already realized that even if we solve the problem of high cost of drugs, which would lower the need, if you will, for so many people, particularly senior citizens, to go over the border, there are still many instances of drugs being reimported, counterfeit drugs being reimported into this country that find their way into the corner drugstore. So the concern of reimportation is there and will continue to be there even if we ever get to the point of solving the other problem that people on the other side of the aisle have mentioned.

I did not want to have a hearing on drug prices, even though we know, as I said before, reimportation is a system of high drug costs. That is going to be at another time. I have already told the ranking member that we are going to have hearings in September.

At any rate, I would like to reiterate that I wanted this hearing to help us gather expert testimony on reimportation, and not focus on scoring political points in relation to high drug prices, which we all already realize exist. For that reason, we have worked up this particular panel.

Mr. Brown did ask for that additional witness late Tuesday afternoon; it might have been Tuesday evening even. The staff brought it up for the first time late Tuesday afternoon, so we are not talking about a request having been made on a real timely basis here insofar as a consumer advocate.

In any case, having said that, Dr. Shepherd, again, your written testimony is part of the record. We would ask you to sort of complement that, supplement it orally.

**STATEMENTS OF MARV SHEPHERD, COLLEGE OF PHARMACY,
UNIVERSITY OF TEXAS AT AUSTIN; ELIZABETH A. WENNAR,
PRESIDENT, UNITED HEALTH ALLIANCE; PETER BARTON
HUTT, COVINGTON & BURLING, ON BEHALF OF PhRMA; AND
DON COPELAND, PRESIDENT AND CEO, ASSOCIATED PHAR-
MACIES, INC.**

Mr. SHEPHERD. Thank you. My name is Marv Shepherd. I am the Director of the Center for Pharmacoeconomic Studies. For the last decade I have been involved in doing research on the Rio Grande border looking at personal reimportation of pharmaceuticals from Mexico.

Mexico obviously is a little bit different than—or the Rio Grande Valley is quite a bit different from the Canadian border, but coming from Michigan, my home State, I am pretty well aware of the problems on both borders. But I have been concentrating in the last decade on the Mexican border problems.

I want to thank you for inviting me, and I will make my comments brief, but I want to touch on a few things. You do have my statements there in writing for you.

I am not convinced that reimportation will solve our problem. It may add costs to us, the costs of controlling the safety or trying to bring in the safety aspect of it. I am not convinced that reimportation would stop people from going to Mexico at all. I will explain that in a little bit. I still think we would still have a tremendous amount of American residents going down to Mexico to buy drugs. There are a couple of good reasons.

No. 1, Texas has faced a problem of Mexican drugs for decades, along with New Mexico, Arizona, and California. But in my work, it is just not Texas, I want to emphasize this. Forty percent of the people who go to Mexico are not Texans, and they come back with drugs. Forty percent of the people who are going to Mexico come back with drugs, but the people who go to Mexico, they represent other States. They represent Maine and Washington, all the way down to New England. So they are not just Texans or Arizonans, they are from everywhere in the States. We found 37 States represented in a sample of 5,000, to give you an example.

As I said, 25 to 40 percent of the people go to Mexico and bring back a pharmaceutical product one way or another. There are three reasons why they do it. We have heard price, price, price, but I will tell you, there is a big one in Mexico and that is called access, because you don't need a darn prescription. You can go down there and you can buy Erythromycin, tetracycline, Premarin; you name it and you can buy it, except for controlled substances, over the counter. If you have a dollar bill in your pocket, you can buy it, so you don't need the prescription. That way, you have got a lot of money you save. You don't have to go to a doctor's office. You can buy your hypertensive medication, you can buy anything you need in any quantities and bring it across the border.

Customs now is allowing 90 days' supply, but I have seen a 180 days' supply coming back from Customs. I have seen people walk across that border six times a day with 90 days' supply. I have seen people in the stores with lists: Uncle Fred needs this, and Aunt Jeanne needs this, my neighbor needs this. They will pull out

\$2,000 or \$3,000 and buy everything in these 90-day supply lots and come back across the border.

I have seen Oxycontin come across the border multiple times on one person. Three times I saw one young lady go across the border and get it and come back. I watched her come back and declare it, no questions asked. She would come right back and go across and get another one. Next time she would come back with a different drug, with three or four controlled substances, 50 units each.

In Laredo I think it is a little different than the McAllen area and the Brownsville area. But in the Nuevo Laredo area, the senior citizens are not the frequent purchasers of drugs. The purchasers of drugs there are young people, 20 to 35. Fifty percent of the group is under 36 years of age. Only 10 percent of the group was over 55 when we did the work, so it wasn't seniors. If you go to McAllen and Brownsville it may be a different percentage, but there is still a lot of youth going down there and buying pharmaceuticals.

The pharmaceutical business in Mexico is big business on the borders, big business. There are more pharmacies than any other store in the streets. It is a huge profit-making business. There are 300 or 400 pharmacies in a five-block area of Tijuana, and there have to be 20 pharmacies in a two-block area of Nuevo Laredo.

They are open pharmacies, dusty and dirty, and there is no pharmacist working in them. There is no law that says a pharmacist has to work in them. They are clerks and merchants selling drugs. They don't even use packaging.

When I see people buy drugs across the border and bring them across, the first thing I notice, and this is terrible to say, they lie. The agent will ask them, did you buy any pharmaceuticals over there? And they will say no. If they have a shopping bag, a plastic shopping bag and they can see the pharmaceutical in it, they will say yes.

The honest people say yes, I bought drugs. That is where I get my data from for my research. The not honest people who got some probably controlled substances or other stuff in their bag say no, and Customs really just lets them walk on through, unless they are really suspicious looking characters. Then they will pull them aside.

But anybody in this room in our age group can walk down there and buy anything, come back, and you can say, I didn't buy anything, and you can walk on through. So there is really no big control over it.

They do control narcotics, they do control controlled substances to some degree. They will get you if you bring back more in any one of those, if they believe you fit that profile. We have seen them tear cars apart. They will do that.

But they lie. People lie because it is cheaper and no doctor's appointment. "I can get any hypertensive medication they want. This does not work for me, I will try this one. So and so is using this one, so I will try this one here." They don't have to go to the doctor to get that changed, so the access really drives a lot of it; not only the price, but the access of trying something that may work better.

I have seen the same person, as I said before, cross many times. I don't mean to bash the U.S. Customs. They have a tough job,

they have limited resources, and it is very difficult. There are better ways of doing what they do, especially collecting data. They are doing everything by hand, pencil and paper. I don't understand that. Nothing is coded. There are no computers. It is just all by hand work. It is just archaic, as far as I am concerned.

I will summarize on two things. First, counterfeiting. We cannot tell the difference, as we saw, whether it proves to be FDA-approved or are counterfeits. I have seen some good counterfeits coming out of Mexico. I have seen some other counterfeits and I could tell by the packaging. There is a little error in the packaging.

The documenting, we need data and we need it fast. We don't know what proportion of imported products are counterfeit or substandard. We do not know what the ill effects are, and to what extent do people mix U.S. drugs and Mexican drugs.

I have raised a lot of questions, but we just don't have the data to make up any kind of good determination or open up the border to any more than we already had. It is a very difficult situation.

Thank you, Mr. Chairman.

[The prepared statement of Marv Shepherd follows:]

PREPARED STATEMENT OF MARV SHEPHERD, DIRECTOR, CENTER FOR
PHARMACOECONOMIC STUDIES, COLLEGE OF PHARMACY, UNIVERSITY OF TEXAS

It is pleasure being here today to discuss the issue of the importation of pharmaceutical products. I have been involved with this area for close to a decade, but my involvement has been mainly on the issue of Mexican prescription drugs entering the U.S. I applaud you for taking on the task of searching for ways to provide affordable and effective pharmaceuticals to the American public. However, there with the importation of pharmaceuticals it is my belief that the costs may not be worth the risk. There are many social, legal and medical issues to address, but my main concerns involve patient safety and lack of control.

This nation is facing a health care crisis. The health care crisis revolves around 1.) limited or no access to health care for some population groups, 2.) high cost of health care services and products especially pharmaceutical products, and 3.) lack of quality in services as exemplified by the high degree of medical and medication errors being documented. All three areas are not limited to but do involve some aspect of pharmaceutical products. But, I am here today to tell you that in my opinion the re-importation of pharmaceuticals will most likely add to the problem list. It will most likely increase the overall costs and most likely contribute to poorer quality of care due to lack of monitoring and management of products and patient care. Let me explain my reasoning.

Texas has faced the problem of drug importation from Mexico for decades, but in the last five to ten years the practice has escalated. It is estimated that from 25 to 40 percent of all U.S. residents who travel to Mexico bring back prescription pharmaceutical products. With the present bill, I can imagine that a higher proportion of U.S. residents will return with Mexican pharmaceuticals. Some will return with products that are safe and effective and others will not.

Personally I do not think the bill will curtail the number of people going to Mexico, because the pharmaceutical product will most likely still be cheaper in Mexico than if the Mexican drug is shipped to the U.S. for sale. The reason is the costs associated with assuring quality, if done prudently and correctly, re-labeling and the profit taking by members of the U.S. distribution system. Remember, the U.S. distributors of foreign acquired drug products only have to offer the product at a lower price than what is currently being offered. The profit takers will be the wholesalers, retail pharmacies, managed care and pharmacy benefit managers not to mention other health care providers who would use the product. In essence, I am not convinced that the savings will be passed on to the consumer.

Studies have shown that many people repeatedly visit Mexico to obtain drug products for themselves, family and friends. There are many social, legal and medical issues to address, but the main concerns I have involve patient safety, lack of control and lack of data to address the practice.

The main reasons why U.S. residents go to Mexico to obtain their prescription drug products are: 1.) Easy Access, most products do not require a prescription in

Mexico, 2.) Lower Prices, some products do have substantial price savings, but not all and 3.) drug products are not available in the U.S. Of course under this proposed bill the latter category could be ignored.

The pharmaceutical business in Mexican border towns is a huge tourist attraction and generates hundreds of millions of U.S. dollars to the Mexican economy. There are over 1,400 Farmacias in Tijuana while in near by San Diego there are just over a hundred. The number of Mexican Farmacias and mail order drug houses will grow even more with this legislation making access easier and more difficult to control.

My major concerns are the lack of medical supervision, the patient's lack of understanding on how to use the product correctly, the indiscriminate use of products. Finally, I have a concern about the assurance of product quality and safety. To me, all of these have a potential to harm, severely injure or kill people. The wording of the present bill states the drug "appears to be approved by the Secretary" . . . appears to be manufactured, prepared, propagated, compounded or processed in an establishment registered pursuant to section 510." I can assure you that many of the counterfeit products I have seen all "appear" to be the "real thing." Making this determination from world-wide distribution systems of drug manufacturers distributors, shippers, wholesalers and sellers will not be an easy task. Plus it will be an expensive task.

The question you have to answer is "do we sacrifice safety for economic savings?" It is a difficult question mainly because we are unsure of the safety profile. Data are lacking on the safety profile of drugs currently being brought into this country through personal importation. We need studies on imported product quality and the extent counterfeit products reach the U.S. public. FDA has done some quick, preliminary work and I have worked with them on collecting these data, but more comprehensive research needs to be conducted. In my opinion, the FDA data are weak and it is very difficult to make generalizations based on the limitations of their studies. More comprehensive research is drastically needed; there are too many risks for the American public just to open up the borders and expect the FDA and Customs to monitor the situation.

Obviously, the more we open the borders the more we give up safety and the assurance of high quality drug products. Currently, I believe we have an extremely safe pharmaceutical distribution system. Sure it can be improved; we do have some problems that need to be addressed such as improve the access to pharmaceuticals for seniors, and develop some strategies to address drug price increases without the sacrificing of research and development within the industry. But when you open up the borders to importation, it is my contention that you will sacrifice safety. Pharmaceutical products become more difficult to monitor and control. The U.S. could turn into a "dumping ground" for substandard drug products because this is where the money is. To do this function of monitoring and assuring drug quality will require a huge investment in resources for the FDA and Customs. For example how do you monitor millions of drug products coming through the mail each month? How do you monitor hundreds of thousands of people returning from Mexico on a Saturday afternoon? How do you monitor the millions of dosage forms and drug units being purchased by a drug chain in one week from foreign drug distributors? Most likely we will not be able to find the necessary resources to do the monitoring and checking and in the end, someone will get hurt, you can count on it.

To put this task in a better perspective, let me give you my experiences in watching people come across the border from Mexico after they purchase pharmaceuticals. Many times people do lie when asked by the Custom's agent "did you purchase any drug products while in Mexico?" I have seen the same people buy drug products, cross the border and lie when asked by the agent. They just put the product in their pocket, purse, bag or under their shirt/blouse. So when you collect data at these points you only get data from the honest people. When you have a long line of people or cars coming back from Mexico, you do not have the time to question the importer. I have seen the same person cross the border multiple times a day bringing their 50 units per drug of controlled substances every time. (No prescription is needed if you bring 50 tablets per controlled substance). I have seen confusion on the part of Custom's agent as to how much and what is allowed to cross the border for a controlled substance. I have seen a 90-day supply and at times even more for controlled substances with and without a prescription come into the U.S. I do not mean to "bash" U.S. Customs; they have a huge complex task and they lack proper resources to get the job done correctly.

When I ask people how the product works for them I have heard answers such as it works great I just need to take two tablets instead of one to get the same effect. I have talked to people in Farmacias who have had long lists of drugs not for themselves but for their family, relatives, and friends. One time I asked the cus-

tomers do you drink the water while you are here in Mexico and she said “no way.” I asked, “will you eat while you are here?” Her response was, “No, No, too risky.” I said, “you will not drink the water or even eat while you are here but you would buy your drug products here, why?” Her answer was “because they are the same as U.S. products look at the label.” I showed here that the product was not made in the U.S. but in Mexico. It still did not register with here. Just because it has the name of a U.S. manufacturer most people believe it is manufactured in U.S. For your information, the vast majority of drug products sold in Mexico are manufactured in Mexico and very, very few have an FDA approval.

In conclusion, it is my belief that some safety will be sacrificed if you open the borders to the American public for pharmaceuticals. I am not convinced that the cost saving will be present, there are many profit takers in the drug distribution system. The cost of monitoring the program and assuring high quality products will be tremendous. Finally, data are lacking on the safety profile of drugs currently being brought into this country through personal importation. I really think we need to examine what products are coming into the U.S.? What proportion of imported products is counterfeit or substandard? What are the ill effects of imported products? To what extent do people mix U.S. made products with imported products? I know I raised many questions and concerns, but I do hope I added some insight into the problems associated with Mexican drugs coming into the U.S. I will be happy to entertain any questions. Thank you so much.

Mr. BILIRAKIS. Thank you very much, Dr. Shepherd.
Dr. Wennar. Is that correct, Wennar?

STATEMENT OF ELIZABETH A. WENNAR

Ms. WENNAR. Correct. Wennar.

My position is, I am the President and CEO of United Health Alliance, which is a physician health organization located in southwestern Vermont. That organization is made up of about 115 physicians, a rural hospital, a nursing home, and a home health agency.

By way of just—I wanted to give you that information so I could help you understand what MedicineAssist is. That is the initiative that we sponsor. We started that initiative about 3 years ago. We started it in response to bus trips that were being made by patients that we were serving going up to Canada to access their medications.

One of the things that I want to point out here, I have heard a lot of talk here about safety and about quality. Now, let me just tell you from the perspective of a provider what that means.

That word is “compliance,” in our minds. In our minds, if a patient cannot comply with the treatment plan as prescribed, and that means being able to take the medications, then we have very little chance of them being able to have a good outcome. That is a physician’s major concern, compliance.

They make an assumption when the patient comes in and they write a prescription that they are going to be able to get them, and that they are going to be safe. They also make the same assumption about those samples that are in their offices, that they are safe.

So one of the things that we began to realize is that our patients weren’t complying with their treatment plans. Guess where they end up when they don’t comply? In the emergency room, back in the physician’s office, and being admitted to the hospital.

So our physicians decided to step up to the plate on this issue. I heard a lot of talk today about the pharmacists being involved, which is certainly true, the pharmacists have to be involved. We want them engaged in this conversation. But we do want the physicians engaged in the conversations, too, for two reasons: one, qual-

ity; and two, because they need to be at the tables when we are having these discussions.

With the kinds of discussions you are having right now, you can't just talk to the pharmaceutical industry, you must have the physicians engaged in this, because they write those orders.

Having said that, we decided that we could not ask or expect people to get on a bus. Not everybody can. One, they cannot afford to, maybe physically or monetarily, so we decided that there must be a way that we could step up to the plate at a grassroots level and develop some type of initiative that would help facilitate the process.

I say "facilitate" because, remember, physicians in this country may not write prescriptions to be filled in another country, in most instances, unless they are licensed in that country.

In this country right now, we know there are some 300-plus physicians that are duly licensed in Canada and in the United States.

Having said that, we decided that we were going to figure out a way for our patients to be able to comply with their treatment plans. Now, we designed the program so that there would be layers of quality in place. I can certainly go into much detail about MedicineAssist, but I would like to sort of quickly skip to something, since I only have 5 minutes. I have outlined quite a bit of this in my written testimony that you have before you.

I would like to talk about something we recently did in the process. We are involved with three pharmacies in Canada in three different provinces, and have been for 3 years. We have facilitated the process. We feel quite good about this now, because we feel like we have put things in place, that extra quality parameters do exist, and people are taking their medications and complying with their treatment plans.

One of the things we did recently was we took it upon ourselves to poll pharmacies in Canada, even those that are not participating through our program, to try to get some sort of idea about the numbers of people who are actually using this in the United States. We wanted some demographic information. We wanted to see what we could identify there.

We finally had to stop counting because we do not have the resources, to tell you the honest truth, to do all the counting. We stopped at 1.1 million U.S. citizens currently bringing in their medications and using this mechanism to access safe, affordable prescriptions.

They are with pharmacies, those pharmacies who are working with physicians there and physicians here. The physicians there act as consultants to the physicians here. The physicians here are the prescribing physicians. They may not have their written prescription up there, but they complete the medical profile information, they work with the Canadian physician, they work with the Canadian pharmacist.

I would challenge anybody to show me a program that completely works so well here in the United States for senior citizens right now. We are very proud of it.

Now, let me tell you, from the standpoint of things, what we have identified here is, one, I have heard discussions today about antibiotics and about a whole litany of other medications: Viagra

and whatever. Let me tell you, that is not what our senior citizens and our elders are looking for. They go for maintenance drugs. Those maintenance drugs are drugs that are life-sustaining drugs. They are going to have to take them for chronic conditions probably for the rest of their lives. There is probably a list of maybe 25 medications that they pretty much take.

Now, Mr. Brown, I have heard Mr. Brown say that his constituent could not be here today. I am telling him, his constituent is sitting here today, because we serve these individuals every day. We feel very comfortable. We do believe that there has to be structure in place.

Having said that, and I am using Canada as a case study, we feel very comfortable with what goes on in Canada. The pharmacists there are working very well with the physicians here. The physicians here are working very well with physicians there. Now, there is a Federal level there, there is a provincial level. We have a Federal level here and we have a State level here. We are mimicking things.

I am here to tell you, maybe Mr. Hubbard could not tell you that it is as good in Canada, but we feel from the provider's side it is as good there.

I have heard a lot of talk today about the Medicare coverage. We would love that, but we don't have it. We don't have it. From a grassroots level, let me tell you what it is like to look into the eyes of people who are just trying to survive. They want to live, and they have taken this upon themselves.

Would they like the medications down the block? Absolutely. But do you know how it feels when you know they are there and you can't get them? You want to talk about living in terror, that is living in terror, because all you want to do is live.

So I am here to tell you that if you really want to do this, we will be glad to sit down with Mr. Hubbard and to tell him how to put the safety things in, and we will tell you how it can save costs for the American taxpayer. We are willing to take it on.

Mr. BILIRAKIS. Your time has expired, but this committee would welcome any suggestions you or any others would have. You don't have to go to Mr. Hubbard, if you don't choose to, if he does not inquire. We are inquiring.

Ms. WENNAR. We would welcome the opportunity.

[The prepared statement of Elizabeth A. Wennar follows:]

PREPARED STATEMENT OF ELIZABETH A. WENNAR, PRESIDENT AND CEO, UNITED HEALTH ALLIANCE

Mr. Chairman, and Members of the Committee: Thank you for inviting me to discuss re-importation of prescription drugs as a means of accessing safe, affordable prescription drugs for US consumers and particularly our elders not currently covered under Medicare.

As you are aware today's healthcare market presents many challenges for consumers, purchasers and our political leaders. 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, particularly the elderly, must pay many times more than their Canadian [and Mexican and European] counterparts for the same drug.

BACKGROUND ON UNITED HEALTH ALLIANCE AND MEDICINEASSIST

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 (115) 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. Approximately one year 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. 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 elderly in 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 access her medications from Canada without having to get on a bus. Today that patient takes her medication 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 A). 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 B). Although the majority of the individuals using MedicineAssist are the elderly on fixed incomes, with no prescription coverage, we are beginning to see individuals that have depleted their pharmacy benefits also attempting to access 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.

Brief of M:

MedicineAssist: See website (unitedhealthalliance.com) and click on icon medicineassist for instructions and information on use. Maintenance drugs only and your personal physician must be involved. No membership fees. A Canadian licensed physician will review medical information and consult with your physician.

Notation:

1. *Personal Re-importation:* A recent poll identified over 1 million U.S. consumers using this as a means to access affordable prescription medications from Canadian pharmacies. Individuals from every State in the U.S. are currently using this mechanism. Means: mail-order and direct.
2. *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.

QUALITY/OVERSIGHT AND SAFETY

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 we 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

to access 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.

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 (see Conclusions/Recommendations). Other countries may be more difficult to monitor and manage.

REASONS FOR PRICE DIFFERENTIAL IN CANADA AND THE U.S.

To put it in the simplest of terms: the Canadian government is the purchaser, therefore they have implemented controls over the costs. Next, they do not allow direct-to consumer advertising. My understanding is that this type of marketing is only allowed in the United States and New Zealand. Essentially our major mode of control is through the approval process by the FDA that essentially controls entry into the market, not pricing. In the U.S. with its non-universal coverage structure, cost containment is undertaken by a myriad of public and private decision-makers, each with their own agenda and objectives. The price differential is of course going to appear even greater when you compare a group that has no coverage and pays out of pocket. They have no purchasing power, because they have no coverage. This is particularly true for about one-third (30 million) of the Medicare population.

I recently visited with health care providers in France and in Canada and they seemed quite perplexed by how we could rationalize the cost/benefit of allowing the prescription drugs to be advertised in the manner that they were on television. Their point was well taken on two fronts: (1) someone has to pay for the costs associated with this advertising and (2) when I proposed that it was intended to educate consumers so that they could be more informed about what was available for their treatment: they asked where's the data to support that this was anything more than "marketing" the drugs the industry wants to sell or promote. They used the example of a drug for chronic indigestion allowing you to continue to eat foods that are clearly not good for you.

REIMPORTATION/IMPORTATION FROM CANADA

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 reimportation from Canada under controlled circumstances can provide an interim solution for those in need of access to affordable prescription drugs. I do believe that with the cooperation of the industry, the FDA, the Canadian regulators and U. S. physicians that under a controlled demonstration project we could achieve a policy that would prove beneficial for all the stakeholders until we can produce a better solution.

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, particularly for the elderly, until we can provide appropriate levels of coverage under Medicare without compromising current medical benefits. Long-term viability will depend on the development of a program that can be implemented not just signed into law [as evidence by MEDSA 2000].

Notation:

1. Canada (as does other countries) has the equivalent of the FDA with regard to oversight.
2. The literature does not support fears about counterfeit drugs being dispensed (at least in Canada).
3. Customer satisfaction and compliance for those currently using re-importation (Canada) appears high.
4. Physicians are engaged in the process. Compliance results in better outcomes and potential lower costs.

The following could/should be considered:

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 US. A set of standards would have to be met and pharmacies would be awarded conditional accreditation during their first year of participation. Full accreditation in

- year two. They would also have to provide data/information to the FDA. Once all requirements were met, FDA would issue unique bar codes for these pharmacies to use when shipping into the US (through Custom).
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.
 3. The role of US and Canadian physicians can be worked through the development of a cross-border association (licensure and protocol development).
 4. Private/Public partnerships should be developed in order to reduce the costs at the Federal level [while maintaining the oversight (FDA)].
 5. 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) the data that would be reported to the FDA could be very beneficial to research and development efforts.
- This concludes my prepared remarks. Thank you again for this opportunity and I would be happy to try to address your questions

Sample Drug Pricing

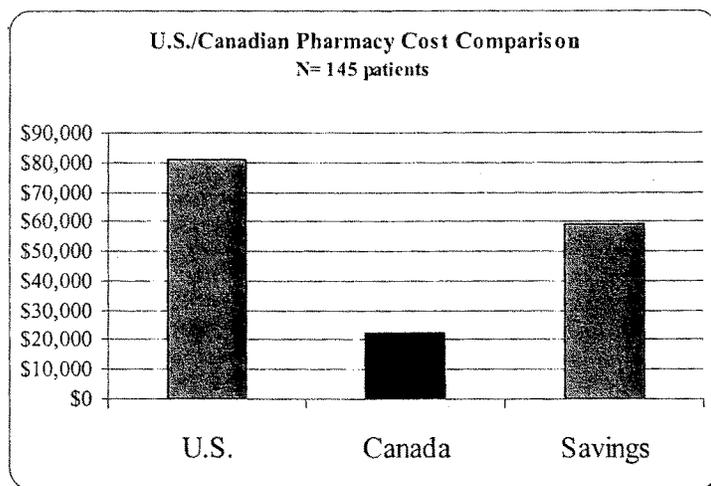
[All dollar figures are reflected in U.S. Currency]

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.

MedicineAssist**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 (MedicineAssist)

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.

Mr. BILIRAKIS. Furnish it to us, whatever suggestions you may have.

Mr. Hutt.

STATEMENT OF PETER BARTON HUTT

Mr. HUTT. Mr. Chairman and members of the committee, I am Peter Barton Hutt, a partner from the Washington, DC law firm of Covington & Burling, where I specialize in food and drug law.

From 1971 to 1975, I served as Chief Counsel for the Food and Drug Administration, and I am the coauthor of the casebook used to teach food and drug law in law schools throughout the country. Each year I personally teach a full course on food and drug law at Harvard Law School.

I am testifying today on behalf of the Pharmaceutical Research and Manufacturers of America.

H.R. 5186, introduced by Representatives Kingston and Gutknecht, would substantially curtail FDA's authority to keep unapproved, adulterated, and misbranded drugs out of the United States. It would radically change the drug approval process that has existed in this country for the last 40 years, and it would seriously undermine the ability of FDA to assure that only safe, effective, and high quality drugs are available to our citizens.

The bill has two sections, one that applies to individuals and the other that applies to pharmacists. The first section of the bill would broadly authorize individuals to import prescription drugs, even though those drugs are or may be unapproved, adulterated, or misbranded.

Under this provision, FDA may not prevent an individual from importing a prescription drug if it appears to be approved. This provision would eviscerate FDA's current authority. Today, FDA can keep a domestic drug off the market and keep a foreign drug out of this country unless it is affirmatively approved by the agency. Any person attempting to bring a drug into the United States today has the burden to prove to FDA that the product complies with United States law.

Under H.R. 5186, that burden would be switched to FDA to prove the product does not comply with United States law. Any product that merely appears to be approved by FDA would be permitted entry, and FDA would have no authority to ask for proof that it in fact meets our requirements.

The bill also completely prevents FDA from keeping drugs out that are adulterated or misbranded. FDA's hands are tied as long as the drug appears to be approved. There is no prohibition at all for adulteration or misbranding.

Now, H.R. 5186 may be intended to apply only to individuals importing drugs in very small quantities for their own personal use, but the language in fact contains no such limitation. It refers only to individuals who are not in the business of importing prescription drugs. This would hamstring FDA enforcement.

The second section of the bill would permit pharmacists to reimport prescription drugs. When Congress passed a reimportation amendment into law 2 years ago, it provided that the amendment would not go into effect until the Secretary of HHS demonstrated it would not pose new health and safety risks. Both Secretary

Shalala then and Secretary Thompson now have each concluded that they could not make that demonstration.

H.R. 5186 would therefore go into effect, despite the risks that both Secretaries concluded a reimportation provision would present.

The simple fact is that FDA already is overwhelmed by the volume of drug imports coming into this country. The reimportation prohibition is an important tool to help FDA stem the tide of violative products.

Just 2 months ago, Congress added another tool in the Bioterrorism Act to give FDA increased power to enforce the current standards for drug imports. But H.R. 5186 would reduce FDA authority over imports and invite unscrupulous parties to bring counterfeit, substandard, and inappropriately labeled and stored products into this country from all over the world, with substantial risks to the American public.

[The prepared statement of Peter Barton Hutt follows:]

PREPARED STATEMENT OF PETER BARTON HUTT, PARTNER, COVINGTON AND BURLING, ON BEHALF OF THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA

Mr. Chairman and Members of the Subcommittee: Thank you for the opportunity to testify today on the important issue of the importation of pharmaceuticals. I am Peter Barton Hutt, a partner in the law firm of Covington & Burling, where I specialize in food and drug law. From 1971 to 1975, I was privileged to serve as Chief Counsel for the Food and Drug Administration. I have co-authored a leading law school textbook on federal food and drug law and have authored numerous articles and reviews of developments in the area. I am here today on behalf of the Pharmaceutical Research and Manufacturers of America (PhRMA) to present the industry's views. PhRMA represents the nation's leading research-based pharmaceutical and biotechnology companies that are devoted to inventing new life-saving, cost-effective medicines.

I. IMPORTATION UNDER THE FEDERAL FOOD, DRUG AND COSMETIC ACT

Section 801(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) requires FDA, working with Customs, to prevent the importation of any drug that "appears" to be "adulterated," "misbranded," or "unapproved." *See* 21 U.S.C. § 381(a).

The **adulteration** provisions in section 501 of the FD&C Act apply where, for example, a drug has been manufactured under unsanitary conditions; it has not been manufactured in accordance with "current good manufacturing practice" (the standard used to ensure drug quality); it contains an unsafe color additive; it fails to meet requirements for purity and strength; or its container is made from a poisonous or deleterious substance. *See* 21 U.S.C. § 351.

The **misbranding** provisions in section 502 of the FD&C Act apply where, for example, a drug has labeling that is false or misleading; that fails to contain adequate warnings against dangerous use in pathological conditions or by children or against unsafe dosages or methods of administration; that lacks adequate directions for its intended use; that is an imitation of another drug; etc. *See* 21 U.S.C. 352.

The approval requirements in section 505 of the FD&C Act require that every new drug sold in the United States be approved in advance by FDA based on proof of safety and effectiveness. It is unlawful under the FD&C Act for anyone to introduce into interstate commerce a new drug that is not covered by an approved new drug application (NDA) or abbreviated new drug application (ANDA).¹ Approval must be sought on a manufacturer-by-manufacturer and product-by-product basis. Approval of an application applies only to the specific drug product identified in the application and manufactured in the facilities and according to the specifications and procedures that are described in the application. When a product is introduced into interstate commerce that does not comply with an approved application, it is considered an unapproved new drug in violation of section 505 of the FD&C Act. It is also misbranded under section 502.

¹ FDA §§ 301(d) & 505(a).

These basic rules cover importation, since importing is a form of introducing a drug into interstate commerce. Thus, a drug that has not been approved by FDA for marketing in the U.S. may not be imported, even if another country has approved it for sale in that country. There is no exemption from the requirements of the FD&C Act for importations of a foreign version of a U.S.-approved drug.²

II. THE DRUG IMPORTATION ACT OF 2002

Summary of Legislation

The “Drug Importation Act of 2002,” introduced by Representative Kingston, would substantially curtail FDA’s authority to keep unapproved, adulterated, and misbranded drugs out of the United States. The bill has two sections, one that applies to individuals and the other to pharmacists. Each would devastate the legal protections currently in place for the American public against unapproved, substandard, counterfeit, and potentially unsafe or ineffective medicines.

Section 2(a) of the bill would add a new subsection (p) to section 801 of the FD&C Act broadly authorizing individuals to import prescription drugs even though those drugs are or may be unapproved, adulterated, or misbranded.

Under this new section 801(p), FDA “may not prevent an individual” from importing a prescription drug that “appears to be approved.” *This reverses and overrides the burden of proof* under existing section 801(a). Under existing law, FDA can keep a drug out if it appears to be unapproved; under the Kingston bill, FDA must let the drug in if it appears to be approved—even if it turns out not to be approved. For example, unscrupulous overseas sellers can make unapproved copies and counterfeits and sell them to unsuspecting Americans. FDA would be powerless to keep those drugs out of the country as long as they “appear” to be approved. By analogy, imagine a similar provision that prevented the Treasury Department from keeping counterfeit \$100 bills out of the United States as long as they “appear” to be genuine.

The bill also completely prevents FDA from keeping drugs out that are adulterated or misbranded. FDA’s hands are tied as long as the drug “appears to be approved”—there is no reference at all to adulteration or misbranding. A drug could easily appear to be approved and yet be adulterated or misbranded (for example, it could be manufactured in violation of current good manufacturing practice or its labeling could fail to meet FDA requirements). FDA has made clear that even approved drugs can be adulterated or misbranded (*see* 21 C.F.R. § 314.170), so an approval standard alone is completely inadequate to allow FDA to enforce the law.

The bill provides that it only covers a prescription drug that “does not appear to be a narcotic” and that “appears to be manufactured” in a registered establishment. However, these limitations are illusory because of the reversed burden of proof. Just as with the approval requirement, it would be a simple matter to evade these requirements through counterfeits and false paperwork so that drugs “appear” not to be a narcotic and “appears” to be made in registered plants. FDA would be powerless to act as long as the drugs meet these appearance standards.

Furthermore, the bill may be intended to apply only to individuals importing drugs for their personal use, but the language in fact contains no such limitation. It refers only to individuals who are “not in the business of importing prescription drugs,” and cites section 801(g) of existing law. Section 801(g), which was added by the reimportation law in 2002 and has never been implemented, merely repeats the same language, without any definition or guidance. FDA would be hamstrung by the need to prove whether an individual is or is not in the “business” of drug importation before the agency could detain violative drugs.

Section 2(b) of the bill would add a new subsection (q) to section 801 of the FD&C Act requiring FDA to establish a program allowing pharmacists to reimport prescription drugs—thereby overriding the prohibition on reimportation established under the PDMA. When Congress passed a reimportation amendment in to law two years ago (the Medicine Equity and Drug Safety Act), it provided that the amendment would not go into effect unless the Secretary of Health and Human Services demonstrated that it would not pose new health and safety risks. *See* 21 U.S.C. § 384(l). Secretary Shalala and Secretary Thompson each concluded that they could not make that demonstration.³ The current bill contains far fewer safeguards than the previous law, yet it omits the demonstration requirement—hence, it would go into effect despite the risks it would present.

The bill also would weaken existing labeling requirements by authorizing the use of “alternative labeling” to avoid the intellectual property rights of pharmaceutical

² *See, e.g.* FDCA § 801(a).

³ *See* <<http://www.fda.gov/oc/po/thompson/medsact.html>>.

companies (new section 801(q)(4)). Such alternative labeling may or may not adequately provide for the safe and effective use of the products in question; it also may or may not comply with FDA approval requirements, yet the bill would allow it.

The simple fact is that FDA already is overwhelmed by the volume of drug imports coming into the United States. The reimportation prohibition is one of the few tools at the Agency's disposal to help stem the tide of violative products. This bill would eliminate that important tool and invite unscrupulous parties to bring counterfeit, substandard, and improperly labeled and stored products into this country from all over the world, with substantial risks to the American public.

Modifications or Improvements Won't Make Reimportation Proposals "Safe"

Having outlined the above concerns, proponents of reimportation believe that, with certain modifications, reimportation can be made "safe." Such modifications have included the incorporation of drug testing or end-product testing requirements, chain of custody provisions and/or limitations to imports from Canada only. Even with these modifications, as explained below, the Kingston proposal, or any other proposal, could not guarantee safety.

Drug Testing and Chain of Custody Requirements

The inclusion of end product testing is not adequate to demonstrate that a drug was manufactured in accordance with U.S. approval standards and quality requirements. Testing at the moment of import also does not ensure the integrity of the drug throughout its shelf life. Drugs are highly sensitive and can become adulterated and dangerous during shipping if not properly controlled and monitored. Some medicines must be stored at very precise temperatures at every point in time from production to use. Gel capsules may melt, and liquid products can become contaminated. Any of these things could cause a drug to have a shortened shelf life, even if it passed testing at the moment of arrival into the U.S.

The inclusion of a chain of custody provision, otherwise known as a drug pedigree requirement, also does not guarantee safety. According to the FDA in testimony on July 9, 2002 before the Senate Special Committee on Aging, the agency stated:

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

FDA's position on end-product testing and drug pedigree can be better understood with the following explanation of the way U.S. drugs must be produced in accordance with exacting standards and detailed specifications outlined in a New Drug Application (NDA) that are extensively reviewed by the Food and Drug Administration (FDA).

The individual steps and controls in U.S. pharmaceutical production are set out in the chemistry and manufacturing controls section (CMC) of the NDA. In addition, the FDA inspects the manufacturing facility prior to NDA approval to assure that the product can be manufactured in full compliance with the procedures described in the NDA. Each lot of manufactured pharmaceutical product is tested by very specific procedures using high standards to insure the product meets all quality specifications. This testing occurs prior to release into the marketplace so that the American patient receives a safe and efficacious product that will treat the underlying medical condition that he or she suffers from. Pharmaceutical companies face a myriad of complex issues as manufacturing processes are designed.

All of the following areas must be carefully addressed by the company and monitored by the FDA to assure that only drug product of the highest quality reaches consumers.

Personnel—People are the most important single element in assuring that the highest quality products are produced. Employees must be competent in their specialties by reason of academic training, experience and continuing job training, which include meeting all aspects of Good Manufacturing Practices (GMP) regulations. A comprehensive awareness of how to insure drug quality and an understanding of their personal contribution is essential for a company to have a total quality system.

Product Design—The quality attributes of products must be "designed-in" during research and development, *confirmed* during clinical evaluations, and *controlled* using well-defined systems throughout manufacturing and distribution. Effective

quality control programs include continuing evaluation of marketed product directed toward product improvement programs.

Facilities, Systems and Equipment—Facilities, systems and equipment must be designed, selected, installed and maintained to be efficient and reliable to help assure that finished product meets the defined quality characteristics. Automation may be used where it contributes to the maintenance and uniformity of quality in both manufacturing and testing operations.

Specifications—Detailed specifications for obtaining and assuring the quality of raw materials, intermediates, packaging components, labeling and finished products must be described in great detail in the NDA. Even something as simple as the water used during manufacturing must meet exacting specifications. Companies must work closely with vendors who certify their products. This gives added assurance of the acceptability of purchased materials as received.

Procedures—Written procedures are prepared and followed that describe in extensive detail all steps required to control manufacturing, to monitor support systems and for the evaluation of processes, intermediates and finished products. A procedure is available that describes the requirement to monitor (audit) all systems and operations as a further method of assuring total control and safety of the product. FDA inspections of manufacturing plants every few years confirm these activities are up to their high standards.

Processes—The establishment of consistently effective production processes is critical to assuring finished product quality. These processes must be supported by in-process control monitoring and/or process validation.

Lot Control—A key element in maintaining administrative control of information on a drug throughout its production is the lot control number system and related documentation. This lot identification system provides the means for establishing a historical record of the entire production, testing and approval procedure. This numbering system provides a necessary method for tracing product distribution and its retrieval if required (e.g., a recall is ordered).

Packaging and Stability Testing—Pharmaceuticals are carefully packaged to insure optimal stability. Products are frequently evaluated for stability so that, as they are distributed to the thousands of pharmacies, doctor's offices, and hospitals, their potency is not lost. Storage conditions are specified in the NDA. Each lot is given an expiration date that, if the appropriate storage conditions are met, assures that the product (in its original container) will have full potency. The labeling on these packages is reviewed and approved by the FDA and contains critical safety and use information for medical practitioners.

Canada-only Limitations

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

At a September 5, 2001, hearing before the Senate Consumer Affairs, Foreign Commerce and Tourism subcommittee, William Hubbard, FDA's Senior Associate Commissioner for Policy, Planning & Legislation, warned,

“Even if the Canadian system is every bit as good as ours, and I don't know whether it is or not... the Canadian system is open to vulnerabilities by people who will try to enter the U.S. market because again that's where the money is.”

During a July 9, 2002 hearing before the Senate Special Committee on Aging, Hubbard further warned,

“I talked to a dozen health Canada officials and I said if [importation of drugs from Canada] would have happened, would you take responsibility for the safety of these drugs coming into America, and they said absolutely not. Why would they? They are not going to their citizens.”

Furthermore, Canadian law explicitly exempts pharmaceuticals intended for export from any regulatory oversight whatsoever. Section 37 of the Canadian Food and Drugs Act provides:

“This 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...”

Even if Canada had the authority to regulate exports, its regulatory system would be quickly overwhelmed. Currently, the Canadian drug market is less than 10% of the U.S. drug market. Even creating a modest U.S. demand for drugs transshipped

through Canada by lifting the current importation ban would pose an enormous challenge to that distribution and regulatory system.

Reimportation by Pharmacies Breaks Drug Distribution Chain Protecting Drug's Integrity

The cornerstone of pharmaceutical development in the United States is the total control of the process from the selection of raw materials, design of the manufacturing process, packaging of the final product, evaluation of the conditions for storage (including the establishment of an expiration date after which the medication should be discarded), and careful selection of the distribution pathway. The risk that patients will receive sub-potent or even counterfeit medicines will occur if the law that restricts the distribution pathway to that chosen by the manufacturer is relaxed, to allow pharmacists or wholesalers to import pharmaceuticals from other countries.

Regulations established by the FDA set forth the licensing requirements for wholesalers, set forth minimum requirements for the storage and handling of prescription drugs and for the establishment and maintenance of records of drug distribution by wholesale distributors. These record keeping requirements also provide for the speedy recall of specific lots of product if necessary. Even in cases where drug product may have originated at the original manufacturer, there is no guarantee that the exacting storage conditions identified in the NDA have been maintained to assure product quality.

The following cases are representative of the unforeseen problems that could arise if pharmaceutical manufacturers lose control of the drug distribution system:

Drug Distribution to Foreign Countries—Pharmaceuticals destined for export routinely have different packaging requirements and even may be manufactured in different dosage forms, shape, size, and color than according to the parameters set forth in the FDA-approved NDA since the country of destination often will have different regulatory requirements. Clearly in the latter case, such product should not be permitted back in the US since it does not meet the criteria set forth in the approved FDA license and would lead to patient confusion. If the product does meet US specifications it must be repackaged prior to any distribution to pharmacies so that the packaging meets FDA labeling requirements.

Product Recall—It is important to note that even if such repackaging efforts are successful, American patients are at risk in the event of a product recall. Although rare, such recalls need to be handled in a rapid and sometimes urgent manner. If a lot were manufactured for export, there are no provisions or obligations on the part of the foreign country to notify those American consumers who receive the re-imported products. Our FDA would not be able to enforce a recall without receiving extensive shipping documentation prior to importation that identified the lot number, the country that the product came from, and every wholesaler and pharmacist that imported the product back into the US. Such an information infrastructure at the FDA would cost tens of millions of dollars to establish and maintain and would clearly be incomplete, increasing the risk to patients who could not be contacted.

Repackaging of Pharmaceuticals—Many pharmaceuticals that are imported or reimported into the US will have to be repackaged to meet the standards set forth in the NDA. There are several difficulties associated in assuring product purity and potency as well as conveying important information to health care providers. The repackager traditionally uses materials that are not specified in the NDA. There is the well-documented case of bleached cotton from a supplier that contained trace amounts of chlorine in the cotton. This resulted in accelerated degradation of the active drug substance, and inactive product. A manufacturer might specify an amber or opaque bottle because of light sensitivity; the use of other materials might accelerate degradation. If the correct materials are not used the patient is at risk of receiving sub-potent pharmaceuticals. Use of non-specified container-closures or repackaging may occur in a facility without appropriate environmental controls and could lead to accelerated degradation because of increased exposure of the pharmaceutical to excessive water vapor. New safety information is often being added to the drug label by the manufacturer following FDA approval. There is no provision for repackagers or importers to keep up with critical label changes that are mandated by the FDA, so that many repackaged goods would be incorrectly labeled.

Unknown Storage Conditions—Not all pharmaceuticals come in pill or tablet form. There are capsule formulations, liquid formulations for oral administration, freeze-dried powders that must be reconstituted, transdermal patches, powders, creams, and lotions for external use, drops for ocular administration, and liquid concentrates for intravenous formulation. Some timed-release pills are designed to carefully control the release of drug following administration. Every product that is approved by the FDA is individually evaluated for stability and potency over the pe-

riod from time of release from the manufacturer to the expiration date. Conditions for storage *in the manufacturers' original container* are specified in the NDA in detail so that the product that the consumer receives will be both safe and efficacious when taken as prescribed. As noted above, the PDMA specifies minimal conditions for storage and handling by distributors. There is no ready way for the consumer or the FDA to know whether the product that is imported into this country has been stored appropriately. Extremes in temperature, humidity, or the repackaging process are likely to result in a product that deviates markedly from the original specifications. Testing may reveal the current potency of a product but would not be predictive of future potency if the pharmaceutical has been inappropriately handled or stored.

Paper Trail and Authenticity Testing—Reimportation proposals rely on importers to provide the FDA with documentation regarding the source of the pharmaceutical being brought into the US. As discussed above, it is inappropriate and dangerous to rely solely on such documents, which can be easily forged. Several years ago a company was victimized in the United Kingdom by a large counterfeit operation that utilized two separate sets of accounts to hide the illegal transactions. The addition of “authenticity” and degradation testing will not provide American consumers with assurance that products are safe and effective. There is no regulatory definition for “authenticity.” Simple appearance or even presence of the active ingredient is false comfort that the drug is identical with that made by the ethical pharmaceutical company. A simple degradation test will not reveal whether the product was properly stored. All drugs marketed in the US must be required to adhere to the same standards of safety, efficacy, and quality in order to insure the safety of American patients.

Safety Issues—Counterfeit preparations are not manufactured in accordance with the original NDA. Counterfeiters may use different starting materials, intermediates or additives that are not acceptable. The counterfeit products are not manufactured in accordance with GMPs. It is extremely difficult to document any of these violations. As the result of a tragic incident of distribution of contaminated cough syrup to Haiti in the mid-1990s, the World Health Organization (WHO) has made the need to test all starting materials and the importance of GMP compliance a priority. The sophisticated counterfeiter is not concerned with the letter of the law or public health. The quality of a medicine is a measure of numerous factors including reproducibility of the physical state in terms of particle size, crystal structure, color, density, and other characteristics. The ability of the active ingredient to be manufactured into the final dosage form with all the other materials (usually 5 to 30 other substances called excipients) as well as the amount of impurities present is the measures of its quality. Pharmaceutical companies have large numbers of personnel and many departments to insure that the necessary procedures are carried out and the standards of drug quality are met. There is no tolerance for impurities or deviation from specifications for injected medicines that must be sterile and pure, as the injection into the blood stream of preparations with small amounts of glass or other contaminants could cause significant medical harm. Sophisticated counterfeiters can and have manufactured pharmaceuticals that look every bit like the ones made by the ethical pharmaceutical company. However, even if the pill or other pharmaceutical preparation has the same active ingredient, there is no guarantee that there won't be dangerous impurities present or that the medicine will have the same clinical activity. Even differences in particle size are critical to the drug's safety and effectiveness. Such differences caused, for example, the lack of activity in a number of aspirin products manufactured and marketed during the 1960s and 1970s.

Hopefully all of these examples illustrate that legalizing importation by pharmacists or other parties other than the manufacturer opens up an avenue for unscrupulous counterfeiters that does not presently exist. Such products may have no active drug ingredient, sub-potent amounts of active ingredient, or potentially toxic additives any of which will place American patient's lives in danger. Even drugs produced by the original manufacturer pose risks if they have not been appropriately stored prior to reimportation. Extremes in temperature and humidity accelerate the deterioration of the pharmaceutical substance. In addition, it is difficult to conceive how a recall could be mounted if the imported products were subject to a safety recall in a foreign country. The manufacturer would not have any knowledge of the distribution system for these imported products.

In order to continue assuring American patients medicines are safe, effective, and meet the highest quality standards, the current controls on manufacturing and distribution must be maintained. Only the full battery of quality testing conducted by the manufacturer coupled with complete knowledge of the domestic distribution process can assure the margin of safety Americans expect.

III. THE MEDICINE EQUITY AND DRUG SAFETY ACT OF 2000

In October 2000, Congress passed legislation to permit the reimportation of prescription drugs by commercial importers. The law did not take effect, due to concerns about whether it could be implemented safely.

The Medicine Equity and Drug Safety Act of 2000 (MEDSA) amended section 801(d)(1) of the FDCA and added a new section 804 to the Act. Under the new section 804, an importer or wholesaler—in addition to the original manufacturer—may reimport U.S.-manufactured drugs into the United States.

The MEDSA went further than the Kingston bill in an attempt to address safety issues and included the following provisions:

- Section 804(b) states that FDA's reimportation regulations must contain safeguards to ensure that imported products comply with section 505 of the FD&C Act (e.g., they must be approved, and they must be safe and effective for their intended uses), as well as sections 501 and 502 (which prohibit adulteration and misbranding);
- Section 804(d) requires importing pharmacists and wholesalers to provide information and records to FDA, including the results of testing necessary to assure compliance with specifications;
- Section 804(e) states that testing required by section 804(d) must be performed by the importer or the manufacturer, and—if the testing is performed by the importer—requires the manufacturer to provide information needed to authenticate the product and to confirm that the labeling complies with the FD&C Act;
- Section 804(g) requires FDA to suspend the importation of specific products or importation by specific importers if the agency discovers a pattern of importation of counterfeit products or products that violate section 804.

Even with these explicit so-called safeguards in place—safeguards that went far beyond those contained in the Drug Importation Act of 2002—two HHS Secretaries refused to implement MEDSA because they could not demonstrate that its implementation would impose no additional risk to the public's health and safety or that it would result in a significant reduction in the cost of covered products to the American consumer.

Specifically, in December 2000, Secretary Shalala declined to implement MEDSA, citing flaws in the legislation that could “undermine the potential for cost savings associated with” prescription drug reimportation and “could pose unnecessary public health risks.” In July 2001, Secretary Thompson also declined to implement MEDSA on the ground that the safety of prescription drugs could not be adequately guaranteed if reimportation were permitted under its provisions. “Opening our borders as required under this program would increase the likelihood that the shelves of pharmacies in towns and communities across the nation would include counterfeit drugs, cheap foreign copies of FDA-approved drugs, expired drugs, contaminated drugs, and drugs stored under inappropriate and unsafe conditions,” he wrote. Accordingly, section 804 of the FD& C Act, added by MEDSA, is not in force.

IV. PERSONAL USE

Notwithstanding the preceding, FDA has had a “personal importation” policy since the mid 1980s. This policy advises FDA inspectors that they may exercise enforcement discretion to permit the importation of an unapproved new drug for personal use in certain situations. In particular, enforcement discretion may be applied if the drug is intended for the treatment of a serious condition for which effective treatment is not available in the U.S., provided the individual seeking to import the product affirms in writing that a U.S.-licensed doctor has assumed responsibility for the individual's treatment with that product. Further, there can be no known commercialization or promotion of the product to U.S. residents by those involved in its distribution. Finally, the product must be imported for personal use, meaning the individual may import no more than a 90-day-supply. The personal importation policy does not permit the exercise of enforcement discretion to permit the importation of cheaper versions of FDA-approved drugs. It was intended solely to allow unapproved medications into the U.S. for compassionate use. In explaining the origins of this policy, FDA's Deputy Commissioner Bill Hubbard emphasized in testimony before the Senate Special Committee on Aging on July 9, 2002:

“...the FDA at that time attempted to carve out an exception to allow patients to bring in a 90-day supply of a drug that is unapproved for which there is no therapy in this country...so if you had a treatment for a given disease already here, you couldn't bring it in, but if you had a disease like a cancer or AIDS that had no treatment, FDA would use its enforcement discretion to allow that in. It's not in the law. It is just enforcement discretion on the agency's part, and that compassionate exception has been misinterpreted...”

To that end, FDA has taken the position that the personal importation policy has outgrown its usefulness and now presents a threat to public health. In testimony before the Subcommittee on Oversight and Investigations of the House Committee on Energy and Commerce in June 2001, Hubbard reported that “importing prescription drugs for personal use is a potentially dangerous practice,—and explained that “FDA and the public do not have any assurance that unapproved products are effective or safe, or have been made under U.S. good manufacturing practices.” Drugs that are manufactured in the U.S., exported, and then reimported by a third party “may not have been stored under the proper conditions, or may not be the real product, because the U.S. does not regulate foreign distributors or pharmacies.” Therefore, he explained, “Unapproved drugs and reimported approved medications may be contaminated, subpotent, superpotent, or counterfeit.” Patients might take a product “that could be harmful, or fatal.” He added that FDA has concluded there is less need for the personal importation policy now than when it was adopted in 1988.

The agency therefore proposed to the Department of Health and Human Services that it eliminate its personal use policy for mail imports:

“And the inescapable conclusion for us is that these drugs are virtually all unapproved in the United States. They are provided without proper manufacturing controls. They often lack instructions for safe use and they may be counterfeit or worse. These factors combined with the rapid increase in the Internet that has caused this explosion of these things leads us to believe that they pose a risk to our citizens that must be reduced.

“So accordingly, we have recommended to Health and Human Services Secretary Thompson that he approve our recommendation to request that the Customs Service deny entry of all of these drugs and return them to their sender. We would create one exception, for patients with serious diseases such as cancer who need an unapproved drug from a foreign country to save their lives or at least to give them hope of saving their lives. “We need to be able to make a blanket assessment that these things are not safe for American consumers and should be turned back, and I believe the Customs Service agrees with that. And so, if Secretary Thompson and the Administration agree, that will be the approach we intend to take.”⁴

V. FEDERAL AGENCIES OPPOSE REIMPORTATION

After enactment of MEDSA in 2000, federal agencies charged with law enforcement and protecting the public health made clear their opposition to reimportation. For example, in 2001 U.S. Customs and DEA officials testified before the House Energy and Commerce Committee that thousands of counterfeit and illegal drugs are already coming across the borders and through the mail from other countries. These agency officials recommended tightening our current regulation of reimportation of pharmaceuticals. In a follow-up letter to the Energy and Commerce Chairman and Ranking Member, a DEA official wrote that the DEA opposes reimportation because it “would hinder the ability of federal law enforcement officials to ensure that drugs are imported into the United States in compliance with long-standing federal laws designed to protect the public health and safety.” In March 2002, the Administrator of the Centers for Medicare and Medicaid Services (CMS) told the Senate Finance Committee that CMS opposes the reimportation of prescription drugs into the U.S. “We have opposed it,” he stated. “There is no way for FDA to monitor and regulate drugs coming in from Canada, Mexico, or other countries.”

As recently noted by the FDA, the current “closed” regulatory system has been very successful in preventing unapproved, adulterated or misbranded drug products from entering the U.S. stream of commerce. Legislation that would establish other distribution routes for drug products, particularly where those routes routinely traverse a U.S. border, creates a wide inlet for counterfeit drugs and other dangerous products that are potentially injurious to the public health and a threat to the security of our nation’s drug supply.”⁵

The Kingston bill would recreate the public health risk of counterfeit, unsafe, and adulterated drugs that Congress sought to eliminate in the late 1980s with the Prescription Drug Marketing Act. Reestablishing a system where wholesalers and pharmacists may import prescription pharmaceuticals in to the U.S., and codifying an

⁴See, e.g., “Continuing Concerns Over Imported Pharmaceuticals,” hearings before the Subcommittee on Oversight and Investigations, House Energy and Commerce Committee, June 7, 2001 (Cmte. Print No. 107-30).

⁵Letter of Lester M. Crawford to The Honorable Thad Cochran, July 17, 2002.

expanded personal importation policy, would recreate the very public health risk that the PDMA was designed to eliminate.

VI. THE PRESCRIPTION DRUG MARKETING ACT (PDMA)

In closing Mr. Chairman, while legislative efforts to eliminate the current reimportation restrictions under the FD&C Act may be new, the health and safety problems posed by counterfeit, subpotent, superpotent or contaminated reimported pharmaceuticals are not. The perils of lax oversight of reimportation from abroad had been examined in a series of groundbreaking Congressional oversight hearings in the mid 1980s by the House Energy and Commerce Committee's Oversight and Investigations Subcommittee, chaired by Mr. Dingell. One well-publicized example uncovered by Subcommittee investigators involved importation and sale to consumers of more than one million counterfeit, ineffective birth control pills, complete with counterfeit packaging and labeling.⁶ The Subcommittee also uncovered numerous instances of reimported products having exceeded their expiration dates or having been improperly stored being sold into the U.S. market.⁷

In calling for legislation to ban the reimportation of FDA-approved drugs sent abroad, the Subcommittee described the public health and safety concerns of allowing "American goods returned" policies as follows: "[T]he clear and present danger to the public health from reimported pharmaceuticals is the threat that subpotent, superpotent, impotent or even toxic substances labeled as U.S.-produced legend drugs will enter the distribution system."⁸ The House Energy and Commerce Committee concluded that permitting reimportation of American drugs "prevents effective control or even routine knowledge of the true sources of merchandise in a significant number of cases."⁹ As a result, "pharmaceuticals which have been mislabeled, misbranded, improperly stored or shipped, have exceeded their expiration dates, or are bald counterfeits, are injected into the national distribution system for ultimate sale to consumers."¹⁰ Indeed, "the very existence of the market for reimported goods provides the perfect cover for foreign counterfeits."¹¹

Investigators also were not persuaded that allowing greater reimportation would lead to lower priced prescription drugs available to U.S. consumers.

Pharmaceuticals reimported by diverters displace full price sales in the wholesale market. Moreover, prices to ultimate consumers are generally not lowered as a result of diversion. Rather, the profits go to the various middlemen, here and abroad, while consumers bear the risk.¹²

In response to the abuses uncovered, the Energy and Commerce Committee reported, and Congress passed, the Prescription Drug Marketing Act (PDMA), which added section 801(d)(1) to the FD&C Act, in order to protect U.S. consumers from the "wholesale market" and the "diversion market" that were bringing in drugs that had been improperly stored, handled, and shipped, and from counterfeit and unapproved products.

Under section 801(d)(1) of the FD&C Act, a drug that is manufactured in the U.S. pursuant to an approved NDA and shipped to another country may not be reimported into the U.S. by anyone other than the original manufacturer.¹³ This prohibition on reimportation applies even if the product fully complies with a U.S. new drug application or abbreviated new drug application. The provision restricting the right to reimport U.S.-drugs to the original manufacturer was designed to ensure that only the party that can truly vouch for the pedigree of a drug is allowed to bring that medicine back into the country. This gives FDA an important tool to pre-

⁶*Dangerous Medicine: The Risk to American Consumers From Prescription Drug Diversion and Counterfeiting*, 99th Cong., 2nd Sess. 22 (Comm. Print 99-2 1986).

⁷See, e.g., *Prescription Drug Diversion and Counterfeiting, Part 1, Hearings before the Subcomm. on Oversight and Investigations of the House Energy and Commerce Comm.*, July 10, Aug. 7, Sept. 19, Oct. 31, Dec. 6, 1985 (Cmte. Print No. 99-61).

⁸*Uncertain Returns: The Multimillion Dollar Market in Reimported Pharmaceuticals*, 99th Cong., 2nd Sess. 23 (Comm. Print 99-GG 1986).

⁹H.R. Rep. No. 76, 100th Cong. 6-7 (1987).

¹⁰*Id.*

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

¹²*Uncertain Returns: The Multimillion Dollar Market in Reimported Pharmaceuticals*, 99th Cong. 2nd Sess. 32. See also, *Dangerous Medicine: The risk to American Consumers From Prescription Drug Diversion and Counterfeiting*, 99th Cong. 2nd Sess. 25-26 ("there is little or no significant benefit to consumers from pharmaceutical reimportation, and there are obvious costs in terms of health and safety risks and the utilization of scarce FDA resources.").

¹³FDCA § 801(d)(1).

vent substandard and counterfeit medicines from coming into the United States under the guise of American goods returned.

The "closed" U.S. drug regulatory system is undoubtedly the most protective in the world. But even this system has not kept unscrupulous criminals from successfully importing unapproved, adulterated or misbranded drug products into the medicine cabinets of American consumers. Easing restrictions on the importation of drugs will make the current situation worse and offers consumers nothing more than a more dangerous drug supply in exchange for the false hope that prices will be lowered. I urge this Subcommittee to reject efforts to erode the ability of the FDA to ensure the safety and efficacy of the drugs sold in the U.S. by easing the current restrictions on the importation of pharmaceutical products.

Thank you for the opportunity to testify. I would be happy to answer any questions you may have.

Mr. BILIRAKIS. Thank you very much, Mr. Hutt.
Mr. Copeland.

STATEMENT OF DON COPELAND

Mr. COPELAND. Mr. Chairman, my name is Don Copeland. I have been a pharmacist in Scottsboro, Alabama, for over 30 years; since 1987, the President of Associated Pharmacies, Incorporated, a buying cooperative of some 750 pharmacies in 43 States. I will provide an oral summary to my written statement, which I ask to be placed in the record.

Either because they cannot afford the cost of prescription drugs in the United States or simply that they like to save money, a number a growing number of Americans are purchasing drugs from foreign sources.

Through previous hearings, this committee is well aware of the dangers of drugs obtained through shadowy Internet companies whose true country of origin may be unknown, and the quality of drugs obtained from Mexico has also been shown to be uneven.

That is why my board and I have been looking into drugs supplied from pharmacists in Canada, where the integrity of the drugs and the regulatory system is beyond question. We have studied this subject, and we support legislation that would allow U.S. consumers to have their prescriptions filled by pharmacists in Canada, with the assistance of their local pharmacy here.

Only non-narcotic U.S.-approved drugs for the consumer's own use would be allowed to be imported. We believe this proposal, which would involve State or provincially licensed physicians and pharmacists, both here and in Canada, is a simple and straightforward way to assure that the patient receives a drug that is safe, effective, and dispensed with care regarding the drug-to-drug or other patient specific conditions.

Here is how our system would work. The local pharmacist would respond to the customer inquiries or bring to the attention of the customer the potential to fill a prescription in Canada for a savings usually averaging between 30 and 50 percent off U.S. prices.

If the customer wished to order from a Canadian pharmacy and gave permission, the pharmacist would notify the patient's doctor and discuss this desire. The pharmacist would assist the customer in providing the information required by Canada, including the prescription, the name, and contact information of the prescriber, the customer's current health condition, and all medications being taken and, with the customer's consent, transmit this information to the Canadian pharmacy.

The U.S. pharmacist would provide drug utilization review for the patient, to make sure that the prescription is compatible with other drugs the patient is taking, and counsel the customer as to the use of the drug, the proper dosage, and any other information that is usually provided for by the pharmacist.

The pharmacist would notify the customer to return to the pharmacy to receive the drug if it was sent directly to the U.S. pharmacy, or to visit the pharmacy to have the drug checked if the customer chooses to receive it at home. The pharmacist would receive payment for these services from the customer, which would be fully disclosed.

The Canadian pharmacy would provide the valid U.S. prescription and the medical history form to a Canadian doctor who would review the information, and, after calling the U.S. physician, if necessary, write a Canadian prescription. The Canadian pharmacy would fill this prescription and send it to the U.S. consumer or to their local pharmacist.

We presented our model to the Mississippi State Board of Pharmacy and sent a copy to the FDA. Even though many Americans are importing drugs from Canada and elsewhere, the FDA told us that such imports are illegal. So we as pharmacists cannot lawfully assist consumers in the importation, and no State board would approve such a plan.

The FDA's own enforcement policy provides for a compassionate use import exemption which allows individuals to bring in drugs from foreign countries if these drugs are not approved for sale in the United States and there is no comparable drug here.

In practice, the FDA is not enforcing the law or the exemption, as written, and allows individuals to import foreign source drugs. If the FDA did not allow this, the bus trips to Canada would stop.

In closing, we believe that neither the law as currently drafted nor the FDA policymakes sense, and in fact, exposes Americans to a significant risk from drugs whose origins are unknown or which are not obtained through or from a licensed pharmacist.

By allowing individuals, with local pharmacists' assistance, if they wish, to import drugs that are approved in the United States from licensed pharmacists in Canada, and enforcing the law against other drug imports, the FDA can fulfill its role of protecting American consumers while licensed pharmacists here do what they are trained to do, which is to provide expert advice on drug labeling, dosage, interaction, and other safety and efficacy-related matters to their customers.

Finally, State and provincial pharmacy boards, all of which are associated with the National Association of Boards of Pharmacy, can, if they wish, regulate the practice as necessary.

Thank you. I will be glad to answer any questions.

[The prepared statement of Don Copeland follows:]

PREPARED STATEMENT OF DON COPELAND, CHIEF EXECUTIVE OFFICER, ASSOCIATED PHARMACIES, INC.

Mr. Chairman, members of the Committee. My name is Don Copeland. I am a licensed pharmacist in the state of Alabama and I am the Chief Executive Officer of Associated Pharmacies, Inc., a buying cooperative of over 750 pharmacies in 43 states. Sitting behind me here is one of our owner members, Fred Sharpe, the pharmacist owner and operator of U-Sav-It Drugs with ten stores in Georgia.

We support legislation that would allow consumers to have their prescriptions filled by pharmacists in Canada with the assistance of their local pharmacy, if they wish. Such legislation should be limited to non-scheduled (i.e., non-narcotic or habit-forming) pharmaceuticals approved for marketing in the United States. We believe the benefit of our proposal is it involves a physician and a pharmacist, both in the United States and in Canada. This assures that the patient-customer is prescribed the correct drug and dispensed the correct drug.

Our members and customers became interested in the importation of prescription drugs from Canada as they became aware through the media that a growing number of consumers in the United States are now accessing prescription drugs by mail or by visits across the U.S. border—primarily Canada and Mexico. We believe no one would question the integrity of the Canadian drug system and so that is where we focused our attention. And we all know that many prescription drugs are available from Canada at prices that are 30-50% lower than the lowest available prices in the United States from local, chain or mail order pharmacies. These savings are so substantial that it is folly to argue with consumers who want to buy from Canada, many of whom are forced to do so for economic reasons.

The cost of prescription drugs, especially for the uninsured, has become a serious health problem. As this Committee may be aware, patients often leave prescriptions with their pharmacists and then fail to pick up the filled prescription. It is the experience of our member pharmacists that over 75 percent of these prescriptions are from cash paying patients. Their inability to afford these drugs obviously puts their health at risk, and may end up costing taxpayer funded programs, like Medicare, much more in hospitalizations than the cost of the prescriptions.

The question my Board of Directors asked is how can our pharmacies and pharmacists help consumers who choose to purchase drugs from Canada. We see a void in pharmaceutical care because Canadian mail order pharmacies do not have access to the patient profiles that are now routinely kept by pharmacists in the United States. Additionally it is left to the patient to verify that the medication they receive from Canada is the same drug and dosage that their physician prescribed. And while most pharmacists will answer a phoned-in question from their customers, even about a drug they did not buy from that pharmacist, consumers who buy from Canada may be inhibited from calling. Finally, my Board members have seen advertisements from companies in Washington State and Kansas City offering to obtain drugs from Canada for consumers. We were informed that it is presently illegal to have this kind of commercial operation in the United States and we have notified the Food and Drug Administration and urged that they take enforcement action.

To be responsive to the financial situation faced by patients who must pay for their own drugs (usually those who are retired, unemployed or underinsured), API pharmacies in the Southeast developed a professional service model intended to bring Canadian-priced drugs to their customers along with local pharmacy services. We presented that model to the Mississippi Board of Pharmacy and we sent a copy to the Food and Drug Administration. Mississippi cannot approve it because FDA says it is not lawful. And FDA cannot approve it because they say their "compassionate" importation rule only applies if individuals are seeking to bring in a drug not approved or available in the United States, a policy that is, thank goodness, not enforced. And, since even personal importation of a prescription drug from Canada may be a crime under the Federal Food, Drug, and Cosmetic Act, a pharmacist assisting a customer in doing so could be considered by FDA to be in a conspiracy to violate the law. I and my members would rather be legal and so would most people.

We are therefore here to recommend legislation that would simply allow consumers to order prescription drugs from Canada and for them to do so through their local pharmacy if they wish.

While we are in favor of wholesale re-importation of drugs from Canada, we are not here to argue that point. We are here in support of a much more modest proposal—that individuals be allowed to do so for their own benefit and that their pharmacist be allowed to help them, if they wish, and to charge them a fee for service, if they wish. Here is how we see this system working with respect to pharmacists and their customers.

LOCAL PHARMACIST ROLE

- The pharmacist would respond to customer inquiries or bring to the attention of customers prescriptions that would result in significant savings to the uninsured—usually 30-50%, but in some cases even more.
- The pharmacist would educate the customer on the availability of such savings by ordering through a pharmacy in Canada and would, if permitted by the customer, notify and discuss with the patient's physician that this is being done.

- The pharmacist would assist the customer in filling out the information required for Canada including the name of the prescribing physician, the customer's health conditions and the medications the customer is taking, and, with the customer's written consent, transmit this information and the customer's prescription to the Canadian mail order pharmacy.
- The pharmacist would provide drug utilization review for the customer to make sure the prescription sent to Canada is compatible with other drug regimens.
- The pharmacist would counsel the customer as to use of the drug, the proper dosage and other information that is provided for that drug in the usual course of that pharmacist's practice.
- The pharmacist would notify the customer to return to the pharmacy to receive the prescribed drug which could be sent from Canada to the pharmacy, or in the alternative, to visit the pharmacy to have the drug checked if the consumer chooses to receive it at home.
- The pharmacist would receive payment from the customer on behalf of the Canadian pharmacy, along with a service fee that is fully disclosed to the customer. It is possible that Canadian mail order pharmacies would absorb that fee into their charge for the drug and pay it to the pharmacist.

CANADIAN PHARMACY ROLE

It is our understanding that the scenario described below is lawful in Canada and that this mirrors the methodology followed by Canadian pharmacies today. Here is what the Canadian pharmacy would do:

- Receive the customer prescription and customer information from the customer or the customer's local pharmacy.
- Provide the customer information and prescription to a Canadian physician who reviews the patient information, the United States' prescription (and the Canadian physician calls the United States' physician where appropriate), and writes a Canadian prescription for the patient and sends it back to the Canadian pharmacy.
- Fill the prescription and mail the prescription back to the local pharmacy or directly to the customer accompanied by the patient's physician's prescription.

In Canada this model is controversial but, as we understand it, lawful. For example, the Ontario College of Physicians and Surgeons questions whether physicians should rewrite prescriptions without examining the patient and the Ontario College of Pharmacy has expressed concern about the filling of such prescriptions. And there are different degrees of concern in the various Canadian provinces. But the bottom line as we understand it is that a Canadian pharmacy may fill a prescription written by a Canadian licensed physician for a United States patient. In light of this, and in light of the demand from United States consumers, there are many Canadian physicians and pharmacies engaged in this practice.

Our pharmacists want lawfully to be a part of this scenario—to provide professional services to their patients and to communicate with the physicians who treat those patients—and to address any patient protection and professional care issues.

TO WHAT PRESCRIPTION DRUGS SHOULD THIS LAW APPLY?

This program should apply only to prescription "drugs" approved for use by the Food and Drug Administration. It is often the case that the "drug product" (pharmaceutical, label and package insert) found in Canada is not identical to the drug product approved for use in the United States. The differences are almost exclusively in the label and package insert, rather than in the "drug" or pharmaceutical itself. Technically, the "drug product", i.e., the "drug," its label and package insert, is not the "drug product" approved in the United States for this reason. The important fact that the "drugs" are identical can be checked by comparing the description of the pharmaceutical in the labels for each product, something that every licensed pharmacist in this country is trained to evaluate. And if FDA wants to argue this point, ask them to tell you exactly how any differences are material to the safety and effectiveness of the drug.

It is not intended that this program would extend to any "drugs" that are not the same as those available here in the United States. Thus, Canadian-approved generic versions of United States-approved prescription drugs would not be available under this program if such versions were not also approved in the United States.

Canadian pharmacies buy pharmaceuticals directly from manufacturers and from prescription drug wholesalers, the same sources that are used by pharmacies in this country. Canada has a first class drug regulatory scheme and no questions have been raised with respect to the integrity of the Canadian drug supply.

We believe the legislation should not apply to any pharmaceuticals that are controlled substances.

CONCLUSION

We now live in a global environment. Citizens of Detroit and Buffalo can cross a bridge and obtain drugs at prices radically lower than available anywhere in United States. Consumers can order such low priced drugs through the internet or by fax or by mail. Pharmacists and pharmacies want to provide their patients with these opportunities and with the added protection of the professional services they provide their patients every day. Pharmacists are trained, licensed and in the patient's community. They should be allowed to bring their skills to the table and to be part of any personal importation program.

The program outlined above is meant to address legitimate treatment and patient safety concerns. There is a valid prescription that is seen by the local pharmacist. The patient and the patient's physician are fully informed as to the nature of the program. The prescription is entered into the patient's profile. The prescription is reviewed by a Canadian physician (who may call the local prescribing physician) and written in Canada. The prescription is filled by a pharmacy licensed in Canada. And the filled prescription is received or can be reviewed by the local pharmacy. At the end of this process, United States' consumers can save 30-50 percent on the cost of their prescriptions.

Thank you very much for your consideration of this presentation.

Mr. BILIRAKIS. Thank you very much, Mr. Copeland.

Dr. Wennar, on your website you offer patients the options of ordering drugs from pharmacy A, pharmacy B, pharmacy C. Why don't you inform your patients of the names and addresses of the pharmacies?

Ms. WENNAR. We intentionally did that because we did not want to do any direct marketing for any particular one pharmacy. There are toll-free numbers there. This is really a facilitation process. This is the patient, their physician, the pharmacist in Canada, the consulting physician in Canada that actually—this whole transaction takes place, but the consumer is given the option to be able to shop without having those names. When they make the phone call, it is answered in terms of the names of the pharmacies, but we would not on our Web site promote them. We would not promote them by name.

Mr. BILIRAKIS. They are given the names of the pharmacies? When?

Ms. WENNAR. Yes. The first time they make contact they are given the name of the pharmacy.

Mr. BILIRAKIS. You give them the telephone calls—

Ms. WENNAR. Toll-free numbers. There is a number where they may reach the pharmacist, there is a number for the customer service unit, and there is a number for physician-to-physician discussion.

Mr. BILIRAKIS. Your definition of "safety" appears to be rather narrow. Do you mean to say that from a provider medical perspective that safety is equivalent to compliance, and not adverse health outcomes?

Ms. WENNAR. No, I am talking about quality here. I think we are mixing words a little bit from the perspective of quality.

Physicians make an assumption. Remember, they write a prescription. They do not usually try and direct you to any particular pharmacy. They make the assumption that you are going to have access to safe, affordable prescription drugs, and that you are going to take them when they write the prescription.

Mr. BILIRAKIS. Well, in the cases where you are helpful to people in terms of getting their drugs, prescription drugs, from Canada—is it limited to Canada, by the way?

Ms. WENNAR. Yes, it is.

Mr. BILIRAKIS. Might any of those drugs be counterfeit?

Ms. WENNAR. Well, I guess I would ask you the same question from the standpoint of—I think we just heard earlier that local pharmacists in our own area could not identify a counterfeit drug. Might any of those drugs be counterfeit?

To tell you the truth, I guess what I am having a problem here with is that none of the literature supports anything in Canada that I can find that they have had these major issues with counterfeit drugs.

These drugs are coming out of the same bottles that are being prescribed for Canadian citizens. Are we to imply that Canadian citizens are being sold counterfeit drugs? Are we to imply that the drugs that are being sold to American citizens are coming out of a different bottle?

I would tell you no. The reason I will tell you no is because I have been to those pharmacies. We do site visits.

Mr. BILIRAKIS. We have heard from the FDA, and they are there to protect us. The testimony was from a person who was not a political appointee, he has been there for many, many years. He did tell us that those problems do exist.

Ms. WENNAR. But what I am having a problem with here is that there is just a huge amount of what I can only classify as propaganda, and this propaganda is intended to scare people.

I have to tell you, I have traveled the roads in Canada. The people in Canada are not afraid to take their medications. We have the equivalent in Canada. If we want to get smart and we want to do this, we have some very brilliant people here in this country and in Canada, and pharmacists in Canada. All the ones we work with have told us they would welcome an opportunity to register with the FDA. They would welcome an opportunity to register on a State-by-State level.

They are more than willing to be held accountable. They are willing to let you do site visits. They are willing to be held to the highest standard. I don't know what more you could ask.

Mr. BILIRAKIS. You are a good witness.

Mr. SANDERS. She comes from Vermont. What else?

Mr. BILIRAKIS. Dr. Shepherd, you have described for us the drugs that come in from Mexico, and based on your personal observation—it is not statistics, it is your personal experience—you have indicated that many people who—that the prescriptions are not required in Mexico. They do not require registration or licensing or whatever of pharmacists, et cetera. Anybody can dispense these drugs. Is that right?

Mr. SHEPHERD. That is correct. The only prescriptions required in Mexico for a drug is for a controlled substance drug, and you have to have a pharmacist on your payroll within the pharmacy to dispense controlled substances. He does not have to be present at the pharmacy.

Mr. BILIRAKIS. You have told us that many of the people, Americans who come across the border to pick up drugs, do so mainly for convenience, that they do not need a prescription?

Mr. SHEPHERD. That is right. It is more economical. They don't have to go to the doctor.

Mr. BILIRAKIS. Just very quickly, do you expect reimportation to decrease substantially if the high cost of prescription drugs is addressed satisfactorily in the eyes of the beholder? But in any case, if we are able to do something about that particular problem, and it is a problem, do you expect that reimportation will substantially decrease?

Mr. SHEPHERD. Definitely, I think it would. Except for seniors—with the seniors, but not for the youth.

Mr. BILIRAKIS. Among the seniors, it would decrease substantially, in your opinion, but not among the youth?

Mr. SHEPHERD. That is right.

Mr. BILIRAKIS. We are concerned about the youth as well as we are the seniors.

Mr. Brown to inquire.

Mr. BROWN. Thank you, Mr. Chairman.

Mr. Hutt, the drug industry—actually, the Secretary's Planning Office in the Department of HHS issued a report in late June, early July, saying that if prices come down in the U.S. that research and development by the drug industry will begin to dry up. That report was not too dissimilar from the PhRMA Web site, which claims, amazingly enough, if prices come down in the U.S. then R&D will dry up.

We did a little research and found, and this was even more amazing, that the Deputy Secretary—the Secretary in the Secretary's Planning Office is a woman named Ann Marie Lynch, who used to work in PhRMA. I did some more looking around and found there were many people from your organization in the White House, in the President's transition staff at HHS.

So sometimes in this committee we have begun to—rather than having to look at HHS reports, we just look at PhRMA Web sites. But that is more editorial comment than anything else.

What struck me is that you claim that if prices come down in the U.S., R&D will dry up. I guess you are saying that prices are too low in other countries because of so-called price controls, or for whatever reason.

If that is the case, why do your member companies, why do Medicare and Pfizer and all these companies, why do they sell in markets where there are so-called price controls?

Mr. HUTT. Mr. Brown, let me begin by pointing out that my area of expertise is food and drug law. I have spent my entire career both implementing and advising clients on how to comply with the Federal Food, Drug, and Cosmetic Act. I am not an expert on foreign drug pricing or, indeed, on domestic drug pricing.

I will be happy to take your questions back to PhRMA and ask them to respond to that particular question, but I am not an employee of the association. I am not familiar with the report you just cited, but I will be happy to answer any question you have about the Federal Food, Drug, and Cosmetic Act.

Mr. BROWN. I was afraid that would be your answer. We don't get very many chances—PhRMA never comes to my office and talks to me. I am not sure why that is. I don't get much chance to talk to PhRMA. I just saw that this guy from PhRMA was here. I see your television ads, usually under a different name. I see the information that you send out on the Hill. I see your Web site.

But I was kind of excited—we could not get a chance to see a consumer on the panel, and I was excited about PhRMA. I will ask a couple of questions. You could pass them on to the people in the second or third row.

Mr. HUTT. I would be more than happy to do that. I am sure they are listening very closely.

But let me emphasize, I would have welcomed any number of consumer advocates here today, because I don't think these are issues that ought to be hidden. They ought to be brought right out, as this committee is doing today.

If you would like to arrange it, I would be happy to meet personally with Ms. Tubbs.

Mr. BROWN. I am glad that you would welcome consumer advocates, because my Republican friends apparently did not, and I know the kind of influence that PhRMA has on my Republican friends, so perhaps you could talk to them prior to the hearing next time and convince them to have some consumer advocates.

My questions really do detail this. Why do drug companies sell in markets where there are price controls, although their definition of price controls is different from mine? I don't think it is price controls when you have compulsory licensing, which brings in competition and lowers prices. I don't think it is price controls when Canada negotiates with the drug companies and gets lower prices. I don't call those price controls.

Price controls might be, in fact, what we do in the medical device industry in this country, where Medicare, HCFA, CMS, says to the wheelchair manufacturers, the stent manufacturers, here is what we are going to charge, here is what we are going to pay, here is what you are going to get. I call that price controls, I wouldn't call the other.

What puzzles me, on drugs—they say they can't make a profit in these other countries, but they are selling lots of prescription drugs in other countries, to their credit, and I imagine they are making money. They have earned \$40 billion worldwide in profits. I can't believe they are all off U.S. sales.

So my question really is if you would ask the PhRMA people to give me some answers on those issues: Why are they selling abroad if they can't make money? Can they make money? Of the \$40 million, is it all U.S. sales?

Let me ask one question of all four of you, since that one didn't work right. Let's assume an individual has a life-threatening disease and requires a prescription drug but cannot afford it in this country.

If you were in that situation where you could not afford the drug and you had to make a choice, you either didn't get the drug in a life-threatening situation or you bought it in Canada, where some people have said that Canadian drugs might not be as safe as the

drugs that you could get in Lorraine, Ohio, what would your response to that be, if each of you—which would you do?

I really want, quickly—

Mr. BILIRAKIS. You used all of your time editorializing that.

Mr. BROWN. I did. I often do that, Mr. Chairman. I just want a 4- or 5-word answer from each.

Mr. BILIRAKIS. I will allow it.

Mr. BROWN. Get a drug in Canada, or not get it.

Mr. SHEPHERD. I get that question a dozen times a week. I will answer and say if your probability of dying is higher if you stay here, you are better off going to Mexico.

Mr. BROWN. Canada or not get the drug?

Ms. WENNAR. What do you think?

Mr. BROWN. I am asking the questions.

Ms. WENNAR. I am there already.

Mr. BROWN. That is the way Bernie always answers it, he answers a question with a question. I am tired of it, so give me an answer.

Ms. WENNAR. Canada with a big C.

Mr. BROWN. Mr. Hutt.

Mr. HUTT. I might answer it in a different way. Everyone in this room, including PhRMA, agrees that there should be a direct approach to improving access for all Americans to the prescription drugs they need. People should not be forced to that kind of choice.

But, Mr. Brown, where you and I disagree is we should not try to solve that problem indirectly by destroying the American drug regulatory system. We shouldn't try to solve that problem by setting up a two-tier system of drugs, those that meet the FDA gold standard and those that are substandard. We shouldn't put up a big sign on the United States "all drugs welcome." We ought to keep our current regulatory system, and we ought to set up a system so no one has to make that choice you are talking about.

Mr. BROWN. For a guy who did not have any opinions, Mr. Hutt—

Mr. BILIRAKIS. Four or five words.

Mr. HUTT. You asked for my area of expertise.

Mr. COPELAND. I think the gold standard aptly describes the situation in the United States, because it takes a lot of gold to buy it. I have absolutely no qualms whatsoever about getting my medication from Canada.

Mr. BILIRAKIS. Okay. You got your answers.

Mr. Burr.

Mr. BURR. Thank you, Mr. Chairman.

Mr. Copeland, I know you did not mean it the way it sounded to me. Because I think if we degrade in any way, shape, or form the benchmark that we set in this country you put far more American lives at risk.

I only hope, and I have worked pretty diligently in the 8 years that I have been here, to make sure that there is a drug benefit. I am sorry that some up here want to make it political. Every hearing is political. The reality is that if they would spend as much time trying to come up with solutions and work on the process—they had an opportunity to vote for a drug bill. They decided not

to because it was not theirs. It was not perfect. It did not provide everything.

Do you know who loses? The seniors that are waiting for drug coverage.

Let me ask you, Mr. Hutt, you are an expert on food and drug law. Do we currently, under U.S. Code, protect the patents of pharmaceutical companies for products that they apply for that patent protection?

Mr. HUTT. We grant patents, and the Food and Drug Administration, under very specific conditions, will not approve a competitive product until the patent expires.

Mr. BURR. And if, because reimportation in fact breaks the patent protection, we allow under some new law reimportation to happen, what type of protection exists for that manufacturer?

Mr. HUTT. The current law would clearly be overridden by the legislation under consideration here.

Mr. BURR. Therefore, what incentive would exist in the marketplace for the pharmaceutical companies, to the degree that they do, to enter the U.S. market earlier than any other market in the world with cutting edge technology and pharmaceuticals and biologics? Is there any incentive left?

Mr. HUTT. It certainly reduces that incentive.

Mr. BURR. Dr. Wennar, are you an advocate of the plan that we passed in the House of Representatives for drug coverage?

Ms. WENNAR. I am an advocate of anything that is going to get access to safe, affordable prescription drugs. So if you can come up with an answer, I am an advocate for it.

Mr. BURR. Are you an advocate for price controls in the United States, Federal price controls?

Ms. WENNAR. I haven't been.

Mr. BURR. I am glad to hear that. Do you believe U.S. pharmacists, pharmacies, should be able to import drugs from anywhere in the world?

Ms. WENNAR. Anywhere in the world?

Mr. BURR. Yes, ma'am.

Ms. WENNAR. I think if you have the appropriate standards in place and you hold people to those standards, I don't care where it is in the world, as long as those standards are equal or better than ours.

And let me just finish. Let me finish. There are places, believe it or not, that do do things that we would learn from.

Mr. BURR. Oh, I agree with you totally. As we worked on the Fedoma legislation in 1997 we looked extensively at some of the European marketplaces and what they did, and some do certain things better than we do here.

The EU, when it came into existence, one the universal standards that they follow is that they harmonized the EU partners process for drug approval which meant that the German process, even though it was more stringent than the Italian process to harmonize, they said we will accept whatever the Italian standard is; and Italian product flows into Germany.

Now, all of a sudden, we realize, and certainly there are tremendous case studies on the problems that certainly countries have, many of them, as part of this EU harmonization.

Under the legislation that we are talking about in the House, where it is basically open to anywhere in the world, all of a sudden we bring into the mix manufacturing in China, we bring into the mix facilities that aren't inspected by the Food and Drug Administration, we bring into the mix sources for raw materials that don't go through any process of verification as to the integrity of the product or whether in fact it is an active ingredient.

I would only ask you this, in concluding, wouldn't that alarm you if we didn't have controls enough to assure that whatever product came in for our patients, in fact, didn't have contaminants from the raw materials, in fact, had the degree of active ingredient that, in fact, doctors were prescribing for their patients?

Ms. WENNAR. I couldn't agree with you more. But what I would say again is that I am going to assume that, in the process of doing this, that you would put those kinds of requirements in place. You would have that expectation.

I do not believe that anybody is suggesting here that we should open the doors to the world with no restrictions at all in terms of standards being met. I mean, we pointed out here that there is to be a gold medal standard of approval. If we are using that standard, then we should hold everybody else to that standard that wants to participate in this process.

Mr. BURR. I assure that you that would be the intent of this committee, I think; and that certainly is the standard that we set when we passed reimportation language. We required the Secretary to verify that all of the things you just talked about could, in fact, be substantiated. In that particular case she said she couldn't, and now we are criticized because of that.

Ms. WENNAR. I am very much aware—

Mr. BURR. Not by you.

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

Dr. Wennar, I am just trying to be considerate here. I understand you have a 5:30 flight out of National.

Ms. WENNAR. I have to tell you this is an important enough subject that I will stay over tonight. I will miss my flight.

Mr. BILIRAKIS. We appreciate that.

Let's see. Mr. Pallone.

Mr. PALLONE. Thank you. I am glad you are not leaving. Really, I am serious.

When we had Mr. Hubbard up before and I asked him specifically—I mean, on the one hand, he was saying, you know, we are getting all of these counterfeit drugs. But, on the other hand, when I said to him, is there any problem, with, you know, a bus load of seniors going to a specific pharmacy in Canada that they know and he said, no, there really isn't a problem there—so I sort of suggested, well, you know, you seem to be critical of the Kingston-Gutknecht legislation, but on the other hand you say that, you know, if people go to pharmacies in Canada, there is not a problem. So why don't you give us some ideas about how to maybe change or amend the Kingston legislation so we can get something that would allow people to go to places where they don't have any real risk?

Now, you seem to be suggesting in your written testimony at the end some kind of quality parameters, I think you described them. But I wasn't clear how we could do that legislatively. I mean, do

you have suggestions about how we could legislate a program that would be—that would be not pose too many risks?

Ms. WENNAR. Well, let me use an example here, okay? I think that you have a wealth of opportunity around this. I mean, first of all, historically, you have to remember CMMS, AKA, HCFA has historically been able to do demonstration projects to demonstrate that something actually can work. Unfortunately, the FDA doesn't have the authorization to do demonstration projects. But, by proxy, personal reimportation has been a demonstration project for the last years.

Mr. PALLONE. Right. But let's say we want to legislate that.

Ms. WENNAR. Now, having said that, this is a perfect opportunity for a public-private partnership to occur here.

Right now, the United States—I am sure you are all familiar with the Joint Commission on Accreditation for Health Care organization who, under the AMA and the American Hospital Association, sponsors that. They accredit health care systems, and you must meet a certain level of standards to be accredited. In the process of being accredited, you, if you are not accredited you can't receive certain type of reimbursement from the Federal level or the State level, Medicaid or Medicare.

I think that there is a clear opportunity here for a similar organization to exist that would create standards that would actually do the accreditation of any entity that wanted to participate in something like this. Once they meet those standards, in concert you could work with the FDA. The difference is the FDA wouldn't have to fund it, nor would the American taxpayer. It could be done in the private sector.

Mr. PALLONE. So we could essentially take the Kingston legislation and put in that type of accreditation program and then anything that was imported from some pharmacy or group that had the accreditation we wouldn't have the problem.

Ms. WENNAR. You need the accreditation process. It could be set at the bar. You can place the bar anywhere you want. You can have the FDA involved in helping to set those standards. But the fact is that they could say you will register with the FDA but you could not register unless you had met those standards and had been accredited. That would mean—

Mr. PALLONE. We simply authorize that.

Ms. WENNAR. It would mean site visits. It would mean a variety of things, anything they wanted to put into it. You can develop standards for it. But they don't need—I heard something about how many more people do you need. You don't need a single more person to be working at the FDA to do this.

Mr. PALLONE. Now that is kind of what Mr. Copeland was suggesting.

Ms. WENNAR. Correct.

Mr. PALLONE. You want to elaborate a little? You had a similar suggestion about doing this with the pharmacies.

Mr. COPELAND. Actually, we were concerned because we are not just talking about seniors. In other words, I have heard the committee talking about passing the Medicare bill; and I support that.

Mr. PALLONE. Yes, but at the end of your—

Mr. COPELAND. And it needs to go beyond that. It needs to go to the other 20 percent or 15 percent of the people that are paying cash out of their pocket that aren't seniors.

Mr. PALLONE. Mr. Copeland, you said at the end—I think it was in your written statement—that you had proposed legislation that would accredit the pharmacies. It seemed like similar to what Dr. Wennar was talking about. I wanted you to explain that.

Mr. COPELAND. In other words, in the United States—and I am a registered pharmacist. My store is going to be licensed and approved. The wholesalers I buy from are licensed and approved. In Canada, it is the same thing. Now if we go to reimportation, then I still don't have a problem with reimportations just basically from Canada because that is what we really studied. But it would need to be from a regulated, licensed wholesaler that is approved to maybe our wholesalers in the United States.

But also, as a quicker thing, our pharmacies—we have met with the Canadians, and we have met with the pharmacies up there. So it could be established our computer system goes to their computer system. In other words, it—

Mr. PALLONE. Well, I know we are running out of time, but I just want to suggest to my Republican colleagues, you know, your bill has gotten a lot of criticism here today from Mr. Hubbard directly and indirectly and some of your colleagues, too, on the Republican side indirectly. But, I mean, it is very easy to adopt what these—what Dr. Wennar and Mr. Copeland are suggesting and then the criticisms go away. I mean, it is not magic from what I can see.

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

Mr. Buyer.

Mr. BUYER. I have a question for Mr. Copeland. You said that almost with a smile that you would have no problem getting drugs from Canada.

Mr. COPELAND. My personal drug.

Mr. BUYER. I think it was the smile that bothered me more than the statement. Let me tell you why.

Mr. COPELAND. Okay.

Mr. BUYER. Because I am not so certain if I were a pharmacist I would be comfortable with the liability question, and we are going to have to deal with this one. Now we have testimony here from the FDA, and the FDA—I wrote down this quote: Pharmacists can't tell the difference in drugs. Now, if a pharmacist can't tell the difference in the drug, and you like going to Canada to get that drug because you can get it at a lesser price and you get a higher mark-up on it so, therefore, you make greater profit—I tell you what. As a lawyer going into the courtroom, I am now smiling.

Mr. COPELAND. I understand liability.

Mr. BUYER. Are you with me?

Mr. COPELAND. I understand liability.

Mr. BUYER. So, help me, how do we work through the liability thing here?

One last statement. I am going to let you speak.

Mr. COPELAND. Okay.

Mr. BUYER. Because if the manufacturer—at some point, if we do this, then do we then sever the liability to the manufacturer and

we say to the pharmacist, if you want to do this, then you accept the responsibility and the liability to do that to your consumer?

Mr. COPELAND. I am sorry, Mr. Buyer. I guess I don't—

Mr. BUYER. It is pronounced Buyer. It is French.

Mr. COPELAND. Okay. In other words, we are dealing with a pharmacist in Canada; and I am—first of all, I am with Dr. Wennar. I am talking about a very limited number of drugs. In other words, I only want to deal with the drugs that Pfizer and Merck and whatever make. I don't want to open this up to any drug. It needs to be a very limited formulary of life-saving, necessary drugs. So I would only want to deal with those drugs that came direct from that manufacturer, direct to that supplier up there, direct to that patient; and that limits your liability.

Mr. BUYER. So you believe if you have limited pathways of distribution that we could keep the liability all on the manufacturer and somehow absolve the pharmacist.

Mr. COPELAND. Well, no, we are always going to have some liability. I understand that. I have liability in my store in case something gets screwed up out of place. But at least that liability, if you keep it within this regulatory process, it is a minimal liability; and I would be very much concerned with maintaining that regulation.

Mr. BUYER. All right. Thank you for your answer.

In the Kingston language in the bill, there is a quote: Individuals not in the business of importing drugs to personally import such drugs.

How would anybody here define what that means? Let me start with you, Mr. Hutt.

Mr. HUTT. I personally am unable to define that. It is used in the prior legislation of 2 years ago, but it is not defined in that legislation either. It has no known source of definition in any other statute that I am aware of; and, therefore, it has an added element of ambiguity and uncertainty.

Mr. BUYER. Do you know how you would define it?

Mr. HUTT. Well, it appears to me that someone who, say, is in the business of importing food but hides drugs in hollowed-out food products would not be in the business of importing drugs, which does not make sense to me.

Mr. BUYER. Mr. Hutt, how about Mr. Copeland here? Mr. Copeland's pharmacy—if he wants to work out a deal with somebody up in Canada, is he now an individual in the business of importing drugs?

Mr. HUTT. Well, if that were his source of income, outward source of income, presumably, yes. But a counterfeiter, presumably, it would not apply to. It is very confusing to me. I regret I can give you no answer.

Mr. BUYER. You know, sometimes when I look back to my years as a prosecutor, defense lawyer on the Judiciary Committee here in Congress, we always have to be careful. Not every one is honorable, Mr. Copeland, you know.

Mr. COPELAND. I guess I deal from my own—

Mr. BUYER. You know, and I like your testimony when you said, hey, I have specific people that I deal with that I trust. And because of your care, because you know your people that you serve, that is why we love pharmacists in our communities. We are all

completely tied to you. But, you know, we are all—we end up making laws not because of the 90 percent, generally. Sometimes it is because of that 10 percent, too.

I just wanted to throw that out there. I yield.

Mr. BILIRAKIS. Thank you.

Mr. Green.

Mr. GREEN. Thank you, Mr. Chairman.

I want to welcome Dr. Shepherd, and I enjoyed your testimony.

I guess the concern I have is—the only reason we are considering this bill is because of the price problems we have in our own country and in—you are right. This is really not a substitute. But, right now, my constituents are voting with their feet or their bus ticket or however to go to Mexico.

In your testimony, you said that the limit of what could be brought back with prescription—explain to me what the DEA's 50 dosage rule regarding controlled substances is. And you said the enforcement of that is spotty at best.

Mr. SHEPHERD. That is correct. Currently, the way it was amended, I think it was 1½, 2 years ago, that a person may go and bring back 50 units of a controlled substance without a prescription and no questions will be asked at the border.

Mr. GREEN. Okay.

Mr. SHEPHERD. And it is not 50 units of multiple drugs. It is 50 units of each drug. However, I haven't found uniformity amongst Customs agents in the interpretation of that.

Mr. GREEN. Does that require a written prescription—

Mr. SHEPHERD. Yes, it does.

Mr. GREEN. [continuing] for the 50 units, the controlled substance?

Mr. SHEPHERD. Right. A written prescription.

Mr. GREEN. Okay. Are you seeing dangerous, potentially highly addictive drugs such as Oxycontin or something like that?

Mr. SHEPHERD. I see a lot of Oxycontin. There is a lot of Oxycontin coming across. The top 15 drugs—when we did the study in 1997, the top 15 drugs coming across from Mexico were controlled substances.

Mr. GREEN. So it is not just me getting my—

Mr. SHEPHERD. No, it is not your hypertension or your cholesterol—

Mr. GREEN. [continuing] antibiotic to take care of my sinus infection.

Mr. SHEPHERD. But they are a part of the group, but it is not just those. Correct.

Mr. GREEN. Let me talk about drugs from Mexico particularly. Do you think—who owns those pharmaceuticals? Because when I have been to those pharmacies and actually taken my daughter, who is now in her residency, and her husband, they are amazed that the trademarks are from U.S. companies. They are PhRMA members.

Mr. SHEPHERD. Yeah. There are about 60 international pharmaceutical firms in Mexico and about 120 national firms in Mexico working. The international firms are subsidiaries of many home companies here in the United States, but they are also subsidiaries of European companies.

But let's be clear that these companies are really owned and operated by themselves. They are subsidiaries and under the license of the Pfizers or the Mercks and stuff, but they are whole entities of themselves.

Mr. GREEN. Okay. Is there any—seeing all these U.S. name-brand drugs in these hundreds of pharmacies, who is behind the drugs and are making them? Are they companies in Mexico? And have you had any evidence that maybe there is organized crime behind some of those pharmacies?

Mr. SHEPHERD. The companies themselves?

Mr. GREEN. The companies themselves that may be incorporated in Mexico, but they are a subsidiary of—

Mr. SHEPHERD. No, I don't have any evidence of any subsidiaries. I have had evidence and seen and worked with some pretty shaky national companies in Mexico, and I have been in—quite frankly, I have visited a couple of counterfeit operations and seen how they work in Mexico.

Mr. GREEN. Do you believe any of the drugs, particularly those—and we have seen drugs that have Pfizer drugs or Glaxo drugs—are they, in fact, Pfizer pharmaceuticals and Glaxo, or do you think they are counterfeit or something else?

Mr. SHEPHERD. Well, we have found Pfizer products to be counterfeited in Mexico, but we don't believe that Pfizer made them. We think that another firm makes them. The counterfeit trade is globally right now—by the World Health Organization's estimate, between 8 to 10 percent of the whole world pharmaceutical market is counterfeit.

Mr. GREEN. But there are subsidiaries of Pfizer and Glaxo in Mexico licensed?

Mr. SHEPHERD. Yes. They are legitimate national companies, and normally they produce—I would say I don't have many problems with their products. I mean, I think they are good companies.

Mr. GREEN. Do they export from those facilities to the United States?

Mr. SHEPHERD. No. I don't think—personally, I don't—there are very few products that are FDA approved and manufactured in Mexico. There is a handful. There are not very many products, even if they are manufactured by that company in Mexico City. Pfizer is probably manufactured in the United States, but very few products are FDA approved in Mexico. I had a list of them. I think there were 17 or 18 2 years ago. There was very few. But more and more companies are going that way.

Mr. GREEN. Should FDA and others attempts to analyze the quality of these drugs, particularly since they are presenting in large quantities in the U.S. market, particularly with border residents or people who are close enough to the border?

Mr. SHEPHERD. That is my recommendation, that they should, but I haven't seen the data on it.

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

Mr. GREEN. Thank you, Mr. Chairman.

Mr. BILIRAKIS. Mr. Strickland.

Mr. STRICKLAND. Thank you, Mr. Chairman.

This has been an interesting, interesting day; and I appreciate all of your testimonies. And Dr. Wennar—

Ms. WENNAR. Wennar.

Mr. STRICKLAND. Wennar.

Ms. WENNAR. That is close enough.

Mr. STRICKLAND. You are a very effective witness, I must say.

I am sitting here thinking that the problem is the price, and if—and I want to ask your personal opinions. If this Congress were to pass the Allen bill, which basically would take the average price of any particular drug, the average price at which it is sold across five markets that are similar to ours, industrialized national markets, and required that those drugs or that particular drug be available in this country at the average price, that is cost control, I would admit. But, in your judgment, would that go a significant way toward solving this dilemma that we are trying to discuss or find a solution to today?

Dr. Shepherd would you give us your opinion? And then each of you, as briefly as you could.

Mr. SHEPHERD. I think this would solve the problem. If you can make the medicines affordable, I think it would solve a lot of your problems right off of the top.

Mr. STRICKLAND. Dr. Wennar.

Ms. WENNAR. You know, I wish it were just a simple yes-or-no answer. I have to tell you honestly I think it is more complicated than that. I have to tell you I am not completely convinced that that will address the issue completely.

Mr. STRICKLAND. Would it be a significant part of the solution, in your judgment?

Ms. WENNAR. It could be a beginning.

I have to tell you the reason I am hedging on this is because I think that the issue here is that, as you have all mentioned today very eloquently, that the real objective here is to have a comprehensive benefit under Medicare for the elderly. We clearly have another population that needs access to safe, affordable drugs.

Mr. STRICKLAND. Absolutely. But what I am trying to get at is the cost issue, and even if we have a comprehensive benefit for the elderly that does not address the cost issue.

Ms. WENNAR. The point I was going to make is take a lesson from the commercial insurance population from the standpoint of what has gone on there. What they have had to do is they have had to cut medical benefits in order to be able to continue to do the things that they are doing under their prescription drug benefits or they have had to cut back on their prescription drug benefits. Because, even for them, with their large group purchasing power, their prices, their cost is still going up. So—

Mr. STRICKLAND. But is their—excuse me for interrupting you, but is their purchasing power cost as low as it would be if we were to implement the Allen bill?

Ms. WENNAR. I guess I would have to say no. I guess if I—you know, if I have to give you an absolute yes-or-no answer, I am not—I have not historically been a proponent of price controls and regulations. But, to answer your question, I guess I would have to say yes. It would go toward something.

Mr. STRICKLAND. Yes. And I am not asking for your, you know, your personal feelings regarding price controls. I am just asking for

your opinion regarding the possible effect if we were to have this approach to price controls.

Dr. Hutt.

Mr. HUTT. In my judgment, that is not the right way to go, because it does not approach the basic issue of comprehensive coverage; and I agree with Dr. Wennar.

Mr. STRICKLAND. Please excuse me for interrupting, but I understand that that may be the case, and that is really not my question. Because you may think that it is totally the wrong thing to do. But what I want to know from you is if you think it would have a certain effect even if that effect may have negative consequences associated with it.

Mr. HUTT. Mr. Strickland, the first question one would need to answer, before I could give you a good clear opinion on that, would be, would drug companies withdraw from foreign markets where they have price control in order to then make the average price higher.

Mr. STRICKLAND. Should that be the major consideration of American legislators?

Mr. HUTT. Yes, it should be struck.

Mr. STRICKLAND. Should not the first concern of American legislators be what is right for the American citizens?

Mr. HUTT. My point is that by imposing this average price, that average price is going to go up dramatically if American manufacturers drop out of these foreign markets.

Mr. STRICKLAND. Are these companies making money in these other countries?

Mr. HUTT. I have no idea whether they are making money or not.

Mr. STRICKLAND. Well, then if you don't know that, you would have no way of knowing that the companies would withdraw from these markets.

Mr. HUTT. I didn't say that they would. I said the first question you would have to answer would be that question. I cannot answer that question.

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

Mr. STRICKLAND. I didn't get my last response, but thank you, Mr. Chairman. You have been wonderful in your treatment of me, and I appreciate it.

Mr. BILIRAKIS. Thank you. Thank you for that.

Mr. Greenwood to inquire.

Mr. GREENWOOD. Thank you, Mr. Chairman.

Dr. Wennar, I believe in your testimony—I think this is a quote from your testimony. You said, with regard to monitoring, that the quality of drugs being shipped to proxy when the country (Canada) could be established. There is no reason that we cannot 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. That is your view.

Ms. WENNAR. Correct.

Mr. GREENWOOD. Well, how, then, do we prevent substandard, dangerous, nonpotent drugs from China, Vietnam, some other country coming into Canada being relabeled and then coming across the border into the U.S.? How would we know? How would we protect against that?

Ms. WENNAR. I guess I am having a hard time—do you not think Canada does that?

Mr. GREENWOOD. Pardon me?

Ms. WENNAR. You don't think Canada does that—

Mr. GREENWOOD. Canada does what?

Ms. WENNAR. —in terms of the way that they regulate things coming into Canada? We would be working with them. I mean, as I said, the fact of the matter is the standard should be equal to or higher, so you would be working with an entity that you are absolutely convinced has a standard that is equal to or higher. And in this regulated country I can tell you they have more layers than we do.

Mr. GREENWOOD. Okay. Mr. Hutt, you are shaking your head “no.” Why is that?

Mr. HUTT. Any drug that is made in Canada for export is exempt from Canadian law. Any drug.

Mr. GREENWOOD. Miss Wennar is shaking her head.

Mr. HUTT. Any drug that is brought into Canada for transshipment to another country under section 37 of the Canadian Food and Drug Act is exempt from Canadian law.

Ms. WENNAR. Do you honestly believe that—and we are talking pharmacies, okay, here. We are talking pharmacist to pharmacist. Do you believe that they are going to put bottles in a pharmacy in Canada and say, aha, that goes to the U.S.; let's open those and send them. We are not going to use those for Canadian citizens because there may be adulterated products there. So the risk for U.S. citizens we don't care about.

This is a totally ridiculous conversation to be having. You are talking about—

Mr. GREENWOOD. Whoa, whoa—wait. Excuse me. Excuse me. I will give you all the time in the world you want, okay?

Ms. WENNAR. Okay.

Mr. GREENWOOD. Okay. There is nothing ridiculous about me trying to learn something from you, all right? I am asking a question.

Ms. WENNAR. Okay. But what I am trying to say—

Mr. GREENWOOD. I would like it if you just help me out to understand the question.

Ms. WENNAR. Okay, I will help you out. I will help you out from the provider's side. A licensed pharmacist takes pride in what they do, and they are licensed, and we are talking about meeting those standards. If they are a licensed pharmacist, do you believe that they differentiate? They don't have ask you where you are from. They are trying to provide access to safe medications. That is their objective. They are trying to help you comply with the treatment plan. For us to make any kind of assumptions around Canadian pharmacists as being different than pharmacists in our own country—

Mr. GREENWOOD. I don't think that my question was about that.

Ms. WENNAR. I understand that. But what I am saying, if you are talking about—you are talking about things that sometimes, from a provider perspective, they don't—they are sitting here saying, what is the problem here? What we want to do is help the people that we serve.

Now, the fact of the matter is that if what we are talking about here, as I have heard people say earlier, that a pharmacist couldn't differentiate from something that was adulterated or not, that nobody could just by looking at it. The fact of the matter, in terms of putting that bottle on the shelf, when they pull it off, they are pouring from the same bottle for the Canadian citizen and the U.S. citizen.

Now, if we think that this has been occurring, why isn't it substantiated in the literature out of Canada to show us that there are counterfeit medications being dispensed to Canadian citizens?

Now, on the other side I guess I would say, be careful how we cast stones. Because in our very country here we have already identified that people have been doing this. There are entities that have intentionally adulterated things. And I find that offensive, and other countries do, too. They find it offensive.

In Canada, when I talk to pharmacists, they can't believe that a pharmacist would do that to somebody with cancer.

Mr. GREENWOOD. I am just about out of time. That is very instructive. Thank you. There was nothing ridiculous about it at all.

Mr. Hutt, do you have a different point of view on this or do you—

Mr. HUTT. I do indeed. Because I think focusing on the pharmacist or, as Mr. Pallone said, the pharmacist and the wholesaler is the wrong focus. The focus has to be on the drug and the standards required under United States law currently for drug manufacture and distribution in this country.

There is only one way that we can keep up our standards for imported drugs. If people want to bring them into this country, they ought to meet the requirements of the Federal Food and Drug and Cosmetic Act that exists today. They—if it is adulterated, it ought to be illegal, if it is misbranded, not as it appears to be. But there ought to be the burden of proof on an importer to make certain that there is a new drug application that FDA has approved for the product. It is in compliance with that, it is in compliance with the adulteration provisions under section 501, the misbranding provisions under 502 and the NDA provisions under section 505. That is where the focus should be.

I don't in any way deny the good faith of the pharmacist, but that is not the right place to look.

Mr. BILIRAKIS. Dr. Wennar is shaking her head and apparently agrees with your statement.

The gentleman's time has expired.

All right, we have three guests here; and I have been trying to be courteous. We are—you know, we are about three and a half—well, we have been at this all afternoon; and we do want our good people to be able to leave relatively soon. So I am going to give Messrs. Kingston, Gutknecht and Sanders 2 minutes each to inquire of you and then excuse you as a panel.

Mr. Kingston.

Mr. KINGSTON. Let me just go down the line.

Dr. Shepherd, if right now you could legally import drugs from Canada over Mexico, would you be—what would your comport level be on a scale of 1 to 10?

Mr. SHEPHERD. Seven or 8.

Mr. KINGSTON. Seven or 8. Dr. Wennar, just a number.

Ms. WENNAR. Ten.

Mr. KINGSTON. Mr. Hutt, I am going to respectfully skip you because we know where you—I mean, you know, it is fine, but you are—

Mr. HUTT. I do not feel insulted.

Mr. KINGSTON. No. That is okay. I have another question for you.

Mr. Copeland.

Mr. COPELAND. If handled by a wholesaler, a reputable wholesaler similar to ours, a 10.

Mr. KINGSTON. Okay. So now do the three of you think that this can happen, that it can be done safely? I mean, you know what really worries me in America today we have this, oh, God, we are going to be sued; oh, gosh, someone is going to be hurt.

I think about the great story about the Panama Canal where, doggone it, we said, we are Americans; we can do anything we want to.

Mr. Hutt, the problem is with your vocation, noble vocation, I hope—and I married into a family of lawyers myself. I am not one. But the problem is you can get a lawyer to take any position you want. And you know, we are Americans, by golly. We can make this work for the safety of the people, for the Mrs. Tubbs of the world, for the Ms. Burrows. I mean, am I wrong on that, Dr. Wennar?

I wanted to start—let me start easy. I don't know if I want to go to Mr. Hutt yet or not.

Mr. BILIRAKIS. You only have a couple of minutes.

Mr. KINGSTON. Yes. I have got 2 minutes, so make it quick.

Ms. WENNAR. I honestly believe that we have the intelligence and the no—I mean, we know how to do this. We have just got to step up to the plate and do it.

As I mentioned to you, you have already had the demonstration project done for you. You have—in every one of those dots right now there are individuals that are bringing medications into the United States for personal use, in every one of those dots. These people are testing it for you. They have taken the risk. They have tested it for you. You just need to give them a little bit more help.

Mr. KINGSTON. Mr. Copeland, you feel it can be done?

Mr. BILIRAKIS. Very briefly.

Mr. COPELAND. Yes.

Mr. KINGSTON. Okay.

Mr. BILIRAKIS. Thank you.

Mr. Gutknecht.

Mr. GUTKNECHT. Well, again, thank you, Mr. Chairman, for having this historic hearing. I think this is an important hearing, and it is an important first start.

Dr. Wennar, I want you to talk a little bit, because you never came back to this chart at the top of the differences between what our consumers can pay for the same drugs in Canada versus the United States.

Ms. WENNAR. The reason I didn't go to that chart is because I heard that we weren't talking about cost.

Mr. GUTKNECHT. Well, we are.

Ms. WENNAR. Okay. This actually represents something that we did in the first 6 months when we started this. Because we had quite a few physicians that were saying it couldn't be possible, that the cost was that much lower in Canada. So what we did was tracked the first 145, 146 individuals in terms of accessing their medications from Canada. There were no substitutions. In other words, nothing was substituted. If the actual medication that was ordered was Lipitor, it was Lipitor that they got.

We tracked it for the first 6 months, and the reality is represented here. You can see what they would have paid on the local market versus the savings that were represented in accessing from Canada. They would have paid probably a little—I think it was a little over \$81,000 they would have paid. They ended up paying about \$22,000.

Mr. GUTKNECHT. For about a 70 percent savings.

Ms. WENNAR. Well, that was the average, yes. Our physicians took a look at that and basically said, you are joking, not really. After that we had requests from all over the country for this one-pager.

Mr. GUTKNECHT. Which really brings us back to the question of this hearing and that is how safe is safe. How much will we pay for that little tiny increment of safety? I think that is a question that consumers are answering every day.

Mr. Chairman, I just want to say that, according to our own Congressional Budget Office, over the next 10 years seniors in America will spend \$1.8 trillion on prescription drugs. Now if we could save 35 percent, we could save \$630 billion. Now I think that people are willing, and consumers are making that decision every single day, that they are willing to take an incrementally minor, tiny, little additional amount of risk to make those kinds of savings.

I would just say, Mr. Chairman, that it is not the Statue of Safety that sits in New York harbor. It is the Statue of Liberty. We are a tough people. We have taken risk, and it is high time that we allow Americans to have access to world-class drugs at world-market prices.

I yield back the balance of my time.

Mr. BILIRAKIS. Thank you.

Mr. Sanders, 2 minutes.

Mr. SANDERS. Thank you very much, Mr. Chairman; and I do appreciate your allowing me to be here.

Mr. Hutt, you are with Covington and Burling, and I know that the pharmaceutical industry has spent a few hundred million dollars in the last couple of years making sure that our people pay the highest prices in the world. How much do they pay your law firm?

Mr. HUTT. I have no idea.

Mr. SANDERS. Okay. Dr. Wennar, the bottom line is, I think, in terms of the wonderful work that you do in Bennington, is how many people, roughly speaking, do you think purchase their drugs in Canada and can you tell us how many safety problems that you are aware of? In other words, after all is said and done, what is going on? Are you hearing a whole lot of people saying that the drugs that they are getting from Canada are adulterated or counterfeit? What is the reality?

Ms. WENNAR. No, I am getting calls from physicians across the country saying that their patients are now taking their medications as they were prescribed and complying with their treatment plans.

Mr. SANDERS. How many folks do you figure you deal with?

Ms. WENNAR. Well, as I mentioned earlier, we did the recent poll in Canada province by province, even with pharmacies that we don't deal with; and, needless to say, they were a little bit skeptical and concerned as to why we were trying to count numbers. But the reality was, by the time—we don't have a lot of resources. We spent about a week doing this, and we stopped counting at 1.1 million elderly people.

Mr. SANDERS. 1.1 million elderly people and how many instances have you heard of counterfeit or adulterated drugs?

Ms. WENNAR. Well, we have had no reports from individuals.

Mr. SANDERS. 1.1 million people and you haven't heard any instances? Oh, my goodness. And how many millions and millions of dollars do you think people have saved and have been—

You and I were in Bennington and we have talked to physicians who say, I am a physician, and I write out prescription drugs, but I am wasting the paper that I am writing on because my patient can't fill it. I am wondering how many senior citizens in this country die so that Mr. Heimbold, the former chairman and CEO of Bristol Myers, can receive \$74 million in compensation in 2001. I know it is very funny for our lobbyists from the drug industry. There is \$76 million in stock options, but they have to charge our people the highest prices in the world.

Thank you for your time.

Mr. BILIRAKIS. The gentleman's time has expired. All time has expired.

Mr. Brown, I will give you an additional couple of minutes.

Mr. BROWN. Mr. Chairman, I really just have one brief question for Dr. Shepherd. Do you believe that the 50 dosage policy should be radically changed, such as lowering the amount of controlled substances that are allowed in the United States? And if so, what effect might lowering the amount have on seniors and are seniors purchasing controlled substances?

Mr. SHEPHERD. Seniors aren't big purchasers of the controlled substances. There may be some instances of it, but they are very small. I think I recommended last year at this hearing that we ban controlled substances coming across from Mexico, and I will stand on that one. My personal recommendation is to stop them altogether.

Mr. BROWN. Okay.

Mr. BILIRAKIS. Any opinion? Mr. Hutt, do you have an opinion on that?

Mr. HUTT. I think it is extremely dangerous to allow our youth to go into—whether it is Canada or Mexico or any other place and bring back controlled substances.

Mr. BILIRAKIS. So they should be banned. You agree with Dr. Shepherd.

Mr. HUTT. I agree with him completely. Of course, I would go further than that, but I certainly agree with that.

Mr. BILIRAKIS. Dr. Wennar, you don't agree.

Ms. WENNAR. No, I am saying you couldn't get them even if you wanted to, because they would not ship them.

Mr. BILIRAKIS. We can get them from Mexico.

Ms. WENNAR. Okay, well, you are not going to get them from Canada. Even if you authorized it, it wouldn't be sent.

Mr. BILIRAKIS. Okay, all right. Well, listen, there will be a number of questions, as you might imagine, in writing that will be submitted to all four of you; and we would appreciate this, you know, a timely response to them.

And our gratitude. The hearing has turned out the way I had intended it to turn out, where we concentrate on reimportation and the advantages, the pluses and the minuses and what not. I think that that has been satisfied and no small thanks to you all. Thank you very much.

Dr. Wennar, sorry you have to spend the night. The hearing is not over, however. Just you are excused.

Unanimous consent to submit a statement by Congressman John Thune into the record dated July 25, 2002. Without objection, that will be the case.

[The prepared statement of Hon. John Thune follows:]

PREPARED STATEMENT OF HON. JOHN THUNE, A REPRESENTATIVE IN CONGRESS FROM
THE STATE OF SOUTH DAKOTA

Thank you, Mr. Chairman for the opportunity to join you today and provide an opening statement at this important hearing on importation of prescription drugs.

I am an original cosponsor of H.R.5186 with my friend and colleague Congressman Kingston because constituents in South Dakota are demanding that Congress address not just access to prescription drugs but also the price of prescription drugs.

I have supported reimportation for years and strongly believe this legislation will lower prescription drug costs for all Americans by increasing competition. It's simply not fair that the same prescription drugs are less expensive in Canada, Europe and other countries than they are here in the US.

H.R. 5186, the Drug Importation Act of 2002 will simply allow individuals and pharmacies to import prescription drugs manufactured in Food and Drug Administration (FDA) approved facilities. As we all know, people in South Dakota and across our nation already travel to Canada to purchase low cost prescription drugs and bring them back into the U.S. This bill would make that practice legal and expand it to allow community pharmacies as well. Both of these pieces are critical to my state where too few people have health insurance, too many people can't afford needed medications and too many small town pharmacies are going out of business.

Congress has already acted to improve access to prescription drugs by providing a generous prescription drug benefit for all seniors.

Now, it is time for Congress to address the price of prescription drugs. By enacting this legislation and allowing the reimportation of prescription drugs we can provide immediate help to seniors. As we all know prescription drugs are essential to the health of millions of Americans and reimportation will improve access to life-saving drugs. Congress should do what it can to help seniors afford the drugs they need to stay healthy.

Thank you again, Mr. Chairman for this opportunity. I appreciate your consideration and I hope that we can work together to ensure that people in South Dakota and across the nation can have access to prescription drugs at an affordable price.

Mr. BILIRAKIS. By agreement with the minority, Mr. Kingston is afforded 5 minutes to use as he pleases to make statements or whatever the case may be regarding, apparently, his legislation. That will be the case.

Mr. KINGSTON. Thank you very much, Mr. Chairman; and let me say to you and to Mr. Brown and all the members of the panel, this hearing was great. We really appreciate the opportunity for some

good, honest dialog. I think that I was just truly impressed with the members' interest in this issue and so thank you very much.

I wanted to say this issue a couple of years ago was one about price. I think today it is actually one about safety. The reason why I say that, the market has already decided the price issue. We are the market.

Our constituents in the United States of America have said, Canada has cheaper drug costs; therefore, I am going to go through Canada. Man, I am going to go through other groups. I am going to mail orders. I am going to get on a bus. I am going to find a way to get to those drug costs, those cheaper drug costs.

In fact, Canada Med, which is available on the Internet, picks up 300 new American customers each and every day. So the price issue is resolved. The only issue that is left is, how are we going to do it safely?

It seems to me that the drug companies—and I have respect for drug companies, but they spend a lot of time, Mr. Chairman, doing things like this advertisement that went out on the radio today: Imported prescription drugs may be dangerous to your health. This went out on radio shows coast to coast. They have somebody who—I am sure they hired an ex-FBI agent. They have somebody else, and they are kind of really broadly quoting and misquoting the FDA and other government agencies, and they are saying that re-importation will increase the potential for terrorists targeting America.

Now, is that productive at this time? I mean, is that really—does anybody really think that drug companies are concerned suddenly about terrorism in America? I mean, drug companies are great citizens, but I do think that is probably not the motivation for this going out and the money that went behind it.

I would like to submit this for the record.

Mr. BILIRAKIS. Without objection, that will be the case.

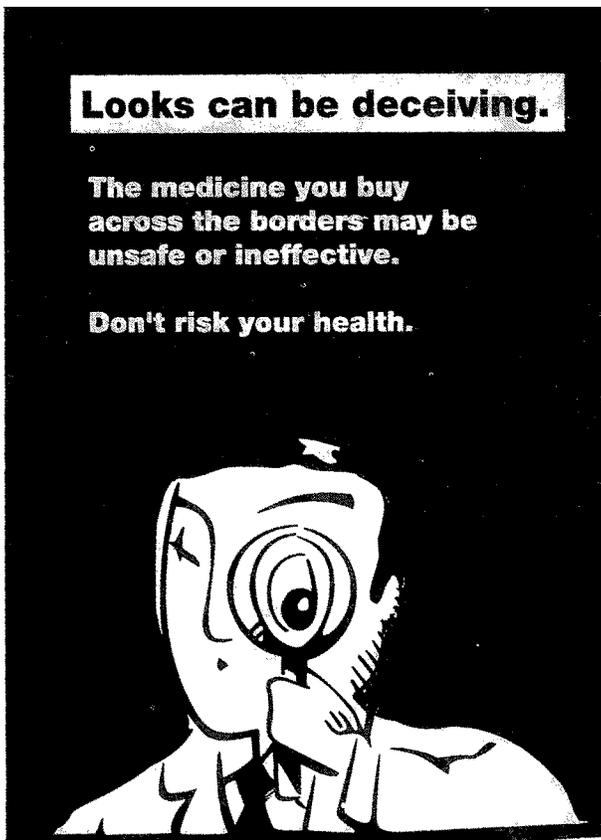
Mr. KINGSTON. I appreciate it.

[The material referred to follows:]

Looks can be deceiving.

**The medicine you buy
across the borders may be
unsafe or ineffective.**

Don't risk your health.



U.S. Food and Drug Administration
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

www.FDA.gov/cder

1-888-INFO-FDA

Things you should know about purchasing medications outside the United States



Occasionally, U.S. residents travel to other countries to purchase medications (drugs) for personal use or order such medications from foreign sources. The U.S. Food and Drug Administration (FDA) is concerned that medications you purchase abroad may present health risks.

FDA would like you to know the following important facts about potential health risks related to using imported products:

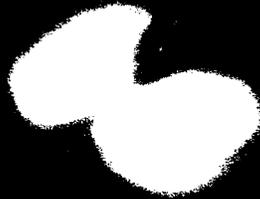
- **Quality Assurance Concerns.** Medications that have not been approved for sale in the United States may not have been manufactured under quality assurance procedures designed to produce a safe and effective product.
- **Counterfeit Potential.** Some imported medications—even those that bear the name of a U.S.-approved product—may, in fact, be counterfeit versions that are unsafe or even completely ineffective.
- **Presence of Untested Substances.** Some imported medications and their ingredients, although legal in foreign countries, may not have been evaluated for safety and effectiveness in the United States. These products may be addictive or contain other dangerous substances.
- **Risks of Unsupervised Use.** Some medications, whether imported or not, are unsafe when taken without adequate medical supervision. You may need a medical evaluation to ensure that the medication is appropriate for you and your condition. Or, you may require medical checkups to make sure that you are taking the drug properly, it is working for you and that you are not having unexpected or life-threatening side effects.
- **Labeling and Language Issues.** The medication's label, including instructions for use and possible side effects, may be in a language you do not understand and may make medical claims or suggest specific uses that have not been adequately evaluated for safety and effectiveness.
- **Lack of Information.** An imported medication may lack information that would permit you to be promptly and correctly treated for a dangerous side effect caused by the drug.

When in doubt, ask your health care professional.

If you have any questions about the use of any medication, FDA encourages you to contact your physician, your local pharmacist or the Board of Pharmacy for the state in which you live.

Remember, medicines you buy outside the U.S. may be unsafe or ineffective. It's not worth risking your health!

**DON'T
LET COST
BLUR YOUR
JUDGMENT.**



Medicines you buy **OUTSIDE** the U.S.
may be **UNSAFE** or **INEFFECTIVE**.

Don't risk your health.



U.S. Food and Drug Administration
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
www.FDA.gov/cder
1-888-INFO-FDA

Things you should know about purchasing medications outside the United States

Occasionally, U.S. residents travel to other countries to purchase medications (drugs) for personal use or order such medications from foreign sources. The U.S. Food and Drug Administration (FDA) is concerned that medications you purchase abroad may present health risks.

FDA would like you to know the following important facts about potential health risks related to using imported products:

- **QUALITY ASSURANCE CONCERNS.** Medications that have not been approved for sale in the United States may not have been manufactured under quality assurance procedures designed to produce a safe and effective product.
- **COUNTERFEIT POTENTIAL.** Some imported medications—even those that bear the name of a U.S.-approved product—may, in fact, be counterfeit versions that are unsafe or even completely ineffective.
- **PRESENCE OF UNTESTED SUBSTANCES.** Some imported medications and their ingredients, although legal in foreign countries, may not have been evaluated for safety and effectiveness in the United States. These products may be addictive or contain other dangerous substances.
- **RISKS OF UNSUPERVISED USE.** Some medications, whether imported or not, are unsafe when taken without adequate medical supervision. You may need a medical evaluation to ensure that the medication is appropriate for you and your condition. Or, you may require medical checkups to make sure that you are taking the drug properly, it is working for you and that you are not having unexpected or life-threatening side effects.
- **LABELING AND LANGUAGE ISSUES.** The medication's label, including instructions for use and possible side effects, may be in a language you do not understand and may make medical claims or suggest specific uses that have not been adequately evaluated for safety and effectiveness.
- **LACK OF INFORMATION.** An imported medication may lack information that would permit you to be promptly and correctly treated for a dangerous side effect caused by the drug.

When in doubt, ask your health care professional.

If you have any questions about the use of any medication, FDA encourages you to contact your physician, your local pharmacist or the Board of Pharmacy for the state in which you live.

Remember, medicines you buy outside the U.S. may be unsafe or ineffective. It's not worth risking your health!

Mr. KINGSTON. I guess the only question to me remains—and I think there have been some valid criticism and concerns about the language in the bill as introduced. I think this committee in its wisdom can perfect that language and find a way to move the reimportation issue safely forward.

I think the Senate actually has not lived up to it. They passed the bill, as you know, but they put a wink in there that would eventually make sure that it never became reality. I think the House can do a better job; and I am confident that, working together on a bipartisan basis, we can do that.

So, again, let me just close with, to me, this is a safety issue. The market has already decided the price issue. The Ruth Tubbs, the Ruth Burrows, the Merlene Frees and all of our seniors and the good folks in Florida and Ohio and everywhere else are already doing this. It is our duty to find a way to protect them.

So thank you very much.

Mr. BILIRAKIS. And you are yielding the balance of your time to whom?

Mr. KINGSTON. To Mr. Gutknecht.

Mr. GUTKNECHT. Mr. Chairman, yield back.

Mr. BILIRAKIS. Yield back.

Mr. SANDERS, anything you would like to add?

Mr. SANDERS. Thank you very much for allowing me to participate today.

Mr. BILIRAKIS. You are welcome.

All right, I guess this hearing is adjourned.

[Whereupon, at 5:30 p.m., the subcommittee was adjourned.]

[Additional material submitted for the record follows:]

PREPARED STATEMENT OF RONALD J. STRECK, PRESIDENT AND CEO, HEALTHCARE DISTRIBUTION MANAGEMENT ASSOCIATION

My name is Ronald J. Streck and I am President and CEO of the Healthcare Distribution Management Association (HDMA). I want to commend the chairman and the members of the subcommittee for holding this important hearing, "Examining Prescription Drug Reimportation: A Review of a Proposal To Allow Third Parties To Reimport Prescription Drugs."

HDMA is the national trade association representing pharmaceutical and healthcare product distribution. HDMA's active member companies operate over 240 distribution centers throughout the country that serve every state, the District of Columbia and U.S. territories. HDMA's distributor members provide services to approximately 129,100 pharmacy settings, including: 19,400 independent pharmacies; 18,500 chain pharmacies; 9,300 food stores; 10,600 hospital pharmacies; 6,400 mass merchandisers; 5,200 long-term care and home health facilities; 58,300 clinics; 1,100 HMOs; and 300 mail-order pharmacies. By concentrating healthcare products, dispensing them in economic quantities and then transporting them to thousands of pharmacies, hospitals, clinics and other healthcare delivery sites, distributors reduce the overall number of transactions required and save the healthcare system an estimated \$146 billion annually.

In the United States today, the great majority of all pharmaceuticals are distributed through healthcare distributors. Pharmaceutical distributors are a vital part of the system that is charged with ensuring product integrity and this is a responsibility that HDMA members take very seriously. If these drugs are not properly stored, handled and accounted for throughout the healthcare distribution system, the results can be troublesome at best, devastating at worst.

It is with these thoughts in mind, that HDMA is opposed to permitting the reimportation of pharmaceuticals. Reimportation, whether restricted to just Canada or not, significantly increases the likelihood of counterfeit or adulterated drugs entering the U.S. market and reaching our medicine cabinets. And we do not believe it will result in the level of savings for the American consumer assumed by many re-

importation supporters because of the many “hidden” costs that have not been factored in.

Prescription Drug Marketing Act

Congress recognized the dangers of reimportation when it enacted the Prescription Drug Marketing Act (PDMA) in 1988 (P.L. 100-293). PDMA was the result of congressional investigations, led by the House Energy and Commerce Committee, that found that, “A significant volume of pharmaceuticals are being re-imported... These goods present a health and safety risk to American consumers because they may have become subpotent or adulterated during foreign handling and shipping.” PDMA’s overall purpose is to “decrease the risk of counterfeit, adulterated, misbranded, subpotent or expired prescription drugs reaching the American public.”

As a result of PDMA, national standards for the storage and distribution of pharmaceuticals in the United States have been established. All distributors are required to meet numerous federal and state regulations to ensure the integrity and security of pharmaceutical products that reach the American public. Every distributor must be licensed in every state in which they have a warehouse facility. Additionally, 42 states have further licensure requirements for distributors doing business in their state, even if their warehouse(s) is located in another state. Every distribution center is subject to inspection by the Food and Drug Administration, Drug Enforcement Administration, Environmental Protection Agency, Department of Transportation, Occupational Safety and Health Administration and the state agency counterparts.

Under PDMA, all licensed distributors must have in place detailed storage and handling procedures that address:

- Temperature and humidity control and documentation
- Inspection of incoming and outgoing product shipments
- Rotation of product to prevent expiration
- Employee training in storage and handling of pharmaceuticals
- Extensive background checks on employees
- Facility and product security
- Procedures for handling recalls and returned goods
- Sanitation of facility
- Disaster plans for both inside and outside the facility
- Comprehensive written policies

PDMA has worked. The extensive handling and storage standards, backed up with strong oversight, have resulted in the “gold standard” when it comes to ensuring product integrity. Overall, the closed method of distribution from manufacturer to distributor to pharmacy to patient has resulted in a system in which Americans do not question the authenticity of the prescription drug they are about to take.

As of this writing, two major reimportation initiatives have been introduced in this Congress and below are HDMA’s comments:

Prescription Drug Price Parity for Americans Act (H.R. 4614/S. 2244)

The “Prescription Drug Price Parity for Americans Act” (H.R. 4614/S. 2244) would allow pharmacists and pharmaceutical wholesale-distributors to reimport prescription drugs from Canada into the United States for resale. Proponents of this legislation, who laud potential cost savings, believe that reimportation will not threaten the safety or health of Americans. They are wrong on both counts.

Canada’s prescription drug regulatory system appears to have served its 30 million citizens well. However, what will happen when Canada’s market expands to serve an additional 287.4 million Americans? Last year, the number of prescriptions filled in the United States was more than ten times the number filled in Canada (3.3 billion vs. 320 million. Where will the drugs come from to meet the new demand?

If reimportation becomes the law of our land, Americans would expect unlimited access to cheaper drugs. In an environment of over-demand and under-supply, criminals will be given a new opportunity to make a quick buck by infiltrating the U.S. market with counterfeit, subpotent, diverted and/or adulterated drugs through Canada. For example, in light of recent changes in U.S. law, Canada has become the leading supply route for the raw ingredients needed to make the illegal drug methamphetamine. American and Canadian law enforcement officials agree that criminals are taking advantage of the lax Canadian regulations and a vast border. (“U.S. Moves to Close Canadian Drug Route For Illegal Stimulant,” *The New York Times*, 3/5/02)

Proponents of this legislation contend that they have addressed these concerns by including a provision in the legislation that requires the importer to test the product

for “authenticity and degradation.” Commenting specifically on this provision, the FDA stated in a July 17, 2002 letter to Senator Thad Cochran, “As a practical matter, meeting these requirements would be an enormous undertaking, and the testing required under the bill would be costly and time consuming, both for the government and importers. Moreover, some of the testing requirements cannot even be met, as there is no testing that can ensure that a shipment of drugs does not contain counterfeits. . . . For most drugs there is no simple laboratory test that can verify the authenticity of the product. . . .”

Putting aside the very serious questions about the validity of testing for “authenticity and degradation,” there are significant costs that need to be considered to meet this requirement. The importer would be required to provide capitalization for constructing, equipping and staffing certified testing facilities or contracting with approved laboratories for the testing.

Another additional cost (liability insurance) must also be considered. Currently, most domestic wholesalers are indemnified by the drug manufacturers they do business with due to the controlled nature of the U.S. supply system. However, if reimportation becomes a reality, this indemnification would disappear. Manufacturers understand that reimportation, even if it is limited to Canada, will diminish the oversight and protections that characterize the U.S. prescription drug supply system. U.S. manufacturers would not, nor should they be expected to, indemnify distributors dealing with products that may or may not have been manufactured by them.

The additional costs do not stop there. Other potential costs are associated with establishing systems and means for relabeling, repackaging, product tracking, documentation, recordkeeping, customs’ fees, insuring compliance with patent and trademark regulations and implementation of processes to deal with returns, recalls and withdrawals.

Since the mid-1990’s, the industry’s net profit margin has been less than one percent. Our most recent data indicates that it was 0.72% last year. Operating in a highly competitive marketplace, distributors pass on their savings from lower operating costs through to their customers. The costs of the additional responsibilities, regulatory burdens and liability exposure that would result from implementation of H.R. 4614 would ultimately have to be passed along—distributors simply do not have the margins to absorb these types of additional expenditures.

Limiting reimportation to Canada does not eliminate the threat to health and safety to Americans. Indeed, Canada would become the gateway for those looking to introduce counterfeit drugs into our country. Therefore, this legislation should be vigorously opposed.

Drug Importation Act of 2002 (H. R. 5186)

The “Drug Importation Act of 2002” (H.R. 5186) would allow pharmacists to reimport FDA-approved drugs for resale in the United States. As it was just introduced on July 23, 2002, HDMA has not had time to conduct an in-depth analysis. However, our initial review indicates that it does nothing to address our overriding health and safety concerns as it relates to how reimported product was stored and handled outside of this country or counterfeit product being able to work its way into the U.S. marketplace. Furthermore, while the ability to do actual reimportation would be limited to pharmacists, there are still practical, operational issues that would have a very direct impact on distributors.

For example, how are returns, recalls and withdrawals to be handled? Certainly, a distributor should not be expected to process product and issue credits for drugs it did not distribute. The issue of liability exposure is another factor that would be of concern to HDMA members. Regretfully, experience has taught us that distributors would be among those cited in lawsuits filed due to injuries resulting from “bad” product. New and potentially expensive inventory control systems would have to be put in place, both at the pharmacy and distributor level, to differentiate pharmacist-imported product from those that passed through a domestic distributor. These are just two concerns we would have regarding this legislation.

While HDMA cannot support this bill, we do agree with its supporters who have cited the central role that pharmacists can have in helping a patient with their medication therapy management. HDMA has been a longtime advocate for recognition of the important role pharmacists have in the healthcare system and that there should be fair and appropriate reimbursement for the pharmaceutical therapy management services they provide.

Conclusion

As the committee knows, legislation was passed by the last Congress that would have allowed for reimportation by pharmacists and wholesaler-distributors. That

legislation required the Secretary of Health and Human Services to certify that reimportation would not result in an increased threat to the health and safety of Americans and that there would be cost savings for the patient before it could be implemented. After an extensive review, then-Secretary Shalala announced that she could not certify these two factors. Her successor, Secretary Thompson, undertook his own investigation and reached the same conclusion.

Limiting reimportation to Canada or “pharmacist-only” would not change these findings. HDMA concurs with the FDA when it states that, “Legislation that would establish other distribution routes for drug products, particularly where those routes transverse a U.S. border, creates a wide inlet for counterfeit drugs and other products that are potentially injurious to the public health and a threat to the security of our nation’s drug supply.” In a time when we are working to tighten our border security due to terrorist threats, now is not the time to loosen them to reimported drugs.

On June 11, 2002, Health and Human Services Secretary Thompson stated, “Opening our borders to reimported drugs potentially could increase the flow of counterfeit drugs, cheap foreign copies of FDA approved drugs, expired and contaminated drugs and drugs stored under inappropriate and unsafe conditions. That is a risk we simply cannot take.”

The stated intent of prescription drug reimportation measures introduced in Congress is to increase consumer access to medications through lower costs. Not only will this not happen to the extent hoped for, but it will in actuality greatly endanger the health and safety of the American public.

The issue is coverage, not price. The reason some seniors are paying higher prices is that they are not in a program that negotiates on their behalf. HDMA supports comprehensive reform of the Medicare program to include an appropriate pharmaceutical care benefit and wants to work with Congress to achieve this end. Thank you.