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A SYSTEM OVERWHELMED: THE AVALANCHE OF IMPORTED, COUNTERFEIT, AND UNAPPROVED DRUGS INTO THE U.S.

HEARING

BEFORE THE

SUBCOMMITTEE ON
OVERSIGHT AND INVESTIGATIONS

OF THE

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COMMERCE
HOUSE OF REPRESENTATIVES

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A SYSTEM OVERWHELMED: THE AVALANCHE OF IMPORTED, COUNTERFEIT, AND UNAPPROVED DRUGS INTO THE U.S.

TUESDAY, JUNE 24, 2003

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

The subcommittee met, pursuant to notice, at 10 a.m., in room 2123, Rayburn House Office Building, James C. Greenwood (chairman) presiding.

Members present: Representatives Greenwood, Stearns, Bass, Walden, Ferguson, Rogers, Deutsch, DeGette, Davis, Schakowsky, Rush, and Dingell (ex officio).

Also present: Representatives Green and Stupak.

Staff present: Alan Slobodin, majority counsel; Ray Shepherd, majority counsel; Arturo Silva, deputy communications director; Jill Latham, legislative clerk; David Nelson, minority counsel; and Chris Knauer, minority investigator.

Mr. GREENWOOD. The meeting will come to order and welcome to our quests and our witnesses.

The chairman recognizes himself for 5 minutes for an opening statement.

More than 2 years ago, on June 7, 2001, I sat in this chair and heard the heartbreaking testimony from Reverend and Mrs. Rode of Athens, Georgia who tearfully described how their son accidentally overdosed on a mixture of drugs he had purchased over the Internet. The drugs purported to be legitimate, but their son died as a result of incorrectly mixing a combination of them.

This terrible tragedy showed that when drugs are purchased over the Internet, patient care can be compromised where there's no interaction with a physician nor dispensing pharmacist aware of the patient's history who can prevent deadly drug interactions or unnecessary prescriptions.

Over the last 5 years several factors, including the advent of Internet pharmacy and the globalization of the pharmaceutical market have led to a dramatic surge in drug imports, especially personal imports, that overwhelmed the FDA. These factors have made FDA's system of import controls less and less tenable.

Two years ago at that same hearing FDA testified that approximately 2 million packages containing drugs were imported into the U.S. every year. The agency complained that it simply did not have enough staff to inspect those packages.

In 2001, FDA could not tell the subcommittee what percentage of those packages contained legitimate versus counterfeit product. They could not determine the country of origin nor describe the conditions under which the drugs were manufactured. In short, FDA could tell us very little about the 2 million packages of drugs that were being imported. Not much has changed since our hearing in 2001 other than the volume of drugs.

And I'd ask the staff to please show slide number 11.

According to a senior supervisory Customs inspector, the mail facility in Miami, Florida routinely receives about 30,000 pharmaceutical shipments weekly offered from South America and Central America, Canada, Europe, the Bahamas and Mexico. Packages containing pharmaceutical products account for nearly one-third of the total volume of packages.

I'd ask to please show slide 12.

This enormous volume of drug packages on March 7, 2003 at the Miami International Mail Branch Facility, according to Customs almost all of these packages contain some form of pharmaceutical product.

Given these numbers, Miami receives approximately 150,000 packages containing pharmaceuticals weekly, 600,000 monthly and approximately 7 million packages containing drugs annually.

And please show slide 13.

According to data provided by Customs, every month approximately 5 million packages enter the commerce of the U.S. or 60 million packages annually. If the estimate from Miami is extrapolated nationally, 20 million packages containing pharmaceutical products are imported into the U.S. every year. This is an increase of over 1,000 percent in only 2 years.

As this subcommittee has heard ad nauseam, drugs procured outside the United States regulatory system can be dangerous for numerous reasons. FDA acknowledges that it cannot monitor nor guarantee the safety and effectiveness of drugs purchased outside the closed U.S. distribution system. FDA has warned the public that drugs purchased from foreign countries could be counterfeit, cheap foreign imitations of FDA approved drugs that could be subpotent or superpotent, expired drugs, contaminated drugs or drugs stored under unsafe conditions.

At this subcommittee's June 7, 2001 hearing which highlighted the public health concerns that these drugs posed to the American people, the FDA proposed to the Department of Health and Human Services that it eliminate its personal use policy for mail imports allowing FDA and Customs to deny entry of all these illegal drugs into the U.S. and return them to senders. No action has been taken on this proposal. And this is, perhaps, understandable given the apparent split in public and political opinion on personal reimportation policy.

Why are U.S. consumers playing Russian roulette with their medications by purchasing them over the Internet from unknown sources? The fact is that the skyrocketing prices of medications are increasingly out of the reach for too many of our seniors and nearly all those on fixed incomes.

Some of the seniors who testified at our oversight hearing in Mr. Deutsch's district in March of this year stated that they often fore-

go other essentials to purchase their necessary medications. In a country as wealthy as ours we have to do better than this.

It is my sincere belief that the Medicare Reform bill that this committee passed last week will insure full access to and the affordability of pharmaceuticals. However, the fact remains that when consumers purchase drugs over the Internet for whatever reasons, they take a leap of faith with their health because there is no guarantee that the drugs they are purchasing are safe or effective.

We're also concerned that FDA may be aggravating a deteriorating drug import problem with instances of poor judgment and ineffective policies. On October 21 of last year, FDA requested that Customs detain at least 1,233 packages of a knock-off Viagara imported into the U.S. through Miami, Florida which appeared to be violative of the Food, Drug and Cosmetic Act. On May 5, 2003 FDA knowingly authorized the release of the 1,233 packages of a unapproved generic Viagara. On May 20 this year, FDA informed the public that it was "taking steps to respond to irregularities related to its handling of a large shipment of unapproved Viagara." The committee is continuing to investigate that the problems identified in Miami, Florida represent widespread issues surrounding FDA's approach nationwide to preventing the dissemination of imported counterfeit or unapproved pharmaceuticals.

Unfortunately, the problem of counterfeit drugs, drugs with no active ingredient and drugs stored in unsafe conditions rendering them useless is no longer restricted to the Internet. Counterfeit drugs and drugs of unknown origin are appearing with greater regularity at U.S. pharmacies and the FDA has shared with me an example of these counterfeit drugs.

This is a container of Serostim. It's a drug, I think, used for treatment of AIDS and other cancer patients. You cannot tell these two packages apart. One is the legitimate product made by the Serono Corporation, the other is a counterfeit. And there is no way in God's earth you could tell these two products apart unless you assay them and look at the chemical contents. And when you do that, you find that the chemical contents are unreliable, at best.

Counterfeit drugs of unknown origin are appearing with greater regularity at U.S. pharmacy. Recently we have seen counterfeit versions of Lipitor, Serostim, Procrit, Epogen and Combivir.

At our second panel today we will hear that because of unscrupulous wholesalers, consumers in Florida cannot know if the pharmaceuticals they purchase are legitimate. However, with the vigorous law enforcement actions and new criminal penalties and tough regulations, the State of Florida is at the forefront of ensuring a safe and effective pharmaceutical supply.

At the end of the day FDA is responsible to ensure that Americans have safe and effective supplies of drugs. Given the expediential increase in the volume of drugs being imported into the U.S., FDA's current approach must be substantially altered to address this new reality.

First, FDA must procure real data on the type and volume of drugs being imported into the U.S.

Further, FDA must also discern from where these drugs are being imported and whether they contain legitimate product or

counterfeits or stored in unsafe conditions, or are subpotent or superpotent.

FDA must also engage in aggressive enforcement actions aimed at the importers of bogus and harmful drugs.

And last, FDA must predicate all of its current regulatory and enforcement action on a risk based assessment of threats to our drug supply. And I can think of fewer more important or challenging tasks.

I would like to welcome our witnesses here this morning. The first panel includes Federal witnesses: Mr. William Hubbard, Associate Commissioner for Policy and Planning at the Food and Drug Administration; Mr. John Taylor, Associate Commissioner of Regulatory Affairs, Food and Drug Administration, and; Ms. Elizabeth Durant, Director of Trade Programs at the Bureau of Customs and Border Protection.

Our second panel consists of witnesses from the State of Florida: Mr. Robert Penezik, Esquire, Assistant Statewide Prosecutor, State of Florida, Office of Statewide Prosecution South Florida Bureau; Dr. Greg Jones, Pharmaceutical Program Manager at the Drug, Devices, and Cosmetic Regulation, Bureau of Statewide Pharmaceutical Services, and; Dr. Cesar Arias, Drug Inspector Supervisor, Florida Department of Health, Bureau of Statewide Pharmaceutical Services.

[The prepared statement of Hon. James C. Greenwood follows:]

PREPARED STATEMENT OF HON. JAMES C. GREENWOOD, CHAIRMAN, SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS

On June 7, 2001, I sat in this very chair and heard gut-wrenching testimony from Reverend and Mrs. Rode of Athens, Georgia, who painfully described how their son accidentally overdosed on a mixture of drugs he purchased over the Internet. The drugs purported to be legitimate, but their son died as a result of incorrectly mixing a combination of those drugs. This unfortunate tragedy shows that when drugs are purchased over the Internet, patient care can be compromised easily because there is no interaction with a physician or dispensing pharmacist who is aware of the patient's history and can prevent deadly drug interactions or unnecessary prescriptions.

Over the last five years, several factors, including the advent of Internet pharmacies and the globalization of the pharmaceutical market, have led to a dramatic surge in drug imports (especially personal imports) that have overwhelmed the FDA. These factors have made FDA's system of import controls, more and more untenable. Two years ago, at the same hearing with the Rode's, FDA testified that approximately 2 million packages containing drugs were imported into the U.S. every year. FDA complained that they simply did not have enough staff to inspect those packages. In 2001, FDA could not tell the Subcommittee what percentage of those packages contained legitimate vs. counterfeit product, determine the country of origin or describe the conditions under which the drugs were manufactured. In short, FDA could tell us very little about the 2 million packages of drugs that were being imported. Very little has changed since our hearing in 2001 other than the volume of drugs.

According to a senior supervisory Customs inspector, the mail facility in Miami, Florida, routinely receives about 30,000 pharmaceutical shipments daily, often from South and Central America, Canada, Europe, the Bahamas, and Mexico. Packages containing pharmaceutical products account for nearly one-third of the total volume of packages. Given these numbers, Miami receives approximately 150,000 packages containing pharmaceuticals weekly, 600,000 monthly, and approximately 7 million packages containing drugs annually.

According to data provided by Customs, every month approximately 5 million packages enter the commerce of the U.S. or 60 million packages annually. If the estimate from Miami is extrapolated nationally, 20 million packages containing pharmaceutical products are imported into the U.S every year. This is an increase of over 1000% in 2 only years.

As this Subcommittee has heard ad naseum, drugs procured outside the United States regulatory system can be dangerous for numerous reasons. FDA acknowledges that it cannot monitor or guarantee the safety and effectiveness of drugs purchased outside the closed U.S. distribution system. FDA has warned the public that drugs purchased from foreign countries could be counterfeit, cheap foreign imitations of FDA-approved drugs that could be sub-potent or super-potent, expired drugs, contaminated drugs or drugs stored under unsafe conditions. At this Subcommittee's June 7, 2001, hearing, which highlighted the public health concerns that these drugs pose to the American people, FDA proposed to the Department of Health and Human Services that it eliminate its personal use policy for mail imports, allowing FDA and Customs to deny entry of all these illegal drugs into the U.S. and return them to sender. No action has been taken on the proposal. This is perhaps understandable given the apparent split in public and political opinion on personal reimportation policy.

Why are U.S. consumers playing Russian roulette with their medications by purchasing them over the Internet from unknown sources? The fact is that the skyrocketing prices of medications are increasingly out of the reach for too many of our seniors and nearly all those on fixed incomes. Some of the seniors, who testified at our Oversight hearing in Mr. Deutsch's District in March, stated that they often forgo other essentials in order to purchase their necessary medications. In a country as wealthy as ours, we must do better. It is my sincere belief that the Medicare reform bill that this Committee passed last week will ensure full access to and the affordability of pharmaceuticals. However, the fact remains that when consumers purchase drugs over the Internet for whatever reason, they are taking a leap of faith with their health because there is no guarantee that the drugs they are purchasing are legitimate.

We are also concerned that FDA may be aggravating a deteriorating drug import problem with some instances of poor judgment and ineffective policies. On October 21, 2002, FDA requested that Customs detain at least 1,233 packages of "knock-off" Viagra imported into the U.S. through Miami, Florida, which appeared to be violative of the Food, Drug, and Cosmetic Act. On May 5, 2003, FDA knowingly authorized the release of the 1,233 packages of unapproved generic Viagra. On May 20, 2003, FDA informed the public that it was "taking steps to respond to irregularities related to its handling of a large shipment of unapproved Viagra." The Committee is continuing to investigate whether the problems identified in Miami, Florida, represent wide-spread issues surrounding FDA's approach nation-wide to preventing the dissemination of imported counterfeit or unapproved pharmaceuticals.

Unfortunately, the problem of counterfeit drugs, drugs with no active ingredient, or drugs stored in unsafe conditions rendering them useless, is no longer restricted to the Internet. Counterfeit drugs and drug of unknown origin are appearing with greater regularity at U.S. drug stores. Recently, we have seen counterfeit versions of Lipitor, Serostim, Procrit, Epogen, and Combivir. On our second panel today, you will hear that because of unscrupulous wholesalers, consumers in Florida cannot know if the pharmaceuticals they purchase are legitimate. However, with vigorous law enforcement actions and new criminal penalties and tough regulations, the State of Florida is at the forefront of ensuring a safe and effective pharmaceutical supply.

At the end of the day, FDA is responsible, to the greatest extent possible, for ensuring that Americans have a safe and effective supply of drugs. Given the exponential increase in the volume of drugs being imported into the U.S., FDA's current approach must be substantially altered to address this new reality. First, FDA must procure real data on the type and volume of drugs being imported into the U.S. Further, FDA must also discern from where these drugs are being imported and whether they contain legitimate product, are counterfeits, are stored in unsafe conditions or are sub-potent or super-potent. FDA must also engage in aggressive enforcement actions aimed at the importers of bogus and harmful drugs. Lastly, FDA must predicate all of its current regulatory and enforcement action on a risk-based assessment of threats to our drug supply. I can think of fewer more important or challenging tasks.

I would like to welcome our witnesses here this morning. The first panel includes Federal witnesses: 1) Mr. William K. Hubbard, Associate Commissioner for Policy and Planning, Food and Drug Administration; 2) Mr. John Taylor, Associate Commissioner of Regulatory Affairs, Food and Drug Administration; and 3) Ms. Elizabeth Durant, Director of Trade Programs, Bureau of Customs and Border Protection.

The second panel consists of witnesses from the State of Florida: 1) Mr. Robert Penezic, Esq., Assistant Statewide Prosecutor, State of Florida, Office of Statewide Prosecution, South Florida Bureau; 2) Dr. Gregg Jones, R.Ph., Pharmaceutical Pro-

gram Manager, Drugs, Device, and Cosmetic Regulation, Bureau of Statewide Pharmaceutical Services; and 3) Cesar Arias, Drug Inspector Supervisor, Florida Department of Health, Bureau of Statewide Pharmaceutical Services

I now recognize the ranking member of the full committee, Mr. Dingell for his opening statement.

Mr. DINGELL. Mr. Chairman, I thank you for your courtesy and I thank you for holding this hearing on the threat of safety to our population from our prescription drug supply.

From my count, this is the third hearing this subcommittee has held on this subject in the past 3 years. Other hearings date back to 1996. I commend you for your continuing interest and attention in this, which is a serious and worsening problem.

I chaired 8 hearings on this issue in the 1980's. After these hearings we passed the Prescription Drug Marketing Act to deal with the threat to the drug supply at that time. But the Food and Drug Administration, FDA's unwillingness to enforce the clear language of the law, the tremendous expansion of direct marketing capability of the Internet, the outrageous prices that seniors and other Americans pay for prescription have all combined to undermine that statute and leave us with a far more serious threat to the safety of our population from prescription pharmaceuticals today.

In 1985 when we began the inquiry into the problems of drug diversion one of the first issues that the subcommittee uncovered was a rather curious situation involving the Orlando District of the FDA. It seems that the Director of Compliance was uncommonly cooperative with those seeking to enter violative drugs into this country. According to testimony, the State of Florida's Department of Health was attempting to seize violative goods and the Orlando District Office of FDA decided instead to allow reexport to Canada and then into Boston.

Seventeen years later we're back again looking at the Orlando Office of the FDA again. And I'm compelled to recall the great statement that this is deja vu all over again. And, again, it is because senior officials in that office have acted with disregard for the needs of the public and they have, in effect, facilitated illegal imports of prescription drugs. We know some 30,000 packages of drugs per day pass through the international mail facility in Miami, largely from the developing world. And FDA has told Customs not to open virtually any of them. Some lower level FDA employees did detain shipments that were subsequentially released on orders from their superiors. They found bold counterfeits, drugs clearly not manufactured in the U.S. or Canada and unapproved drugs tested as subpotent by the terms of their labels. These conscientious civil servants found exactly what this agency, which we had thought of as the gold standard, that public health internationally expected of them. Orders went from Orlando with the concurrence of FDA headquarters, release the products and tell Customs never to bother us with the likes of them again.

While very troublesome by itself, this is much a part of the broader problem. FDA has ignored the clear language of the statute and has invited massive import of counterfeit, adulterated and misbranded drugs by means of a so-called enforcement discretion policy, a policy by the way which kills, maims or hurts American citizens. Moreover, FDA's interpretation of the wholesale provision

of the Act has undermined PDMA's goal of making the buying and selling of pharmaceutical products transparent. We have, I think here then, something of a scandal at FDA.

Legitimate manufactures must go through tough hurdles to get a drug approved. They spend millions to ensure that manufacturing facilities comply with good manufacturing practices. But at the same time FDA allows any fly by-night Internet con man to send whatever placebos, poisons, over-aged drugs or pharmacueticals which are contaminated and adulterated or unsafe he or she chooses through the mail, through UPS, through FedEx, through area contract carriers or to be walked across our southern border without so much as a warning to the consumer.

Further, those drugs can be commingled with domestic counterfeits, stolen goods, watered-down products, other adulterated and misbranded drugs. These can all wind up behind the pharmacy counter leaving the poor consumer to believe that the drugs are supposed to be safe and effective as labeled because their local pharmacist and the FDA appear to say so. Other consumers buy the unsubstantiated claims found in the Internet or at their walk-in mail order storefront that the drugs are FDA approved. Again, a falsehood in which FDA appears to cooperate quite actively, or at least by its total disregard to fail to protect the American public.

This state of affairs is a health crises waiting to happen. Indeed, I think it has in it the seeds of a splendid scandal, and I anticipate that that will follow shortly.

It is not acceptable to this committee. It is not acceptable to the American people. The FDA needs to enforce the law, and if they can't do so, they should tell us why they can't or why they won't. And that is why this hearing is valuable.

This Administration needs to tell the Congress as it promised to do 2 years ago what the added authority that it needs happens to be and how it should and can, and will protect the American public from a situation which I think we will find on review to be intolerable.

Thank you, Mr. Chairman.

Mr. GREENWOOD. The Chair thanks the gentleman and recognizes the gentleman from New Hampshire, Mr. Bass for an opening statement.

Mr. BASS. Thank you very much, Mr. Chairman. I want to commend you for holding this interesting and timely hearing. And I also appreciate your opening statement, which I listened to quite carefully. And most of it I agree with heartily.

I guess what I would like to do in opening is to make two points, vis-à-vis this issue. First, the issue of counterfeit drug importation, generic knock-offs and so on, the slide we saw by baskets of drugs from Florida are not going to be solved by adding 5,000 or 15,000 or 50,000 FDA policemen inspecting every package. The reason why these orders are made is because the prices of drugs elsewhere in the world are lower than they are in the United States. Whether you agree or disagree with that, that is what is creating the demand. And as long as there is a disparate or a difference between what one drug costs in the United States and what it costs abroad and there is a mechanism to make the sale, i.e., direct mail or the Internet, it is going to happen. And my humble opinion, there are

not going to be Internet police, the FDA's not going to be like the Transportation Security Administration, and we are not going to be able to afford to do that.

The issue, frankly, is what do we do over the long term about equalizing prices of drugs so that the demand doesn't exist for people who are low and middle income, for the most part, bearing the bulk of the responsibility for high priced drugs. Because poor people get essentially free drugs and seniors, hopefully when we pass this Medicare Prescription Plan, will get the same type of benefit. And, obviously, wealthy people under the age of 65 are not going to worry about going to the Internet and so forth. What it really is a relatively small group of low and middle income working Americans who are financially against the ropes and looking for any way they can possibly can to deal with a chronic illness or an expensive prescription.

I buy the argument that foreign countries artificially depress drug prices. But we have a carve out, I believe, in NAFTA for pharmaceuticals so that we don't have a free trading agreement with Canada.

Now, I represent a district of about 630,000 people. I have a border with Canada and a good road up there. And every day of the week there are bus load after bus load of people, mostly seniors, going up there to buy prescription drugs. I cannot imagine that the FDA is going to station people at the border to slap senior citizens up against the buses and try to throw them in jail and fine them. What we need to have is as a Congress and as an agency is a plan to solve the problem through the free market system. And that may not involve the lowering of prices in the United States necessarily or the raising of prices in foreign countries, but the plan has to result in an environment where there is no demand for these foreign drugs by people who are desperate for prescriptions.

Now last, I would suggest that it is just as easy to manufacture a counterfeit drug domestically as it is for a foreign country. In fact, it is easier. Why bother. If you are going to break the law, you can make it in my district as easily as you could in Mexico or Canada. And there is, indeed, an issue on the sale of counterfeit drugs domestically in drugstores. We had a hearing on that issue. So it may be an import/export problem, but it is just as likely to be a domestic problem.

I am also interested to note that I have not heard from Canadian sources that there is a more severe problem of domestically manufactured drugs in Canada that are counterfeit than in the United States.

So these are all interesting issues, but the fundamental problem here is free market and capitalization. And if you have a price somewhere else that is lower than it is there, they are going to move toward one another one way or another. It is a fundamental law of economics and the economic equivalent of water running downhill, not uphill.

So, that is the way I see the fundamental issue. I appreciate your holding this hearing today, Mr. Chairman. And I look forward to hearing from our witnesses.

And yield back.

Mr. GREENWOOD. The Chair thanks the gentleman and recognizes the ranking member Mr. Deutsch for an opening statement.

Mr. DEUTSCH. Thank you, Mr. Chairman. Thank you for holding this hearing.

Mr. Chairman, today is really the same hearing we have been having year after year on foreign drugs entering the U.S. Each time we do, the problem has not only grown in scale and the drugs coming from more suspicious countries.

I am particularly concerned about the residents in my State. We're facing a Hobsons choice. On the one hand drug prices have increased at an unreasonable rate. Each day I learn of more and more seniors who are forced to make some serious decisions as they try and budget for their medications. Some, not all have turned to the Internet. Others have turned to the new Canadian walk-in pharmacies throughout South Florida to find relief. Understandably the lower rates of pharmaceuticals they are able to obtain from the Canadian storefront operations make a sizable difference in day-to-day living for many. However, it concerns me greatly that we are learning of an overabundance of foreign drugs entering the U.S. from a variety of potentially dangerous sources, sources whose practice provide no meaningful protection to consumers.

This need for affordable prescription drug coverage for many individuals advances many of the problems we will discuss today. From the Florida witnesses we will hear that a great deal of counterfeiting and other forms of pharmaceutical trickery are occurring in my State. This includes Medicaid drugs being sold and resold and how a broad array of drugs from abroad are being reimportated, relabeled and somehow slipped back into the formal distribution chains.

I believe that many of the scams discussed today are happening directly as a result of the high price of prescription drugs. Indeed, I was hoping that the Medicare bill that came before this committee last week might truly provide some meaningful relief to those being squeezed by the high drug prices so that the needs to purchase drugs outside regular channels would lessen. However, I fear that should the bill marked up last week in this committee pass into law, this questionable practice will only continue.

That being said, Mr. Chairman, I do want to point out that the FDA in someways has already made a bad situation in Miami facility and turned it into complete chaos. Thanks to a leadership by HHS to devise some meaningful guidance for field staff, the Miami facility has become a shocking version of FDA mismanagement.

Over the past several months committee staff have visited this facility and noticed a staggering amount of drugs entering the U.S. from all over the world. Actually, the numbers that staff has told us at this point is 30,000 per day. 30,000 packages per day of drugs entering through just one of 14 facilities throughout the country, most who enter with almost no meaningful FDA review or scrutiny. We have photos and description of these drugs, and much of what staff documented will be contained in the memo that was written by investigators from both sides of the committee.

In fact during today's hearings we will learn that the Miami facility has been so overwhelmed with foreign drugs that they accidentally released huge volumes of fake Viagara to the public de-

spite knowing through formal testing that the product was potentially dangerous. We will also learn that entire bins of other counterfeit drugs such as Ciprofloxin were sent back to its overseas source when repeatedly we were told by the FDA that returning to sender was against the law.

We will hear that in addition to the 1,233 shipments of potentially dangerous fake Viagara that was released, hundreds of other shipments were shoved out the door with no authorization from the headquarters. Some of these may have even been the subject of an FDA import alert, so were not even allowed to enter into the U.S. in the first place.

Finally, we will hear that Customs Miami was not regularly provided import alerts from FDA on which dangerous drugs it should be stopping. Instead Customs was told by FDA staff they should log into FDA's website to find out when alerts were posted.

Mr. Chairman, as the House and Senate debate the so-called merits of the drug bill before us this week, we will hear debate on the reimportation issue as a way to provide access to more affordable pharmaceuticals. However, it is already occurring and on a large scale. The volume of product now entering this facility is so overwhelming to both Customs and the FDA, neither agent can effectively do its job. We have learned that senior FDA officials in Florida now tell Customs to stop only large shipments entering the Miami facility. Anything small about the size of a toaster sails right through. I suppose that criminals smart enough to counterfeit drugs down to the package hologram have figured out this high tech system.

Indeed, the fact that millions of drugs from all over the world are entering the U.S. with no meaningful scrutiny by the FDA is clearly known by FDA Commissioner McClellan and HHS Secretary Thompson. Yet rather than face this fact, Secretary Thompson continues to ignore the problem despite his reassurance and recommendations FDA has made almost 2 years before, nothing has actually changed. In fact, the problem has increased and it has only become more unmanageable. Because this problem has been allowed to develop into a lucrative business for criminals, it is my opinion that much of what we are discussing today will only be solved when we comprehensively address the issue of prices and access. If we do not, we will only continue to see this problem worsen and may see the entire U.S. drug supply put in jeopardy. In fact, one measure for whether we are effectively addressing the price issue might be to continue measuring the number of individuals who continue to go outside regulated channels to buy their medicines. What this says is volumes to these mail facilities tell us. We are doing a good job, we are solving the price problem. Look at the volume. In short, Mr. Chairman, I think that the chickens have come home to roost. As the result of not addressing meaningful and affordable prescription drug benefits for our Nation's seniors, we are rapidly putting the integrity and safety of the U.S. drug supply and turn our own citizens at grave risk.

With that, Mr. Chairman, I yield back. And thank you for having this hearing.

Mr. GREENWOOD. The Chair thanks the gentleman.

The Chair notes that the chairman of the full committee, Mr. Tauzin, hopes to be with us but is attending a meeting right now. And without objection, his opening statement will be a part of the record, as will without objection the staff report covering the investigation of this matter be made a part of the official record.

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

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

Thank you Chairman Greenwood. And let me also express my deep appreciation to Mr. Dingell and Mr. Deutsch, for their strong support of the Committee's continuing bipartisan investigation of this issue.

This investigative work, with numerous visits to border checkpoints and international mail facilities, has provided essential information to help understand the risks and, indeed, has exposed what appears to be the failure of our regulatory safety net to protect the American public from counterfeit, dangerous and poor-quality drugs imported into this country.

With so much attention focused on the personal importation of drugs—to provide cheaper medicines or alternative therapies—the information about the safety of imports, the ability of our system to ensure people get what they think they are getting, is of critical importance for policy makers.

Mr. Chairman, the facts before us—some of which you just cited—actually suggest that there really is no safety net at all. The deluge of imported drugs has blasted holes right through it.

Staff estimates that, based on Customs data, something like 20 million packages containing some kind of pharmaceutical product from abroad pass through our mail facilities and borders each year, with only a tiny percentage ever stopped for inspection.

I understand we will hear this morning from Florida officials, who will describe the impact of this flood of uninspected drugs into that state, and the public health threats they have had to confront as a result. I am curious to know how sure they are that the drugs Floridians order through the mail are safe to use.

Now we must remember that this troubling situation did not just pop up last week. Almost exactly two years ago, Customs and FDA officials testified to this subcommittee that they were unable to handle what was then estimated as 2 million packages a year. Yet in just that short amount of time, with the increase of Internet sales and other promotions, the problem has grown enormously.

This hearing should help make clear that we are not talking about potential risks or hypothetical threats here. We know, from staff and federal inspections that dangerous substances from shady outfits are passing through to American consumers. There should be no doubt that people already have been harmed by this—and more will be as this deluge continues.

It is also essential to get a grip on this issue because of the on-going pressures to increase personal drug imports—either for unapproved foreign medicines or for medicines that might save patients money. The debate surrounding imports of cheaper drugs from abroad has been particularly intense because of the current Medicare legislation we've all been working on.

Yet however appealing it is for us to enable people to find a personal supply of medicines from the cheapest sources available, we must not disconnect our desire to help them from the reality of our current border/mail controls, and the situation of drug preparations beyond our borders.

Keep in mind, as much as people in this country are attracted to promises of cheaper drugs from abroad (and over the Internet) the crooks and scamsters are there to exploit this situation—and doubtless will increase efforts to meet any growing demand—to the detriment of public health and safety. And right now, it doesn't look like the protections Congress has erected are being put to use.

This hearing should help clarify what is happening in the field, and I hope will also underscore the point that this Committee takes very seriously its responsibilities to protect the public health and the agencies of our jurisdiction should do so as well.

Thank you again, Mr. Chairman, I look forward to the testimony and yield back the remainder of my time.

Mr. GREENWOOD. The Chair recognizes the vice chairman of the committee, the gentleman from Oregon, Mr. Walden for an opening statement.

Mr. WALDEN. Thank you, Mr. Chairman. I am going to waive the opening statement in lieu of additional time for Q&A.

Mr. GREENWOOD. The Chair intends to give everyone the same amount of time for this hearing. It is an important hearing. So if the gentleman would like to make an opening statement, he will get the same amount of time, but The Chair appreciates his decision.

The Chair also notes the presence of the gentleman from Texas, Mr. Green, who is not a member of this subcommittee, but is joining us because of his interest and his constituents have in this issue. And he will be entitled to ask questions but not, pursuant to our rules, to make an opening statement.

So the Chair recognizes the gentleman from New Jersey, Mr. Ferguson for his opening statement.

Mr. FERGUSON. Thank you, Mr. Chairman.

I would like to thank you for the opportunity to participate in this hearing, and also thank you as well as the committee staff for your diligence in pursuing this matter that's really vital to the public health of our Nation and our people.

Our Nation is facing a crises due to the tidal wave of counterfeit and improperly dosed drugs that are illegally imported from all over the world into our country and sold to unsuspecting consumers. These so-called pharmaceuticals can range from simply being fakes that contain primarily sugar or starch to drugs containing deadly doses of controlled substances. The scary thing is that we have no mechanism in place to properly test and monitor the safety of these drugs shipped to our country from all points throughout the world. It is the FDA's job to protect American consumers from problems stemming from drugs manufactured in our country. The FDA has repeatedly said that they cannot guarantee the safety of drugs shipped to the U.S. from other countries.

Quoting a recent FDA letter, "Prescription drugs purchased from foreign countries generally are not FDA approved, do not meet FDA standards, they are not the same as drugs purchased in the United States. Drugs from foreign countries do not have the same assurance of safety as drugs actually regulated by the FDA. They could be outdated, contaminated, counterfeit or contain too much or too little of the active ingredient."

Also today we will hear about how dramatically overburdened our Customs officials are to the influx of dangerous foreign drugs. Based on the estimates of senior Customs inspectors in Miami, the facility there faces approximately 7 million pharmaceutical shipments annually. This is just one facility, thereby making the national number of imported pharmaceuticals absolutely frightening.

The increase in imported unregulated pharmaceuticals has simply overwhelmed our current system that was designed to insure the safety and effectiveness of drug products. If our public health officials cannot guarantee the safety and efficacy of these drugs, how can we in good conscience let our children, our seniors and our other consumers of this Nation gain access to these drugs?

I look forward to hearing the testimony of the panels. I appreciate this hearing.

And I will just close, because I have a couple of more minutes, just addressing a point that my friend Mr. Bass was making in terms of the problems that we face with drug price disparities around the world. And I would only suggest that, you know, we do face a problem of high cost of prescription drugs in our country today, and we are addressing that problem. We have spent countless hours marking up a bill in this committee last week. We are going to have that bill on the floor this week. That bill is going to go a long way toward helping seniors in our country afford the prescription drug medication that they need for the quality of their life, for their very lives in some instances.

We will not solve that problem by imposing price controls on drugs in this country. We hear a lot about free markets and free trade and how free markets and free trade will help us solve the drug pricing problem that many of our seniors face and others face in our country today. Well, I would suggest that it is precisely anti-capitalistic, anti-free market, anti-free trade to suggest that importing other country's price controls into our country will somehow help us over the long term to solve this problem. We are taking the right steps with the bill that we passed out of this committee and that we are going to pass out of this House this week in using the market and using the capitalist system by offering choices to seniors. We are taking the right steps to try and bring prices under control and to make these products more available to those who need them.

I would suggest that precisely the wrong approach is to look at countries like Canada and others which essentially use a kind of a socialist price control structure to make these products more affordable to their own people and by importing these socialist tendencies and price controls and other mechanisms into our country is precisely the wrong way to go.

I would simply suggest that looking at the way we are doing it in our bill is the way that we are actually going to be able in a positive and a proactive way to address the problem of rising prescription drug costs. And by looking at countries; I mean look at a country like France or Canada. You do not see people going to France or Canada to get their health care. Why? Because they have a system which do not encourage innovation, it does not encourage the best health care in the world.

Where is the best health in the world? It is in the United States. We have people all over the world coming to the United States to get their health care. Why? Because we have the best system in the world. And why do we have that system? Because we have the best doctors, the best researchers, the best research and development anywhere in the world. We need to maintain that.

We should not be importing these socialist tendencies and price controls, and socialized medicine of other countries in the U.S. to try and control our costs. What we should do is find out ways that we can use the market, use more choices for seniors to achieve that goal.

I yield back. Thank you.

Mr. GREENWOOD. The Chair thanks the gentleman and recognizes the gentle lady from Colorado.

Ms. DEGETTE. Thank you, Mr. Chairman.

I would ask unanimous consent to submit my full written statement for the record.

Mr. GREENWOOD. Without objection.

Ms. DEGETTE. I am eager to hear the witnesses today. So let me just make a couple of points in addition to my written statement.

Like everyone, I am very concerned about high prescription drug costs for my seniors. And, in fact, just last week I was stopped in a parking lot in Denver by one of my constituents who said to me "I am very concerned about your position on drug reimportation because I get my drugs from Canada." And she has a legitimate concern.

Her concern is she wants to be able to afford her prescription drugs every month. But upon last year's hearings, which I thank the chairman for holding, and all of the research we have done, it is clear to me that opening the borders to unlimited importation of drugs from other countries is not only a poor idea, but it threatens the health of our constituents.

And so I think if we are going to try to think about how to control the price of drugs, we need to do that without finding other ways to reimport drugs at lower prices which may, in fact, be dangerous to our constituents' health.

I remember last year in the hearing seeing the packages of yellow pills that contained not medical products, but yellow highway paint. I remember standing on the floor last year with two packages of what was called Viagara; one was real, one was not and they looked identical.

So I think that the issues that we are dealing with are very serious issues. They are not just serious in terms of drug prices. They are serious in terms of our constituents' health and well-being. And, frankly, I cannot think of anything that we are elected to do in the U.S. Congress if it is not to protect the health and well-being of our constituents.

As I understand it, the problems with drug reimportation and counterfeit drugs are getting much more serious. And I am eager to hear the witnesses today talk about this. And I am also eager to work with my colleagues on both sides of the aisle so that we can try to find some solutions both to the drug reimportation issues, but most importantly to the underlying issue, the issue which will not be mentioned, right? And that is the issue of how do we give our seniors the same kinds of low and appropriate prescription drug prices that are available in many other countries, including Canada.

And with that, Mr. Chairman, I yield back.

Mr. GREENWOOD. The Chair recognizes the gentleman from Florida, Mr. Stearns, for his opening statement.

Mr. STEARNS. And good morning. And thank you, Mr. Chairman, again for holding this hearing, the latest I guess in a series over the past few years on the influx of counterfeit drugs and unapproved drugs.

I am especially troubled, as my colleague who is the ranking member, that most of these drugs appear to be coming from our State down in Miami, Dade County.

And, of course, the ramifications of this problem are far reaching: huge lucrative criminal profits, danger to public health, disruption to commerce and the fair profits that the manufacturers themselves should be earning for all their research and their efforts.

In 2001 South Florida criminals counterfeited Procrit, a drug used to boost the immune systems of cancer and HIV patients by relabeling, hiding drugs in Texas and North Carolina and then slipping it into the supply so that seriously ill patients could have, and probably did receive, weakened dosages. This amounted to about $46 million in criminal activity.

So what is the solution? There does not seem to be enough manpower to sift through the packages. And looking at the photos, that I guess came from the Miami hearing, we just are a little puzzled what to do. Is it new bar coding or tagging?

At a reception last month one of my staff was given in identifying consumer goods use of little vials. I have one of these little vials, Mr. Chairman. You cannot see it, but within this liquid is 150 nanoblock ICs. It's just barely perceptible, these tiny flecks that are supposedly the next revolution in tagging products. But the question is who is going to pay for these tiny computerized flecks that are going to be used for labeling? The wholesalers? The manufacturers? No. Ultimately the consumers.

I look forward to examining these issues at this hearing, and I especially look forward to the testimony of the three Florida officials that have come here, Mr. Robert Penezik, Dr. Gregg Jones and Dr. Cesar Arias, and thank them for their kindness in coming here.

As we know, through strong and collective leadership efforts in Florida through the legislature, the Attorney General and Governor Jeb Bush, the Governor signed a new law just 2 weeks ago "The Prescription Drug Protection Act." Among other things, it tightens up the wholesale activity and improves the chain of custody documentation. And, Mr. Chairman, I just thought that I would just touch on some of the things that this act incorporates, which I think is very helpful.

The new legislation requires or provides for:

(1) Vastly improved documentation of vital pharmaceuticals in order to prevent their counterfeiting; (2) Full pedigree papers on all prescription drugs by July 1, 2006; (3) Due diligence by those receiving these pedigree papers; (4) Full authority by the Florida Department of Health to destroy medication that has been adulterated or improperly stored; (5) Full authority by the Florida Department of Health to shutdown licensed wholesalers in violation of State statute until the deficiencies are corrected; (6) Increased criminal penalties for pedigree papers as well as other violations involving adulterated drugs, and; (7) Increase permitting requirements for drug wholesalers in Florida, including raising bonding requirements and stricter background checks.

So, Mr. Chairman, I think the State of Florida is to be commended for this new Prescription Drug Protection Act, implementation. Between the cup and the lip is the hard problem. And we just

hope it can be done. And perhaps we can hear some more from the three individuals from Florida.

So I look forward, again, to this testimony and I commend you for this hearing.

Thank you.

Mr. GREENWOOD. The Chair thanks the gentleman and recognizes the gentleman Mr. Rogers for an opening statement.

Mr. ROGERS. Thank you, Mr. Chairman.

I am going to waive in lieu of time for questions. Thank you.

Mr. GREENWOOD. I am sorry. I did not notice the reemergence of the gentleman from Florida, Mr. Davis is recognized for his opening statement.

Mr. DAVIS. Thank you, Mr. Chairman.

As another Floridian on the committee, I am keenly interested in what we are about to hear. And I just wanted to briefly say that there are 3 issues that I believe we are all focused on.

One is the increasing desperation of seniors not just in Florida, but around the country as well as their family and friends in finding affordable prescription drugs. And the increasing desperation in the level of risk that people are willing to undertake to simply have some drug versus nothing at all.

The market is a cruel thing and until Congress acts to provide some relief to seniors, I think we are going to continue to see some of the steps you are about to describe it.

Second, we have an obligation as elected officials to make sure that seniors are in a position to make informed choices about quality and about exactly what they think they are purchasing, and that being accurate. And ultimately to make sure that they are safe. Because in some cases the mistakes that are made in terms of what people take are unforgivable or fatal mistakes.

And finally, the law should be enforced. And I recognize that what I have just described are competing and perhaps in some cases irreconcilable forces and everybody, Congress, the FDA has chosen to avoid some of the painful choices. But one thing we do owe the public here today is to have a very open and honest discussion. And if none of us likes the choices we are forced to confront here, we ought to at least be honest with the public as to what those choices are and they can participate with us in making some of the hard decisions about how we stop this growing problem from getting worse. So I look forward to your testimony.

And, Mr. Chairman, once again commend you on calling this hearing and the manner in which I know you will conduct this hearing.

Mr. GREENWOOD. The Chair thanks the gentleman.

[Additional statement submitted for the record follows:]

PREPARED STATEMENT OF HON. GENE GREEN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS

Thank you, Mr. Chairman, for allowing me to join you here this morning to discuss the reimportation of prescription drugs.

Prescription drug costs are increasing at an alarming rate. Drug spending is currently the fastest growing segment of national health care spending, increasing by 15.1 percent in 1998, 19.2 percent in 1999, and 17.3 percent in 2000.

Spending on prescription drugs currently accounts for more than 11 percent of total personal health spending, and that number is expected to increase to more than 17 percent of personal health expenditures by 2011.

Millions of Americans cannot afford to keep up with these ever escalating drug costs.

In absence of a Medicare prescription drug benefit, seniors especially are struggling to pay for their medications. They are forced to ration their prescriptions, cut their pills in half, or go without them, because they cannot afford these lifesaving medicines.

More troubling, citizens of the United States pay the highest prices in the world for prescription drugs. Canada, France, Italy, Germany, Japan, and the United Kingdom all negotiate on behalf of their citizens to obtain lower prices for brand name drugs.

As a result, purchasers in these countries pay significantly less for prescription drugs than uninsured senior citizens in the United States.

Seniors don't mind paying a fair price for their prescription drugs, but they don't think they should have to pay more than seniors in these industrialized countries. As a result, many of them are taking advantage of the internet to buy cheaper reimported drugs.

Like my colleagues, I have many concerns about the safety of reimported drugs. Affordability cannot come at the cost of safety when we're talking about potentially life-saving medications.

That is why I support proposals which would subject reimported drugs to the exact same safety mechanisms already in place for drug manufacturers.

Dr. David A. Kessler, former FDA Commissioner under Presidents Bush and Clinton, stated that the importation of these products can be done without causing a greater health risk to American consumers than currently exists.

Unfortunately, the FDA seems to have given up on its obligation to ensure that drugs entering the stream of commerce are safe and effective.

A staff visit to the Miami International Mail-Branch Facility revealed that the system for processing imported foreign prescription drugs and controlled substances in the facility has broken down, allowing these products to enter the country with little or not review or testing.

This poses a serious public health problem that could put the lives of many Americans, especially our seniors, at risk.

The system's failure can certainly be attributed to the fact that the volume of incoming drugs is simply too great to allow for any real investigation into their quality.

But the larger problem seems to be FDA's interpretation of the law, which has turned this into an overly burdensome and resource intensive process.

This hearing is an excellent opportunity to assess the extent of this problem, and what we can provide to the FDA, both in terms of resources and regulatory reform, to help ensure that the drugs entering the marketplace are safe.

I look forward to hearing from our witnesses on this issue, and once again thank the Chairman for allowing me to sit in on this hearing.

Mr. GREENWOOD. The Chair formally welcomes our first panel: Mr. William Hubbard, Mr. John Taylor both from the FDA, Ms. Elizabeth Durant, Director of Trade Programs at the Bureau of Customs and Border Protection.

Pursuant to the rules of our committee and the House, I should advise you that you are entitled to be represented by counsel. Do any of you wish to be represented by counsel. All right, seeing no such desire, do any of you object to giving your testimony under oath? In that case, I would ask you to stand and raise your right hands, please.

[Witnesses sworn.]

Mr. GREENWOOD. You are under oath, and we'll begin, Mr. Hubbard, with you and you are recognized for 5 minutes for your opening statement.

TESTIMONY OF WILLIAM K. HUBBARD, ASSOCIATE COMMISSIONER FOR POLICY AND PLANNING, FOOD AND DRUG ADMINISTRATION; JOHN M. TAYLOR III, ASSOCIATE COMMISSIONER OF REGULATORY AFFAIRS, FOOD AND DRUG ADMINISTRATION; AND ELIZABETH G. DURANT, DIRECTOR OF TRADE PROGRAMS, BUREAU OF CUSTOMS AND BORDER PROTECTION

Mr. HUBBARD. Thank you, Mr. Chairman. As you noted, I'm accompanied by John Taylor our chief enforcement official at FDA.

I have a written statement, but I will not read that, but will make a few brief oral remarks, if I may.

I would like to thank the committee for its longstanding interest in these issues of counterfeit and imported drugs. Counterfeiting is much in the news now, and FDA, Mark McClellan is very concerned that we make sure that this problem doesn't get worse. And FDA is clearly committed to work on that.

Let me just start with one quick illustration of the recent Miami case with Procrit. This is some of the actual product that was seized in the Procrit example. There is a real Procrit and a counterfeit Procrit. And I would like to have it brought up to the chairman, if I may, to share with the committee.

This is a drug that is used to deal with anemia and kidney failure in cancer and AIDS patients. Three suspects have been arrested in this case and have now pled guilty. But, you know, this is a dangerous product. It was basically replaced with Miami tap water. And so that clearly points out the problem we see with counterfeiting.

With counterfeiting in Miami we are concerned that consumers are going to the Internet to buy drugs increasingly. Let me show you a couple of examples, if I may. If we could show the eDrugnet example.

This is a website that promises to sell FDA approved drugs to patients. Our investigators have sought out the source of this site, and it is in Thailand, although it appears to be domestic and promises FDA approved drugs.

The next site has a Miami Beach address and suggests that it is an American business purchasing and selling American drugs. It is in Israel.

The next one says "It is the most trusted pharmacy in Canada." This site is registered in Barbados, which I believe is an island off of Venezuela, not in Canada.

So these raise very serious questions about what people are buying. But let me show you what people are actually getting when they go to these sites.

Here is a muscle relaxant that raises real concerns about things that come like this. No labeling, no information about what it is.

Here is a drug someone thought they bought from Holland. And, unfortunately, the actual drug that they got has Cyrillic script, which is unintelligible to me, certainly. We do not even know the name of it. But being Cyrillic means it either came from Russia or one of the former Soviet Republics since Cyrillic only is used in those countries. And, of course, it has no information to even determine what the drug is.

This is an antibiotic, it is an antibiotic of last resort, a very serious drug. You only use it when other antibiotics do not work. The person that purchased it over the Internet claimed they were going to treat their cryptococcal meningitis. You should not be treating cryptococcal meningitis with drugs purchased from the Internet.

Here is Lipitor. Now, this is an interesting example. This drug was made in Germany, then distributed to Ireland, then sold to Thailand, then sold to an American. So this drug has been all around the world and where it has exactly been, who has held it, what they have done with it, how it could have been affected.

Here is a controlled substance, a scheduled opiate that clearly is totally against the law and it should not be purchased in any way.

Here is one that someone purchased, one would suspect that they know that they should not have been buying it because it is a travel book and inside it is carved out and there are pills. And we see these things all the time.

So these are not carefully selected examples just to show you horror stories. These are typical of what we are seeing in the mail facilities everyday. I think some of the committee's members have been out there to see that.

Now, some say Canadian drugs are different, that this stuff from the Third World should not be let in, but the Canadian drugs are okay. So we have been screening Canadian drugs. And let me show you a few examples of those.

This is a high blood pressure drug. Looks like a perfectly legitimate product. The problem is it has no information for the patient. We are all used to going in the drug store and getting antibiotic. It gives a doctor's name, our pharmacist's name and whether to take it with food or what time to take it, or whatever. This has none of that. So it's just a bottle of pills, as far as the patient is concerned.

And here are three other examples that patients bought for osteoporosis, for diabetes and for glaucoma. These drugs need to be refrigerated. If these drugs are not refrigerated, they are very complex proteins that breakdown. They become ineffective, maybe unsafe. These arrived in the mail just like this. So these are totally useless drugs in terms of effectiveness. They may, indeed, be dangerous.

Another example is a Canadian drug called Lipivir, which appears to be some sort of knock off Lipitor, but we do not really know. And the patient probably thought they were buying Lipitor.

Yet another example is a drug for depression. This is a drug that should only be prescribed in 3 month intervals because it is for a high risk population. This person was given a 10 month supply of this. So, clearly, it's a danger to that patient.

Another patient apparently that had seizures ordered a drug called gabapentin. And this is what he got.

Mr. GREENWOOD. This looks like one of those cereal commercials.

Mr. HUBBARD. Yes. This patient should have been given 1 month's drugs. This is about 4 years supply. Now, you can say, well okay, he needs it for a long time. The problem is they start expiring in August. So in 6 weeks these drugs are going to be useless. And this patient paid $1500 to a Canadian pharmacy for those drugs.

Yet another drug, this is a drug for high blood pressure called Idopamide. It is a generic drug. The interesting thing about it is that he paid $30 for it. You can get it in the United States for $20. Because, in fact, generic drugs are cheaper in the United States than they are in Canada. And many seniors and other patients can take generic drugs.

And then I will go to one last example from a website that we'll show to the members, to the committee, please. Now, this is a site that promises to sell FDA approved drugs to American citizens from Canada. The businessman that owned this was living in Arizona, apparently. And we got an example of this from an 82 year old gentlemen in Michigan who ordered drugs off of this site for his seizures and his enlarged prostate. And this is what he got. He got a Tupperware container with some drugs made in India. These are fake knock offs of Proscar and Neurontin. We have no idea whether these are real drugs or not. But he was led to believe that this site would give him good, cheap Canadian drugs. In my view he wasted his money.

So these are actually what's coming in from Canada. And I will also mention that the particular individual running this site, we happened to find, had been arrested in Arizona and jailed for an unrelated fraud charge.

So in summary, Mr. Chairman, we find that very few if any of these drugs purchased by our citizens from foreign sources meet contemporary standards for pharmaceutical prescribing, dispensing, labeling and handling.

And with that, Mr. Chairman, I will end my remarks.

Mr. GREENWOOD. The Chair thanks the gentleman.

Mr. Taylor, did you wish to make a statement of your own. You are recognized for 5 minutes for that purpose.

TESTIMONY OF JOHN M. TAYLOR III

Mr. TAYLOR. Thank you, Mr. Chairman.

I appreciate the opportunity to discuss our mutual concerns related to the importation of drugs into the United States. My testimony will dovetail Mr. Hubbard's, but it will also focus on the irregularities related to FDA's handling of a large shipment of unapproved Viagara, apparently from Belize.

For public health reasons, FDA remains concerned about the importation of prescription drugs into the United States. In our experience, as Mr. Hubbard has explained, many drugs obtained from foreign sources that either purport to be or appear to be the same as U.S. approved prescription drugs are in fact of unknown quality.

FDA believes that the overall quality of drug products in this country is very high. And FDA continues to safeguard the drug supply in this country as evidenced by our recent success in the counterfeit Procrit criminal case, the AstraZeneca criminal case and our ongoing investigation regarding counterfeit Lipitor. FDA, however, cannot offer the same assurance to the public about the safety and quality of drugs purchased from foreign sources.

With the available resources and competing priorities facing the agency, experience shows that we are unable to visually examine the large volume of parcels containing prescription drugs that arrive in the mailing services each day. As a consequence, FDA must

employ a risk-based enforcement strategy to deploy our existing enforcement resources in the face of multiple priorities including homeland security, food safety and other tasks.

FDA shares the committee's concern about the volume of drugs that are entering the United States. And as a result, we are reevaluating, refining and improving the programs and procedures that we are employing to ensure that we are developing priorities for import detentions, employing our resources to high volume field locations, training employees to identify high risk products and utilizing import alerts to target products based on potential risks. So these are the things that we are going to be working on now and in the future so that we can better allocate our limited resources.

FDA's import groups have a major role to play in implementing these strategies, and this turns me to Florida District's Miami import group. During its history Florida has prided itself in having an excellent working relationship with Customs and other Federal, State and local agencies as well as the import community. This close working relationship with Customs has led to many innovations and improvements in how we handle imported products and its lead to many awards for the Florida District Office, including Vice President Gore's Hammer Award for reinventing government.

Recently, however, FDA advised the committee and the American public of irregularities related to its handling of a large shipment of unapproved Viagara. Through a series of procedural irregularities foreign versions of Viagara were detained and subsequently released by FDA to consumers. After the products were released by FDA, the agency sent a letter to each consumer who received these unapproved foreign versions of Viagara alerting them to the fact that such products were unapproved drugs under the Act and that the agency cannot provide any assurance of quality, safety or effectiveness for these products. Because of the discovery of these irregularities, FDA's conducting an ongoing internal review of these events thoroughly assessing the matter and taking steps to ensure that these mistakes do not occur in the future.

In the wake of the discovery of these irregularities, FDA has undertaken or will undertake several steps to ensure that import detentions are handled properly in the future, as well as taking steps to ensure that our risk-based strategies are applied properly.

First, Florida district managers held an all hands meeting with the personnel at the Miami import group where they discussed the detention of the unapproved Viagara and at this all hands meeting district managers also conducted training on Section 801 of the Act and the regulation and internal procedures that govern the proper handling of import detentions. The managers also reemphasized the importance of reviewing records carefully and making regulatory decisions in accordance with agency policy.

Two. The District implemented new requirements regarding the initialing and dating of mail entry reports so that Miami import group can more easily determine what records have been reviewed and whether they have been reviewed property.

Third. The District is drafting new standard operating procedures for the handling of mail entries.

Fourth. The District apologized to Customs supervisor at the Miami mail facility for the improper handling of the detained unapproved Viagara.

Fifth. The District will have biweekly meetings with the Assistant Port Director of Miami or her representative in order to strengthen the Miami import group's relationship with its partners.

Sixth. The District will meet with Customs supervisors at the Miami facility on a monthly basis in order to enhance our working relationship with Customs.

Seven. The District will provide Customs with hard copies of all import alerts that the agency issues.

Eight. The District will review its import operations, quality assurance audit plan and determine whether it is sufficient. If it is not sufficient, then that plan will be amended to ensure that it provides the proper guidance to the import staff.

And Nine. The regional and District management will review several proposals that are focused on improving the management structure and the supervisory ratio in the Miami import group so that there is greater management oversight within that operation.

In addition to these steps, today Howard Lewis, an FDA employee, begins serving on an indefinite basis as Florida's District Import Program Manager. Mr. Lewis is from FDA's New Orleans' district and has a strong management and compliance background and a wealth of knowledge of domestic and import compliance issues. These strengths will allow him to identify additional improvements that will strength the Miami import group's role in protecting the public health.

Once we are satisfied that we have taken steps to ensure that the above mentioned irregularities will not occur in the future, we are also prepared to conduct a case study in Miami that helps us better identify the type of pharmaceutical products that are being imported through the Miami facility and the type of health impacts that they might cause.

In closing, Mr. Chairman, FDA remains concerned about any possibility that unsafe drugs may find their way into the American drug supply. We'll remain vigilant as we refine and improve the programs that we use to ensure the availability of safe medicines for consumers.

We appreciate the committee's interest in this matter and we look forward to continuing to work with you in furtherance of this goal.

Thank you again for the opportunity to participate in today's hearing. I'll be happy to answer any questions.

[The prepared statement of William K. Hubbard and John M. Taylor III follows.]

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

INTRODUCTION

Mr. Chairman, Ranking Member Deutsch and Members of the Subcommittee, I am William K. Hubbard, Associate Commissioner for Policy and Planning at the U.S. Food and Drug Administration (FDA or the Agency). With me today is John M. Taylor, Associate Commissioner for Regulatory Affairs at FDA.

We appreciate the opportunity to testify on the continuing problem of unapproved imported prescription drugs. Our testimony will focus on FDA's efforts to assess and

respond to the public health threats posed by the importation of unapproved drugs, as well as the introduction of counterfeit drugs from foreign and domestic sources that also poses a threat to the health and safety of United States consumers. We will discuss FDA's importation policies and procedures, the enforcement strategies regarding imported, unapproved, and counterfeit pharmaceutical products, and plans to strengthen management oversight at FDA's Miami Import Office and the Miami International Mail Facility.

As FDA has previously stated to this Subcommittee, the overall quality of drug products that consumers purchase from U.S. pharmacies remains high. The American public can be confident that these medications are safe and effective. FDA cannot, however, offer the same assurance to the public about the safety and quality of drugs purchased from foreign sources.

FDA is working on a number of fronts to address the influx of unapproved and counterfeit prescription drugs coming into the U.S. from foreign sources. These efforts include: 1) educating the public to the significant potential safety issues presented by the purchase of drugs from foreign countries, 2) working with professional groups to disseminate FDA's message on the potential dangers of Internet drug sales, 3) partnering with state governments and other Federal agencies to develop more effective enforcement strategies, and 4) undertaking monitoring of and enforcement against Internet pharmacy outlets that present the most significant concerns. Recent high-profile regulatory actions send a strong message that FDA is actively working to take strong steps to protect the public from conduct that threatens the U.S. drug supply.

PUBLIC HEALTH AND SAFETY CONCERNS

The Federal Food, Drug, and Cosmetic (FD&C) Act prohibits the importation of unapproved, misbranded, or adulterated drugs into the U.S. In general, drugs imported by individuals fall into one of these prohibited categories. This includes foreign versions of U.S.-approved medications. In addition, under provisions enacted as part of the Prescription Drug Marketing Act (PDMA), it is illegal for anyone other than the drugs original manufacturer to re-import a prescription drug that was manufactured in the U.S.

A large and growing volume of parcels containing prescription drugs ordered by individuals from foreign sources is entering American commerce through U.S. Postal Service international mail facilities. Members of this Subcommittee have witnessed these large volumes at locations such as the Dulles, Virginia, mail facility. Evidence strongly suggests that the volume of these foreign drug importations is increasing steadily. The volume presents a substantial challenge for the Agency to adequately assess and process these parcels, resulting in an increased workload for Agency field personnel at ports-of-entry, mail facilities, and international courier hubs.

FDA remains concerned about the public health implications of personally imported prescription drugs and the introduction of counterfeit drugs into the stream of commerce. In our experience, many drugs obtained from foreign sources that either purport to be or appear to be the same as U.S.-approved prescription drugs are, in fact, of unknown quality. FDA cannot assure the American public that drugs imported from foreign countries are the same as products approved by FDA.

FDA has long taken the position that consumers are exposed to a number of potential risks when they purchase drugs from foreign sources or from sources that are not operated by pharmacies properly licensed under state pharmacy laws. These outlets may dispense expired, subpotent, contaminated or counterfeit product, the wrong or a contraindicated product, an incorrect dose, or medication unaccompanied by adequate directions for use. The labeling of the drug may not be in English and therefore important information regarding dosage and side effects may not be available to the consumer. The drugs may not have been packaged and stored under appropriate conditions to prevent against degradation, and there is no assurance that these products were manufactured under current good manufacturing practice (cGMP) standards. When consumers take such medications, they face risks of dangerous drug interactions and/or of suffering adverse events, some of which can be life threatening. These risks could include potential side effects from inappropriately prescribed medications or side effects due to drug contamination.

Patients also potentially are at greater risk because there is no certainty about what they are getting when they purchase some of these drugs. Although some purchasers of drugs from foreign sources may receive genuine product, others may unknowingly buy counterfeit copies that contain only inert ingredients, legitimate drugs that are outdated and have been diverted to unscrupulous resellers, or dangerous sub-potent or super-potent products that were improperly manufactured.

Moreover, consumers who are desperately seeking a cure for a serious medical problem may be more willing to accept a product of unknown origin.

Furthermore, in the case of foreign-based sources, if a consumer has an adverse drug reaction or any other problem, the consumer may have little or no recourse either because the physical location of the manufacturer or because the operator of the pharmacy often is not known or the seller is beyond the consumers reach. In addition, as a condition of doing business, many of these foreign operators require the U.S. consumer to sign a document releasing the operator from all potential liability. FDA has only limited ability to take action against these foreign operators.

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. The advent of the Internet has significantly compounded this problem. As a consequence, tens of thousands of parcels that FDA is unable to review as a result of the Agency's limited resources and multiple competing enforcement priorities are released by the Bureau of Customs and Border Patrol (BCBP), even though the products contained in these parcels may violate the FD&C Act and may pose a health risk to consumers. We acknowledge that this is not an optimal public health outcome and are working on strategies to better utilize our available resources to minimize potential public health risks.

The Agency has responded to this challenge by employing a risk-based enforcement strategy to deploy our existing enforcement resources in the face of multiple priorities, including homeland security, food safety and counterfeit drugs. As an example, the Agency utilizes Import Alerts to identify particular shipments that may pose significant potential risk to public health. In the case of the increased volume of unapproved sildenafil (generic Viagra), arriving at the Miami facility, the Agency has issued an Import Alert to instruct field personnel to work with the BCBP to detain all such shipments from specific manufacturers, distributors and countries of origin.

PUBLIC OUTREACH AND EDUCATION

Public outreach is an important tool that the Agency uses to inform consumers about potentially dangerous or ineffective drugs. FDA is expanding its public outreach to further educate consumers about potentially dangerous practices associated with some Internet drug sales. We also are conducting outreach to explain the nature of compliance and enforcement actions we already have taken. This effort includes FDA Talk Papers, articles in FDA Consumer magazine, and information on FDA's website to help educate consumers about safely purchasing drugs online. FDA's website also provides consumers with an opportunity to submit information to the Agency about sites that may violate the FD&C Act.

FDA is committed to developing more effective education strategies. With this goal in mind, FDA has created public education brochures and posters entitled, "*Things you should know about purchasing medications outside the United States*" to alert consumers to the health risks of buying medications outside the U.S. Cross-border travelers at certain land border stations are provided with another brochure entitled, "*Looks Can be Deceiving*," which describes the dangers of purchasing drugs directly at cross-border pharmacies. This also is available on FDA's website.

In October 2000, FDA's Center for Drug Evaluation and Research (CDER) launched an education campaign on the subject of buying prescription medicines online entitled, "*Shop Smart*." This effort is part of FDA's "Buying Rx Drugs Online" education program. The centerpiece of this multi-media campaign is FDA's website: http://www.fda.gov/oc/buyonline/default.htm that includes information for consumers, including tips and warnings, how to spot health fraud, frequently asked questions and how to report suspect pharmacy sites. The website is one of the most frequently visited webpages on FDA's website.

Another central piece of our campaign is a brochure entitled, "*Buying Prescription Medicines Online: A Consumer Safety Guide*." The brochure was produced by the CybeRx-Smart Safety Coalition, a partnership of Internet companies, trade associations, health and consumer organizations and other government agencies. The brochure is available in hard copy from FDA, the Federal Consumer Information Center and the National Council for Patient Information and Education (member of CybeRx-Smart). It also is posted on FDA's website. The number of consumer inquiries received by FDA has grown steadily with the circulation of the brochure. In addition, a 30-second radio public service announcement was produced and distributed to stations throughout the U.S. The release has been broadcast on 233 radio stations in 46 different states with an audience of almost 6 million. Two print public service

announcements (one for medical devices and one for prescription medicines) were produced and sent to over 100 national magazines.

The January/February 2001 issue of the FDA Consumer magazine included an article entitled, *"Buying Drugs Online: Its Convenient and Private, But Beware of 'Rogue Sites.'"* The article is available online and thousands of reprints have been distributed at conferences and exhibits around the country.

PARTNERING WITH HEALTH PROFESSIONAL ORGANIZATIONS

FDA continues to meet with organizations representing state regulatory and law enforcement bodies, consumers, health care practitioners and industry. The purpose of these meetings is to discuss and coordinate efforts to address issues relating to online drug sales, including who should regulate and how they should regulate; whether and what policy changes should be considered; and when to develop partnering arrangements. The organizations we regularly meet with include:

- The National Association of Boards of Pharmacy
- The Federation of State Medical Boards
- The National Association of Attorneys General
- The American Medical Association
- The American Pharmacists Association
- The National Consumers League AARP (formerly the American Association of Retired Persons)
- The American Society of Health-Systems Pharmacists
- The National Association of Chain Drug Stores
- The National Community Pharmacists Association
- The Pharmaceutical Research and Manufacturers Association
- Pharmaceutical Security Institute
- Healthcare Distribution Management Association

WORKING WITH STATE REGULATORS

State pharmacy boards have primary responsibility for the licensing of pharmacies and regulating the dispensing of drugs. FDA has been working with the states to address concerns regarding importation of foreign prescription drugs. In February 2003, FDA hosted a nationwide call with 38 state boards of pharmacy, other state regulatory agencies and consumer groups to discuss current Internet drug sale practices. While some state laws are stronger than others, FDA has actively engaged with a number of states in jointly pursuing Internet sites that are engaged in illegal prescription drug sales. FDA is continuing to expand its cooperative activities with states in order to address effectively the many challenges in this area of electronic commerce. FDA also is continuing to work closely with our partners in the states in support of their efforts to curtail illegal and potentially dangerous operations, especially when they involve misleading claims about drug safety.

Discount Prescription Center

A recent example of the effective application of state pharmacy law to a drug importation case is seen in the May 13, 2003, warning letter issued by the West Virginia Pharmacy Board (the Board) to Discount Prescription Center of Fairmont, West Virginia, telling that firm to cease its violation of state law. Discount Prescription Center solicited patients and arranged for a Canadian pharmacy to dispense and ship prescription drugs to the patients. FDA considers the firms operations to be illegal and a potential risk to public health. FDA expressed support for the Boards effort to stop this firm from violating the law in a letter to the Executive Director and General Counsel of the West Virginia Board of Pharmacy. FDA stated in the letter that we believe that operations such as Discount Prescription Center expose the public to the significant potential risks associated with imported prescription medications that are not FDA-approved. In addition, FDA has offered assistance in any future efforts by the Board to stop similar firms.

Rx Depot

On March 21, 2003, FDA issued a warning letter to a storefront operation known as Rx Depot. We commenced this action in conjunction with the Arkansas State Board of Pharmacy. Rx Depot generally obtains unapproved drugs from Canada for U.S. consumers, exposing the public to the significant potential risks associated with unregulated imported prescription medications. Rx Depot and similar companies have often stated incorrectly to consumers that FDA condones their activities and even that their prescription medications are "FDA approved." This could lead consumers to conclude mistakenly that the prescription drugs sold by the companies have the same assurance of safety as drugs actually regulated by FDA.

FDA believes that operations such as Rx Depot expose the public to significant potential risks associated with unregulated imported prescription medicines. FDA's warning letter notified the firm that the Agency considers the firms operations to be a risk to the public health, and in clear violation of the drug safety laws that protect Americans from unsafe drugs. Although FDA addressed its warning letter to the Rx Depot in Arkansas, FDA also sent a letter to the president of Rx Depot, in Tulsa, Oklahoma. The warning letter applies to all locations of Rx Depot and its affiliates. While Rx Depot responded to FDA's warning letter, that response was inadequate and FDA is developing an effective response.

We issued our warning letter in conjunction with action by the Arkansas State Board of Pharmacy. The Arkansas State Board of Pharmacy issued its own letter to the firm on the same day as our warning letter instructing the firm to cease violating state law immediately.

FEDERAL ENFORCEMENT ACTIVITYFD

As Office of Regulatory Affairs (ORA), including the Office of Criminal Investigations (OCI), works with state and Federal investigative agencies and prosecutors to uncover violations of the FD&C Act and other laws with respect to unapproved, misbranded, illegally imported, or otherwise unsafe or substandard drug products.

Recent criminal and civil cases provide insight into the seriousness of the risks these products pose to the public health. With respect to Internet drug sales, FDA to date has initiated the following actions:

- 150 Internet-related drug arrests, 60 involving Internet pharmacies;
- 102 convictions, 34 convictions involve Internet pharmacy cases;
- 95 open Internet drug criminal investigations;
- 90 sites are under active review for possible regulatory or civil action;
- Nearly 200 cyber warning letters sent to domestic and foreign online sellers;
- 5 preliminary injunctions;
- 15 product seizures; and
- 11 product recalls.

DRUG COUNTERFEITING

FDA 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. The Agency is concerned about a spate of drug counterfeiting and tampering cases that have occurred in recent months, and is aggressively pursuing these types of enforcement cases.

FDA's OCI has opened 73 counterfeit drug cases since October 1996. Investigations have so far netted 44 arrests and 27 convictions. Fines and/or restitution have been imposed in excess of $250,000. FDA has seen a gradual, but troubling, increase in the incidence of finished dosage form counterfeit activity. Much of this activity has targeted high volume, high cost drugs where counterfeiters attempt to obtain the highest return possible in a short time period. Many of these drugs are used for treating cancer and AIDS patients. The public perception of a more dramatic increase in counterfeit drug activity stems from the fact that the latest several counterfeits have appeared in the wholesale market and received wider distribution than has been the case historically.

Reporting of Information on Counterfeit Drugs by Manufacturers

On April 22, 2003, the Pharmaceutical Research and Manufacturers of America (PhRMA), which represents the countrys major research-based pharmaceutical and biotechnology companies, announced the adoption of a voluntary program to report suspected instances of drug counterfeiting to FDA. The information provided by PhRMA members under this program will be helpful to the Agency because it will assist FDA in carrying out its responsibilities to protect the safety and integrity of the nation's drug supply by enhancing the Agency's ability to detect quickly and remove counterfeit drugs from the marketplace.

Under this program, PhRMA member companies have agreed to notify FDA's OCI within five working days of determining that there is a reasonable basis to believe that a product has been counterfeited. The program also applies to counterfeits discovered in foreign countries if there is clear evidence that the counterfeits are intended for distribution in the U.S. Drug manufacturers already conduct their own investigations of suspected distribution of counterfeit drugs. This formal collaborative agreement will strengthen FDA's ability to assure the safety and effectiveness of drugs used by U.S. Consumers. The reporting program went into effect on May

1, 2003. The two most recent cases of counterfeit prescription drugs in which FDA has played a significant role are those involving the drugs Procrit and Lipitor.

Procrit

On May 21, 2003, the U.S. Attorneys Office for the Southern District of Florida filed charges against Eddy Gorrin, William Chavez and Duviel Gonzalez for unlawful sale and wholesale distribution of counterfeit versions of Amgen, Inc.'s, prescription drug Procrit, a medication indicated mainly to help cancer, anemia and HIV patients increase their red blood cell count.

Between January and February 2003, Gorrin intentionally engaged in the sale of counterfeit versions of Procrit. During that same time period, Chavez and Gonzalez also were engaged in unlawful wholesale distribution of counterfeit Procrit without a state license. The undercover operation and tests conducted by FDA's Forensic Chemistry Center revealed that the vials being distributed by all three men labelled as "Procrit" did not contain any active ingredient for Procrit, but instead, contained only bacteria-tainted water. In early June 2003 all three defendants plead guilty to criminal charges in the Southern District of Florida. The defendants face up to 10 years in prison and a $250,000 fine.

Lipitor Investigation

On May 23, 2003, FDA issued an alert on a counterfeit version of Pfizer, Inc.'s, prescription drug, Lipitor. The alert warned health care providers and others that three lots of counterfeit Lipitor represent a potentially significant risk to consumers. One in five people have high cholesterol that may lead to cardiovascular disease, such as heart disease and stroke. According to the American Heart Association (AHA), every 33 seconds, someone in the U.S. dies from cardiovascular disease. (Source: AHA 2002 Heart and Stroke Statistical Update) Lipitor is the number one prescribed cholesterol-lowering medication, and is currently used by more than 18 million people. Lipitor is proven to lower total cholesterol and decrease the risk of developing cardiovascular disease. FDA investigators have aggressively pursued a variety of leads all along the supply and distribution chain in an effort to identify the source of this counterfeit activity.

In conjunction with the manufacturer of this product, FDA published a list of lot numbers to identify the counterfeit product. We urged health care providers and patients alike to check the packaging very carefully before using this product. Patients who have any of the product (labeled as "Repackaged by MED-PRO, Inc.") with the specified lot numbers were told not to consume it, and to return the product to their pharmacies. On June 3, 2003, FDA announced that its continuing investigation of counterfeit Lipitor identified additional counterfeit quantities of the cholesterol-lowering product. The investigation is ongoing.

FDA's advice to health care providers and consumers remained the same as when the Agency issued its original alert on counterfeit Lipitor. They should check the packaging very carefully before using Lipitor. Patients who have any of the product with any of the lot numbers we identified should not take it, and they should return the product to their pharmacies. We want to reemphasize this warning today.

As part of the FDA's ongoing efforts to investigate and respond to unscrupulous counterfeiting activities, FDA's OCI is investigating this case of counterfeit Lipitor in carrying out its public health mission. FDA regularly conducts investigations and testing to identify and remove from the market products that are counterfeit, have been tampered with, or are otherwise unsuitable.

FDA is working closely with the individual states and with health professionals, particularly pharmacists and pharmacy associations, to alert them to this counterfeit product. Many patients taking Lipitor do not receive it in the 90-tablet bottles, but pharmacists provide it in smaller quantities, which do not contain the identifying lot numbers. Patients who are not sure whether they have the tainted product were instructed to check with their pharmacist.

FDA will continue to work closely with Pfizer, Inc., on this counterfeiting problem. FDA supports the activities of legitimate manufacturers to inform the public about counterfeit products and how to identify them. In addition Pfizer, issued its own press release supporting the vigorous enforcement of the law to protect patient safety. The company continues to work closely with FDA and other regulatory authorities to help prevent the importation of counterfeit medicines.

Other counterfeit prescription drug cases in which FDA has had a central role include:

- *Serostim (somatropin (rDNA origin)) for injection*—In late 2000 and early 2001, FDA became aware of consumer complaints about adverse effects and a recall was initiated at the distributor level for Serostim, a growth hormone often used to treat AIDS wasting. After further investigation by the manufacturer, Serono,

Inc., and FDA, Serono issued press releases regarding the apparent counterfeiting of two lots of the product. In May 2002, Serono became aware that counterfeit Serostim displaying a fake lot number again had been distributed. Laboratory analysis by FDA showed that the product contained no active ingredient, and that the product did not originate from Serono.

- *Neupogen (filgrastim) for injection*—In the spring of 2001, based on observations by a distributor about the appearance of Neupogen, a colony stimulating factor used mostly in cancer patients, the manufacturer, Amgen Inc., analyzed a suspect lot and determined that the vials contained only saline solution. Amgen issued Dear Health Care Professional letters nationwide informing patients, physicians, pharmacies and wholesalers about the counterfeiting of Neupogen. The counterfeit product was labeled with fake lot numbers and/or wrong expiration dates.
- *Epogen (epoetin alfa) for injection*—In May 2002, FDA, state regulators and the manufacturer, Amgen Inc., became aware that a potential counterfeit of Epogen was in commerce. The product, Epogen, is used to stimulate red blood cell production in cancer and AIDS patients. Amgen analysis indicated that certain vials of a counterfeit product labeled as Epogen contained active ingredient approximately 20 times lower than expected. Further investigation revealed that a major wholesale distributor was holding approximately 1,600 cartons of counterfeit product. Later that month, Amgen warned health care professionals that two additional counterfeit lots of Epogen had been discovered.
- *Combivir (lamivudine plus zidovudine) tablets*—In the spring of 2002, the manufacturer, GlaxoSmithKline (GSK) received four complaints that bottles containing 60 tablets of Combivir had been replaced with Ziagen tablets. In addition, the firm determined that counterfeit Combivir labels had been placed on authentic bottles of Ziagen tablets, a different GSK product with a label containing a black box warning about the dangers of possible fatal hypersensitive reactions to Ziagen. A black box warning placed at the beginning of an FDA-approved lable is the strongest warning to prescribing physicians, health care professionals and consumers, that severe adverse reactions have been experienced from use of the product. Both Combivir and Ziagen can be used as part of a combination regimen to treat HIV infection. The concern in this case was that if an individual were to take the wrong tablet and is sensitive to Ziagen, a potentially life-threatening hypersensitivity reaction could occur. In May 2002 distributors were advised to initiate a recall to their customers.
- *Zyprexa (olanzapine) tablets*—In the winter and spring of 2002, bottles of Zyprexa, an Eli Lilly and Company product, indicated for the treatment of schizophrenia and acute bipolar mania, had been emptied and replaced with white tablets labeled as aspirin. The tampering situations occurred in two strengths and in three different lots. In May 2002 Lilly issued a press release and Dear Health Care Professional letter concerning the tampering situation.

OVERVIEW OF FDA'S IMPORT PROGRAM

FDA Import Regulations

Pursuant to the FD&C Act, FDA is responsible for the safety and effectiveness of domestic and imported pharmaceuticals. Section 801 of the FD&C Act gives FDA, in conjunction with BCBP, authority for regulating the importation of drugs and certain other products. This includes the authority to refuse admission of any article that appears to be in violation of the FD&C Act.

Under Section 801(a) of the FD&C Act, a drug is subject to refusal of admission into the U.S. if it appears that it: 1) has been manufactured, processed or packed under unsanitary conditions, 2) is forbidden or restricted for sale in the country in which it was produced or from which it was exported, or 3) is adulterated, misbranded or in violation of section 505 of the FD&C Act, which relates to new drugs. To determine whether a product is in compliance, FDA may collect an analytical or documentary sample from the shipment for evaluation, and the shipment is held until the results of the examination are known. If it appears that the article may be subject to refusal, FDA gives the importer a written notice and an opportunity to present testimony, either verbally or in writing, to overcome the appearance of the violation. Alternately, the importer may request permission to bring the article into compliance. If FDA denies the request to recondition the article and the article is refused admission, it must either be re-exported or destroyed.

Import Alerts

FDA's ORA, Division of Import Operations issues import alerts to inform staff about problems, such as with specific commodities or shippers. Because they are dis-

seminated Agency-wide and are shared with other agencies, import alerts help ensure that FDA's regulation of imports is uniform and effective. As with all regulatory guidance, they are subject to the Agency's good guidance practices regulation and must have management concurrence before they are implemented.

Detention Without Physical Examination

In some instances, a product may be detained as soon as it is offered for entry into the U.S. This procedure is the administrative act of detaining a product without physical examination and is based on past history and/or other information indicating the product may violate the FD&C Act. A product may be subject to an import alert recommending detention without physical examination until FDA has new information indicating such action is no longer warranted.

Guidance to ORA Field Staff

FDA's ORA provides guidance to FDA field personnel giving them detailed policies and procedures for processing imported products, including imported prescription drugs. In addition to import alerts, the principal guidance documents are the Investigations Operations Manual, Chapter 6, and the FDA Regulatory Procedures Manual (RPM), Chapter 9.

Because the volume and types of imported products varies by FDA district—one district may receive a large percentage of drugs, while another may receive mostly food products—many districts also have standard operation procedures tailored to their unique workload. All of FDA's import organizations, however, are required to handle and process all FDA-regulated products offered for import. The Agency's field work, therefore, is quite varied and does not focus solely on drugs.

Importation of Prescription Drugs

All imported drugs are required to meet the same standards as domestic drugs, and thus must not be unapproved, misbranded, or adulterated. All imported drugs are required to meet the same standards as domestic drugs. Drugs imported by individuals that are unapproved, misbranded, or adulterated, are prohibited. This includes drugs that are foreign versions of FDA-approved medications, and drugs that are dispensed without a prescription. As stated previously, under the FD&C Act, FDA-approved drugs that are manufactured in the U.S. and exported may not be imported by anyone other than the manufacturer.

At mail facilities, BCBP officials identify parcels that should be brought to FDA's attention. BCBP places these packages in a secure location that they maintain for FDA and other agencies. As with all imports, if it appears that the product may be subject to refusal, FDA will issue a notice to detain the product and provide the owner or consignee an opportunity to respond. Due to these requirements and the volume of regulated products imported by mail, 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 while a notice, opportunity to respond, and Agency decision are pending.

FDA Personal Importation Policy

Under FDA's personal importation policy, as described in guidance to the Agency's field personnel, FDA staff 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 U.S.

The current personal importation policy permits the exercise of FDA's enforcement discretion to allow entry of an unapproved prescription drug 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 to the patient.
- 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.
- The individual seeking to import the product affirms in writing that it is for the patients 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 BCBP and FDA inspectors, and even health care practitioners, in identifying a medicine simply by its appearance or its labeling, which may nonetheless falsely identify a product. From a practical standpoint, FDA inspectors cannot always visually examine drug products contained in a mailed parcel and accurately determine their content, identity or the degree of risk posed to the individual who will receive these drugs. Also, largely because of the advent of Internet sites selling prescription drugs from all points around the globe, the volume of parcels containing prescription drugs has increased dramatically. This increase in volume presents a significant challenge for BCBP and FDA. However, in order to respond to this growing concern, utilizing a risk-based approach, the Agency has deployed its limited enforcement resources across competing priorities, across field offices, and across regulatory product categories to protect the public health from unapproved products that pose the most significant potential public health concern. These enforcement activities are described in more detail below.

FDA IMPORT ENFORCEMENT EFFORTS TO PROTECT PUBLIC HEALTH

FDA has conducted numerous investigations and enforcement activities of imported products. The Agency has taken action when it believes imported products, including prescription drugs, pose a significant public health risk. FDA takes regulatory action in the import arena, which covers a wide range of products including foods, drugs, medical devices, human and animal drugs and biological products. If a situation appears to involve criminal activity, FDA's ORA has the option of referring the information to the Agency's OCI.

FDA has a number of enforcement tools that can be used to regulate imported products. These include: 1) warning letters, 2) recalls, 3) seizures, 4) injunctions, or 5) prosecution. FDA may issue a warning letter in a number of scenarios including when: 1) a party fails to hold its entry intact before FDA releases it, 2) a party consistently imports in violation of the FD&C Act, or 3) an importer presents misleading information, or 4) FDA informs an importer that the Agency has requested that BCBP deny immediate delivery privileges.

FDA also may ask a firm to voluntarily recall an imported product if FDA deems it a potential health hazard or if there is some evidence of distribution of detained or refused merchandise. FDA may opt to seize a product if it: 1) represents a health hazard and has been or is likely to be distributed following detention or refusal, 2) has been previously refused, or 3) has been identified fraudulently in documents submitted to FDA.

Injunction may become the action of choice when FDA sees a pattern of violations with some recognizable danger of reoccurrence. This is a judicial action that may result in quicker corrective action than a prosecution, and, if successful, it legally enjoins the defendants from continuing to violate the law. Prosecution may be used when conventional import enforcement approaches are determined inadequate to correct violations or the violation is sufficiently egregious to warrant punishment. Prosecution may be warranted when there is: 1) continued illegal distribution after receipt of a notification of detention, 2) submission of false or misleading entry documents, 3) repeated entry of previously refused products, or 4) evidence of fraud.

None of the potential actions described above are mutually exclusive. In some cases, FDA may take complementary steps that involve a combination of these actions in order to protect the public health from drugs that violate the FD&C Act. Evidence of this type of mix of regulatory actions can be seen in FDA's ongoing work on the counterfeit Lipitor matter.

Many imported prescription drugs that are arriving at mail facilities are ordered over the Internet. FDA has increased its capability to monitor the Internet and identify sites that potentially violate the FD&C Act, through the use of various search tools and by upgrading its data handling capabilities. In some cases the Agency will conduct exercises to better understand the products that are coming in through specific ports-of-entry. The Agency is currently conducting such exercises at two FDA import locations. These actions help the Agency to better understand the type and extent of unlawful conduct on the Internet and to more accurately assess whether its enforcement efforts have had an impact on illegal behavior.

Miami Enforcement Successes

FDA has had numerous enforcement successes on prescription drug import cases. One such example that is worth noting is a Miami broker, Eagle Global Logistics that continued to improperly import FDA regulated medical device, pharmaceutical,

and radiation emitting products after being advised of reporting errors. The broker had a 22 percent error rate, and working with BCBP, the broker was assessed penalties of $30,000 for failing to exercise responsible supervision and control.

Florida District's Miami Import Office recommended penalties to be assessed against Catalysis Corporation, an importer and broker that continued to declare over-the-counter drugs as cosmetics despite FDA efforts to counsel the company. BCBP approved a $46,000 penalty against the importer for aiding illegal importation under Title 19, *United States Code* 1595a(b). Actions seeking additional penalties are pending.

Other ORA Enforcement Successes

AstraZeneca

On June 20, 2003, officials from FDA's OCI joined with representatives of the U.S. Attorney's Office for the District of Delaware, the Department of Health and Human Services (DHHS), and the Defense Criminal Investigative Service (DCIS) to announce that AstraZeneca Pharmaceuticals LP had pleaded guilty to a large-scale health care crime. The firm agreed to pay $355 million to resolve the associated criminal charges and civil liabilities. The massive conspiracy involved illegitimate pricing and marketing of Zoladex, an AstraZeneca drug for the treatment of prostate cancer. The various schemes used by the firm caused multimillion-dollar losses to Federally and state-funded insurance programs and individual patients.

FDA's OCI began investigating AstraZenecas pricing and marketing practices after a private individual filed a civil False Claims Act suit. The broadly-based investigation, which also involved the Office of the Inspector General for the DHHS, the DCIS and the Federal Bureau of Investigation, discovered that AstraZeneca employees were using several illegal methods to stimulate the demand for Zoladex by enabling prescribers to reap illicit profits.

The agreement included the following provisions:

AstraZeneca pleaded guilty to criminal conspiracy to violate the Prescription Drug Marketing Act by causing Medicare, Medicaid and other Federal providers to be overcharged for Zoladex that had been provided as free samples to urologists. As part of the plea agreement, the company agreed to pay a $63,872,156 criminal fine.

- AstraZeneca also agreed to settle its civil liabilities and to resolve allegations that its fraudulent drug pricing schemes, and sales and marketing misconduct had caused false and fraudulent claims to be filed with Federal and state health care programs.
- AstraZeneca agreed to payments of $266,127,844 to the U.S. government for claims filed with the Medicare, TriCare, Department of Defense and Railroad Retirement Board Medicare programs, and $24,900,000 to the U.S. and state governments for claims involving state Medicaid programs.

The investigation, which is continuing, also resulted in charges against three physicians for conspiring with AstraZeneca to bill patients and third party payers for free Zoladex samples. Two of the prescribers have pleaded guilty.

Procrit

As previously stated, on May 21, 2003, the U.S. Attorney's Office for the Southern District of Florida filed charges against Eddy Gorrin, William Chavez and Duviel Gonzalez for unlawful sale and wholesale distribution of counterfeit versions of the prescription drug Procrit. In early June 2003 all three defendants plead guilty to criminal charges in the Southern District of Florida. The defendants face up to 10 years in prison and a $250,000 fine for these actions.

Lipitor

FDA's ORA is conducting a significant investigation to respond to unscrupulous counterfeiting activities involving Lipitor. FDA is conducting this activity in close cooperation with health professionals, particularly pharmacists and pharmacy associations and has issued statements to alert the public about this counterfeit product.

Kwikmed

On October 1, 2002, a Federal Grand Jury in Arizona returned a 198 count indictment against Kwikmed, Inc., Cymedic Health Group, Inc., four owners of these corporations, and two physicians associated with the corporations. The indictment alleges that defendants operated Internet websites, two of which include kwikmed.com and cymedic.com, through which they sold prescription drugs, including Viagra, Celebrex, Xenial, and Propecia. The websites did not require a consumer to have a prescription before receiving the drugs. Instead, the customers were required to complete a questionnaire, which the website told customers would be reviewed by a physician.

Customers were charged a fee for this purported medical consultation. The indictment alleges that in the overwhelming majority of applications, no medical reviews, consultations, or physical examinations by a physician took place before drugs were shipped to customers. Defendants repackaged drugs obtained from a drug wholesaler, even though defendants were not a registered manufacturer or a licensed pharmacy and there was never a licensed pharmacist involved. The drugs dispensed were adulterated because of the defendants failure to follow cGMP in packaging, holding, and labeling of the drugs.

The indictment alleges that during the course of the conspiracy the defendants and others generated sales in excess of $28 million, which was billed to consumers as charges for prescription drugs, doctor consultations, and shipping. These sales resulted from the defendants distribution of at least 48,816 new orders for prescription drugs and 41,817 refills of those orders. The indictment charges defendants with several violations of the FD&C Act, as well as conspiracy, mail fraud, and money laundering. The charges were the result of an investigation by FDA and the U.S. Postal Inspection Service.

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 an online pharmacy that illegally sold prescription drugs over the Internet to consumers. On June 18, Pusztai and Yates were sentenced respectively to more than 15 and 6.5 years. 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 Mens Clinic, and related sites, that sold a variety of prescription medications.

In September 1999, OCI received information regarding the Norfolk Mens 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 and business records. Based on these purchases and information gathered through 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 misbranded drugs. The company also plead guilty 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 been manufactured in New Zealand for distribution in Australia.

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 2 years in prison. The case was initiated on information received from BCBP concerning an Internet website called Medications Express. Bevins sold Mexican prescription pharmaceuticals from this website and claimed that a doctor's prescription was not necessary. He continued to sell Mexican prescription pharmaceuticals through the mail from Sun City, California, even after discontinuing the Medications Express website. 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.

Dagoberto Paz-Tamez diet drug case

This case involved the sale of unlabeled/adulterated diet drugs in Pasadena, Texas by an alleged medical doctor from Mexico. The alleged doctor, Dagoberto Paz-Tamez, is not licensed to practice medicine in the state of Texas or anywhere else within the U.S. This case was assembled in conjunction with the Harris County Precinct 6 Constable's Office, the Texas Department of Public Safety (DPS), and the U.S. Postal Inspection Service.

Investigation revealed that Paz-Tamez had been selling unlabeled diet pills to patients for several years in the Pasadena, Texas area. A sample of the diet pills was submitted to the Harris County Precinct 6 Constable's Office by a confidential informant. These samples were later submitted to FDA's Forensic Chemistry Center and were found to contain amphetamines and other dangerous substances.

On August 22, 2002, Paz-Tamez was arrested in Pasadena, Texas. Diet drugs and U.S. currency were seized consisting of the following: $10,236 in U.S. currency, 4,350 tablets, 30,488 gelatin capsules, and 44.5 pounds total weight of unlabeled diet drugs. The diet pills and tablets seized were found to contain mazindol (an amphetamine discontinued in the U.S.), diethylpropion (an amphetamine), diazepam (generic for Valium), and hydrochlorothiazide (a diuretic).

On March 16, 2002, Paz-Tamez was convicted of Possession of a Controlled Substance and Delivery of a Dangerous Drug. He was later sentenced to ten years of deferred probation.

FLORIDA DISTRICTS MIAMI IMPORT OFFICE

FDA's Florida District Office (FLA-DO) import operations are strategically located throughout the district with the largest operation in Miami, Florida. Their work assignments encompass all of FDA's regulated products and are not limited to pharmaceutical products. Miami is the largest port-of-entry for fresh seafood in the U.S. It is also one of the main ports in the U.S. for fresh produce. Moreover, Miami is the major distribution point for Latin American electronics, device, and drug products.

Consequently, the Miami Import Office is responsible for a very dynamic and busy port that handles a large volume and variety of imported products.

One of the busiest locations for the Miami Import Office is the Miami International Mail Facility. The import activities at the mail facility that focus on imported pharmaceutical products are a top priority for the district office. They do this by examining products at the Miami International Mail Facility including commercial drug shipments, large parcels shipped to individual consignees and parcels that are suspected to contain counterfeit or unapproved drugs. The FLA-DO and the Miami Import Office work in collaboration with the BCBP, and use a team approach to work on commercial entries and the review of import-export documents. This collaboration has a history of regulatory and enforcement success against problematic importers and brokers, and during 2002 this collaboration led to the collection of ten fines, the conducting of ten seizures and the initiation of 268 penalty cases. Most of the seizures were related to medical devices, and drugs.

Organizational Structure of the Florida Districts Miami Import Office

Florida District's Import Operations oversees all import activities and import personnel throughout the Florida District. An Import Program Manager (IPM) reports to the Director of Investigations in the FLA-DO, who reports to the Florida District Director. The District's Compliance Branch also provides some assistance to Florida District's Import Operations. The import operation has 38 field employees, 33 of whom are in Miami. These 38 employees include the IPM, 2 supervisory consumer safety officers, 4 compliance officers, 1 consumer safety technician, 2 students, 2 legal instruments examiners, 9 consumer safety inspectors, and 17 consumer safety officers.

Joint FDA Import Group/BCBP Initiatives

For many years, the FLA-DO has had an excellent working relationship with BCBP. This working relationship has led to many innovations and improvements in how FDA and BCBP handle imported FDA-regulated products.

The Miami Import Office has worked with BCBP to develop a joint FDA/BCBP team called "Team 488." This team has created a Work Agreement and Standard Operating Procedures for processing joint regulatory and enforcement actions. Its purpose is to increase cooperation and enhance compliance of imported products. As a result of the work of this team, the Agency has achieved increased detection of substituted products and reduced erroneous declarations.

In addition, the Miami Import Office is in the process of implementing a new data system to store and review electronic data from private laboratories for products detained without physical examination and to store information regarding the inspection of private laboratories. Private laboratory analytical package review has customarily been conducted by transmitting hard copy reports and certificates from the private laboratory to FDA import groups responsible for detentions without physical examination. This pilot program is designed to expedite the import process, promote a paperless system, and better protect the public health.

In addition, there has been an increase in FDA/BCBP cooperation regarding:

- The collection and handling of liquidated damages claims.
- The detection of substituted products at the time of sampling and at the time of destruction.
- The collection of civil money penalties for the substitution and destruction of refused goods.

- The ability to ensure compliance among importers for exporting and destroying refused goods.

This working relationship also has led to many awards for the FLA-DO including the Hammer Award for reinventing government. Despite the strong role that FLA-DO has played and continues to play in protecting the public health, recent events have caused the Agency to conduct an internal review of the Florida District's Import Operations.

Recent Developments Regarding FDA's Miami Import Office

As discussed above, the Miami Import Office is responsible for conducting a large percentage of the Florida Districts varied import assignments. Recently, FDA advised the Energy and Commerce Committee and the American public of irregularities related to its handling of a large shipment of unapproved Viagra apparently from Belize. Through a series of procedural irregularities, foreign versions of Viagra were detained and subsequently released by FDA to consumers. FDA is conducting an ongoing internal review of these events and is taking steps to ensure that these mistakes do not occur in the future.

The Circumstances Surrounding the Discovered Irregularities

As we discussed earlier in this testimony, under the FD&C Act, unapproved, misbranded, and adulterated drugs are prohibited from importation into the U.S. and may be subject to detention. If the Agency detains a drug that is in violation of section 801 of the FD&C Act, its implementing regulations require the Agency to issue a notice of detention to the products owner or consignee and offer an opportunity for a hearing before it can refuse admission of the product into U.S. commerce. In the case of the 1,233 packages of unapproved "generic Viagra", the Agency issued a single notice of detention to BCBP, and BCBP was incorrectly designated as the consignee for the products. This was done despite the fact that the products were destined to multiple owners. After detaining the product in this manner, FDA directed BCBP to release the unapproved "generic Viagra." After the products were released by FDA, the Agency sent a letter to each consumer who received these unapproved foreign versions of Viagra, alerting them to the fact that such products are unapproved drugs under the FD&C Act and that the Agency cannot provide any assurance of quality, safety, or effectiveness for these products. The details regarding this detention and the subsequent release of the unapproved Viagra were provided to the Committee in our response to Chairman Tauzins June 5, 2003, letter.

The Agency's Internal Review

These irregularities in the Agency's administration of the Act, its regulations and FDA internal procedures led the Agency to initiate an internal review into how Miamis Import Office handles the detention of pharmaceutical shipments at the Miami International Mail Facility. The internal review is continuing. Nonetheless, the Agency acknowledges that administrative mistakes were made. As of this date, the Agency has taken several actions to rectify the situation and we expect to make additional improvements in the future. We believe that these FDA short-term and mid-term steps will strengthen our Miami Import Office operations.

Next Steps Based on the Agency's Ongoing Internal Review

In the wake of the discovery of these administrative mistakes, Florida District managers have undertaken several steps to ensure that import detentions are handled properly in the future. *First,* Florida District (the District) managers held an all-hands meeting with the personnel at the Miami Import Office where they discussed the circumstances surrounding the detention of the unapproved "generic Viagra." At this all-hands meeting, the District managers also conducted training on section 801 of the FD&C Act and the regulation and procedures that govern the proper handling of an import detention. The managers reemphasized the importance of properly reviewing records and making regulatory decisions in accordance with Agency policy. *Second,* in addition to reminding compliance personnel that documents must be reviewed carefully before making regulatory decisions, the District implemented new requirements regarding the initialing and dating of mail entry reports so that District personnel can more easily determine what records have been reviewed and whether they have been reviewed properly. *Third,* the District is drafting new standard operating procedures for the handling of mail entries. *Fourth,* the District acknowledged its mistake to the BCBP supervisor at the Miami mail facility regarding the improper handling of the detention of the unapproved Viagra shipment. *Fifth,* the District is going to be conducting bi-weekly meetings with the BCBP Assistant Port Director for Miami or her representative in order to strengthen the Miami Import office's relationship with its partners. *Sixth,* the District will meet with the BCBP supervisor at the Miami mail facility on a monthly basis in

order to enhance our working relationship with BCBP. *Seventh,* the District will provide BCBP with hard copies of all of the Import Alerts that the Agency issues. *Eighth,* the District will review its Import Operations Quality Assurance Audit plan and determine the type of specific changes that are in order. *Ninth,* the Regioal and District management will review several proposals that focus on improving the management structure and the supervisory ratio in the Miami Import office so that there is greater management oversight.

In addition to these measures, Howard Lewis has been assigned, on an indefinite basis, as the Florida District's IPM. Mr. Lewis is from FDA's New Orleans District and he has a strong compliance background and a wealth of knowledge on domestic and import compliance issues. These strengths will allow him to identify additional improvements that will strengthen the Miami Import Offices role in protecting the public health. The steps noted above are designed to ensure that the Miami Import Office is working at an optimal level and that product will be detained properly in the future. In addition to the continuing improvements in Miami, FDA is focused on making improvements to all of its import operations that will enhance the Agency's management of its import operations and its ability to protect the public despite the increasing volume of imported products.

Strategic Planning

In order to target its limited import resources more efficiently as part of a risk-based import surveillance system, the Agency also is developing Agency-wide strategies and action items that are meant to protect the public health by decreasing the risk that unsafe, ineffective, or violative products will enter U.S. commerce through our borders, ports and other import hubs. To achieve the most cost-effective approach to managing import risks, theses strategies and action items focus on building a foundation that will allow the Agency to engage in a more rigorous analysis of risks and apply this approach to all phases of the full import life cycle.

In the Risk Management Goal contained within the Commissioners Strategic Action Plan there are several action items that will help FDA achieve this goal. These action items include:

- The development of procedures for implementing Center policies to reduce import examination rates for articles imported from foreign facilities where inspections demonstrate substantial compliance with manufacturing, processing, or sanitation quality and safety principles.
- The development of an information-sharing Memorandum of Understanding with at least one other country concerning product safety, quality and/or security issues.
- The development of a strategic integrated WorkPlan for field import activities that is uniformly managed, planned, evaluated, and supported/resourced by all of FDA's Centers.
- The revision of Compliance Program Guidance Manuals (CPGMs) and the Regulatory Procedures Manual (RPM) to incorporate import policies and guidance to improve efficiency and effectiveness of FDA's use of Import Alerts and Detention Without Physical Examination.
- The modification of CPGMs, the RPM, Compliance Policy Guides (CPGs), the Investigations Operations Manual (IOM), and Establishment Inspection Report formats so that during domestic inspections inspectors examine, report, and track counterfeit imported products, returned imported products, rejected imported products, and compliance files concerning imported products.
- The exploration of the development of Risk Assessment Predictive Approaches that capture and repurpose risk information for use in import entry screening and enhanced targeting of import operations and resources.
- The creation of a closed docket to gather information on technologies being implemented by industry to ensure proper shipping conditions (time-temperature indicators) and the integrity (anti-counterfeiting and anti-tampering) of human drug products and shipments while in international distribution and shipping routes.

FDA believes that as each of these strategies and action items is completed, it will have an impact on the Agency's import operations and they will improve the Agency's ability to protect the public health by decreasing the risk that unsafe or ineffective FDA-regulated products will enter U.S. commerce through our borders and ports.

Improvements to FDA's Import Compliance Program

FDA is reevaluating, refining, and improving the programs and procedures that it is using to ensure the availability of safe and effective drugs to U.S. consumers. As part of our efforts to improve the programs and procedures that are used to en-

sure the availability of safe and effective drugs to U.S. consumers, FDA is considering several concepts that will improve the Agency's ability to target resources applied to regulation of imported drug products. As with all of FDA's activities, priorities are established based on benefit/risk to public health. In terms of prioritizing the Agency's domestic and import compliance workload, products that present a direct health hazard to the user are FDA's highest priority. Such products include those that have a reasonable potential for causing direct serious adverse effects, or where there is documentation of injury or death. Examples of such products include counterfeit Procrit and counterfeit Serostim. Products that are not themselves hazardous can still present an indirect health hazard in that the consumer may delay or forgo proven medical treatment and the use of approved therapies. These are also a top priority for the Agency. Examples include unapproved products that are promoted for the treatment of cancer, Alzheimers disease, arthritis, heart disease, high cholesterol and high blood pressure.

DRUG COST INITIATIVES

The Administration also currently is engaged in a number of initiatives to reduce the costs of prescription medications. These actions will result in more affordable prescription drugs and will reduce the incentive to look to foreign sources for cheaper medications.

New Medicare Drug Benefit

The President is working with Congress on legislation this year to bring more choices and better benefits to the Medicare system. The President has committed up to $400 billion over the next ten years to pay for modernizing and improving the Medicare system. An essential component of this legislation is a prescription drug benefit, which will make medicines more affordable for senior citizens.

New Rule on Generic Drugs

On June 18, 2003, FDA published its final rule to lower prescription drug costs for millions of Americans by improving access to generic drugs. These changes are expected to save Americans over $35 billion in drug costs over the next 10 years. FDA's final rule provides the generic industry with enhanced predictability and certainty, while avoiding unnecessary and lengthy litigation, preserving intellectual property protections and protecting the process of developing new breakthrough drugs. Specifically, the proposed rule would allow only one 30-month stay for each generic drug application, clarify that certain patents cannot be listed, and improve the declaration that innovators must make about patents they submit to FDA for listing in the Agency's Orange Book publication that lists all drug products approved under section 505 of the FD&C Act.

New Funding

The Presidents 2004 budget proposes an unprecedented increase of $13 million in spending for FDA's generic drug program. This will be the largest infusion of resources into the generic drug program in history, increasing the programs size by about one-third. The proposed increase in FDA's generic drug budget will allow FDA to hire 40 experts to review generic drug applications more quickly and initiate targeted research to expand the range of generic drugs available to consumers. The improvements in the efficiency of review procedures are expected to save consumers billions more by generally reducing the time for approving new generic drugs.

New Education Outreach and Scientific Study

FDA will expand its educational programs and partnerships involving generic drugs to help health care practitioners and consumers get accurate information about the availability of generic drugs for their health care needs. Further, FDA will undertake additional scientific studies of certain types of generic drugs to improve the approval process.

Bipartisan Approach on Affordable Prescription Drugs

Last week, the Senate voted in favor of bipartisan legislation sponsored by Senators Gregg and Schumer that would complement FDA's rule by providing greater access to more affordable generic drugs. The Senate bill would codify elements of FDA's final rule and adds a provision limiting 180-day exclusivity to accelerate generic competition in the marketplace.

New Drug Development

FDA is taking steps to support market competition as a means of addressing the cost of developing and manufacturing drugs, and the availability of generic drug alternatives. Two new FDA initiatives in the Commissioners Strategic Action Plan ad-

dress important factors affecting the cost of new drug development and the cost of drug manufacturing.

New drug development presents uncertainties that increase the business risk and costs to the innovator. Higher costs can create barriers to competition for new drugs and new innovators—those companies that don't have access to the capital available to more established drug companies. Although some scientific and technical uncertainties are inherent and unavoidable in drug innovation, others can be reduced or eliminated. Such reductions will help speed patient access to new drugs and reduce the cost of drug development. FDA has begun major initiatives to reduce some of those sources of uncertainty. For example, sponsors may be uncertain about what specific evidence is required to demonstrate safety and effectiveness for a given disease. As a result, they may continue research with a drug that will not lead to the required evidence.

FDA has identified several priority disease areas and new technologies that the Agency believes are good candidates for new work to clarify regulatory pathways and clinical endpoints. The targeted disease areas include cancer, diabetes and obesity. The targeted technologies include cell and gene therapy, pharmacogenomics and novel drug delivery systems.

A planned formal guidance for industry will help to minimize guesswork and improve the design of clinical trials. This will benefit participating patients and allow more cost-effective use of Research and Development funds. FDA also is taking steps to identify and address the root causes of avoidable delays in new drug review through retrospective analysis, better review management and prospective evaluation of our review process from the perspective of both FDA and drug innovators.

CONCLUSION

The standards for drug review and approval in the U.S. are the best in the world, and the safety of our drug supply mirrors these high standards. The employees of FDA constantly strive to maintain these high standards. However, a growing number of Americans are obtaining prescription medications from foreign sources. U.S. consumers often seek out Canadian suppliers, sources that purport to be Canadian, or other foreign sources that they believe to be reliable. While some foreign drug manufacturers submit their products to FDA for approval, the imported drugs arriving through the mail, through private express couriers, or by passengers arriving at ports of entry are often unapproved new drugs that may not be subject to any reliable regulatory oversight. FDA cannot assure the safety of drugs purchased from such sources.

The vigilance of FDA and BCBP inspectors is an important tool in detecting imported products that violate the FD&C Act. Given the available resources and competing priorities facing these agencies, however, experience shows that inspectors are unable to visually examine many of the parcels containing prescription drug products that arrive through the mail and private courier services each day. Many of the packages that the Agency is able to examine appear to contain foreign versions of U.S.-approved products. The growing volume of unapproved imported drugs, which often are generated from sales via the Internet, presents a formidable enforcement challenge. As a consequence, the Agency must employ a risk-based enforcement strategy to deploy our existing enforcement resources in the face of multiple priorities, including homeland security, food safety and counterfeit drugs. In sum, at this time the Agency cannot assure the American public that drugs purchased from foreign sources are the same as products approved by FDA, or that they are safe and effective. The Agency acknowledges the concerns raised by the Committee regarding recent problems with enforcement in the Miami field operations and has already undertaken several actions designed to address the specific issues that were cited. The Agency looks forward to continuing to work with the Committee to identify additional solutions to address these pressing concerns. We appreciate and share the Committees interest in assuring that the American public has access to safe and affordable medicines and we look forward to working further with Congress and other concerned parties on this important public health goal.

We would be happy to answer any questions you may have.

Mr. GREENWOOD. Thank you, Mr. Taylor.

Ms. Durant.

TESTIMONY OF ELIZABETH G. DURANT

Ms. DURANT. Mr. Chairman, members of the committee, thank you for this opportunity to testify. Today I would like to discuss

with you the Bureau of Customs and Border Protection efforts to address the ever-increasing trend of personal and bulk importations of pharmaceutical products into the United States.

Although the main focus of the Bureau of Customs and Border Protection is to protect the United States from terrorist attacks, BCBP also enforces over 400 requirements for more than 40 other Federal agencies at U.S. borders. These include the laws that prohibit the importation of illegal or unapproved pharmaceuticals that fall under the jurisdiction of the Food and Drug Administration.

The BCBP is concerned with three ways that pharmaceuticals are imported: those that are purchased through the Internet and shipped through our international mail or express courier facilities; those carried into the United States by individuals transiting our land borders; and bulk shipments of adulterated or counterfeit pharmaceuticals. Millions of packages come through mail and express courier facilities every year. Thousands of packages, particularly in the mail, are found to contain illegal and unapproved pharmaceuticals. We also estimate that 10 million people cross the land border annually carrying the same unapproved products. A disturbing trend is the increase in bulk shipments through the mail indicating that these products could be making their way to pharmacy shelves.

Detecting prohibited pharmaceuticals among the tens of millions of parcels passing through our facilities each year presents a massive challenge. Our limited resources require a risk management approach, with which we utilize advance intelligence, records of past seizures, and other factors to locate packages that present the most significant threat.

We work in cooperation with the FDA on this important function. Our laboratories help us find discrepancies in shipments of bulk and finished pharmaceuticals. FDA establishes effective national standards for the interdiction of pharmaceuticals subject to FDA laws.

Based on an operation nicknamed "Operation Safeguard" that we have carried out over the last couple of years, we have found the volume of pharmaceuticals shipped through international mail to be enormous. We have also found that a significant number of these do not contain an active pharmaceutical ingredient, but merely contain substances such as starch or sugar. Other problems include expired materials, unapproved products, improper usage instructions, and products made in facilities not under proper regulation. The vast majority of the pharmaceuticals that enter the U.S. via the mail do so in a manner that violates present FDA or other requirements.

Additionally, we have found that many parcels contained different types of pharmaceuticals that, if taken simultaneously, could cause dangerous interactions. Individuals not under the direct supervision of a physician could easily purchase these products. Thus, we cannot assume that these products would be used properly. It is important to note that after 3 weeks of one phase of Operation Safeguard, the quantity of illegal and defective pharmaceutical shipments slowed significantly.

During a phase of Operation Safeguard that took place at two international mail branches, 31 parcels containing 52 different

types of questionable pharmaceuticals underwent intensive chemical analysis. The analyses of these products showed that 8 of the so-called pharmaceuticals or 14 percent contained no identifiable active ingredient and 40 percent contained a substance that is regulated under the Federal Controlled Substance Act. Additionally, during this phase of the operation it was found that large parcels of fake or gray market pharmaceuticals are being split into different mail shipments but arrive at the same address. Accordingly, there is a possibility that State side pharmaceutical distributors could be using these products as a source of supply.

This summer, the Bureau of Customs and Border Protection intends to conduct "blitz" operations at four international mail branches. Our scientists will work with inspectors to target, examine, and test packages containing pharmaceuticals. This operation will enable us to evaluate the type, volume and quality of imported medication.

It is clear that this remains an overwhelming problem and we are working cooperatively with the FDA to improve our enforcement efforts in this area including efforts to address the immediate return of imported pharmaceuticals and travelers who attempt to import pharmaceuticals upon their return to the U.S.

From an overall perspective, a spiraling volume of goods at our borders has put immense pressure on our ability to enforce the Nation's laws while facilitating international trade and protecting the borders against the threat of terrorism. Although we have taken some positive steps, successfully identifying and handling imported pharmaceuticals presents a daunting challenge for us.

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

Thank you, Mr. Chairman.

[The prepared statement of Elizabeth G. Durant follows:]

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

Mr. Chairman, members of the Committee, thank you for this opportunity to testify. I am Elizabeth Durant, Executive Director of Trade Compliance and Facilitation at the Bureau of Customs and Border Protection (BCBP). Today I would like to discuss with you BCBP efforts to address the ever-increasing trend of personal and bulk importation of pharmaceutical products into the United States.

Although the main focus of the BCBP is to protect the United States from terrorist attacks, BCBP also enforces over 400 requirements for more than 40 other federal agencies at U.S. borders. These include the laws that prohibit the importation of illegal or unapproved pharmaceuticals that fall under the jurisdiction of the Food and Drug Administration, or FDA.

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

Millions of packages come through mail and express courier facilities every year. Thousands of packages, particularly in the mail, are found to contain illegal and unapproved pharmaceuticals. We also estimate that 10 million people cross the land border annually carrying the same unapproved products. A disturbing trend is the

increase in bulk shipments through the mail indicating that these products could be making their way to pharmacy shelves.

Detecting prohibited pharmaceuticals among the tens of millions of parcels passing through our facilities each year presents a massive challenge. Our limited resources require a risk management approach, with which we utilize advance intelligence, records of past seizures, and other factors to locate packages that present the most significant threat.

We work in cooperation with the FDA on this important function. BCBP laboratories help us find discrepancies in shipments of bulk and finished pharmaceuticals. FDA establishes effective national standards for the interdiction of pharmaceuticals subject to FDA laws.

Based on an operation nicknamed "Operation Safeguard" that we have carried out over the last couple of years, we have found the volume of pharmaceuticals shipped through international mail to be enormous. We have also found that a significant number of these do not contain an active pharmaceutical ingredient, but merely contain substances such as starch or sugar. Other problems include expired materials, unapproved products, improper usage instructions, and products made in facilities not under proper regulation. The vast majority of the pharmaceuticals that enter the U.S. via the mail do so in a manner that violates present FDA or other requirements.

Additionally, we have found that many parcels contained different types of pharmaceuticals that, if taken simultaneously, could cause dangerous interactions. Individuals not under the direct supervision of a physician could easily purchase these products. Thus, we cannot assume that these products would be used properly. It is important to note that after three weeks of one phase of Operation Safeguard, the quantity of illegal and defective pharmaceutical shipments slowed significantly.

During a phase of Operation Safeguard that took place at two International Mail Branches, 31 parcels containing 52 different types of questionable pharmaceuticals underwent intensive chemical analysis. The analyses of these products showed that 8 of the so-called pharmaceuticals or 14 percent contained no identifiable active ingredient and 23 (or 40 percent) contained a substance that is regulated under the Federal Controlled Substance Act. Additionally, during this phase of the operation it was found that large parcels of fake or gray market pharmaceuticals are being split into different mail shipments but arrive at the same address. Accordingly, there is a possibility that state side pharmaceutical distributors could be using these products as a source of supply.

This summer, BCBP intends to conduct "blitz" operations at four International Mail Branches. BCBP scientists will work with inspectors to target, examine, and test packages containing pharmaceuticals. This operation will enable BCBP to evaluate the type, volume and quality of imported medication.

It is clear that this remains an overwhelming problem and BCBP is working cooperatively with the FDA to improve our enforcement efforts in this area including efforts to address the immediate return of imported pharmaceuticals and travelers who attempt to import pharmaceuticals upon their return to the U.S.

From an overall perspective, a spiraling volume of goods at our borders has put immense pressure on our ability to enforce the nation's laws while facilitating international trade and protecting the borders against the threat of terrorism. Although we have taken some positive steps, successfully identifying and handling imported pharmaceuticals presents a daunting task for BCBP.

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

Mr. GREENWOOD. Thank you.

And the Chair recognizes himself for 8 minutes for questioning.

Let me start with you, Mr. Hubbard. We have heard of limiting these importations and we heard from Mr. Bass a question about well where is the harm? We see all of the counterfeit drugs, we hear the horror stories about them having no potency. We hear the horror stories about them being tainted and so forth. But where are the deaths, where are the injuries?

It strikes me that, for instance, if you are a cancer patient and you order your drugs over the Internet and those drugs do not have in them the molecules that you need to treat your cancer and you

die from cancer, you are not going to die from necessarily the counterfeit drug, but you may very well die prematurely from the disease or you may not get a cure for a disease and the medical examiner will diagnose the death, attribute the death to the disease not to the drug. Am I right about that? Is that the assumption that you folks at FDA make?

Mr. HUBBARD. You are absolutely right, Mr. Chairman. You would not expect to take these drugs and have an immediate adverse reaction that would cause injury or death. What really is happening, as you say is, patients are not being treated. So the example you gave is correct. And the example of, say, of a person with hypertension whose blood pressure should be lowered 40 points, maybe it is not lowered at all, maybe it is lowered 10 points. And he is not going to know that, but yet he is being injured by taking that subpotent or ineffective drug.

Mr. GREENWOOD. And I would think that that would be the same for a cholesterol control drug?

Mr. HUBBARD. Absolutely.

Mr. GREENWOOD. If you were taking Lipitor, whether it is counterfeit Lipitor or real Lipitor, you probably figure you have got the problem under control. You are not necessarily rushing back to have cholesterol counts taken unless you are very conscientious. And, in fact, your cholesterol may rise, may be doing all kinds of damage to your cardiovascular system and you have no way of knowing it.

Mr. HUBBARD. That is absolutely true. And, of course, in the case of a diabetic or someone with a very serious acute illness, missing a dose or taking an ineffective drug could be, frankly, hazardous in the shorter run.

Mr. GREENWOOD. Now, the intention of this hearing is to reexamine the problem, and we hope to hold and intend to hold another hearing in July to really go at the solutions. But I just want to press you little bit about that. Because we have talked, and I have talked to Mr. McClellan about a risk-based approach.

We know that given 30,000 parcels a day coming into the United States that there are a variety of sources. Some of them are big commercial websites and the product may be coming from Thailand and then through Canada down into the United States. Another possibility may be Aunt Myna sending Aunt Betsy some drugs that she forgot to take with her when she was visiting and so forth. And so there is a whole range of sources and volumes of these drugs.

And so if we do not return every package to sender, including Aunt Myna's package, what do we do, where do we start to look for the highest risk and places where we could clamp down that would have the greatest impact in protecting safety?

Mr. HUBBARD. As you say, we obviously have to focus on the large commercial shipments and the ones that can pose an expanded risk to patients. I will ask Mr. Taylor to expand upon that.

Mr. TAYLOR. Yes. Sure.

Mr. GREENWOOD. Please do.

Mr. TAYLOR. Mr. Chairman, I mean just as a general rule, the two type of products that we would give the highest priority to are those products that lead to affirmative harm to a consumer or in the alternative, there are in some cases, and again as we have al-

luded to today, there are some products that are marketed in a way that might cause a person to decide not to use the unapproved version instead of the approved version this product. So, generally across all our programs, those are the highest priority products that we focus on.

But taking that and actually implementing that requires some additional steps. In the context of imports, we need to take and evaluate information better so that we develop priorities for import detentions. Obviously, as we have discussed today the numbers are so overwhelming that we cannot necessarily detain every product that is violative, but in terms of focusing on those products that pose the greatest harm to the public, I think we need to take steps to develop priorities that really help us decide when we should go ahead and do a detention.

I think we also need to make sure that we are employing resources at the busiest import facilities, whether they be mail facilities, whether they are handling drugs, foods or the other competing priorities that we have to deal with. But I think we need to go back and make sure we are utilizing our limited resources most efficiently.

I think we also need to go back and take stock of where we are and retrain our people regarding those products that we deem compose the greatest risk. And then, obviously, that training needs to be updated as additional information comes to us regarding potential risk.

Mr. GREENWOOD. Let us assume, excuse me for interrupting but time is short. But let us assume that there is a website that purports to be a Canadian source and, in fact, it is established through investigation that the real source may be in India or Thailand or some combination of places, and that the drugs that are coming through there are really consistently substandard or counterfeit, dangerous. Walk me through what we could do about that. How do you go shutdown a facility in another continent and prohibit its materials from coming in? And even if you said this company is called the YXZ company and when we see their packages come in, we will put them off? What seems a pretty simple matter to change your company's name to the ABC company and continue to send the product in.

Mr. TAYLOR. Well, your question certainly underscores some of the challenges in dealing with some of these Internet sites. But walking through the process, what we would do is we would triage the site and try to determine the nature of the products, how many times we have seen these products in the past. We would try to get as much information as we can that we could share with the foreign government where the site resides so that we could try and work with that government to identify those instances where products have been sent from the company so that we have better information that would allow us to interdict those products when they reach our borders.

Obviously, it is challenging because of the volume of products coming from overseas. And the reason why we employ this strategy is because, as you know, from a jurisdictional standpoint we cannot necessarily if the site is, indeed, overseas, it is difficult to hold the site owner culpable. So what we need to focus on is ensuring that

we can try and stop the product at the border. In addition, if the product somehow has made its way into domestic commerce, we would make it a high priority to do recalls, talk papers, physician letters if it is appropriate as well as using seizures and criminal prosecutions to try and assure that the product is not spread through the domestic market.

Mr. GREENWOOD. We have talked about resources and Mr. Bass in his opening statement said something about even if we had 12,000 drug police, it would not be enough. And I tend to concur with that. The volume if you use this current system that you have in place, the number of personnel that you would need to really have a pretty foolproof system would be unrealistic. We could not do it. So is it not the case that we really need to change the system that we use to approach this problem rather than simply call for more resources?

Mr. TAYLOR. I think that is correct. I mean, currently I have 537 investigational personnel devoted to this task. And those bodies do not just handle pharmaceutical products. They handle foods, biologics, they are involved in preventing the spread of BSE to this country. They are involved in taking steps to prevent the monkey pox outbreak from growing. They are involved in homeland security and food safety. So those 500 some odd people are vested with a large job, and it is simply not true that increasing the resources will not really cause a big dent. We really need to change the system.

Mr. GREENWOOD. My time has expired.

The Chair recognizes the ranking member, Mr. Deutsch, for 8 minutes.

Mr. DEUTSCH. Mr. Chairman, I would like to see if we can have Mr. Dingell ask the first series of questions.

Mr. GREENWOOD. All right. Mr. Dingell is recognized for 8 minutes.

Mr. DINGELL. This is quick, just yes or no. We have no exact inventory for what the various bags of products were in the Miami facility during the time that the staff visited in March. Is that correct?

Mr. TAYLOR. That is correct.

Mr. DINGELL. All right. Thank you.

Mr. TAYLOR. If the product is not detained, we do not have——

Mr. DINGELL. Thank you. My time is limited.

It is known, however, that a large shipment of approximately 1,233 shipments of purported fake Viagara were detained during the October/November timeframe. Is that not correct?

Mr. TAYLOR. That is correct.

Mr. DINGELL. What happened to those shipments?

Mr. TAYLOR. They were released, sir.

Mr. DINGELL. The staff inquired into whether those were detained, why they were detained and FDA immediately released it. Is that right?

Mr. TAYLOR. We did not immediately release it. We released it several—the product was released several months after the detention. But, yes, it was released.

Mr. DINGELL. A curious set of events.

Mr. TAYLOR. Yes.

Mr. DINGELL. The staff inquires as to why these are being detained and you release them. The staff was concerned about the safety. You released them. A very curious arrangement.

Can you tell us why these were released? What was the grounds on which they were released?

Mr. TAYLOR. Sure. When the information surrounding this detention first came to me, my inclination was to have the staff go back and detain the products properly.

Mr. DINGELL. Did you establish that these were safe? Did you establish that these were, in fact, Viagara? Did you establish that this shipment was, in fact, Viagara which was generic or not? On what grounds was it released?

Mr. TAYLOR. Sir, I did know that the product was indeed unapproved Viagara. Those were the facts that were provided to me.

Mr. DINGELL. So, that's curious. Is this a regular practice of releasing shipments of prescription pharmaceuticals with so little attention and care?

Mr. TAYLOR. Well, actually if you may, in this particular case, as I said before, my inclination was to detain these products properly. However, when provided with information regarding——

Mr. DINGELL. You are supposed to keep illegal shipments. You are supposed to keep out shipments of prescription pharmaceuticals that do not meet good manufacturing practices, that do not comply with our patent laws. You are supposed to see to it that you have a careful coordination with the Customs Service and that they have clear understandings of your policies.

Mr. TAYLOR. Absolutely.

Mr. DINGELL. Is that not so?

Mr. TAYLOR. That's absolutely correct.

Mr. DINGELL. Do you have agreements in written form of cooperative management agreements with Customs Service on matters of this kind? Yes or no.

Mr. TAYLOR. I do not know if we have a cooperative agreement, but we——

Mr. DINGELL. You do not.

Mr. TAYLOR. Okay.

Mr. DINGELL. I happen to know you do not.

Now, can you tell us whether you contacted Pfizer, which is the patent holder on this matter to find out what was going on there or did you not?

Mr. TAYLOR. We have spoken to Pfizer about this matter.

Mr. DINGELL. Did you call them in connection with this release?

Mr. TAYLOR. No. I did not personally, no.

Mr. DINGELL. Did anybody at Food and Drug?

Mr. TAYLOR. I am not sure. I know that we have had discussions with them regarding this particular shipment in this matter.

Mr. DINGELL. Now Food and Drug has had many warnings that the Miami facilities had problems. They have a huge backlog of shipments. FDA has made reference to 1,233 shipments of fake Viagara in response to the June 5 request for information sent by this committee. Is that not so?

Mr. TAYLOR. Correct.

Mr. DINGELL. In your June 19 response to the committee you explain how 1,233 shipments of fake Viagara were released. In re-

sponse in mentions that there is a discussion and a resulting decision by Mr. Taylor to release these shipments of Viagara, that is at page 4 Exhibit 20. Do you know what all this other product in the photo is?

Mr. TAYLOR. I'm sorry, sir, which photo? What number?

Mr. DINGELL. The staff will show you the photo. Page 4, Exhibit 20.

And I ask unanimous consent that that be inserted in the record.

Take it down and show it to him.

Mr. GREENWOOD. Without objection it will be.

Mr. DINGELL. Exhibit 20.

Staff reported at the time of their March 2003 visit there was a fake product being stored in a cage, but also huge quantities were stored outside the cage, and you will see that in Exhibits 15 and 16. Who authorized the release of the product outside the cage of at least 928 additional packages?

Mr. TAYLOR. Well, first, sir, clearly it appears that the product is unapproved. I am not sure if it is fake or not.

In the case of those situations where we do not detain the product, the product is set aside and therefore it is released if indeed we do not decide to detain the product. And the release would be based on our discussions with Customs.

Looking at this product again, it looks like the product is indeed unapproved. I cannot say that it is necessarily fake, which seems to connote counterfeit, but it definitely is unapproved product here.

Mr. DINGELL. Do you know whether it was approved or not approved?

Mr. TAYLOR. It says Viagara, and based on the indications here and the note that is on top of this bag, at the very least it looks like it is unapproved product.

Mr. DINGELL. It is unapproved product?

Mr. TAYLOR. Correct.

Mr. DINGELL. All right. So FDA is busily releasing unapproved product.

Now, Customs provided a Xerox copy of some fake Viagara from a company by the name of DurusPharma. That is in the Committee Memo in Exhibit 17. I assume you are familiar with that product?

Mr. TAYLOR. I am familiar with that product, and we have an import alert that was put——

Mr. DINGELL. Now, I would note that an import alert for Dureas Pharma was issued by Food and Drug before April 4, 2003. Why was this import then permitted after you had had an import alert for a product coming in from these people?

Mr. TAYLOR. The import alert does not prevent the product from entering. What the import alert does is it sensitizes the staff of FDA and Customs for the need to make it a priority in terms of detaining the product.

Mr. DINGELL. Apparently it did not have much effect because not much happened, their product was released, is that not so? What purpose did this import alert serve then?

Mr. TAYLOR. I mean in regards to the DurusPharma product, I am not familiar with the specific shipment you were talking about. But I——

Mr. DINGELL. Well, my time is limited to 5 minutes, but I find this to be a very curious situation.

Can you tell me what the distinction between FDA's definition of a counterfeit drug and the Belize drug that was found during this inquiry by the committee staff?

Mr. TAYLOR. Sure. In Section 201(g) of the Act there are several components to the definition of a counterfeit drug. One, just to paraphrase, one part of the definition focuses on sort of the trademark or property right, the use of a trademark or some symbol as an initial signal as to whether a product is counterfeit. However, the second part of the definition focuses on the product marketed in lieu of the authentic. So, for example——

Mr. DINGELL. Well now you would note that the patent on Viagara is still in place, is it not?

Mr. TAYLOR. Indeed. But I also——

Mr. DINGELL. There is no proper admission, there is no proper marketing of Viagara as a generic at this time?

Mr. TAYLOR. That is right. But that does not mean that the product——

Mr. DINGELL. And so you still went ahead and released it. Can you explain that to us?

Mr. TAYLOR. Sure. We released based on the fact that I had to weigh competing priorities, the need to deal with homeland security and pending BSE issue, versus the resources that would be needed to—which at that time looked to be 4 to 8 weeks of moving personnel over to solely and properly detain this product. Given that very difficult decision——

Mr. DINGELL. In other words, you were busy doing other things?

Mr. Chairman, is my time up?

Mr. GREENWOOD. Your time is up, sir.

Mr. DINGELL. Thank you, Mr. Chairman.

Mr. GREENWOOD. The Chair advises the gentleman——

Mr. DINGELL. I ask unanimous consent that I be permitted to submit a list of questions to the Commissioner of Food and Drug and ask to have a place kept in the record so that those can be inserted. Because this is a most curious behavior by this agency.

And I thank you.

Mr. GREENWOOD. We are continuing to investigate it. And without objection the gentleman's request will be in order.

The gentleman from New Hampshire, Mr. Bass is recognized for 8 minutes.

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

Before I begin, I just want to make sure that my position relevant to the substance of this hearing is clear. Counterfeit drugs are bad and they are illegal and they violate all kinds of law besides the issue of importation. In fact, counterfeit drugs are just as likely to be manufactured domestically as they are abroad.

Second, the artificial price controls that are imposed by foreign governments with socialized medicine systems are also not right. And they create an inequity in the marketplace. However, for better or for worse and for one reason or another, the manufacturers of these drugs have accepted this system and are playing by the rules of that foreign government, which is unfortunate. And in my opinion we ought to be vigorously pursuing trade negotiations with

these countries so that they terminate these artificial barriers or creation of price controls that result in the inequities.

Mr. Hubbard, I did not hear you when you passed around this counterfeit Procrit package and the authentic one. Very briefly, where were these made?

Mr. HUBBARD. I am not sure.

Mr. BASS. Are they as likely to have been made in the United States or not?

Mr. HUBBARD. Well, certainly American citizens were engaged in the manufacturing. Where they got some of the material is not known.

Mr. BASS. So this is not necessarily a reimportation issue. These could have been in Washington, DC as likely as India, right?

Mr. HUBBARD. Yes.

Mr. BASS. Okay. Fine. So this is a counterfeit drug issue, not an importation issue.

Why do you think that the guy who purchased the drugs, why would anybody purchase drugs over the Internet? What is the No. 1 reason, in your opinion, to do it?

Mr. HUBBARD. Well, there are two things. Obviously, is the price differential, as you have pointed out. Second, there is quite a bit of purchasing of what we call life style drugs, like Propecia for hair growth, Zenecal for weight loss, and Viagara. And those individuals when, we have asked them, say they do not want to go to their doctor and admit they have got that problem, and so they just go straight to the Internet and buy the drug.

Mr. BASS. If the FDA had some mechanism whereby they could establish FDA approved drug purchasing program over the Internet, would that solve the problem?

Mr. HUBBARD. Well, we certainly could point consumers to a program run by the State Boards of Pharmacy called VIPS, which does authenticate Internet sites that sell drugs. In fact, there are legitimate sites like merckmedco.com, and those are perfectly legitimate. But many of these sites, of course, are not legitimate and they aren't even in the United States.

Mr. BASS. Well, let us say for example it was legal drugs that were manufactured in facilities that were approved by the FDA, no matter where they were. In your opinion would that eliminate at least part of the problem that you face with this avalanche of drugs coming across a border?

Mr. HUBBARD. Obviously, such assurance would ameliorate our concerns. The problem there, of course, is you still have drugs moving around in ways that are outside normal licensing procedures.

Mr. BASS. Well, if drugs sold within the United States were the cheapest in the world, what would your situation look like versus in some instances, the most expensive in the world?

Mr. HUBBARD. We would certainly hope that that might cause fewer counterfeit drugs and therefore they would be buying safer drugs. As I pointed out, generic drugs are cheaper in this country. We hope patients would certainly buy those in this country before they went to an Internet site or overseas.

Mr. BASS. Clearly one of the issues is moving to more generics. But I guess my point is that if the underlying problem here is that many drugs sold in the United States are more expensive than

they are anywhere else in the world, for one reason or another which those issues need to be addressed, and therefore by the natural movement of a free market we are a beacon of profitability for both legal and illegal manufacturers of these drugs. And is it not true that the issue here is ultimately if prices were the same or competitive between the U.S. and any other country, then the only issue you would be facing would be the issue of counterfeiting; and illegal, people who are violating patent laws, people who are violating FDA regulations that require that drugs be manufactured, you know, be licensed properly by the Food and Drug Administration?

Mr. HUBBARD. That may be true. You know, again, the price issue is not one FDA can do much about except for the things that we are trying to do such as get more generics on the market and get more new drugs on the market. But we can't directly regulate prices, obviously.

Mr. BASS. Right. Okay.

I will yield back to the chairman.

Mr. GREENWOOD. I thank the gentleman and recognize the gentleman from Florida, Mr. Deutsch.

Mr. DEUTSCH. Thank you, Mr. Chairman.

Actually even before, even with the limitation on time, I also want to respond to some of the comments actually Mr. Ferguson made in the opening comments. And I think this is part of sort of debate. I am glad he is still here and maybe he will take his time.

You know, saying that America has the best health care system in the world, I just do not agree. We have 40 million Americans who woke up this morning, went to work and do not have health care insurance. I mean, that is not the best health care system in the world.

We have, literally, by any objective standard in terms of first world country, western industrialized countries, we spend more on health care per capita than any other country. Yet on objective standards life expectancy, instances of cancer, the instances of hypertension, other issues we are the worst.

So, again, I can agree that at the high end of the scale we have the best innovations. But to say we have the best health care system in the world, unfortunately I think is an absolute mistake and a misnomer of the facts that exist in America today.

Mr. Hubbard, let me respond to something, and this is a series of questions and it is getting somewhat frustrating, in fact incredibly frustrating. We had a field hearing, I believe it is 4 months ago in South Florida. We asked the FDA to get their arms around the amount or the number of people, the amount of scripts being written or the number of people who are availing themselves of purchasing drugs through the Internet or specifically through Canada. Do you have any sense of what that number is today?

Mr. HUBBARD. Mr. Deutsch, we made an attempt to extrapolate from a study 3 years ago and we have said since then we believe the number has increased.

You know, whether we could do a survey——

Mr. DEUTSCH. Let me just respond. Again, this goes pretty fast. Your answer is no? Your answer is no. Four months, your answer

is no. Let me tell you, there are some people who do know. I mean, Glaxo knows. I mean the pharmaceutical companies know.

Mr. Chairman, one of the suggestions I think we might have to do is pull some of the companies in here who seem to know.

How could I have any trust, how could any American watching, listening, reading about this tomorrow, you have no idea, you have no concept how many—you do not know if the millions or tens of millions. Is that accurate?

Mr. HUBBARD. We think it is in the single digit millions based on what——

Mr. DEUTSCH. Answer my question. You do not know if it is in the millions or 10 million, is that accurate?

Mr. HUBBARD. We do not have an accurate figure.

Mr. DEUTSCH. You do not have a clue. You do not have a clue.

Mr. HUBBARD. I would dispute that. I think we do have a clue.

Mr. DEUTSCH. You do not know if it is 5 million, 10 million, 15 million?

Mr. HUBBARD. I am not sure those numbers matter that much.

Mr. DEUTSCH. You do not think it matters?

Mr. HUBBARD. It is too much and it should not be coming in at all.

Mr. DEUTSCH. Well, you said that it does not matter much, because you just testified under oath that people are doing it for lifestyle reasons. Have you talked to any seniors?

Mr. HUBBARD. I said some people, Mr. Deutsch.

Mr. DEUTSCH. Well, I am asking you a question. Have you talked to any seniors? Have you ever talked to a senior that has purchased drugs through the Internet?

Mr. HUBBARD. Mr. Deutsch, I——

Mr. DEUTSCH. I am asking you a question.

Mr. HUBBARD. Yes, I can——

Mr. DEUTSCH. Have you personally talked to a senior?

Mr. HUBBARD. I get hundreds of letters——

Mr. DEUTSCH. Have you personally—answer the question, sir?

Mr. HUBBARD. Yes. Yes.

Mr. DEUTSCH. Who have you talked to?

Mr. HUBBARD. Individuals who have called to complain that we——

Mr. DEUTSCH. Do you have a record of that? Can you supply the committee the name of any senior?

Mr. HUBBARD. I have——

Mr. DEUTSCH. Can you describe a particular senior that you have talked to?

Mr. HUBBARD. I certainly know that seniors contact——

Mr. DEUTSCH. That is not my question. That is not my question. My question is have you talked to a senior?

Mr. HUBBARD. Yes.

Mr. DEUTSCH. And who is it? Can you describe that person?

Mr. HUBBARD. I would be glad to get you——

Mr. DEUTSCH. Please do. Describe the person? Who is it? Where do they live?

Mr. HUBBARD. Generally we are talking——

Mr. DEUTSCH. Generally? I just asked you a question. You are under oath. Have you talked to a senior?

Mr. HUBBARD. Yes, Mr. Deutsch, I——

Mr. DEUTSCH. And who have you talked to? And describe the person. I do not need the name of the person.

Mr. HUBBARD. Okay. We have talked—I would rather not go into details, but——

Mr. DEUTSCH. Do generalizations. I am asking you a question. Have you talked to a senior in the United States, one of the 10, 15 million seniors who woke up this morning who did not want to purchase their drugs through the Internet but did because they had to? Have you talked to one?

Mr. HUBBARD. Mr. Deutsch, we try to——

Mr. DEUTSCH. Answer my question.

Mr. HUBBARD. Yes, Mr. Deutsch.

Mr. DEUTSCH. Describe in a general way who that person is, where are they from, what is their age, what drugs are they purchasing? What person? What person, Mr. Hubbard? One person?

Mr. GREENWOOD. Will the gentleman yield?

Mr. DEUTSCH. No, I do not want to yield. I want him to answer the question. He has already lied under oath that he has talked to seniors that he cannot describe——

Mr. GREENWOOD. The Chair will intervene. The gentleman does not know that the witness has lied. The gentleman——

Mr. DEUTSCH. Well, I have given him every opportunity to describe in a general way. He has testified under oath.

Mr. GREENWOOD. I suggest to the gentleman give him the opportunity to provide that information to the committee.

Mr. HUBBARD. I will be happy to.

Mr. DEUTSCH. No. And I want you, you are here right now, describe in a general way a senior who you have told me now you have talked to seniors.

Mr. HUBBARD. Okay. But just briefly an email exchange——

Mr. DEUTSCH. Is that talking?

Mr. HUBBARD. Well, certainly I was at a meeting in——

Mr. DEUTSCH. You can tell me yes or no have you talked to a senior who has actually purchased a drug through the Internet?

Mr. HUBBARD. I——

Mr. DEUTSCH. Yes or no?

Mr. HUBBARD. Yes, Mr. Deutsch.

Mr. DEUTSCH. And when? Describe in a general way. And are you telling the truth?

Mr. HUBBARD. In Philadelphia 1 month ago after I gave a talk, several seniors came up to me and we had a discussion. I can't describe for you what they look like and who they were——

Mr. DEUTSCH. What did they describe to you? What did they tell you they did?

Mr. HUBBARD. They basically said we are very concerned that you are attempting to keep us from buying drugs from Canada. And I said we are concerned about the safety.

Mr. DEUTSCH. And would they tell you that they were doing it?

Mr. HUBBARD. Certainly one of the lady—a 76 year old lady said "Yes, I am doing that. Will you take away my drugs?" And I said no.

Mr. DEUTSCH. Okay. And what you are describing is is exactly that. Let me talk very specifically. Okay. Because first of all, again,

I mean it is an offense to the 10 million seniors that woke up in America today that did not have a choice that had to purchase their drugs, not because they want to. You know, my mother-in-law does it? There are tens of thousands of seniors in South Florida who are doing it every day. There are a dozen prescription Canada pharmacies that have opened up. I do not like it. I wish it did not occur, because I agree with you that it definitely is a risk factor.

In fact, the most interesting thing that you said today was providing those websites. Because I tell you, you look at those websites and it looks like they are coming from Canada. I mean, you know, the names of the website. And what are we doing to let seniors know that those are bogus websites?

Mr. HUBBARD. We certainly are trying to alert seniors.

Mr. DEUTSCH. What are we doing? What are we doing?

Mr. HUBBARD. We have got information on websites. We hand out brochures at the border. We do a lot of press——

Mr. DEUTSCH. What are we doing? I mean, let me tell you, that is something that really concerns me. Because there is no question that there are seniors who are going to those websites.

You know, can we shut them down? You had a Miami Beach address. Has someone gone to that address?

Mr. HUBBARD. Not as——

Mr. DEUTSCH. Have you gone to the U.S. Attorney in the Southern District of Florida and told them about that website and that address?

Mr. HUBBARD. I understand that's a bogus address and the site is not really in Miami Beach. But we can get more information on the site.

Mr. DEUTSCH. I mean, is there an investigation? Has someone gone to that location? I mean, because that is fraud. This is law enforcement issues. I mean, I think what you have said and what you have testified to is that the Canadian system, and we know it is going through the Canadian system, that there is a certain amount of efficacy that exists there. All right. And, again, there are issues we have gone in, there are counterfeiting issues in the United States. There are both these issues which we are going to get testified in the second half, whether you go to the local Eckerd or CVS. And the same way if you go to a Canadian pharmacy in Canada.

But you know what? One of the things, again, that really concerns me is exactly what you are describing, that if people are going on the Internet and thinking they are buying Canadian, because obviously people know. I mean, these are people who ought to be put in jail forever who are doing this, because the reality is I agree with you a 100 percent that those type of situations there is no control.

I mean, Mr. Taylor, did you want to respond particularly on those investigations?

Mr. TAYLOR. Well, I wanted to respond more broadly. I think your point is absolutely right. When we started doing our Internet investigations, there were a lot of different factors that were causing people to purchase products over the Internet, but one of the biggest factors lately, indeed, appears to have been price. And so what we have done is we have adjusted our public health message

to make sure that we are reaching, doing a better job of reaching just those very people in the elderly community and other communities where their conditions are comprised to make sure they understand the competing interest. And a lot of that refinement came at the wake of the March hearing where we, indeed, did try and take stock of people's perceptions of purchasing products through the website. And one of the things we recognized is that people—we need to do a better job of letting people know of the balance that they——

Mr. DEUTSCH. Could I just follow up with one very short question.

Mr. TAYLOR. Yes.

Mr. DEUTSCH. Okay. You guys have come up with something that is real, that is significant, that can help people today. Okay. That we got bogus sites up there. You know, got Canadian flags that are called Canada Drug, whatever. I mean, how do we let people know that besides people who are listening to this hearing and what can we do tomorrow to let that happen? Because that is very problematic, I mean, for real people today who want to avail themselves of an alternative system?

Mr. TAYLOR. FDA has a website regarding online drug sales. And one of the things that we have done is we have sent warning letters that we brought significant cases. IF there are sites that are a particular public health concern, what we have tried to do is post that material so that people can use that material to help inform them regarding their purchasing choices. And this website is accessed almost more than I think any other part of the FDA website. And we found it very useful in getting the word out.

But also in regards to each case that we have brought, we have tried to do a better job of including a talk paper or something so that people who do not have access to the website can learn more about the sites or products that we feel are problematic because of the reasons that Mr. Hubbard stated earlier.

Mr. GREENWOOD. The time of the gentleman has expired.

The Chair would note that this is obviously an important issue, lives are at stake in this issue. The charge of lying under oath is a serious issue as well, one that this committee would almost be compelled to pursue.

The Chair would note for the record that there is no evidence that the gentleman, Mr. Hubbard, said anything but the truth under oath. He cited a particular case of a woman in Philadelphia for instance, and the Chair would want the record to show that.

The Chair recognizes the gentleman from New Jersey, Mr. Ferguson, for 8 minutes.

Mr. FERGUSON. Thank you, Mr. Chairman.

At the risk of bearing the wrath of my friend from Florida, I just want to address a point that he was making about a point that I was making earlier regarding the health care system in our country.

I still contend, and I do not know too many people who know anything about health care who would not agree with the fact that we have the best health care system in the world. There is no question that not everyone has access to that system, and that is a problem and that is something that all of us are concerned about

that we are trying to address just about everyday that we go to work here in Washington and providers and others around the country. That is one of our main challenges is making this great health care system available to everyone, not just to some or most Americans.

But anyone who would question that we do not have the best doctors, the best nurses, the best medical facilities, the best researchers, scientists, pharmaceutical companies; those who do enormous work, do enormous research, invest untold hours of time and energy and billions and billions of dollars in research to find new medicines and cures for tomorrow and procedures and devices, and everything else that simply is not the case.

We clearly have the best health care system in the world. That is why not only patients from all around the world want to come to the United States to be treated, but it is also why the best and brightest minds in the world want to come to the United States to be trained to go to school, to become a part of this system. Because it is the best in the world.

So we may have a disagreement or we may acknowledge that today there is a problem. Not everyone has access to it. We have a pool of uninsured Americans today, that is a problem that we are trying to address. But I don't think anybody who knows anything about health care would disagree with the fact that we have the best health care system in the world. It is something we should be proud of. It is something that we need to continue to work very hard and be diligent to maintain. And the work of the FDA and our oversight, and work with the FDA to make sure that they are continuing to be a part of that great health care system is, of course, a part of what we are doing here today.

I do have a couple of questions which I am going to get to in a second. A couple of my colleagues, including my friend Mr. Bass from New Hampshire, have used the term reimportation. And I have a problem with that term because it is a misnomer, it is an inaccurate term because it suggests that reimportation means taking drugs that were manufactured here in the United States and shipped to other countries, are then reimported into the United States. And that is simply inaccurate.

What people mean when they are talking about reimportation today is taking drugs that were manufactured in other countries, not under the strict guidelines of the FDA, not in facilities that have the strict oversight of the FDA, these are not subject to our high standards of efficacy and safety here in the United States. We have some of the very best standards in the world. That's one of the reasons our health care system is the best in the world. So to suggest that reimportation is simply bringing drugs back in here to the United States that were made here and subject to our very high standards is inaccurate, and that's one of the reasons I don't like or use the word reimportation. It is simply the importation of illegal drugs into the United States.

That kind of law in our country allows for bringing drugs into the United States that are made in other countries as long as the Secretary of Health and Human Services can certify that those drugs are safe. That hasn't happened. President Clinton's Secretary of HHS couldn't do it, President Bush's Secretary of HSS couldn't

do it. We simply do not have the ability to say with a high level of certainty that drugs manufactured and made in other countries, not subject to our standards, not subject to our FDA are safe for American consumers. If they were, they would be allowed into this country today.

So, for those who use the word reimportation and suggest that we should be liberalizing these laws or relaxing these regulations are actually suggesting and recommending that we relax our safety standards to let more of these cheap drugs into the United States without regard to the safety of the American people. I have a problem with that.

Now, I would agree with my friend Mr. Bass that we need to be working with our trade partners to encourage them not to impose price controls or other completely anti-market, completely anti-capitalistic, anti-freedom and free market policies in their own countries. But it also means we should certainly not be importing their price controls, their socialist tendencies into the United States.

That was my second opening statement, I guess. Let me get to my questions.

Mr. Hubbard, let me ask you a very basic question. Is it safe for you as a consumer today to import pharmaceuticals from foreign countries outside of the U.S. distribution chain and outside the oversight of the FDA?

Mr. HUBBARD. We do not believe it is.

Mr. FERGUSON. Why?

Mr. HUBBARD. Because we have seen so many instances of drugs that don't meet specifications. In fact, none of them meet specifications. There are these sorts of examples we have today of drugs that simply should not be dispensed or sold to Americans.

Mr. FERGUSON. And there is no way right now at HHS or at the FDA that anyone with any certainty can say that drugs made outside of the U.S. are safe for U.S. consumers?

Mr. HUBBARD. We don't see how to do that. We have said you can think of ways to ameliorate the risk, but you can't eliminate it and you would lower safety if you allowed those sorts of foreign drugs to be imported, in our view.

Mr. FERGUSON. But there are lots of folks who go to Canada or bring drugs in from other places in the country? Some of these Internet sites or mail-order Canadian operations are saying that Congress made the personal importation of a 3 month supply of drugs legal and allowable. Are they correct or is this a violation of law?

Mr. HUBBARD. No, they are not. There is a personal importation policy that is limited to experimental drugs for people with serious diseases. These websites often misquote that statement and say that it is okay to bring in 3 months' supply when in fact that is only for experimental drugs.

Mr. FERGUSON. After this subcommittee's June 2001 hearing, the FDA proposed to the Department of Health and Human Services that it allow FDA and customs to deny the entry of all of these illegal drugs into the U.S. and return them to sender. What is the current status of that proposed regulation?

Mr. HUBBARD. Well, we still believe that was a good recommendation. We have not heard back from the department. But

there is a procedural problem that Mr. Dingell and others have pointed out that FDA cannot deal with this huge influx of these products and we either must let them in or go to the very expensive process of notifying people, and the latter is not feasible.

Mr. FERGUSON. Well, that was 2 years ago when you were talking about that proposed regulation. Has that been implemented?

Mr. HUBBARD. No, it has not. But, you know, I think we would still believe that that is a procedural change that Congress should look at.

Mr. FERGUSON. But that is not something that you feel you can do at FDA without some sort of congressional approval?

Mr. HUBBARD. I believe we have concluded in consultation with our lawyers that we need a statutory change to effectuate that recommendation.

Mr. FERGUSON. Okay. I yield back and my time is up.

Thank you, Mr. Chairman.

Mr. GREENWOOD. The Chair thanks the gentleman and recognizes the gentleman from Florida, Mr. Davis, for 8 minutes.

Mr. DAVIS. Thank you, Mr. Chairman. I would like to ask a few questions to try to develop the record a little further, and I will be brief and ask you to please be brief. And I have got some general questions to ask you. These will probably be best answered by Mr. Hubbard or Mr. Taylor.

Is it correct that a large shipment of approximately 1200 shipments of purportedly fake Viagara were detained in the October/November timeframe?

Mr. TAYLOR. That is correct.

Mr. DAVIS. Okay. And it is true that the Office of Criminal Investigation took an interest in this product as a possible case to investigate as reflected in Exhibit 3?

Mr. TAYLOR. I believe that is correct.

Mr. DAVIS. Okay. And you are aware that as far back as January of this year OCI sent samples of the fake Viagara to your research lab in Ohio for chemical analysis?

Mr. TAYLOR. Yes. The Forensic Chemistry Center.

Mr. DAVIS. And you are further aware that when the staff of this committee interviewed senior management from your Office of Regulatory Affairs in the Florida District office they were unaware that this product was being tested by the FDA?

Mr. TAYLOR. That is my understanding.

Mr. DAVIS. Okay. All right. Would you agree that when the OCI is sending product for testing as they did in this case, that information should have been shared with the Office of Regulatory Affairs?

Mr. TAYLOR. My understanding, sir, is that even though it was not shared with the managers of the Florida District, that there were some employees at ORA that were aware of that. But indeed, the staff is correct, it was not shared with the District Director who was interviewed by the staff and the head of the inspections branch.

Mr. DAVIS. So you would agree that it should have been shared and in the future it ought to be shared?

Mr. TAYLOR. Absolutely.

Mr. DAVIS. Okay. You are also aware that the test results came back and showed a sizable difference in the active ingredient from what was advertised, what actually was in the product?

Mr. TAYLOR. The test results showed that in some cases even though the product contained the same active ingredient, solidenafil, which is the active ingredient for Viagara, that in some cases it was possibly subpotent and in one case it might have been superpotent.

Mr. DAVIS. So as far as your word "some case," could you give me some general sense of proportion here?

Mr. TAYLOR. I do not have it in front of me, sir, the analytical results. The information on the analytical worksheet defines those parameters. I do not have it in front of me. But that is the general finding of the analytical laboratory.

Mr. DAVIS. Is it in the record? Okay. What exhibit is it? Okay. I have got Exhibit 3 that has been handed to me. And you can, perhaps, look at this and come back and comment in a later question that reflects what appears to be the level of proportions, and they appear to be significant. So, if you want to refer to this during a break in the questioning, my question to you now and then again is going to be after you reviewed the exhibit, did a significant proportion of this product represent a significant health risk to consumers.

Mr. TAYLOR. Based on the analysis, it certainly shows that there was variance in the level of active ingredient in the product. I cannot say definitively that the subpotent product presents a risk to the public, but certainly in the context of being superpotent, in some populations that could indeed present a risk.

Mr. DAVIS. Okay. Was this information you have just referred to shared with other parts of the FDA in order to prevent the release of the product?

Mr. TAYLOR. It was not shared with me at the time of the release of the product.

Mr. DAVIS. And why not?

Mr. TAYLOR. Sir, I do not know. That is part of what we are trying to determine as part of our ongoing internal review. I became aware of these analytical results as part of our ongoing review to determine why these mistakes occurred.

Mr. DAVIS. So you are taking steps to understand why the mistake occurred——

Mr. TAYLOR. Absolutely. Absolutely. We have an ongoing internal review. Based on what we know up to this point, we have several steps that we are going to take and they are outlined in the written testimony. But if indeed there need to be additional steps that need to be taken based on the continuation of this internal review, we will do so.

Mr. DAVIS. And this product was ultimately released to the public?

Mr. TAYLOR. Yes, sir, it was.

Mr. DAVIS. Do we have any idea about accidents, injuries, deaths or problems?

Mr. TAYLOR. No, we do not have any adverse reports at all. Subsequent to its release we sent a letter to the consumers that or-

dered the product and we have heard back from some of them. We have no reports of adverse events.

Mr. DAVIS. Is this investigation still continuing with respect to possible injury of the public?

Mr. TAYLOR. Well, we are continuing to monitor our adverse events site, in our Medwatch System, and to this date we have not seen anything that suggests that this product has harmed anyone.

Mr. DAVIS. What other products were released at the same time as well as the product we have just been describing?

Mr. TAYLOR. I do not have it in front of me, but indeed there were other products released around——

Mr. DAVIS. I am told slide 2 reflects some of those additional products. Would you agree with that?

Mr. TAYLOR. Yes, sir. Yes, sir.

Mr. DAVIS. What is that product and what are the quantities?

Mr. TAYLOR. It appears to be 928 packages of what appears to be possibly additional Viagara from Belize.

Mr. DAVIS. And who authorized the release of that and has there been any investigation as to any injury of the public as a result of that release?

Mr. TAYLOR. I do not know who authorized the release of it. I presumed that it was released as part of our general process for handling these products. But it was not released as part of the same discussion that led to the release of the 1,233 packages that you——

Mr. DAVIS. You say you do not know what was released that day? Are you going to be able to figure out what was released on that day?

Mr. TAYLOR. That is what we are trying to do. I cannot guarantee it, but that is something we are trying to determine as part of our ongoing review.

Mr. DAVIS. Perhaps one of the few things we can agree upon here today is what the rate of growth has been in this problem. Can you give me some numbers as to the fact, including projections about what the growth of the problem is going to continue to be if nothing changes in terms of government policy?

Mr. TAYLOR. Well, as Mr. Hubbard said, I do not have the exact number but obviously over the last 2 years we have seen a growth in the number of mail packages based on proliferation of foreign websites and the proliferation of storefront pharmacies.

Mr. DAVIS. Can you give me some sense of proportion or quantity here, even if it is general or speculative?

Mr. TAYLOR. Millions. I mean, we are talking millions of packages coming through. And there is nothing to suggest that trend will not continue.

Mr. DAVIS. So what has been the rate of growth in these packets from last year or the last 2 years, would you say?

Mr. TAYLOR. I do not have the exact number, sir. Based on the type of data that others have collected and based on our own extrapolation from 2 years ago——

Mr. DAVIS. You fear in the face of explosive rate of growth it's just going to compound immensely in the absence of any change in official policy?

Mr. TAYLOR. Yes. It certainly has been explosive growth and there is no reason to suggest it will not stop.

Mr. DAVIS. Has there been any prosecution undertaken by any law enforcement authorities with respect to these websites providing the bogus information that were discussed earlier?

Mr. TAYLOR. You mean in regards to the——

Mr. DAVIS. Viagara or any product?

Mr. TAYLOR. In regards to this particular Viagara shipment, there were some discussions initially with the Department of Justice. However, a case was not initiated on the Viagara.

In regards to some of the other products that we have talked about, the answer is yes.

Mr. DAVIS. There are prosecutions that have been undertaken?

Mr. TAYLOR. Ongoing investigations into some of these products.

Mr. DAVIS. What exactly would you suggest that Congress needs to do to be a part of the solution here? We are spending our day talking about the problems so far. And it is easy to sit here and criticize you, but what we are entitled to, and what the public is entitled to, for you to be painfully direct with us as to exactly what Congress needs to do to be part of the solution here? Because if you are not part of the solution on this, you are part of the problem.

Mr. TAYLOR. I quite frankly, as a starting point, looking at some comprehensive solution that just does not focus at providing additional resources. Because as I stated earlier, providing us with additional investigators does not seem to be the answer. And no matter how many investigators you provide us, it seems that based on the numbers we still struggle to look at these packages and prevent their entry into the United States.

Mr. DAVIS. So what else besides resources?

Mr. WALDEN [presiding]. The gentleman's time is——

Mr. DAVIS. Mr. Chairman, if I could just finish this last question, then I will stop there.

What else besides resources?

Mr. TAYLOR. Well, I guess what I am saying is that resources are not the answer, that some type of comprehensive solution that focuses on why people are purchasing these products and importing them into the United States seems to be the answer.

Mr. HUBBARD. Perhaps I could add, Mr. Davis, that several suggestions have been ones that have come up over the years. One would be some sort of disclosure to know whether these are legitimate or illegitimate websites.

And, of course, there is the return to sender, a policy that we proposed to Congress. So there are some ideas that have been out there that Congress could certainly discuss.

Mr. DAVIS. Thank you. Thank you, Mr. Chairman.

Mr. WALDEN. You're welcome.

Ms. Durant, in your testimony you state that Customs found that large parcels of fake or gray market pharmaceuticals are being split into different mail shipments but arrive at the same address. Can you expand on that?

Ms. DURANT. It is just a growing trend. Bulk pharmaceuticals are of particular concern because we believe those are the most likely to go to distributors that might end up in pharmacies that people consider to be legitimate in the United States.

We are going to, this summer, conduct an operation at four of our major mail sites to try and get a better handle on whether we have growth in that area. Our last operation indicated that as much as 14 percent could be phoney or counterfeit or just contain starch, etcetera. So we do plan to redo that operation this summer so that we can see if the 14 percent is stable or whether we should have——

Mr. WALDEN. Fourteen percent are drugs that are not pure?

Ms. DURANT. Of all the packages we detained and analyzed, because it does take a chemical analysis, 14 percent were counterfeit or had inactive ingredients that were not what people thought they were, imported.

Mr. WALDEN. Okay. I want to pursue this issue of perhaps those counterfeit drugs getting into our pharmaceutical chains. Is that happening to those that get broken up and then end up at the same address; are you seeing a flow of imported drugs going into existing pharmacies, if I went down here to CVS or somewhere?

Ms. DURANT. We do not trace that. The FDA——

Mr. WALDEN. Who does? FDA does? Are you seeing that? Is anybody checking that?

Mr. TAYLOR. We work with the States to look at what is going into the wholesale market. And based on the recent counterfeit cases that we have worked on, we think that the wider distribution patterns of those counterfeit products is based on a wider introduction into the whole sale market.

Mr. WALDEN. What do you mean by that? What is happening?

Mr. TAYLOR. Okay. I am sorry.

Mr. WALDEN. If my constituents go to a pharmacy in any town in America?

Mr. TAYLOR. Sure.

Mr. WALDEN. Are they certain those drugs have not come in through a reimportation system that is not being regulated and inspected?

Mr. TAYLOR. Well, obviously, as part of working with the States, we have dual jurisdiction or complimentary jurisdiction with the States regarding pharmacy issues. And so if the States, for example in the context of these storefront pharmacies that have proliferated or in the context of some other situation where a pharmacy believes that the product that they are getting is what it purports to be, we would work with them to try and determine that source.

I think that——

Mr. WALDEN. But that is if the pharmacy thinks that. What if the pharmacy is part of the game here?

Mr. TAYLOR. Well, that is exactly right, and that is why I was going to go on. But that is just one part of the chain.

What we really are relying upon is a closed regulatory system that has worked very well to ensure that the American public is getting good quality products. And I still think that the American public should feel confident that the products that they——

Mr. WALDEN. But I have heard from some of my colleagues that there are storefront pharmaceutical pharmacies being set up that are, you know, Rx Canada, I do not know the names but that are being set up that are apparently importing directly from other

countries. They would have no reason to come to you to say hey check us out, right?

Mr. TAYLOR. Right. They would not come to us to say check us out. However, it is occurring.

We have sent a warning letter to a storefront pharmacy, actually two warning letters. One, and the entity is Rx Depot. We sent one in conjunction with the State of Arkansas, and then we sent another warning letter to the President of the company who is in Oklahoma. So we essentially made sure we were sending it to two locations.

In that context it was a storefront pharmacy that was facilitating the purchase of products from Canada and specifically as part of its marketing scheme it was claiming that the products were U.S. approved products.

We have received a response to our warning letter that we deem inadequate, and we will respond accordingly. At the same time the States are taking action against that storefront pharmacy and we are also working with the States very closely to identify other storefront pharmacies that might require some type of follow up action.

Mr. WALDEN. Okay. Back to Ms. Durant. Customs has the responsibility to detain all imported controlled substances. Are you seeing a similar increase in the importation of controlled substances? Can you give the committee a better understanding of the procedures and resources that must be expended to seize and destroy a controlled substance?

I understand perhaps Valium and some of these other controlled substances are making their way into——

Ms. DURANT. We have seen an increase. Although we do not have hard numbers, we have seen an exponential increase in all areas including controlled substances like Valium.

We are required for every detention and seizure to give the victim of that seizure, if you would, or the importer, due process which requires us to detain. Even if it is under our own authority to seize, we do have to give a notice of seizure. There is a petition period and a forfeiture. And during the time that we have those drugs, we have quite considerable care and custody requirements.

Mr. WALDEN. But are you seeing an uptick, though, in the number?

Ms. DURANT. Yes.

Mr. WALDEN. Okay. Now, I want to move on to another topic, which is the safety of our food supply. Does FDA have jurisdiction over imported foods?

Mr. TAYLOR. We have jurisdiction over some imported foods. We regulate about 80 percent of the food supply and USDA regulates the other 20 percent.

Mr. WALDEN. And of the 80 percent that you regulate, how much of that is inspected, what percent that comes across the border?

Mr. TAYLOR. For imported foods, I think the latest figure that I saw was probably about 1.7 percent of imported food.

Mr. WALDEN. Because the issue that I get is we get all this food imported and we do very little inspection. Why can we not get our pharmaceutical drugs imported? I mean, what is the difference? They could be poisoning our food supply or using different chemi-

cals to raise food to compete with our farmers and you do not inspect it to see if it meets the U.S. standards because you can only inspect 1 percent? Do we not also have an issue on that front as well?

Mr. TAYLOR. Well, I mean, I think sir, in order to protect the public health we are trying to balance our resources across all the programs. As I noted earlier in my testimony, the investigational bodies that we devote to import functions work on import related issues that effect all our products. So with our limited resources, whether it be foods, pharmaceuticals, medical devices what we are trying to do is a better job of assessing risk, and then using that to determine our priorities and then directing our resources in a manner that best protects the public health.

Mr. WALDEN. Do you see a difference in threat assessment between imported food and imported drugs?

Mr. TAYLOR. As of right now our work on foods is directly directed to threat assessments and intelligence that we have regarding specific food commodities. And as part of our risk-based strategy we use that intelligence information, information that we get from several sources, to determine what foods we give greater targeting to.

Mr. WALDEN. Do you have a risk threat assessment for imported drugs?

Mr. TAYLOR. For imported drugs, no we do not. We do not have the same type of risk assessment that we have for food. However, to the extent that we are privy to intelligence that relates to drugs, we obviously would take those steps in accordance with whatever information we receive.

Mr. WALDEN. All right. My time is up.

Mr. TAYLOR. And one of the reasons why, is in the context of the bio-terrorism legislation, one of the requirements is that we do a threat assessment regarding food. So we have contracted one out, but we have also done one on our own.

Mr. WALDEN. Is there not the same sort of requirement for threat assessment for importation of drugs?

Mr. TAYLOR. No, sir, not as part of that Act. Not that I know of, sir.

Mr. WALDEN. All right. Thank you.

My time has expired.

Ms. Schakowsky is next.

Ms. SCHAKOWSKY. I thank you, Mr. Chairman.

As one who has worked on health care issues, prescription drugs and particularly with the elderly for a long time, I feel like those people are the largest consumers, as other consumers of prescription drugs in this country kind of get it at both ends by this administration and actually every one leading up to this: That is that we have done nothing to control the price of drugs and they keep escalating And while they have certainly added to the longevity and quality of life, they are inaccessible to many seniors. So it is no wonder that they are going to, and others, that they are going to do whatever they can to get the prescription drugs that they need. And it seems to me, as long as we keep resisting doing anything about the cost of pharmaceuticals, the resource for which a lot of it has been done with taxpayer dollars so let us not get too carried

away with R&D, because a lot of that is already provided by the taxpayers of this country. And then so they look for other solutions and then we fail to protect them from unsafe and dangerous, in some cases, drugs or ineffective drugs.

I was looking at the upcoming testimony of Robert Penezik, I do not want to say it wrong, the Assistant Statewide Prosecutor for the State of Florida, who listed the most commonly—let me use his words so I do not say it wrong, characterize these wrong. Hold on.

"The most commonly found drug to either have been counterfeited or otherwise adulterated drugs," and when I compare that to the list of drugs and the price in the United States as compared to the price in Canada, here is what I find. Celebrex is on that list. It is 63.5 percent discounted in Canada. Or Flonase Nasal, 64 percent less in Canada. Lipitor, 38 percent less. As interested as all of us are in Viagara. Let me just point out that Tomaxafin for breast cancer is 91.3 percent less in Canada than in the United States. So is it any wonder that consumers are turning to other places to get it?

But the problem, he also says this and this is where anyone is free to answer. Maybe this is mostly a question for Customs, I am not sure. But what he says is as prosecutors we are now seeing a trend of prior illegal narcotic traffickers entering into the prescription drug business.

I mean, imagine. Now it is not going to be cocaine, it is going to be Lipitor or Celebrex that are going to be blackmail that if you think about, is not any surprise. Because people want, need, demand these. And so we get kind of back to the demand side, are we not going to make these available to people at a reasonable price, but at the very least then what are we going to do about this growing criminal element that is now involved in the trafficking of prescription drugs? I would like to ask Customs.

Ms. DURANT. Customs has no specific information regarding that. I can check back and see if perhaps our sister agency has any indication and provide it for the record. I do not have any specific information that would indicate that that is true today.

Mr. TAYLOR. Sure, I can comment on this.

We have seen a wide array of people starting to get involved in counterfeiting products. And our response to these type of defendants is the same response that we would have in other counterfeit cases, which is really to respond to the counterfeit situation in two complimentary ways. Our first priority is to protect the public health by, first of all, in trying to figure out how far the counterfeit products have been dispersed, initiating recalls, educating the public to the potential harm from taking the products, working with the States, the pharmacies and the manufacturer of the invented product to learn more about the product so that we can find more information about what the product contains. And then as a sort of a complimentary role but not a mutually exclusive role, we would also conduct a criminal investigation to try and determine who is responsible for the introduction of these counterfeit products. And in some cases we have seen people who have been involved in other illegal activities involved in possibly the counterfeiting of pharmaceuticals.

Mr. SCHAKOWSKY. It was stated in your testimony, Ms. Durant, and I think we have hit on it somewhat that people who go to their local pharmacy may now be finding that these products are on the pharmacy shelves. Let me say the serving trend is the increase involved shipments through the mail indicating that these products could be making their way to pharmacy shelves. There is a possibility that stateside pharmaceutical distributors could be using these products as a source of supply.

So what is it that will assure people that when they go to their Walgreens or CVS they are not going to find that these products are on the shelves?

Mr. TAYLOR. Well, let me just give you a concrete example of some of the steps that we take to protect the public. I think the ongoing Lipitor investigation is a good example of where were fearful that the product had made its way to pharmacies.

When we first learned of this information, we did one recall that based on the information that we had before us that was focused on, quite frankly, the size of containers that are commonly sent to pharmacists. So as part of our initial recall and outreach to the community we focused on getting the message to pharmacies to be on the lookout for identifying information that would have helped them determine whether or not the product they had was indeed counterfeit as opposed to the authentic Lipitor.

In addition, we informed the public to the potential risk of taking the product. And at the same time, as part of both our regulatory and criminal investigation, we tried to determine, and we are still looking at how widely the product was dispersed.

So these are some of the steps that we take once we discover that a product might be counterfeit to try and protect the public.

Mr. SCHAKOWSKY. Let me say this last sentence. I think the best thing you could do for yourselves is to encourage this administration to establish a program that helps to lower the cost of drugs to the American public instead of in the Medicare bill that just came out of this committee, there is a prohibition on the Department of HHS to actually negotiate for lower drug prices under a Medicare prescription drug program. This will only make your job harder. And as long as those drug prices are sky high, we are going to see that there is going to be efforts on the part of consumers and therefore on the parts of the criminal elements to bring these drugs into the United States.

Thank you, Mr. Chairman.

Mr. WALDEN. The gentle woman's time has expired.

The Chair recognizes Mr. Rush.

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

This question may have been asked and answered already, however I want to see if I can get an answer for myself.

Much of today's hearing has spoken to the fact that reimported drugs are unsafe and even lethal in some cases. Can you remind the committee of the death rates of consumers when they have taken these drugs? In other words, how many American citizens have died because of imported and unsafe drugs?

Mr. Taylor, can you answer that for me?

Mr. TAYLOR. Sir, I do not have those specific figures. As part of——

Mr. RUSH. Does any of the panel have those figures?

Mr. HUBBARD. We believe that is an unknowable thing, Mr. Rush, because there is no system that tracks such injuries. And people that buy these drugs will tend to be not the sort of people that would report. They recognize that they bought them outside of the normal practice to buy them.

But as we discussed before you came in, the more likely injury from these drugs is that someone would not have their disease treated. You do not take a fake drug and have an adverse effect because it just does nothing. What happens is your illness is not treated, and that effect can occur over many months or even years.

Mr. RUSH. So these drugs are not lethal in themselves? They do not cause death or injury?

Mr. HUBBARD. Yes. Generally many of these drugs themselves are not going to immediately hurt you. They are just not going to help you. And the purpose of taking a drug, of course, is to treat an illness, not to just take a placebo or a sugar pill. And many of these drugs in fact are just that, they are subpoent or they are lacking in any active ingredient. You would not expect an injury from that, but you also would not get the medicinal treatment that the drug was intended for.

Mr. RUSH. I want to switch my line of questioning here. The FDA, is it not the case that because it is Customs and not FDA that typically works—Customs typically works mail facilities. And Customs inspectors would be the ones to intercept those products for which FDA has an import alert. What is the coordination nexus between the FDA and Customs, and how can you better provide better coordination between the FDA and Customs?

Mr. TAYLOR. I can start.

In the context of the mail facilities, you are absolutely correct. Customs sets aside packages that they think are of concern. FDA, who does not traditionally have a presence at the mail facility, will then come by and take a look at the packages that Customs has set aside. And pursuant to our own statute, we will make a decision whether or not to detain a product. And if we do decide to detain a product, then we need to issue a notice of detention, a notice of hearing and notice of refusal, thereby giving the right of the owner of the product to oppose or argue that the product is indeed not in violation of the Act and should be imported to the United States.

Mr. RUSH. Well, are you aware that when staff interviewed Customs officials in Miami they were told that they do not regularly receive import alerts from the FDA?

Mr. TAYLOR. I am aware, and that is why in my oral testimony and my written testimony I cited one of our improvements is going to be the fact that we are going to provide written or hard copies to Customs of all import alerts so that we can insure that communication problem does not occur in the future.

Mr. RUSH. Thank you, Mr. Chairman.

Mr. WALDEN. The gentleman yields back his time.

The Chair recognizes the gentleman from Michigan, Mr. Stupak, I believe, is next.

Mr. STUPAK. Thank you, Mr. Chairman.

Many of us have been here for the last 4 or 5 years going through this, and nothing seems to change here. I guess the only thing that changed is the volume is getting greater. Is that fair to say, Ms. Durant?

Ms. DURANT. Yes, it is.

Mr. STUPAK. I know you have testified a couple of times here.

Ms. DURANT. Yes, it is.

Mr. STUPAK. There is no due diligence here and follow up a policy or any kind of procedure to handle this drug situation, is there? There is no due diligence on behalf of the FDA? We just keep going around circles here for the last 4 or 5 years, right?

Ms. DURANT. FDA continues to work with us, but I think we are jointly overwhelmed by this problem in terms of the volumes.

Mr. STUPAK. Ms. Durant, before you detain a drug—could we put slide 9 up there?

When you get a drug in, you have it detain it, correct?

Ms. DURANT. That is correct.

Mr. STUPAK. Okay. And the drug on the packaging must have on their written declaration affirming personal use, it must have a 90 day supply or less, right? The evidence of medical supervisor or prescription on the package and product that has to be unavailable in the U.S. Those are the four criteria we look at, right?

Ms. DURANT. Those are among the criteria that we look at.

Mr. STUPAK. Okay.

Ms. DURANT. We detain other types of pharmaceuticals besides those.

Mr. STUPAK. But from the FDA's import guidance, those are the four things you basically look at?

Ms. DURANT. Those are among the things we look at. We look at source countries, we look at packaging for potential counterfeit.

Mr. STUPAK. And if it does not have those four things, can you not just send the package back?

Ms. DURANT. No, we cannot under our own authority. We can seize controlled substances under our own authority. But the FDA actually has the jurisdiction. So we detain it. We put it aside for the FDA to——

Mr. STUPAK. If the FDA told you, and I am looking at this is our October 2000 hearing. The FDA import guidelines, this is from the Department of Customs, those four factors that I listed for you: Written declaration affirming personal use, 90 day supply or less, evidence of medical supervision or prescription and product unavailable in the U.S. If the FDA told you if it does not have these four criteria, our import guidance, could you just ship that package back?

Ms. DURANT. If the FDA told us, we could ship it back.

Mr. STUPAK. Has that not been what we have been saying, at least myself and some of the others saying since 2000 just the FDA give them the guidance so you can just ship it back, right?

Ms. DURANT. We would like that guidance from the FDA.

Mr. STUPAK. Sure. So the FDA has to give Customs, tell you to ship it back if it does not have those guidance, right?

Ms. DURANT. That would be correct.

Mr. STUPAK. So slide number 9 there with all those packages, how many of those would you anticipate had the guidance, those four criteria on the package?

Ms. DURANT. Well, that is not the only criteria that we——

Mr. STUPAK. Sure. Sure. But how many would just have these four?

Ms. DURANT. Probably not——

Mr. STUPAK. None of them, right?

Ms. DURANT. Probably not.

Mr. STUPAK. In fact in October when we did the Dulles and Oakland facilities, none of them had that four criteria on. Of the 513 packages we seized off the line, none of them had that criteria?

Ms. DURANT. That would probably be correct.

Mr. STUPAK. So all 513 could have been shipped back, they would not have been sitting in some bins like we have right here, correct?

Ms. DURANT. I'm sorry?

Mr. STUPAK. All 513 could have been shipped back, they would not have been sitting in bins like that? We would not have this big huge supply, you would not be holding detaining drugs, correct?

Ms. DURANT. If the FDA——

Mr. STUPAK. Would just provide you to do that?

Ms. DURANT. [continuing] provided that guidance. Correct.

Mr. STUPAK. Correct? FDA, why do you not do it?

Mr. HUBBARD. I think, as we have explained, our law would require that each of those packages be put into our system and address——

Mr. STUPAK. No, no, no. These are your FDA import guidelines I have read. It does not say to detain. It said it had to have four specific things. That is your guideline. You even reiterate it in your testimony. Why do you not just tell Customs if it does not have these four factors, ship it back?

Mr. HUBBARD. Personally I wish we could.

Mr. STUPAK. Why do you not? You do not need congressional oversight on that.

Mr. HUBBARD. No. Unfortunately, our attorneys tell us we cannot do that.

Mr. STUPAK. Your attorneys? All right. In your testimony today you said large commercial shipments is what you look for, correct? Mr. Taylor, you said that, too, right?

Mr. HUBBARD. That was referring to trying to prevent commercialization. Because we cannot deal with these small packages, we have got to deal with the big ones.

Mr. STUPAK. What is large? What is large? A gentleman there has a package in his hand, is that large? It is right behind you there. It is on the screen. It is on over here. Are those large? Quantify large for me.

Mr. TAYLOR. I personally did not mention large package.

Mr. STUPAK. Oh, yes. Mr. Dingell you said large commercial shipments, additional steps we prioritize, we cannot detain everything, the greatest public harm, the business facility, train and retrain people.

Let us just start large. Quantify large for us.

Mr. TAYLOR. You cannot quantify large. I guess——

Mr. STUPAK. And why do you not use your four guidelines and ship them back so we do not have thousands of packages sitting here?

Mr. TAYLOR. My point is that merely saying something large, that is just one factor. Obviously, at the end of the day the most important factor is the harm that a product could cause or——

Mr. STUPAK. Well, wait a minute. You do not know what harm it is causing. You only inspect, what? About 1 percent, if you do that?

Mr. TAYLOR. Well, to the extent that we do look at the products, we do apply this risk-based approach——

Mr. STUPAK. Well, we know that the facilities tell us you guys do not even come by. They detain it and you do not even come by.

Mr. TAYLOR. Obviously the resources prevent us from——

Mr. STUPAK. No, no, that is not a resource issue. It is a policy issue. Now you are either going to come by or not. If you do not have the people to do it, why do you not just send it back? It does not have these four criteria. You do not have to worry about resources then.

Mr. TAYLOR. Because, as Mr. Hubbard explained, we still are bound under the Act to follow the——

Mr. STUPAK. Now wait now. Wait now. Now, you do not get to Section 801 until Customs accepts it. If you tell Customs not to accept it, it doesn't trigger Section 801. Your attorneys are right on 801 once you accept it. But you do not have to accept it if you just enforce your own policy and guidelines that you refuse to do.

Mr. TAYLOR. Sir, those policies and guidelines that you are talking about, they are what we call our personal importation policy. They do not make—as part of that policy——

Mr. STUPAK. Excuse me. Slide number 9. Are those not for personal use right there? That is your personal importation guidelines?

Mr. TAYLOR. I'm sorry, sir.

Mr. STUPAK. Well let me go to another one. You guys put out these alerts, right? Import alerts, that is authority to detain products. Last time we had testimony last fall on the drug Acutane, we talked about that, about the dangers of Acutane and FDA was going to put out an import alert on that. Has FDA ever done that?

Mr. TAYLOR. Yes, they have.

Mr. STUPAK. When did they do it?

Mr. TAYLOR. Sir, I do not have the exact date, but it was I believe the middle of December.

Mr. STUPAK. Middle of December?

Mr. TAYLOR. Yes.

Mr. STUPAK. Did you provide that to Customs?

Mr. TAYLOR. I do not know if—obviously, in the context of Miami, it looks like there is some miscommunication issues. But I know that Customs was involved in the discussions surrounding that import alert.

Mr. STUPAK. So if they did not have it, you only send it to certain facilities or what on Acutane?

Mr. TAYLOR. No. In terms of Acutane, we worked with Customs not only at the policy—at the time that we were putting the import alert together. And I know we communicated to Customs. The only

reason I am hesitating is in light of the information that we have determined as part of our ongoing review that there were communication issues in Miami that do not allow me to say definitively that was shared all throughout Customs.

Mr. STUPAK. Right. And you have those same communication problems in Dullas and Oakland and the rest of the places.

How do you know if it's Acutane in a box if you have never opened it?

Mr. TAYLOR. Obviously, that is one of the challenges.

Mr. STUPAK. Well, if you would just follow your four guidelines, you would not even have to open a package, would you?

Why cannot FDA just tell Customs not to accept it, because if you accept it you go into Section 801? Why cannot the FDA just put forth a policy that says if it does not follow these guidelines for importation of use, we reject it? Why do you not just do that?

One more question while you are at it so I have an answer for me, since the 106th Congress we have talked a lot about the importation of drugs through the web, the Internet, we have had the bill—I have had the bill to ban it. Okay. Certain criteria had to be followed. FDA has never taken a position on my bill. I have reintroduced it again this year. Would the FDA finally take a position on our bill, either support it or not support it? When you talk about needing insight and supervision from Congress, I have been around since the 106th Congress trying to give you that input and the FDA refuses to even take a position on our legislation. Would you promise this committee that to at least look at our bill and tell us whether or not you will support it or not to cut down on these Internet purchases of drugs? Yes or no. You going to take a position on it or not this year? It has been 4 years we have been waiting?

Mr. TAYLOR. Sir, I do not know if the administration has a position on your bill. This is simply information I do not possess.

Mr. STUPAK. Could you ask them to do that? It has been 4 years and we are still waiting for an answer.

Mr. GREENWOOD. The time of the gentleman has expired.

Mr. STUPAK. Thank you.

Mr. GREENWOOD. The gentleman from Texas, Mr. Green is recognized for 8 minutes.

Mr. GREEN. Thank you, Mr. Chairman.

And to follow up my colleague from Michigan, I think the concern I have is that the commercial quantities that we see on the slide as compared to the individual quantities. And if you could leave that slide back up, I want to talk about that a little bit.

Our seniors, in fact when I went home last Friday, I had seniors at a group in Houston, one of the couples asked me, said we get our pharmaceuticals from Canada because we cannot afford them if we got them here in Houston, Texas. And I said well the concern I have is that you buy from those places, although they had a reputable pharmaceutical and what have you. What I am seeing up there is does not look like it is for personal use, it looks like it is for commercial use. It is not my seniors from Houston, Texas or from Chicago buying individual 90 day supplies, or even 6 month supplies. I know the law is 90 days. But I have seniors who drive to Mexico from Houston, 6½ to 7 hours, just like people go across

to Canada. And I have actually bought pharmaceuticals in Latin America.

And so I can understand the concern from the FDA, but I am also concerned that we are seeing commercial importation of drugs that have no quality control on them.

Like my colleague from Chicago, if we had an affordable system, we would not have this problem. That people would not have to if they could not get them for half the price in Canada or Mexico, or even off the web it somebody says they are from Europe.

I understand there is significant risk associated with taking imported pharmaceuticals, and the product impose significant risk. For example, it seems that drugs manufactured in the United Kingdom, Canada, France, Japan and other industrialized countries would probably be far safer than drugs manufactured in some lesser developed countries. When we heard about Belize or the Bahamas, or someone else that maybe does not have these infrastructure like these.

Does the FDA have a system of gauging the potential risk based on where the drugs are imported from?

Mr. HUBBARD. No, we do not. We have no statutory direction to do such a thing. There is no such thing as reciprocity or equalization along those lines that you are suggesting, Mr. Green.

Mr. GREEN. So we would have to actually give the FDA the statutory authority to look at pharmaceutical manufacturers, say, in France or western Europe that want to import into the United States or export into the United States? There is no FDA authority now if someone is exporting in the United States that their factories or their plants have to be meet some quality?

Mr. HUBBARD. Well, if a facility in another country wants to sell a drug in the United States, that's perfectly acceptable if that facility is making an FDA approved drug and that facility has been inspected and improved by the FDA to make that drug.

Mr. GREEN. Okay. And that happens, I assume? We import pharmaceuticals on a commercial basis?

Mr. HUBBARD. Yes, that is correct.

Mr. GREEN. Do these same plants——

Mr. HUBBARD. They also make finished pharmaceuticals. Some finished pharmaceuticals. The actual pill that you purchase come from foreign plants that are inspected by FDA.

Mr. GREEN. Okay. Is there any of this information available to the customers or is it just to the businesses or the people, you know, the pharmacists or we call them PPMs that may import these?

Mr. HUBBARD. Well, generally if you the patient get a drug from any licensed pharmacy, you are almost certain to get an FDA approved that from an FDA inspected facility.

Mr. GREEN. Okay. What about a senior citizen that is not going to a licensed pharmacy in the United States, but using a website that says they are in Canada, that may or may not be true, but is there any security that we could give this group saying, you know, these are the places that you can buy your own individual prescriptions from?

Mr. HUBBARD. Not for foreign sites. There certainly is a system to identify the legitimate domestic sites called VIPS, run by the

National Association of Boards of Pharmacy. But for the foreign sites, there is no assurance that a patient is getting a drug from a legitimate site or that it is a truthful site. In many cases we see sites that are not truthful.

Mr. GREEN. Well, and it seems like that there should be, like my colleague from Michigan talked about his legislation to give the FDA that authority to do that. Because again the frustration is, is that I cannot sit here and say I am going to tell that couple that I just talked to last Friday that we are going to shutdown your only way you can afford your pharmaceuticals that your doctor tells you to. Or shutdown my constituents who will drive to Mexico and go over and buy their pharmaceuticals. And, again, it is in their own individual quantities because they know they can be stopped by Customs if they have anything larger than that. However, at one time before the increase in I guess surveillance at the border, I had people paying for their trip and buying it for other neighbors. And they had the prescriptions, but it was not in their names. But I do not encourage them and tell them, you know, you are going to seized. However, I do not know how many people that are 65 or over that the Customs detains in bringing back medication.

Mr. HUBBARD. May I just say, Mr. Green, it is important the constituents know we do not threaten or search or otherwise intimidate citizens bringing drugs back for their own use.

Mr. GREEN. Well, if it is not the FDA, it would be Customs, I would assume that would be doing it.

Ms. DURANT. That is correct. That is correct.

Mr. GREEN. Because I know FDA does not have the manpower to do it at the borders, but Customs has agents there. And they will ask if you are bringing back pharmaceuticals.

Ms. DURANT. They do ask. They do ask and they do check. And we do take it away. I hope we do not intimidate them too much. But if it does not meet that criteria, we do, we take them.

Mr. GREEN. Okay. But an individual could bring back a 90 day supply if they have a written prescription from their own doctor?

Ms. DURANT. I believe that is the case, 50 dosage units comes to mind.

Mr. HUBBARD. That is for controlled substances, I believe. For prescription drugs the 90 day supply issue is for experimental drugs for which there is no therapy in the United States. Legally they should not be bringing back any other prescription drug. However, FDA does not attempt to take those drugs away from patients who have gone to buy them.

Mr. GREEN. Well, I can tell you the pharmaceuticals that they are purchasing and bringing back, it is probably a rarity, and the only reason they're doing it is because of cost. They just can't afford them in the United States, so they'll go to Mexico or Canada.

Thank you for your testimony. Obviously we need to empower the FDA and hopefully this hearing will also allow Customs and FDA to have a working relationship. Because, again, those look like commercial quantities that should not be accepted in the United States.

Thank you, Mr. Chairman, for allowing me to sit in.

Mr. GREENWOOD. The Chair thanks the gentleman.

As everyone can tell, we have a series of votes that start now. So I think probably the prudent thing rather than to squeeze the testimony from the next panel, is to dismiss this panel. We thank you kindly for your patience and your testimony today.

And we will recess. I am going to guess it will be at least 1:15 until we finish this series of four votes and get back and bring on the second panel.

So the hearing is now recessed.

[Brief recess.]

Mr. GREENWOOD. The committee will come to order.

The Chair thanks the witnesses for our patience. We should be able to sail right through now.

The chairman officialy calls for Mr. Robert Penezik, Assistant Statewide Prosecutor for the State of Florida, Office of Statewide Prosecution and Dr. Greg Jones, Pharmaceutical Program Manager at the Drug, Devices, and Cosmetic Regulation, Bureau of Statewide Pharmaceutical Services, and Dr. Cesar Arias, Drug Inspector Supervisor for the Florida Department of Health, Bureau of Statewide Pharmaceutical Services.

Thank you all for coming here. I think that you are aware that the Oversight Investigation subcommittee takes it testimony under oath and I need to ask if any of your gentlemen have objection to giving your testimony under oath this afternoon? Good.

I should also advise you that you have the right to be represented by counsel. Did any of you want to be represented by counsel? I didn't think so. Okay.

If you would stand and raise your right hand then?

[Witnesses sworn.]

Mr. GREENWOOD. Okay. You are under oath. And, Mr. Penezik, we will start with you and you are recognized for 5 minutes for your opening statement.

TESTIMONY OF ROBERT M. PENEZIK, ASSISTANT STATEWIDE PROSECUTOR, OFFICE OF STATEWIDE PROSECUTION, STATE OF FLORIDA; GREGG JONES, PHARMACEUTICAL PROGRAM MANAGER, DRUG, DEVICES, AND COSMETIC REGULATION, BUREAU OF STATEWIDE PHARMACEUTICAL SERVICES; AND CESAR ARIAS, DRUG INSPECTOR SUPERVISOR, FLORIDA DEPARTMENT OF HEALTH, BUREAU OF STATEWIDE PHARMACEUTICAL SERVICES

Mr. PENEZIK. Thank you for the honor, privilege and opportunity to speak to this subcommittee. Mr. Chairman and members of the committee, I am Robert Penezik, Assistant Statewide Prosecutor for the State of Florida. Today, I will talk about the issues and problems raised in the Interim Grand Jury Report, which served as the conduit of the legislation, and ultimately the law signed by the Governor on June 13, 2003.

The citizens of the State of Florida and the United States are safer today due to the collective efforts of a broad spectrum of representatives in the State including: Governor Jeb Bush, Attorney General Charlie Crist, State Senators Durell Peaden and Walter "Skip" Campbell, State Representative Ed Homan, Department of Law Enforcement Commissioner Tim Moore, Secretary of Health Dr. John Agwunobi, Statewide Prosecutor Pete Williams, and last

but not least the members of the Seventeenth Statewide Grand Jury.

The overall process that led to the new State law, was truly government at its best, because all parties recognized the problem and worked diligently and tirelessly to solve it. I think it is especially important to recognize the contributions of Governor Bush and Attorney General Crist for their leadership and vision.

This morning, millions of people took a prescription drug. Most consumers probably gave little or no thought to where their prescription drugs came from or who handled them before they received them from their pharmacist. We all know that significant precautions are taken in the preparation and manufacture of our prescription drugs. However, most of us are unaware of the current lack of controls on prescription drugs once they leave the custody of the manufacturer.

To put it in the simplest of terms, before the new legislation in Florida, when you walked into any pharmacy that I'm aware of, you had no idea who handled your prescription drug, how it was handled, or if anyone had done anything inappropriate to it. Further, the pharmacists who dispensed your medication might themselves not even know the trail your prescription drug had traveled. Unless the drug store bought all of the prescription drugs it dispensed directly from the manufacturer, the risk is present. This is the problem that I would like to address and to discuss with you today.

I personally before I got involved in this investigation never gave a pause or a moment's thought when I ingested or took my own prescription. After this investigation I cannot tell you that there is not a single prescription that I would fill for myself or my family that would not cause me to at least give thought about the safety and prior whereabouts of that prescription drug.

Some background about the Interim Grand Jury Report. At the end of last year, Governor Bush was briefed on the adulterated and counterfeit prescription drug problem in Florida caused by, among other things, the secondary pharmaceutical drug wholesale market. Governor Bush immediately petitioned the Florida Supreme Court to convene a Statewide Grand Jury. The Seventeenth Statewide Grand Jury was impaneled in early 2003 and, after weeks of testimony, the Grand Jury issued the "First Interim Report of The Seventeenth Statewide Grand Jury" in February 2003.

In the Interim Report, the Grand Jury made a number of significant findings and proposed a comprehensive series of recommendations. The Grand Jury expressed its concern for the high risk of adulterated and counterfeited drugs entering the prescription drug supply of the State of Florida. It heard testimony of the many ways by which these adulterated drugs enter the stream of commerce and eventually end up on the shelves of our pharmacies, clinics and hospitals. They heard about prescription drugs that were sometimes sold three, four, five times without any apparent legitimate economic reason, before reaching the ultimate dispenser.

The Grand Jury also found that the "pedigree papers," or paper audit trails that track the drugs from the manufacturer to the point they are dispensed, are the most effective way to prevent diverted, adulterated or counterfeit drugs from entering the market-

place. Such pedigree papers would allow each purchaser of prescription drugs to determine who previously handled the drugs, and would thus serve to greatly minimize the introduction of adulterated drugs into the marketplace. However, the Grand Jury found that the pedigree paper standing alone was not enough. It stated, "we believe that Florida should require pedigree papers to be delivered all the way from the manufacturers to dispensers and that all buyers be required to verify pedigree papers through the exercise of due diligence."

The Interim Report of Florida's Seventeenth Statewide Grand Jury Report illustrates the potential danger to the citizens of Florida as well as the citizens of this Nation. The Grand Jury found that the wholesale pharmaceutical industry in Florida has been corrupted by the infiltration of a criminal element that is potentially reaping enormous illicit gains while tainting the prescription drug supply. The Grand Jury made several recommendations to address these problems The Grand Jury made several recommendations to address these problems, including:

1. Creating a standardized form of pedigree paper; 2. Require pedigree papers in every transaction from the manufacturer to the end-user; 3. Create new crimes for offenses involving pedigree papers; 4. Increase the penalties for anyone who introduces adulterated or counterfeit prescription drugs into the stream of commerce; 5. Clarify the definition of an authorized distributor of record; 6. Give the Florida Department of Health clear authority to shut down wholesalers in violation of State statutes; 7. Give the Florida Department—I have been asked to stop. May I continue or do you want me to——

Mr. GREENWOOD. No, you may finish your statement, sir.

Mr. PENEZIK. Thank you, sir.

Give the Florida Department of Health clear authority to seize and destroy drugs that pose a threat to the public health, and; 8. Increase the requirements to become a licensed pharmaceutical wholesaler in Florida.

Based on this compelling report from the Seventeenth Statewide Grand Jury, Florida Attorney General Charlie Crist immediately crafted legislation to address the problem and enact the Grand Jury's recommendations. The Florida Legislature responded quickly, and many of the Grand Jury's recommendations were proposed in bills sponsored by various legislators. That bill was signed by Governor Jeb Bush on Friday, June 13, 2003.

Among other things, Florida's new legislation requires or provides for:

1. Vastly improved documentation of vital pharmaceuticals in order to prevent their adulteration or counterfeiting; 2. Full pedigree papers on all prescription drugs by July 1, 2006; 3. Due diligence by those receiving pedigree papers; 4. Full authority by the Florida Department of Health to destroy medication that has been adulterated or improperly stored; 5. Full authority by the Florida Department of Health to shut down licensed wholesalers in violation of State statutes until the deficiencies are corrected; 6. Increased criminal penalties for pedigree paper violations, as well as other violations involving adulterated drugs; 7. Increased permit-

ting requirements for drug wholesalers in Florida, including raising bonding requirements and stricter background checks.

It is extremely important to note that the legislation was a product of cooperation between the Attorney General, law enforcement, the Florida Legislature, the regulators at the Florida Department of Health, and representatives of the legitimate prescription drug whole industry. This bill and law is an important first step in identifying and solving this problem. The legislation imposes an immediate requirement of pedigree papers on a select list of approximately 35 prescription drugs that have been shown by law enforcement to have been counterfeited or mislabeled. And the opportunity exists later to add to those drugs if necessary.

As you know, prescription drugs are wholesaled and dispensed in every State and often travel through many States before they arrive at their ultimate destination. Therefore, an action or lack of an action in one State can easily affect the citizens of another State. That is why we believe it so important to have a uniformed law applied and enforced nationwide.

By now you have probably heard the horror stories involving counterfeit prescription drugs. For example, the doctor who thought his son was being injected with a growth hormone, when in reality he was getting insulin. The young boy who thought he was receiving medicine to increase his red blood cell count, but was actually receiving counterfeit medication. More recently you may have heard of the individuals placing tap water in vials of medication and then labeling those vials with the name of a cancer medication. These despicable counterfeiters are preying upon people who already have suffered a great misfortune.

Much of the illegal activity is centered on very expensive so called high-end drugs. However, it should be noted that fraudulent activity has been detected in lesser priced drugs as well.

In conclusion, the business of selling counterfeited and adulterated drugs is booming. As with almost all criminal activity, the motive is money. In the case of buying and reselling adulterated prescription drugs, the money that can be made from illegal activity is staggering. As prosecutors, we are now seeing a trend of prior illegal narcotic traffickers entering into the prescription drug business. Unfortunately for consumers, the drug traffickers have not had a moral enlightenment. Rather, they now apply the tools of their illegal trade to the prescription drug business.

Most of us probably know someone that takes one or more prescriptions drugs daily. I do have a 17 month old child, 2 parents and an 83 year old grandmother who takes prescriptions drugs. I have a goal that someday when I walk into a pharmacy there will be a sign at that pharmacy saying we trace every drug that we have in our possession and we know the origin, who has handled it and how it was handled. I also have a goal that I do not want to ever have to give pause when I take another prescription drug or administer one to my child.

Thank you, Mr. Chairman.

[The prepared statement of Robert M. Penezik follows:]

PREPARED STATEMENT OF ROBERT M. PENEZIC, ASSISTANT STATEWIDE PROSECUTOR, STATE OF FLORIDA

Thank you for the honor, privilege and opportunity to speak to this sub-committee. Mr. Chairman and Members of the Subcommittee, I am Robert Penezic, Assistant Statewide Prosecutor for the State of Florida. Today, I will talk about the issues and problems raised in the Interim Grand Jury Report, which served as the conduit of the legislation, and ultimately the law signed by the Governor on June 13, 2003.

The citizens of the State of Florida and the United States are safer today due to the collective efforts of a broad spectrum of representatives in the State including: Governor Jeb Bush, Attorney General Charlie Crist, State Senators Durell Peaden and Walter "Skip" Campbell, State Representative Ed Homan, Department of Law Enforcement Commissioner Tim Moore, Secretary of Health Dr. John Agwunobi, Statewide Prosecutor Pete Williams, and the members of the Seventeenth Statewide Grand Jury. This overall process that led to the new State law, was truly government at its best, because all parties recognized the problem and worked diligently and tirelessly to solve it. I think it is especially important to recognize the contributions of Governor Bush and Attorney General Crist for their leadership and vision.

This morning, millions of people took a prescription drug. Most consumers probably give little or no thought to where their prescription drugs came from or who handled them before they received them from their pharmacist. We all know that significant precautions are taken in the preparation and manufacture of our prescription drugs. However, most of us are unaware of the current lack of controls on prescription drugs once they leave the custody of the manufacturer.

To put it in the simplest of terms, before the new legislation in Florida, when you walked into a pharmacy, you had no idea who handled your prescription drug, how it was handled, or if anyone had done anything inappropriate to it. Further, the pharmacists who dispensed your medication might themselves not even know the trail your prescription drug had traveled. Unless the drug store bought all of the prescription drugs it dispensed directly from the manufacturer, the risk is present. This is the problem that I would like to discuss with you today.

First, I believe it would be helpful to define a few terms included in the testimony.

Drug Diversion—is the movement of legal drugs into the illicit marketplace.

Adulterated drugs—are counterfeit, mislabeled, diluted, improperly stored and/or improperly handled prescription drugs are all considered to be adulterated drugs under Florida Statutes. Any of these acts make the drugs unfit for human consumption.

BACKGROUND & INTERIM GRAND JURY REPORT

At the end of last year, Governor Bush was briefed on the adulterated and counterfeit prescription drug problem in Florida caused by, among other things, the secondary pharmaceutical drug wholesale market. Governor Bush immediately petitioned the Florida Supreme Court to convene a Statewide Grand Jury. The Seventeenth Statewide Grand Jury was impaneled in early 2003 and, after weeks of testimony, the Grand Jury issued the "First Interim Report of The Seventeenth Statewide Grand Jury" in February 2003 (the "Interim Report"). Copies have been provided to the Members of the Subcommittee.

In the Interim Report, the Grand Jury made a number of significant findings and proposed a comprehensive series of recommendations. The Grand Jury expressed its concern for the high risk of adulterated and counterfeited drugs entering the prescription drug supply of the State of Florida. It heard testimony of the many ways by which these adulterated drugs enter the stream of commerce and eventually end up on the shelves of our pharmacies, clinics and hospitals. Some prescription drugs were sold and resold 4 and 5 times, without any apparent legitimate economic reason, before reaching the ultimate dispenser.

The Grand Jury also found that the "pedigree papers," or paper audit trails that track the drugs from manufacture to the point they are dispensed, are the most effective way to prevent diverted, adulterated or counterfeit drugs from entering the marketplace. Such pedigree papers would allow each purchaser of prescription drugs to determine who previously handled the drugs, and would thus serve to greatly minimize the introduction of adulterated drugs into the marketplace.

However, the Grand Jury found that the pedigree paper standing alone was not enough. It stated, "[w]e believe that Florida should require pedigree papers to be delivered all the way from the manufactures to dispensers and that all buyers be required to verify pedigree papers through the exercise of due diligence."

The Interim Report of Florida's Seventeenth Statewide Grand Jury Report illustrates the potential danger to the citizens of Florida as well as the citizens of this

nation. The Grand Jury found that the wholesale pharmaceutical industry in Florida has been corrupted by the infiltration of a criminal element that is potentially reaping enormous illicit gains while tainting the prescription drug supply. It is important to note that we are not referring to the major prescription drug wholesalers. Rather, Florida's concern arose with some of the other 400 wholesalers licensed in the Florida and another 900 wholesalers licensed to ship prescription drugs into Florida. As the Grand Jury noted, Florida's licensing requirements for prescription drug wholesalers was inadequate.

The Grand Jury made several recommendations to address these problems, including:

1. Create a standardized form of pedigree paper.
2. Require pedigree papers in every transaction from the manufacturer to the end-user.
3. Create new crimes for offenses involving pedigree papers.
4. Increase the penalties for anyone who introduces adulterated or counterfeit prescription drugs into the stream of commerce.
5. Clarify the definition of an authorized distributor of record.
6. Give the Florida Department of Health clear authority to shut down wholesalers in violation of state statutes.
7. Give the Florida Department of Health clear authority to seize and destroy drugs that pose a threat to the public health.
8. Increase the requirements to become a licensed pharmaceutical wholesaler in Florida.

FLORIDA LEGISLATURE

Based on this compelling report from the Seventeenth Statewide Grand Jury, Florida Attorney General Charlie Crist immediately crafted legislation to address the problem and enact the Grand Jury's recommendations. The Florida Legislature responded quickly as well, and many of the Grand Jury's recommendations were proposed in bills sponsored by Florida Senators Durell Peaden and Walter "Skip" Campbell, together with Florida Representative Ed Homan. This led to the passage of Senate Bill S 2312, the "Prescription Drug Protection Act," which was signed into law by Governor Bush on Friday, June 13, 2003. A copy of this bill may be found at MyFlorida.com. Further information regarding the adulterated drug problem is addressed in a report issued by the Office of Program Policy Analysis and Government Accountability (OPPAGA). A copy of the OPPAGA report can be found at www.oppaga.state.fl.us.

Among other things, Florida's new legislation requires or provides for:

1. Vastly improved documentation of vital pharmaceuticals in order to prevent their adulteration or counterfeiting.
2. Full pedigree papers on all prescription drugs by July 1, 2006.
3. Due diligence by those receiving pedigree papers.
4. Full authority by the Florida Department of Health to destroy medication that has been adulterated or improperly stored.
5. Full authority by the Florida Department of Health to shut down licensed wholesalers in violation of state statutes until the deficiencies are corrected.
6. Increased criminal penalties for pedigree paper violations, as well as other violations involving adulterated drugs.
7. Increased permitting requirements for drug wholesalers in Florida, including raising bonding requirements and stricter background checks.

In describing the new legislation, Florida Attorney General Charlie Crist said, "We now have new tools to combat this type of health care fraud. Our most vulnerable citizens now have a place to go when money overwhelms compassion."

It is extremely important to note that this legislation was a product of the cooperation between the Attorney General, law enforcement, the Florida Legislature, the regulators at the Florida Department of Health, and representatives of the legitimate prescription drug wholesalers. The legislation imposes an immediate requirement of pedigree papers on a select list of approximately 35 prescription drugs that have been shown by law enforcement to have been counterfeited or mislabeled. (Should law enforcement detect criminal activity in additional drugs, the legislation also provides for the emergency listing of such new drugs on the full pedigree paper list by the Florida Attorney General.) The pedigree paper requirement on the remainder of all prescription drugs, regardless of whether they are sold by authorized distributors of record, takes effect on July 1, 2006, in order to allow the pharmaceutical drug industry to develop cost effective technology for the tracking of every prescription drug shipment.

Attorney General Crist is proud of this accomplishment and is hopeful that other states and the nation will consider taking similar action. Prescription drugs are wholesaled and dispensed in every state and often travel through many states before they arrive at their ultimate destination. Therefore, an action or lack of action in one state can easily affect the citizens of another state. That is why we believe it so important to have uniform laws applied and enforced nationwide.

By now you have probably heard the horror stories involving counterfeit prescription drugs. The doctor who thought his son was being injected with a growth hormone, when in reality he was getting insulin. The young boy who thought he was receiving medicine to increase his red blood cell count, but was actually receiving counterfeit medication. More recently you may have heard of the individuals placing tap water in vials of medication and then labeling those vials with the name of a cancer medication. These despicable counterfeiters are preying on people who already have suffered a great misfortune.

Much of the illegal activity is centered on very expensive drugs such as Epogen, Neupogen and Procrit, which are used in the treatment of cancer or HIV. However, it should be noted that fraudulent activity has also been detected in such lesser priced drugs like Lipitor and Viagra. In our opinion, the list of prescription drugs that could potentially be adulterated or counterfeited is quite large.

Below are the prescription drugs most commonly found to have been either counterfeited or otherwise adulterated: Neupogen; Gammagard; Epogen; Gammimune; Procrit; Oxycontin; Serostim; Viagra; Nutropin AQ; Viramune; Panglobulin; Sustiva; Venoglobulin; Prevacid; Zyprexa; Risperdal; Trizivir; Rocephin; Combivir; Avandia; Epivir; Lamisil; Viracept; Cipro; Megace; Lipitor; Crixivan; Celebrex; Serostim; Mepron; Diflucan; Aricept; Norvir; Zoloft; Zocor; Ziagen; Vioxx; Zithromax; Albuterol; Ipatropium; Flonase; and Nizoral.

CONCLUSION

The business of selling counterfeited and adulterated drugs is booming. As with almost all criminal activity, the motive is money. In the case of buying and reselling adulterated prescription drugs, the money that can be made from illegal activity is staggering. For example, a 2001 investigation discovered that South Florida criminals had counterfeited Procrit, a drug used to boost the immune systems of cancer and HIV/AIDS patients. The criminals re-labeled approximately 110,000 bottles of low strength Epogen to make the bottles appear to contain high strength Procrit, a drug 20 times the strength of the Epogen in the bottles. The criminals resold the re-labeled drugs into the wholesale market with forged pedigree papers, passing the drugs through four states. Investigators located 800 boxes of the counterfeit Procrit at a large Texas wholesaler, which had unknowingly purchased the counterfeit Procrit. In addition, investigators found some of the product in Kentucky. In all, investigators recovered less that 10% of the counterfeit Procrit. It is estimated that the criminals in the chain may have made an illicit profit of approximately $46 million. As prosecutors, we are now seeing a trend of prior illegal narcotic traffickers entering into the prescription drug business. Unfortunately for consumers, the drug traffickers have not had a moral enlightenment. Rather, they now apply the tools of their illegal trade to the prescription drug business.

Most of us probably know someone that takes one of the above-mentioned prescription drugs. This, more than anything, illustrates the need for Congressional action. Thank you for the opportunity to speak to this sub-committee. I am happy to respond to any questions you might have.

Additional reports filed by the State of Florida are available at:
http://www.oppaga.state.fl.us/reports/pdf/0318rpt.pdf
http://myfloridalegal.com/grandjury17.pdf
http://www.muflorida.com/includes/directoryshtml

Mr. GREENWOOD. Thank you, sir. Appreciate your testimony.

Mr. Jones, you are recognized for your testimony.

TESTIMONY OF GREGG JONES

Mr. JONES. Thank you Mr. Chairman and members of the subcommittee for the chance to raise the awareness of problems effecting the safety and the integrity of our Nation's drug supply. Mr. Arias on my left and I gained much of our early investigative experience working the cases that came before you in 1986 to 1990.

I have submitted a written statement and will try to keep my verbal statements brief.

Despite the shocking stories you will find our testimony, I am confident that the United States drug supply remains unequalled in safety and efficacy. A Florida task force has been intensely and tirelessly investigating criminal prescription drug diversion since late 2001. Local, State, and Federal criminal law enforcement involvement has been essential in unraveling and revealing a nationwide secondary wholesale market that is riddled with corruption. The FDA's Office of Criminal Investigation plays a vital role in our investigation.

This corruption is allowing the entry and counterfeit of adulterated drugs into our drug supply and is damaging the legitimate wholesale industry.

Our citizens and health care professionals have complete confidence that their prescription drugs are safe and effective. Unlike other countries around the world, our citizens have never had to worry whether their drugs are counterfeit or adulterated in anyway. Physicians place a blind faith in ordering a drug for a patient and assume the potency and the identity that they ordered. They have never had to worry or, as you have indicated earlier, suspect that a cancer patient who failed to respond to a treatment and it was the result of the drug being counterfeit or subpotent.

When I tell pharmacists and physicians that increasingly the numbers of drugs that they use don't travel in the traditional route from manufacturer to wholesaler to pharmacy, they are shocked. Prescription drug laws strive to maintain our drugs in a closed distribution system that is licensed and tightly regulated from manufacturer to drug wholesaler to pharmacy to patient. In reality, major holes exist in the integrity of our prescription drug delivery system allowing large quantities of questionable drugs to enter our drug supply. These include stolen and hijacked drugs including a case we had from last year where HIV and transplant drugs requiring refrigeration were hijacked. One Miami wholesaler was offered the same drug stolen from their own warehouse.

Drugs bought off the street of Miami from victimized Medicaid patients enter the drug supply. The pharmacy labels are peeled off and removed with lighter fluid and heat guns.

Special low priced drugs sold to closed pharmacy and other health care entities are still prevalent in the secondary market. A good case of this are the doctors recently buying excessively large amounts of the drug Lupon for office use at reduced prices and selling these into the wholesale market.

Counterfeit drugs, both subpotent and even contaminated with dangerous bacteria that is life threatening to immuno compromised patients taking these drugs to save their life is prevalent in our drug distribution system today. In the past 2 years 10 counterfeit drugs have moved through Florida valued at tens of millions of dollars. It is gut wrenching to think about the poor father, a physician no less, that injected his son with counterfeit growth hormone 3 times before giving in to his son's complaints about the inflammation and the burning from the contaminated drug.

Some day many of us, if you have not already, will have to sit in an oncologist's office and receive a devastating diagnoses, maybe

even for those you hold dearest; your spouse, your parents, worst of all a child. Millions of questions will flood your mind. The last one you need to worry about is whether the drug that you are going to get to save your life, such as the drugs that we have here, are counterfeit or subpotent.

We also see drugs that are sold for export at reduced prices and never exported. Last summer Mr. Arias stopped sales in Miami of 50 pallets of Gammagard, Baxter's immune globulin that was found stored in an unlicensed Miami food warehouse.

We are seeing ever increasingly drugs that have been repackaged as in the case of the recent counterfeit Lipitor. Every major wholesaler distributes large numbers of commonly used repackaged drugs to pharmacies. This is an alarming new avenue for counterfeit or smuggled foreign drugs to easily make their way to the pharmacy shelf.

We have found the pedigree paper to be a valuable tool for regulators and law enforcement. There is very little use of the pedigree paper outside of our State and I have situations where drugs are offered to customers with papers or without papers. Drugs with pedigree papers costing more.

The PDMA became law in 1988 and today 15 years later, the final rule on pedigree set to take effect in 1999 has been stayed a fourth time. This subcommittee recognized the importance of knowing a drug's origin 15 years ago as a tool for wholesalers in the industry to identify where a drug has been before they buy it. Your vision of the pedigree revealing the true source of a drug has never been implemented nationwide.

Florida's legislators recognized the value of the pedigree, and in 2006 if a Florida wholesaler did not buy a bottle of a drug directly from the manufacturer, they will need a pedigree back to the manufacturer and must pass it all the way to the pharmacy.

In September of this year a full pedigree will be required for a list of 30 drugs that are commonly counterfeited and adulterated.

Only when State laws and Federal laws alike are strengthened will we have the tools necessary to fight this problem. Regulators cannot convince law enforcement to investigate or prosecutors to prosecute when violations are only misdemeanors. We have worked with many States over the past 2 years, and I am convinced that most States have these problems and do not know it. Our counterparts are learning the corrupt wholesaler is changing.

It is mindboggling to think about all the issues effecting prescription drugs today. Patients that buy drugs from foreign countries with or without a prescription, lifestyle drugs purchased with a questionnaire over the Internet or just buying drugs off of the street. These patients are taking a conscious risk.

The laws that we are addressing today effect the mainstream drug supply of our country and are designed to work behind the scenes preventing problems so that physicians, pharmacists and citizens will have complete trust that the drugs used to treat our sickest from cancer patients to our children with ear infections can have complete confidence.

Thank you for the opportunity to discuss these important issues effecting the safety and the integrity of not only Florida, but our Nation's drug supply.

[The prepared statement of Gregg Jones follows:]

PREPARED STATEMENT OF GREGG JONES, PHARMACEUTICAL PROGRAM MANAGER, STATE OF FLORIDA

Mr. Chairman and Members of the Subcommittee, I am Gregg Jones, Pharmaceutical Program Manager for the Bureau of Statewide Pharmaceutical Services, Florida Department of Health (FLDOH) and registered pharmacist. I have 18 years of drug regulatory experience with Florida's Department of Health. Also present representing Florida's Department of Health is Mr. Cesar Arias, Drug Inspector Supervisor in South Florida. Together Mr. Arias and I represent 34 years drug diversion investigative experience with the FLDOH. We both gained much of our early investigative experience working in Miami on many of the cases and issues that came before this committee from 1986 to 1990.

Thank you for the opportunity to discuss the issues affecting the safety and integrity of our nation's prescription drug supply. Despite the concerns that we are raising today, I am confident that the United States drug supply remains unequaled in safety and efficacy. We will share problems being faced in Florida with counterfeit and adulterated drugs entering the wholesale drug market, the schemes, the magnitude of the problem, and efforts to fight the problem.

The Bureau of Statewide Pharmaceutical Services is a part of the Florida Department of Health, a public health agency, whose mission is to promote and protect the health and safety of all people in Florida through the delivery of quality public health services and promotion of health care standards. The Bureau is responsible for enforcing Florida's Drug and Cosmetic Act that is modeled after the federal Food, Drug and Cosmetic Act. We license over 4500 companies, approximately 1000 out of state. We have a broad range of regulatory responsibilities that include the licensure and inspection of Drug, Device, and Cosmetic manufacturers, including compressed medical gas manufacturers, dispensers of medical oxygen for home use, veterinary drug distributors, drug return companies, and drug destruction companies. We have a small administrative staff and a total of nine drug inspectors all of whom are registered pharmacists. Our inspectors are not sworn law enforcement officers. All actions taken by the Bureau are done under Florida's Administrative Procedures Act, although we are increasingly making referrals of violations to law enforcement agencies and work very closely with these agencies in the investigation and prosecution process.

Florida currently has approximately 435 licensed drug wholesalers, including brokers that do not take possession of drugs. We also license approximately 975 out-of-state drug wholesalers that sell prescription drugs into the State of Florida. The 975 out-of-state drug wholesalers are made up of many drug manufacturers and multiple locations of major wholesalers.

WHOLESALE INDUSTRY

The number of small secondary drug wholesalers who typically sell drugs among themselves is increasing. The drugs they sell appear to travel from secondary wholesaler to secondary wholesaler to secondary wholesaler, until ultimately they are sold to a primary wholesaler, or directly to a pharmacy. Many of the small secondary drug wholesalers never handle products and only generate elaborate paper trails, their existence only serving to hide the original source of the drugs. State laws vary widely as do enforcement actions, and minimal penalties allow the entry of counterfeit and adulterated drugs into our drug supply. We are working closely with other states and we know that our counterparts are also concerned about the increase in small drug wholesalers entering tainted drugs into the national drug supply through their states.

A Florida task force has been intensely and tirelessly investigating the criminal side of Florida prescription drug diversion since late 2001. The task force includes members from the Miami-Dade Police Department, the Attorney General's Offices of Statewide Prosecution and Medicaid Fraud, and the Florida Departments of Law Enforcement and Health. Criminal law enforcement involvement has been essential in unraveling and revealing a nationwide secondary drug wholesale market riddled with corruption drugs of questionable integrity.

The prescription drug distribution system in this country is complex. Ideally the prescription drug distribution system of the United States would be a closed system of distribution from manufacturer to wholesaler to dispenser to the patient. The most recognized closed distribution system for drugs is found with controlled substances. Every unit of a controlled substance is tracked from the manufacturer to the distributor and to the dispenser through a uniform federal system administered by the Drug Enforcement Administration. Many states expand on this tracking and

some monitor information on the flow the actual prescriptions of the most abused controlled substance. This system has been continually strengthened for many decades.

The U.S. prescription drug industry is one of the most tightly regulated and monitored industries in the world. Oversight and licensing is extensive from drug development, approval, manufacturing, and distribution, to medical prescribing, administering, and pharmacy dispensing. Unlike controlled substances, however, the history of drug wholesale regulation is very short. When the 1987 Prescription Drug Marketing Act was being drafted, a little over 30 states licensed their wholesalers. It has only been 11 years since all states were required to license their drug wholesalers in accordance with federal guidelines established by the Food and Drug Administration. A huge gap existed in drug protection between the time a drug left the manufacturer and arrived at the pharmacy, hospital, or doctor's office. These same concerns remain today, fifteen years after the passage of the Prescription Drug Marketing Act. A crime is committed every time a diverted drug enters the system through an unscrupulous wholesaler, yet little threat of punishment, and the lure of millions of dollars in profits, continues to fuel the problem nationwide. A diverted drug is one that has left the regulatory channels of licensed wholesalers, thereby bypassing health authority oversight.

CHRONOLOGY

Events leading to the present situation in Florida:

1992—Florida's Legislature as part of complying with FDA guidelines on licensure of drug wholesalers required the pedigree paper, once created to go back to the manufacturer and be passed on, even by an authorized distributor of record once it was created. The intent was to prevent an authorized distributor of record from not passing a pedigree paper when it purchased a drug from a non-authorized distributor of record.

Mid 90's—FLDOH began warning and educating drug wholesalers that did not provide pedigrees of drugs that were purchased from non-authorized distributors of record.

Late 90's—FLDOH began seeing increases in the number of small wholesalers whose primary function was dealing in expensive brand name medications that were purchased from licensed wholesalers and resold to licensed wholesalers. In conjunction with the City of Miami Police Department, the Attorney General's office of Medicaid Fraud, and FDA's Office of Criminal Investigation among other local, state, and federal law enforcement agencies FLDOH investigated the proliferation of drugs dispensed to Medicaid patients being sold to "Street Brokers" and then sold back to pharmacies.

2001—FLDOH began verifying pedigree papers finding large numbers to be falsified. Counterfeit drugs began to proliferate. With the assistance of FDA's South Florida Office of Criminal Investigation, FLDOH sought the assistance of Florida's Attorney General's Office of Statewide Prosecution in the case of a small secondary wholesaler dealing in a counterfeit of the drug Serostim.

Late 2001—FLDOH began working with the Florida Department of Law Enforcement investigating the sources of drugs in both licensed and unlicensed drug wholesale operations. This investigation rapidly developed into a task force composed of the Miami-Dade Police Department, the Attorney General's Offices of Statewide Prosecution and Medicaid Fraud, the Florida Departments of Law Enforcement and Health.

In November of 2001 the FLDOH sent a letter to every licensed drug wholesaler in the format of Q and A regarding the pedigree paper due to the increase in counterfeit and adulterated drugs entering the market with false pedigree papers or no pedigree papers at all. The industry was informed that the FLDOH had begun to initiate action where pedigrees were at issue. In short it said that Florida's pedigree requirement was stricter than the federal law requiring:

1. PEDIGREES TO GO BACK TO THE MANUFACTURER

2. PEDIGREES MUST BE PASSED ON EVEN BY AN AUTHORIZED DISTRIBUTOR ONCE CREATED.

3. AUTHORIZED DISTRIBUTOR STATUS IS TRANSACTION (BOTTLE) SPECIFIC (If you purchased a bottle of a Rx Drug from any one other than direct from the Manufacturer, you must pass on a Pedigree showing every prior sale of that bottle.)

The drug wholesale industry responded with serious concerns about FLDOH's interpretation of the state law and requested a delay in the implementation of FLDOH's interpretation of the pedigree from the Secretary of Florida's Department of Health, John Agwunobi, M.D. After meeting with industry, Dr. Agwunobi, an-

nounced the formation of an Ad Hoc committee composed of representatives from industry and government. This committee met monthly for 7 months. Dr. Agwunobi charged the committee with presenting recommendations to resolve the pedigree paper dilemma that satisfy the department's public health mission to protect the public from misbranded and adulterated drugs, while attempting to lessen the regulatory cost of compliance on the regulated industry. This charge included empowering the department by providing investigative tools to trace the source of drugs that are counterfeit or that have been diverted from regulated distribution channels so as to identify and prosecute the person or persons putting these drugs into the marketplace. This committee recommended that licensing requirements be strengthened, penalties be increased, and a full pedigree be enforced for certain high cost drugs.

In December of 2002, due to increasing concerns over the safety and security of Florida's prescription drugs, Governor Jeb Bush petitioned Florida's Supreme Court to impanel a Grand Jury to investigate counterfeit and adulterated drugs entering Florida's drug supply.

In February of 2003 the Seventeenth Statewide Grand Jury of Florida issued its First Interim Report. It is an understatement to say that the findings were shocking. The report speaks for itself and can found at http://myfloridalegal.com/grandjury17.pdf.

Also in late February of 2003, Florida's Office of Program Policy Analysis and Government Accountability (an office of the Florida Legislature) released a report on its investigation of counterfeit and diverted drugs within the prescription drug wholesale market. Essentially both entities made the following recommendations.

1. Clarify state law related to pedigree papers and direct the department to enforce the state law.

"Requiring pedigree papers to accurately trace drug sales histories back to the manufacturer is vital to ensuring the integrity of Florida's prescription drug market." "pedigree papers are necessary for investigators to trace counterfeit and diverted drugs back to their source."

2. Authorize the department to strengthen the permitting process.

3. Authorize the department to levy increased administrative penalties and fines.

4. Consider increasing criminal penalties for prohibited acts involving prescription drugs.

In May of 2003, the Florida Legislature passed the Prescription Drug Protection Act, a comprehensive rewrite of Florida's prescription drug laws aimed at protecting Florida's citizens from counterfeit drugs and drugs adulterated by diversion. Governor Bush signed this law into effect on June 13, 2003, less than two weeks ago. At the signing Governor Bush stated, "The bill I am signing today supports our efforts to ensure that when our citizens fill their prescriptions, they get what their doctor ordered." Florida Attorney General Charlie Crist said "It is hard to imagine a more heinous individual than one who is willing to profit from the suffering of others."

The new law raises the standard for wholesalers by adopting new and more strict requirements for permitting wholesalers including the following provisions:

- Raises bond requirements to $100,000
- Requires stricter background checks
- Requires every wholesaler to designate a contact person responsible for all transactions enhancing accountability for the drugs wholesalers distribute.
- It strengthens criminal laws by creating new felony crimes penalizing anyone who tries to obtain or sell drugs without proven history or "pedigree papers." It also creates more serious felonies for forging drug labels, prescription drug trafficking of more than $25,000 worth of prescription drugs and the sale of prescription drugs that result in injury or death to a person.
- It requires wholesalers to authenticate prior transactions on the pedigree papers.
- The law requires that by 2006, all drugs (each bottle) not purchased from a manufacturer, must have a pedigree that goes back to the manufacturer, and is passed all the way to the retailer by anyone that receives a pedigree. It eliminates the ambiguity of the industry's current interpretation of Authorized Distributor of Record. In the interim, it allows the FLDOH to create a list of specified drugs for which full pedigree requirements must be met. The full pedigree requirement will go into effect for a list of 30 drugs in September of this year.
- Increases regulatory authority of the Department of Health by allowing the department to shut down wholesalers operating in violation of Department of Health rules and to seize and destroy adulterated drugs posing an imminent danger to the public.

PROBLEMS OBSERVED IN THE WHOLESALE INDUSTRY

I am sure there are legitimate drugs in the secondary market but many of the drugs we see moving among small wholesalers are of questionable origin. These drugs all enter at some weak point in the system, usually a small drug wholesaler.

Special priced drugs from Health Care Entities

Drugs sold at reduced price to closed-door pharmacies, nursing home pharmacies, and physicians represent a large amount of drugs in the secondary market. These drugs are often looked on as not presenting a public health threat because the drugs are good, only being diverted from their intended channel of trade. However, a fraud is being committed against the manufacturer, and both state a federal drug distribution laws are being violated. The pathways these drugs take into the mainstream wholesale market punch holes in the integrity of our closed drug distribution system and allow the entry of drugs from every conceivable scheme of diversion.

The drug Lupron is a good example. It is sold to physicians cheaper than to drug wholesalers. Physicians all over the country have been buying excessive amounts of the drug, in some cases obtaining drug wholesale licenses to sell these products back into the market. Others simply sell the drugs with no license to drug wholesalers or unlicensed individuals willing to violate both state and federal law.

Stolen Drugs

Within the last 2 years we have seen the same drugs stolen from one wholesaler sold back to them. A trailer containing $3,000,000 worth of drugs was hijacked in route to South Florida from the wholesaler Cardinal and the entire contents removed. A trailer hijacked in Miami last fall contained HIV and Transplant drugs requiring refrigeration.

Drugs Intended for Export

Drugs are often sent to Miami freight forwarders for shipment overseas. These are most often drugs shipped form the manufacturer to a location of their customer who has represented themselves to be a charitable group or agent of a foreign account. A couple of years ago a generic drug sold to a South American hospital at 10% of the domestic price was shipped to Miami for export but within a week the drug showed up in a large Southeastern U.S. wholesaler. Last summer 50 pallets of Gammagard, Baxter's immune globulin was shipped to a freight forwarder in Miami for export. The drug was transferred to an unlicensed food storage warehouse where it stayed for several months while small quantities were diverted to Miami wholesalers. One of the wholesalers was actually an authorized distributor of Baxter, thus was not producing a pedigree when selling the product.

Repackaged Adulterated/Counterfeit/Foreign Unapproved Drugs

The recent case of counterfeit Lipitor being repackaged by MED-PRO, Inc., of Lexington, NE illustrates this alarming new avenue for substandard drugs to enter the market and easily make their way to pharmacies, nursing homes and other institutions. It is a common practice for drugs to be repackaged from large containers into units convenient for dispensing such as 30's 60's and 90's for sale to pharmacies by all levels of the wholesale market. Some drugs are repackaged in unit dose packages for sale to nursing homes or other institutions. A recent case in Florida involved a smuggled a foreign drug being repackaged into unit dose. In our case, the drug was purchased from a licensed wholesaler, however no pedigree was issued. The paperwork, which is the only thing left behind after a sale, did not identify the foreign drug. This scheme has a huge potential for entering tainted drugs into the market because the original packaging is lost. (Florida's new law will require repackagers to provide pedigree papers.)

Medicaid Drugs diverted from patients into the wholesale market

Sophisticated operations buy drugs from patients and the drugs are resold into the wholesale market. We are certain that this form of diversion is not unique to Florida and is happening in other states. The obvious public health threat is the lack of proper handling, especially for refrigerated items.

Counterfeit Drugs

Between 1985 and 2001 only 5 counterfeit drug cases were investigated by Florida's Department of Health. During the past 2 years, ten counterfeit drugs have moved through Florida drug wholesalers valued in tens of millions of dollars. With every new case we are shocked at the level of sophistication in the reproduction of labels, seals, and containers. The Serono product Serostim has been counterfeited to the point that the company has abandoned the drug wholesale system to deliver its product and now ships only directly to certain pharmacies authorized to dispense

their product. **In several of our cases the pedigree paper played a critical role.**

The number of smaller wholesalers selling directly to pharmacies and hospitals is increasing. They send emails, faxes, and sell online with daily specials. They are finding a new outlet for diverted drugs without having to sell them into the mainstream wholesale market. No pedigree is provided and the pharmacist or physician has no clue where the drugs have been. This is why the pedigree should go to the retail level, as required by the Florida legislation, effective 2006.

We have found that the pedigree paper is a useful tool in uncovering counterfeit drugs for regulators, law enforcement, and equally if not more important in terms of prevention, the drug wholesalers themselves. Both Federal and Florida law requires that the pedigree be passed prior to the sale. Wholesalers could use the pedigree to insure the quality of the drugs they purchase. Our findings however, are more consistent with the Florida Grand Jury when they reported "It's not surprising to us that no one checks the pedigree papers because they simply don't want to know the true background of what they're buying. This is nothing less than a blatant example of willful blindness." There is very little use of the pedigree paper outside our state, and we have seen situations where drugs are offered to customers "with papers" or "without papers" drugs with pedigree papers costing more.

CONCLUSION

Florida will begin enforcing pedigree requirements that are bottle specific (must go back to the manufacturer), be passed on by everyone, regardless of authorized distributor status once a pedigree is created, for a list of 30 drugs, beginning in September of 2003. In 2006 all pedigrees will be furnished to the pharmacy. While the future is bright for technological advances like computer chips the size of grains of sand storing information on a label as complete as the serial number of the bottle, this technology is years away and we can not delay the protection of our drug supply any longer. The PDMA became law in 1988 and today, 15 years later, the final rule on pedigrees, set to take effect in 1999, has been stayed for a fourth time. This is a valuable tool that the Florida legislature recognized should be utilized with it's original intent, to simply reveal the true source of a drug.

In 1987 this committee found that "American consumers cannot purchase prescription drugs with the certainty that the products are safe and effective" and "the integrity of the distribution system for prescription drugs is insufficient to prevent the introduction and eventual retail sale of substandard, ineffective, or even counterfeit drugs." As evidenced by the problems we have shared here, these same concerns still remain today, fifteen years after the passage of the Prescription Drug Marketing Act. Only when State laws and federal laws alike are strengthened will we have the tools necessary to fight this problem. Tougher licensing requirements and penalties are needed for perpetrators of the unconscionable crime of counterfeiting drugs used by the sickest and most vulnerable patients.

The environment for corrupt prescription drug wholesalers is changing in Florida. A tremendous effort is being made by our Governor, legislature, health officials, law enforcement, and the regulated wholesale drug industry, working together to identify and remedy the problems in our drug delivery system and restore trust to our healthcare professionals and our citizens. We have a responsibility to do a better job of insuring the safety and efficacy of the drugs on which we depend to improve the quality, extend, and even save the lives of our citizens.

Thank you for this opportunity to discuss these important issues affecting not only Florida's, but also our nation's prescription drug supply. I would be happy to answer any questions.

Mr. GREENWOOD. Thank you, Mr. Jones.

Mr. Arias?

TESTIMONY OF CESAR ARIAS

Mr. ARIAS. Good afternoon, Mr. Chairman. I want to thank the committee for the honor to speak to you about prescription drug diversion activities and counterfeit drugs, which have recently been uncovered in Florida.

I'm a registered pharmacist employed by the State of Florida Department of Health as a Drug Inspector Supervisor in the Miami area for 16 years. Our inspector and I in South Florida have witnessed the growth of pharmaceutical drug diversion over the span

of my career, and increased drug counterfeiting over the last 2 years.

When I started the job, the primary force behind pharmaceutical drug diversion was the different prices charged for the same drug by the pharmaceutical manufacturers to the different classes of trade. That is still a major cause for diversion, but today there are many other sources for diverted drugs including foreign drugs, stolen drugs, drugs purchased from unlicensed street brokers, and this includes counterfeit drugs.

The street broker is an individual who is unregulated and has no clue how to handle or store these pharmaceuticals which are temperature-sensitive products. The integrity of the drugs acquired through these channels is clearly a public health concern because there is no guarantee as to the drug's quality or stability. There is no way to know under what conditions these products have been stored or handled.

These brokers or illegal distributors funnel huge amounts of diverted drugs from the streets of South Florida back into the drug distribution system. Not just in Florida, but also throughout the Nation.

Our office was involved in one investigation involving drugs purchased off the street where a wholesaler in Ft. Lauderdale sold over $1 million in very expensive drugs to treat HIV and cancer. And these were sold through some of the largest wholesalers in the Nation in a 6 month period. All of the drugs had come from the streets of Miami via 2 unlicensed street brokers who would store these temperature sensitive injectable drugs requiring refrigeration at above 90 degrees, for hours at a time, in the trunks of their vehicles.

Our office is currently working cases as part of a task force, which is overseen by the Attorney General's Office of Statewide Prosecution, for which Mr. Penezik works. The task force includes the Florida Department of Law Enforcement, the Medicaid Fraud Control Unit of the Attorney General's Office, the Miami-Dade Police Department and the Florida Department of Health. During the last year and a half, the task force's efforts have resulted in identifying 11 different organizations, which the task force is currently investigating. These organizations, or cells, are responsible for the diversion of an estimated $250 million a year in pharmaceuticals that are obtained from the streets of Florida. These cases involved numerous types of prescription drug diversion including cargo thefts, burglaries, smuggling of foreign made drugs and the diversion of specially priced drugs sold to specialty physicians.

Some of these cells have perfected schemes, which involve the opening of shell corporations in other States. These companies obtain wholesale licenses for the sole purpose of creating false pedigree papers. The shell companies allow these folks to fool other States' officials and the ultimate customers to believe that the drugs have been obtained from legitimate wholesalers when in fact the drugs come from the streets of South Florida.

It was through the efforts of the task force that the presence of counterfeit Epogen and Procrit, was detected in the Nation's drug supply. This was the direct result of an undercover purchase of 100 boxes of counterfeit Epogen by a Florida Department of Law En-

forcement agent. The importance of the pedigree was made evident in this case. When the purchase of the Epogen was made, the investigators had no clue, even after examining the boxes, that the injectable drugs or products were counterfeit. What we knew was that the pedigree was false and therefore we had diverted product. Only after we submitted some of the boxes to the manufacturer and to the FDA did we learn that they were counterfeit. Up until that moment in April 2002 neither the FDA nor Amgen, the manufacturer, were aware that there was a problem of this sort with their product.

Subsequently our investigation discovered that up to 110,000 doses of Epogen 2000 unit product strength had been relabeled and converted to Epogen and/or Procrit 40,000 units strength. In effect, roughly about 25,000 patients received a 1 month supply of diluted drugs, about 1/20th of the required strength or the actual labeled strength.

Due to Florida's intervention and the information sharing with the FDA's Office of Criminal Investigations and the Texas authorities seized large amounts of counterfeit Epogen at a national wholesaler in Kentucky, and counterfeit Procrit at a second national wholesaler in Texas, respectively.

Through the efforts of the task force, we have been able to shut down about a dozen wholesalers in Florida and have alerted various other States to assist them in shutting down others in their respective States. The task force, through the efforts of FDLE, has shared information with FDA's Office of Criminal Investigation, which have followed up in other States and conducted search warrants, collected evidence to make criminal cases. It was through the evidence collected by the task force and shared with the Office of Criminal Investigation for FDA that led to the recent seizures and recalls made of the counterfeit Lipitor found in a Nebraska repacker and a Kansas City wholesaler.

In each instance in which counterfeits or diverted drugs have made their way into the mainstream distribution system it has been through a dishonest wholesaler. Once the drugs enter the system they can end up in any pharmacy in the Nation. That is why there is no patient in the Nation that can know with 100 percent certainty that the drugs they are getting are what they are purported to be or if they are, that they have not been in the trunk of someone's car, or sitting in a hot warehouse or a crackhouse in South Florida.

The work of the task force has exposed the tremendous problem that we are experiencing in Florida with drug diversion and counterfeiting. The law recently signed by Governor Jeb Bush, Florida's Prescription Drug Protection Act increases penalties, requires a new standard for wholesale licensing, and strengthens the pedigree paper requirement. People throughout Florida rely on the safety of our pharmaceutical supplies, and our efforts to protect them. Hopefully, Florida's new law and the work of our task force will be a model for the rest of the Nation.

Thank you for allowing me to bring this matter to your attention.

[The prepared statement of Cesar Arias follows:]

PREPARED STATEMENT OF CESAR ARIAS, FLORIDA DEPARTMENT OF HEALTH

Good morning my name is Cesar Arias. I want to thank the committee for the honor to speak about prescription drug diversion activities and counterfeit drugs, which were recently uncovered in Florida. As a registered pharmacist employed by the State of Florida Department of Health as a Drug Inspector Supervisor in the Miami area for 16 years, I have witnessed the growth of pharmaceutical drug diversion over the span of my career, and increased drug counterfeiting over the last two years.

This is not the same job I had 16 years ago. When I started on the job, the primary force behind pharmaceutical drug diversion was the different prices charged for the same drug by the pharmaceutical manufacturers to the different classes of trade. That is still a major cause for diversion, but today there are many other sources for diverted drugs including foreign drugs, stolen drugs, drugs purchased from street brokers, and even counterfeit drugs.

The street broker is an unregulated individual, who has no clue how to handle or store these temperature-sensitive products. The integrity of the drugs acquired through these channels is clearly a public health concern because there is no guarantee as to the drug's quality or stability. There is no way to know under what conditions they have been stored or handled.

These brokers funnel huge amounts of diverted drugs from the streets of South Florida back into the drug distribution system(not just in Florida, but also throughout the nation. I was involved in one investigation involving drugs purchased off the streets where a wholesaler in Ft. Lauderdale sold over $1 million in Neupogen for treating HIV to one of the largest wholesaler in the nation in a six-month period. All of the Neupogen had come from the streets of Miami via two unlicensed street brokers who would store this temperature sensitive injectable drug(requiring refrigeration(at above 90 degrees, for hours at a time, in the trunks of their cars.

Our office is currently working cases as part of a Task Force, which is overseen by the Attorney General's Office of Statewide Prosecution. The Task Force includes the Florida Department of Law Enforcement (FDLE), Medicaid Fraud Control Unit of the Attorney General's Office and the Miami-Dade Police Department. During the last year and a half, the task forces joint efforts have resulted in identifying 11 different organizations, which the Task Force is currently investigating. These organizations, or cells, are responsible for the diversion of an estimated $250 million a year in pharmaceuticals just in Florida. These cases involved numerous types of prescription drug diversion including cargo thefts, burglaries, smuggling of foreign made drugs and the diversion of specially priced drugs sold to specialty physicians.

Some of these cells have perfected schemes, which involve the opening of shell corporations in other states (about 20). These companies obtain wholesale licenses for the sole purpose of creating false pedigree papers. The shell companies allow these folks to fool other states' officials and the ultimate customers to believe that the drugs have been obtained from legitimate wholesalers when in fact the drugs come from the streets of South Florida.

It was through the efforts of the Task Force that the presence of counterfeit Epogen and Procrit, was detected in the nations drug supply. This was the direct result of an undercover purchase of 100 boxes of counterfeit Epogen by a Florida Department of Law Enforcement agent. The importance of the pedigree was made evident in this case. When the purchase of the Epogen was made, the investigators had no clue, even after examining the boxes, that the injectable products were counterfeit. What we knew was that the pedigree was false and therefore we had diverted product. Only after we submitted some of the boxes to the manufacturer and FDA did we learn that they were counterfeit. Up until that moment in April of 2002 neither the FDA nor Amgen, the manufacturer were aware that there was a problem with counterfeit Epogen.

Subsequently our investigation discovered that up to 110,000 doses of Epogen 2000 Units strength had been relabeled and converted to Epogen and Procrit 40,000 Units strength. In effect, 25,000 patients received a one-month supply of diluted drugs(1/20th of the required strength. Due to Florida's intervention and information sharing, the FDA's Office of Criminal Investigations (OCI) and the Texas authorities seized large amounts of counterfeit Epogen at a national wholesaler in Kentucky, and Procrit at a second national wholesaler respectively.

Through the efforts of the Task Force, we have been able to shut down about a dozen wholesalers in Florida and have alerted various other states to assist them in shutting down others. The Task Force(through the efforts of FDLE(has shared information with FDA's OCI, which have followed up in other states and conducted search warrants, collecting evidence to make criminal cases. It was through the evidence collected by the Task Force and shared with OCI that led to the recent sei-

zures and recalls made of the counterfeit Lipitor found in a Nebraska re-packer (Med-Pro) and a Kansas City wholesaler (Albers Medical).

In each instance in which counterfeits or diverted drugs have made their way into the mainstream distribution system it has been through a dishonest wholesaler. Once the drugs enter the system they can end up in any pharmacy in the nation. That is why there is no patient in the nation that can know with 100% certainty that the drugs they are getting are what they are purported to be(or if they are(that they have not been in the trunk of someone's car, or sitting in a hot warehouse or a crackhouse in South Florida.

The work of the Task Force has exposed the tremendous problem that we are experiencing in Florida with drug diversion and counterfeiting. The law recently signed by Governor Jeb Bush, Florida's Prescription Drug Protection Act increases penalties, requires a new standard for wholesale licensing, strengthens the pedigree paper requirement. People throughout Florida rely on the safety of our pharmaceutical supplies, and our efforts to protect them. Hopefully, Florida's efforts will be a model for the rest of the nation.

Thank you for allowing me to bring this matter to your attention.

Mr. GREENWOOD. Thank you, Mr. Arias.

And the Chair recognizes himself for 8 minutes for inquiry.

Let me get right back to you, Mr. Arias. You have described in some detail how law enforcement officials have found the counterfeit products at the user end and even at the wholesale end. Have you been able to get to the manufacturing sources? Have you been able to find where these counterfeit drugs are actually being produced?

Mr. ARIAS. We are actively investigating a case right now, Mr. Chairman.

Mr. GREENWOOD. Okay. And as we look at some of these counterfeit products, the packaging, I mean it is so skillfully done. It sort of raises a question in my mind as to how this can be done by criminal elements. For instance, it seems to me that most products have a fairly unique plastic bottle, or a tube or a box. And so they either reproduced or purchased from the same producer, I would think. And I am wondering what you have learned about that and has anybody gone to the people who produce the packaging, the raw plastic bottles and so forth and said are you selling this to anybody besides the actual legitimate manufacturer?

Mr. ARIAS. Well, we have alerted FDA about that issue as well as the recent case in which they made the three arrests in Miami, and the people have pled guilty. The individual purchased the stoppers and the crimps, this metal crimp around here. They bought that on the Internet. So FDA has been made aware of that situation.

Mr. GREENWOOD. So you can buy stoppers and crimps like that on the Internet?

Mr. ARIAS. That is what we learned from this individual.

Mr. GREENWOOD. Do any legitimate manufacturers acquire their stoppers and crimps on the Internet? It would seem to me there would probably be more conventional paths for those things to go in, that it seems to be suspect automatically if it is being sold on the Internet?

Mr. ARIAS. I am not the expert on that issue. But I imagine there are more conventional ways of ordering these.

Mr. GREENWOOD. It would seem to be a potentially very fruitful way to investigate these entities if you went to the sources of the packaging materials. Because I have a hard time imagining, although it may be possible, that these guys are actually not only re-

manufacturing or manufacturing the drug from scratch, but they are also remanufacturing the containers and the packaging from scratch.

Mr. ARIAS. Well, the individuals that were arrested and have pled guilty were putting the whole thing together. They were buying the empty vials, cleaning them out and then putting tap water and, you know, ordering like I said the crimps and the stoppers from the Internet and putting it together with some crude machinery that they created.

There is other individuals that are more ingenious in that they are converting a 2,000 unit strength, which is the weakest strength of these products, removing the little labels from the vials and putting a 40,000 unit label. In essence they are converting a $250 product into $4500. And if they were to test for this protein, qualitatively it would be there. Quantitatively it won't be there, but qualitatively it would be there. So it was a much more devious effort, and that is why a large amount of that product never was detected.

Mr. GREENWOOD. Either under your new law or existing State and Federal laws, what kind of penalties are you able to exact for that kind of offense?

Mr. PENEZIK. Under the new law for counterfeiting a prescription drug it will be a first degree felony.

Mr. GREENWOOD. And that would——

Mr. PENEZIK. In the State of Florida that is punishable by 30 years in prison.

Mr. GREENWOOD. Okay. Now, who has gone to jail so far in Florida as a result of this? The new law is too brand new, you haven't completed any prosecutions under the new law?

Mr. PENEZIK. Mr. Chairman, it does not go into effect until July 1.

Mr. GREENWOOD. Okay.

Mr. PENEZIK. We have prosecuted people under our old law and people have gone to court and have pled guilty and are being punishing for——

Mr. GREENWOOD. Are we getting jail or they getting probation for that?

Mr. PENEZIK. Some parts of that I would respectfully wish not to discuss because it is part of an ongoing investigation. But people, they are being punished. There are individuals that will be to prison because of their conduct.

Mr. GREENWOOD. Okay. Very well.

Ms. Arias, could you expand a little bit more about the case of, is it Nuepogen?

Mr. ARIAS. Correct.

Mr. GREENWOOD. That is not the one you were just holding up or is it?

Mr. ARIAS. The Nuepogen was the case in, I believe it was in 2000.

Mr. GREENWOOD. That is the HIV drug?

Mr. ARIAS. It is used to elevate the white blood cell count. And so when you are immune comprised, they treat you with this product to build your defenses.

Mr. GREENWOOD. Now, you said that the wholesaler was able to get this from street brokers and then sell it to one of the largest wholesalers in the Nation, is that right?

Mr. ARIAS. Mr. Chairman, all it takes it one dirty wholesaler to close their eyes or be willfully negligent, and that is all it takes. Once that happens, these people have a license and the next guy up the line, he is buying from a licensed entity. So unless the pedigree is confirmed, and that's why the pedigree is such an important tool for discovering diverted and counterfeited products.

Mr. GREENWOOD. And what is a street wholesaler? What does that mean to you?

Mr. ARIAS. When I refer to the street brokers——

Mr. GREENWOOD. Street brokers.

Mr. ARIAS. [continuing] these are people that are in the business of buying pharmaceuticals that are either stolen from hospitals or pharmacies, or they are paid for by third party insurance. And those products make their way back into the system.

Mr. GREENWOOD. Have you discovered any evidence, any of you, that products are being diverted from the actual manufacturer? IT would seem to be one relatively easy way to do this would be if you work in some warehouse or some manufacturing facility for a totally legitimate manufacturer that where you are moving fork lifts or moving pallets with great quantities of drugs to throw some of that in the trunk of your car and then go ahead and alter the labeling or do whatever you want to maximize the profit? Are you finding that to be the case?

Mr. ARIAS. Well, Florida does not have that many manufacturers, although just the other day I had a conversation with a Miami-Dade police officer who called me that they had gotten a complaint or an allegation that a truck was going to get hijacked. And so nothing happened. They were monitoring it. But in Florida we do not have that many manufactures. So the thefts would be from a wholesale establishment or a pharmacy, or that type of thing. We do not have that many manufacturers, per se.

Mr. GREENWOOD. Final question. I have been a legislator now for 22 years or something like that. And I know full well from all of that experience that what ends up on the President's desk or the Governor's desk is not necessarily what I started out asking for and compromises are made along the way. Were there stronger tools for law enforcement that you sought from the State legislature in Florida that you did not quite get?

Mr. PENEZIK. Yes.

Mr. GREENWOOD. What did you have to peel off in the negotiation process? What do you wish you had?

Mr. PENEZIK. Well, I would just qualify the answer with saying I was not in Tallahassee when those decisions were being made and I was not when the compromises came about. So there may be very good reasons why they took place.

I understand that there is an industry argument that a full pedigree on all drugs just cannot happen now. So that part that was phased in, I would like to see it not take so long to be phased in.

The authorized distributor of record, which really has not been discussed much and I do not want to get the committee into the weeds with my long protracted definition and problems with that,

but basically under the current scheme federally and in our State, an authorized distributor of record does not have to pass on the pedigree when they purchase a prescription drug, even if they do not purchase that prescription drug directly from the manufacturer.

So, in other words, anytime an authorized distributor of record buys any prescription drug whatsoever regardless of who they buy it from, as long as they are an authorized distributor from the manufacturer, they wash in my eyes the pedigree. It stops and starts all over again.

So if you can get your drugs to an unscrupulous authorized—excuse me. An unscrupulous authorized distributor of record, your pedigree washes.

And it is also very important to note manufacturers do not make the decision who the authorized distributor of record is. It is a very low threshold. I believe it is 2 to 3 shipments a year from the manufacturer of any of the manufacturer's drugs and you become an authorized distributor of record for all the drugs, regardless of whether you purchase them from the manufacturer or not.

Mr. GREENWOOD. Okay. Thank you, sir.

My time has expired.

The gentleman from Florida, Mr. Deutsch is recognized.

Mr. DEUTSCH. Thank you, Mr. Chairman.

I guess I have a series of questions with some charts. But before I do that, I am just trying to get a general sense. I mean, you sat through our first panel which really dealt with importation from overseas, I mean that was the main issue in terms of the Customs step that this committee has done. I mean, how would you relate that problem to the problems you folks discover?

Mr. PENEZIK. I would say that, and I know that the committee flushed out that not all these drugs are headed to just your average citizen who orders them over the Internet. These drugs are also finding their way into the wholesale secondary market. In other words, they are being imported or reimported and then find themselves distributed into——

Mr. DEUTSCH. I guess what I am trying to get a sense of, I mean and I have actually read the Grand Jury Report and I am aware of what you folks have done. And you have done a fabulous job, a very significant job for the people of Florida. And I appreciate it. I know the people in Florida appreciate it. But I guess what I am trying to get a feel for is to me it almost seems like there are really two issues.

You know, the reimportation issue and this issue of the wholesale distribution issue and really fraud and criminal activity that is going on that is not directly related to the whole phenomenon of overseas purchases of prescription drugs. Is that an accurate perspective that I am sharing?

Mr. PENEZIK. Well, from my point of view that is accurate. They are two different issues or problems. They do interact with one another, but they are definitely two separate issues.

Mr. DEUTSCH. I want to thank all three of you for being here. We have a selection of slides called from a PowerPoint presentation that Mr. Jones, that unfortunately we cannot go through the entirety as each of these 12 slides are shown. Could one or both of

you please describe the point that they were designated to illustrate? If you can look at the first one.

Mr. JONES. This slide represents a portion of a spreadsheet that shows over $17 million worth of pharmaceuticals that were sold from a small wholesaler in Tennessee to—that were bought from a small company in Florida sold to a small wholesaler in Tennessee. And all of the products that were involved, all of these were drugs that came off the streets, HIV drugs and some counterfeits.

Mr. DEUTSCH. It is a huge amount, obviously.

Mr. JONES. I think the significance of this number——

Mr. DEUTSCH. Over a relatively short period of time? You are looking at, just got a month and a half.

Mr. JONES. But also as Mr. Arias mentioned earlier, there are over 11 groups that this Task Force is looking at, and this is just one of the groups. If you extrapolate at this point, this is where the drugs left the street and went to and entered the wholesale market, it is $17 million for this group. If you extrapolate that, you are looking at hundreds of millions of dollars.

Mr. DEUTSCH. If we can go to the next slide, because I want to try to get through as many as we can. If you comment what that is attempting to describe?

Mr. JONES. This is just a series of the counterfeits that we have move through Florida in the past 15 years, between 1985 and 2000. Counterfeit Cecior, back in the mid 1980's. There was also another antibiotic, Pipericil. Some counterfeit birth control pills Demulen. An arthritis drug, Feldene. And the anti-viral drug Retrovir.

Mr. DEUTSCH. The next slide.

Mr. JONES. These are the drugs that have moved through Florida, counterfeit drugs in the past 2 years in comparison to the previous slide.

Mr. DEUTSCH. Actually, if you could go back to that other slide for a second. I have actually looked closely at these, and I will tell you, I mean you have to really be an expert to distinguish between the counterfeit. I mean, there is no way a lay person could ever figure this out. These are, obviously, very sophisticated operations.

Mr. JONES. In the Procrit, this Procrit that was counterfeited, we alerted Texas officials that they needed to look at this project. And the first call I had from the Texas people is that the product looks good to us, it does not look bad. And we asked them to have it analyzed anyway. And it turns out that a large volume of it was counterfeit.

Mr. DEUTSCH. I'm sorry. The next slide.

Mr. JONES. I will let Cesar talk about this when he addressed it in his testimony. This is the——

Mr. ARIAS. Okay. This is the product that was relabeled from the 2000 unit product to 40,000 unit product. And the only thing this gentleman or these people did was remove this little label on the actual vial. He left the—or these people left the rest of the product intact. They did counterfeit the boxes. And they did save the original inserts, as well. For the most part as far as we could tell, the inserts were good. So they were asking their source to save these inserts.

Mr. DEUTSCH. The next slide.

Mr. JONES. I think if you can hit the—there is another part of this slide. This was created just to demonstrate, this is a new Amgen product, which is a more sophisticated version of Procrit and Epogen used to stimulate red blood cells.

This vial, which as you can see, hold 1 milliliter, one-fifth of a teaspoon full, cost $800 for the pharmacy. And the point that we are trying to make here is that this is an ongoing problem and there are many strengths of that drug with the same colored vial, all the strengths have the same color, same size vial. And this product could be easily counterfeited the same as the Procrit and the Epogen.

Mr. DEUTSCH. That is amazing, $800 just in terms of the ability to put colored water in there if you could pass it off.

Mr. JONES. Tremendous amounts of profit can be made in this.

Mr. DEUTSCH. May we get the next slide.

Mr. JONES. This slide demonstrates the diversion of special priced pharmaceuticals. This is the Lupron case. This is the trail that we saw where TAP Pharmaceuticals sold this Lupron injectable used to treat prostate cancer to oncologists and urologists at reduced price, lower than they would sell to a wholesaler. And the trail this drug took was to a small drug wholesaler in Miami that brought it in illegally. The corrupt wholesaler. IT went to a drug wholesaler in Texas. It came back to Central Florida. It went to a midsized wholesaler in Ohio. And from there that midsized wholesaler sold it to major wholesalers nationwide.

The same thing has been happening with the AstraZeneca product Zoladex, which is a similar type of product.

Mr. DEUTSCH. You know, there are a number of other slides. And, again, they will be in the record and I appreciate that.

I just as a closing sort of comment, I mean I listened to all three of your testimonies. What do we tell people in Florida today, the people in the whole country, particularly I mean you folks are the experts in Florida right now, what do we tell people in Florida?

Mr. PENEZIK. You will be safer than you were. It was a great first step. But there is a lot of work that needs to be done. And they also need to understand that a wholesaler anywhere in this country can effect what happens in the State of Florida. And there needs to be national guidelines, a national law, and it needs to be uniformly enforced.

Mr. DEUTSCH. Thank you.

Mr. GREENWOOD. The Chair thanks the gentleman.

The gentleman, Mr. Stupak is recognized for 8 minutes.

Mr. STUPAK. Thank you, Mr. Chairman.

When you do your investigations you have subpoena power?

Mr. PENEZIK. Yes, sir.

Mr. STUPAK. What do you use your subpoena power for?

Mr. PENEZIK. Congressman, what I would like to let you know is that when I issue a subpoena one of the down sides to it is anybody brought in under my subpoena is granted a form of immunity. So typically I will issue a subpoena for a cooperating witness, or a subpoena for testimony from people that I do not anticipate are going to be charged.

Mr. STUPAK. You use that as an investigative tool?

Mr. PENEZIK. Yes, sir.

Mr. STUPAK. And you can get documents and everything else with the subpoena, right?

Mr. PENEZIK. Not only can I get documents, I can require that someone attend or be held in contempt of court if they don't.

Mr. STUPAK. Yes. Yes. One of the crazy things, the FDA does not have subpoena power. Probably the only regulatory agency in the Federal Government that does not have subpoena power. Some of us tried to give them subpoena power in the last bill and they did not want it. So I just wanted to ask that.

When the FDA has done these import alerts, do they provide you with the import alerts?

Mr. PENEZIK. Not to my office of Statewide Prosecution, but the Department of Health would be better suited.

Mr. JONES. I think we do receive those import alerts from the Office of State Federal Relations.

Mr. STUPAK. Okay. And then what do you do with them?

Mr. JONES. We circulate them to our inspectors. They look for these products. If they see them, unfortunately the trails of these products do not take us back to the point where they are imported.

Mr. STUPAK. So we had some testimony earlier today, especially on the drug Acutane there, if Miami never got it, you never would have received it in Florida then, right? If Customs does not receive it, you would not have necessarily received it?

Mr. JONES. That is true.

Mr. STUPAK. Okay. In Florida you had a case there where, and there was some testimony about it today, recent recalls of the counterfeit Lipitor. And I understand that this was originally with a buy by your Task Force. I further understand that not only Lipitor but also counterfeit Celebrex was involved in that buy. But without you going into the specifics, could you describe how that buy came about, the pattern of movement of volume of these illegal drugs and did you notify the FDA that it would involve Lipitor and Celebrex?

Mr. ARIAS. To answer the lat part of your question, yes, we communicate very well with them. We have a pretty good relationship.

Mr. STUPAK. As to Lipitor and Celebrex?

Mr. ARIAS. Yes.

Mr. STUPAK. Did they do anything with the Celebrex? We know they did with Lipitor.

Mr. ARIAS. We seized the product in Florida and we notified them, and they were aware of it.

Mr. STUPAK. But with the Celebrex, did they do the recall and all that like they testified they did with Lipitor, do you know.

Mr. ARIAS. I have not seen that, but that doesn't mean it has not happened. I am not aware of it.

Mr. STUPAK. Yes. Our information says they did one but not the other. They did recall the Lipitor but not the Celebrex.

Mr. ARIAS. Right. I do not know.

Mr. STUPAK. Okay. But could you tell me a little bit more about your buy without getting too much into jeopardizing anything?

Mr. ARIAS. Well, usually the way this works is we get complaints by different owner of pharmacies or wholesalers that are trying to do the right thing.

Mr. STUPAK. The complaint is that this drug is being sold other places?

Mr. ARIAS. It is being offered. It is being offered at acutely discounted prices.

Mr. STUPAK. Is that usually the best indication?

Mr. ARIAS. That is their best indication, yes sir. And then what happens is we ask the company that is making the complaint to ask for a pedigree from their source.

Mr. STUPAK. Sure.

Mr. ARIAS. And if they get that pedigree, then we verify the pedigree. And that is why the pedigree is such an important tool in ferreting out the counterfeit and the diverted products.

Mr. STUPAK. And the pedigree comes from the pharmaceutical companies?

Mr. ARIAS. Correct. It goes all the way to the manufacturer.

Mr. STUPAK. Do they have to notify like the State of Florida regulatory system that they have issued a pedigree to an individual or a company? I mean, is it in duplicate? Like if I send you one, do I then as the drug company have to forward it to Tallahassee to some agency, regulatory agency?

Mr. ARIAS. No. The pedigree goes with the product.

Mr. STUPAK. Okay.

Mr. ARIAS. So that the seller is obligated to furnish it to the buyer.

Mr. STUPAK. Sure.

Mr. ARIAS. Until it gets to the last wholesaler before it goes to the end user. By the end user, I mean the pharmacy or the hospital or the physician.

Mr. STUPAK. Okay.

Mr. ARIAS. They do not get a pedigree, unfortunately.

Mr. STUPAK. Okay. Would it help if they did?

Mr. ARIAS. I would say yes, but the law does not require that.

Mr. STUPAK. Sure. And this pedigree, it accompanies the invoices, is that it?

Mr. ARIAS. It has to either accompany the product or precede the sale.

Mr. STUPAK. Sure. Go ahead. Anything else you want to add on that one, on that question, my question?

Mr. ARIAS. No. I just want to emphasize the importance of the pedigree.

Mr. STUPAK. Sure.

Mr. ARIAS. Without it a lot of these counterfeits that we have identified in Florida, we did not know they were counterfeit when we were looking at them.

Mr. STUPAK. Sure. But without the pedigree?

Mr. ARIAS. The pedigree was the tool that allowed us to know that there was a problem with that product, that it was—it did not come through the proper channels.

Mr. STUPAK. Is this a pedigree unique to Florida or do other States use it?

Mr. ARIAS. I will let my boss answer that one.

Mr. JONES. We have not seen it used in very many instances. I believe Nevada may be a State that is looking to use it. But we very rarely see the pedigree.

Mr. STUPAK. Sure. You mentioned Texas, and they said no it looked like the real thing. Do they use a pedigree?

Mr. JONES. I do not think they are enforcing a pedigree requirement in Texas either. The problem has been with the delay of the implementation of the final rule on the pedigree at the Federal level.

Mr. STUPAK. The counterfeits there, the drug counterfeits there, did those originate in Florida?

Mr. ARIAS. I believe that there is still some doubt as to the Neupogen IQ.

Mr. STUPAK. Okay.

Mr. ARIAS. But we are pretty certain that the Epogen, Procrit and Serostim came through—was originated in Florida.

Mr. STUPAK. You have that slide up there, slide No. 1, which came out of Tennessee. It went from Tennessee to Florida. That was legitimate. And then from there it got counterfeited? In Florida?

Mr. ARIAS. No, no. That graph just states the monies that were transacted between a Florida wholesaler, a very small wholesaler, to a Tennessee wholesaler.

Mr. STUPAK. Okay. Mr. Penezik, am I saying that right?

Mr. PENEZIK. Yes, sir.

Mr. STUPAK. In your testimony you stated that one counterfeit shipment may have yielded as much as $46 million in profit.

Mr. PENEZIK. Yes, sir.

Mr. STUPAK. This sounds the word street brokers like street drug money. Can you tell us about the involvement of individuals that specialize in like large sales of street drugs moving into counterfeit pharmaceutical products?

Mr. PENEZIK. There are instances of people from a variety of criminal backgrounds that are moving into this business, several of our targets, prior people convicted or people convicted in prior instances of racketeering, drug trafficking, a variety of offenses. This is just more streamlined and from their point of view more safe. It also has got a high, high profit with very little risk for them.

There is not a whole lot of effort that they put behind this business. There is no special qualifications that are needed to be a prescription drug wholesaler in our State. You do not have to have any special training. There is a questionnaire.

Mr. ARIAS. The new law some provisions.

Mr. PENEZIK. The new law will require that, but my understanding is in most States there is no special criteria needed. Therefore, the criminal element just moves itself in. They set up a small office. They need a fax machine and a computer. They comply with the licensing requirements and they are in business.

Mr. GREENWOOD. The time of the gentleman has expired.

Does Mr. Dingell care to inquire?

Mr. DINGELL. No.

Mr. GREENWOOD. That being the case, we want to thank the witnesses for your presence. Thank you for being on the cutting edge of this important issue.

We congratulate you for the fine work that you do.

You are excused.

And this hearing is adjourned.

Before I do adjourn, without objection we will hold the record of this hearing open for 30 days so that the questions that have been put by members to the FDA can be inserted into the record and for those members who wish to add their opening statements to the record.

The committee is adjourned.

[Whereupon, at 2:25 p.m., the subcommittee was adjourned.]

[Additional material submitted for the record follows:]

PREPARED STATEMENT OF MARY R. GREALY, PRESIDENT, HEALTHCARE LEADERSHIP COUNCIL

The Healthcare Leadership Council (HLC) appreciates the interest of the subcommittee on the issue of reimportation. It is critically important that Congress examine and understand the threats that reimportation of medicine poses for patients, including threats from counterfeit, adulterated, or substandard medicines coming into the United States. We believe that other approaches, such as a comprehensive Medicare prescription drug benefit, will provide more choice, quality and lower costs without stifling innovation and research, and without endangering the safety of beneficiaries.

American consumers have been led to believe that, if prescription drugs are reimported from Canada, their out-of-pocket costs will be the same as for patients in Toronto or Montreal, and that they will be assured of a safe product that is readily available. That is simply not the case. Consider the following facts:

- **Accessibility.** The Canadian market is less than 10 percent of the American market. Currently the number of Americans securing reimported drugs "under the table" is relatively small and the Canadian market can handle the demand. If reimportation were made legal, the amount of drugs available for the U.S., with its much larger population, would be minimal and inconsistent.
- **Safety.** Even with current safeguards in place, the World Health Organization estimates that eight percent of the drugs currently entering the U.S. market are counterfeit. Consider the potential harm if reimportation were made legal. Ten former FDA commissioners have consistently expressed their views that drug reimportation is dangerous for consumers and patients, including the current FDA commissioner who stated that the FDA could not assure the safety of reimported drugs at this time.
- **Cost.** Canadian price controls only apply to drugs sold in Canada. Price controls do not apply to exported products, meaning if drug reimportation were made legal, there would be no guarantee of the Canadian price. In addition, inspections, testing, storage, repackaging and liability insurance will significantly raise the price of reimported drugs. An unintended consequence of reimportation should not be to place an additional large cost burden on those in the drug supply chain.

HLC's top priority is to promote the highest quality health care possible. We believe that the best way to achieve this goal is through competition, innovation, research and continuous quality improvement in the private marketplace. Federal policy should support such innovation, not stifle it. HLC continues to urge that Congress reject price controls, such as reimportation, and instead focus on coverage for more Americans.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Washington, DC 20204

June 23, 2003

The Honorable W.J. "Billy" Tauzin
Chairman
Committee on Energy and Commerce
House of Representatives
Washington, D.C. 20515

Dear Mr. Chairman:

Thank you for the opportunity to respond to the report on imported pharmaceutical safety that was prepared by the staff of the Committee on Energy and Commerce. We are responding to the draft dated June 20, 2003.

The standards for drug review and approval in the United States are the best in the world, and the safety of our drug supply mirrors these high standards. The employees of the Food and Drug Administration (FDA or Agency) constantly strive to maintain these high standards.

However, a growing number of Americans are obtaining prescription medications from foreign sources. U.S. consumers often seek out Canadian suppliers, sources that purport to be Canadian, or other foreign sources that they believe to be reliable. While some foreign drug manufacturers submit their products to FDA for approval, the imported drugs arriving through the mail, through private express couriers, or by passengers arriving at ports of entry are often unapproved new drugs that may not be subject to any reliable regulatory oversight. FDA cannot assure the safety of drugs purchased from such sources.

In FDA's experience, many drugs obtained from foreign sources that either purport to be or appear to be the same as U.S.-approved prescription drugs are, in fact, of unknown quality. Because FDA cannot assure the American consumer that such products are safe and effective, consumers using foreign prescription medications run the risk that such products may be:

- Expired, subpotent, contaminated or counterfeit drug, the wrong or a contraindicated product, an incorrect dose, or medication unaccompanied by adequate directions for use.
- Drugs with labeling in a foreign language or where important information regarding dosage and side effects are not available.
- Drugs that have not been packaged and stored under proper conditions to avoid degradation.
- Drugs that have not been manufactured using current good manufacturing practice standards.

Furthermore, some websites based outside the U.S. may dispense drugs in the absence of a doctor-patient relationship, resulting in prescription products being provided without proper physical examination or medical history. In such instances, patients may be more likely to receive inappropriate medications, may fail to receive needed medical care, or may not be properly made aware of risks of side effects or other drug interactions.

In addition to these concerns, it is illegal under the Federal Food, Drug, and Cosmetic (FD&C) Act to import unapproved, misbranded, and adulterated drugs into the U.S. This prohibition extends to foreign versions of U.S.-approved medications. It is also illegal for anyone other than the drug's manufacturer to re-import a prescription drug that was originally manufactured in the U.S. The relatively "closed" regulatory system that we have in this country has been very successful in preventing unapproved or otherwise unsafe drug products from entering the U.S. stream of commerce.

The vigilance of FDA and Bureau of Customs and Border Protection (CBP) inspectors is an important tool in detecting imported products that violate the FD&C Act. Given the available resources and competing priorities facing these agencies, however, experience shows that inspectors are unable to visually examine the large volume of parcels containing prescription drug products that arrive through the mail and private courier services each day. Many of the packages that the Agency is able to examine appear to contain foreign versions of U.S.-approved products. The growing volume of unapproved imported drugs, which often are generated from sales via the Internet, presents a formidable enforcement challenge.

As a consequence, the Agency must employ a risk-based enforcement strategy to deploy our existing enforcement resources in the face of multiple priorities, including homeland security, food safety and counterfeit drugs. For example, the Agency utilizes Import Alerts to identify particular shipments that, based on all available information, are likely to pose the most significant risk to public health. In the case of the increased volume of unapproved generic sildenafil arriving at the Miami facility, the Agency has issued an Import Alert to instruct field personnel to work with CBP to detain all such shipments from specific manufacturers, distributors and countries of origin.

The Agency shares the Committee's concern about the volume of violative and unapproved prescription drugs entering the United States. In an effort to address this problem, we have engaged in an aggressive campaign to alert the public to the risks they face when purchasing drugs from foreign sources. At the same time we are devoting resources to the following cooperative enforcement activities: working with our Canadian counterparts on strategies to address the importation problem and referring websites and pharmacies to the Canadian government for investigation; collaborating with individual states on joint enforcement activities; partnering with other Federal agencies to obtain convictions of those who introduce counterfeit drugs into commerce.

In addition, we recognize that the desire for access to more affordable prescription medications has become a significant motivating factor leading consumers to turn to foreign sources for pharmaceuticals. We strongly support efforts to make prescription drugs more affordable and have taken several significant steps to accelerate access to more affordable, safe and effective prescription drugs. These steps include: new initiatives to accelerate approval of innovative new medical procedures and drug therapies; changes to FDA regulations to reduce litigation that has been shown to delay access to more affordable generic drugs; and proposed increases in resources available for approval of generic drugs.

In sum, the Agency simply cannot assure the American public that drugs purchased from foreign sources are the same as products approved by FDA, or that they are safe and effective. The Agency acknowledges the concerns raised in the Committee staff report and has already undertaken several actions designed to address specific issues raised about our field operations in Miami. However, the increased trend of consumers purchasing unapproved prescription drug products from foreign source remains a significant issue, and the Agency looks forward to continuing to work with the Committee to identify solutions to address these concerns. A more detailed response to the observations identified in the Committee on Energy and Commerce staff report is attached.

Please let me know if you have additional questions, or if I can be of further assistance.

Sincerely,

Mark B. McClellan, M.D., Ph.D.
Commissioner, Food and Drugs

FDA Response to
Concluding Observations Section of Committee on Energy and Commerce Staff Report, draft dated June 20, 2003

1. Volume of Controlled Substances. The Committee staff report raises concerns about the quantity of controlled substances being shipped to the United States through Miami utilizing the U.S. mail and private carriers.

FDA Response: We acknowledge the observation of the Committee staff that the volume of controlled substances being shipped to the United States continues to be a significant concern. These products are a substantial subset of the total volume of unapproved drug products entering the United States. With respect to controlled substances, the Drug Enforcement Administration (DEA) is the lead agency for detaining, reviewing and destroying such products, and the FDA's role is limited.

2. Cooperation with the Bureau of Customs and Border Protection (CBP). The Committee staff report raises several concerns about the quality of the working relationship between FDA and CBP.

FDA Response: Overall, the Agency has a strong working relationship with CBP at the National and local levels. When FDA is developing an Import Alert on prescription drugs or updating an established alert, we routinely consult with CBP on the development and implementation of Import Alerts. We also routinely consult with CBP on how to effectively work together in order to implement these alerts in the field. Not surprisingly, there are instances where coordination with CBP can be improved, particularly at specific field locations, and the Agency continually strives to identify opportunities to improve our relationship, through meaningful procedural or policy reforms. In the case of Miami, a field operation with a very high volume of incoming prescription drug shipments, the Agency will strive to coordinate even more closely with Customs as it implements various procedural reforms to better manage the increasing demand.

3. Concerns about FDA Inspections at the Miami Mail Facility. The Committee staff report also identifies concerns regarding the management of field resources at the Miami mail facility and irregularities associated with the detention and subsequent release of 1,233 individual incoming mail parcels of generic sildenafil.

FDA Response: The Agency has acknowledged that irregularities have surfaced in the manner that the Miami Import Office handled the detention of pharmaceutical shipments at the Miami mail facility. We are conducting an ongoing internal review of these problems. Once these mistakes were discovered, the Agency took various actions to address these problems. On May 20, 2003, FDA issued a talk paper acknowledging that specific products were improperly detained and released and the Agency sent a letter to each of the consumers who may have received those products alerting them that they are unapproved drugs under the Act and that the

Agency cannot provide any assurance of their safety or effectiveness. In addition, in order to improve the Agency's utilization of its limited enforcement resources available at the Miami facility, the Agency instituted a detailed action plan including both procedural and management reforms designed to minimize the possibility that such a problem will reoccur. In addition, a new manager with a strong compliance background has been transferred to Miami to serve as the Florida District Import Program Manager on an indefinite basis. Other longer-term measures to further enhance FDA import operations in Miami are also being developed.

4. Potential Risks Associated with Imported Prescription Drugs. The Committee staff report reiterates concerns about potential risks associated with unapproved drug products entering the United States through U.S. mail and private carriers from foreign sources.

FDA Response: The Agency acknowledges the significant potential risks associated with imported prescription drugs. As described in the letter accompanying these responses, the Agency is using its available resources to address a number of high enforcement priorities with respect to imported products, including assessing potential threats to homeland security associated with imported food and drugs and ensuring the safety of imported foods. With respect to the increasing volume of imported unapproved drugs entering the United States, the Agency acknowledges the difficulties identified by the Committee. In the short term, the Agency is working with CBP to target its enforcement activities on the products that pose the highest potential risk, utilizing our system of Import Alerts. In the longer-term, the Agency is working with various Federal agencies and stakeholders to develop improved methods to identify, inspect and detain unapproved imported prescription drug products that pose a potential risk to public health.

PHARMACEUTICAL DISTRIBUTORS ASSOCIATION SUPPORTS FEDERAL AND STATE EFFORTS TO PROTECT THE INTEGRITY OF PRESCRIPTION DRUGS

Counterfeit drugs pose serious risks to consumers and to the economic viability of wholesale distributors. The businesses of prescription drug wholesalers are severely damaged when counterfeit and adulterated drugs enter the prescription drug distribution system. The Pharmaceutical Distributors Association (PDA) is a trade association of licensed prescription drug wholesalers. PDA's members have in the past and will in the future report any instances of counterfeiting or other plainly unlawful activity to the FDA. The PDA strongly supports efforts to effectively and practically protect the prescription drug supply against counterfeit, adulterated or misbranded products. That effort should allow licensed legitimate businesses, large and small, to continue to be a part of the wholesale prescription drug industry so that access to drugs is as broad as possible and so that their costs do not increase unnecessarily. There is no profit to legitimate businesses in buying or selling counterfeit or adulterated drugs.

Most prescription drugs distributed in the United States are first purchased by one of three drug-company-authorized distributors and then sold by them to large hospitals, health care providers and to retailers. Some are also sold by these big three to other licensed distributors, including PDA's members. The three major wholesalers have facilities throughout the country and they distribute 90% of the volume of pharmaceuticals that are not shipped directly by their manufacturers to retail or to health care facilities. The other licensed wholesale distributors that they sell to play an important role in the distribution of pharmaceuticals. They serve the markets that the big three cannot address efficiently. The smaller wholesalers serve veterinarian and physician's offices and small clinics, emergency medical units, military and private industry health clinics and dispensaries, and small pharmacies. These small wholesalers also sell to other wholesalers.

Some licensed wholesalers buy drugs from manufacturers in anticipation of reselling when prices are increased by those manufacturers. Because pharmaceutical companies have a variety of open market pricing and rebate programs, there is an active trade in pharmaceuticals among licensed wholesalers. This trade often begins with favorable pricing from the manufacturer which may occur near the end of sales quarters. Such favorable pricing is brought to the wholesale distribution system by licensed wholesalers who invest in lower priced inventory. The economic effect of these purchases and sales and active trade in pharmaceuticals is to dampen prices.

PDA was formed three years ago to address regulations promulgated by the Food and Drug Administration that threatened to make all or part of the businesses of many licensed wholesale distributors of prescription drugs unlawful and severely disrupt the way drugs are distributed in this country. The PDA and other trade associations of prescription drug distributors and retailers met with FDA and successfully sought a stay of those FDA regulations. The regulations, while well-intended, would have required that the prescription drug pedigree that must accompany certain wholesale drug transactions, report all prior sales of the product back to the manufacturer, even if the product was purchased from a drug-company-authorized

wholesaler that is exempted by law from providing a pedigree to its customer. As FDA recognized in granting the stay:

> An unauthorized wholesale distributor that purchases a product from a manufacturer or authorized distributor of record without an identifying statement showing the prior sales of the drug could not provide an identifying statement to its purchasers, and therefore, could not conduct further wholesale transactions of the drug in compliance with § 203.50.

FDA thus recognized that certain licensed wholesalers could not continue in all or part of their businesses. In support of these smaller licensed wholesale distributors, the PDA has testified at FDA's administrative hearings on wholesale distribution and before the Small Business Committee of the House of Representatives. PDA also contributed information to the consulting firm that put together the background material to the FDA's June 2001 Report to Congress on the Prescription Drug Marketing Act. PDA has also actively sought amendments to the Prescription Drug Marketing Act that would allow the many licensed wholesalers who are not direct purchasers from pharmaceutical manufacturers to continue in their businesses.

PDA has been an industry leader in working with the Florida Department of Health to revise Florida laws and regulations to prevent counterfeited, misbranded or otherwise illegal products from entering or being sold in the United States. PDA's President, Sal Ricciardi, served on the Ad Hoc Committee on Pedigree Papers appointed by Florida Health Secretary John Agwunobi, M.D. to address prescription drug distribution in Florida. During the meetings of that Committee, the Department's employees admitted that Florida's licensing requirements for prescription drug wholesalers are very weak. PDA strongly supported amendments to make Florida's licensing requirements for wholesalers the toughest in the nation. Tough licensing standards are the first line of defense against bad actors in the marketplace and PDA supports state regulatory authority efforts to strengthen licensing standards and requirements.

PDA's goal is to engage in practices that assure the integrity of the pharmaceuticals bought and sold by its members and to thereby protect the health of consumers and legitimate, licensed prescription drug wholesalers in their businesses. New technologies are on the horizon that will permit wholesalers and retailers to verify the integrity of prescription drugs that are in the drug distribution system. Technology vendors have demonstrated their inventions at industry trade shows and to regulatory authorities. FDA should ascertain how theses technologies can be incorporated into the manufacture and packaging of prescription drugs so that prescription drug integrity can be assured throughout the chain of distribution. Such technology should also be able to protect the integrity of the pharmaceutical supply from counterfeiting, adulteration and misbranding that may occur outside the borders of the United States.

Pharmaceutical Distributors Association
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Contact: Bruce Krichmar, 1-800-323-6894

Jon Borschow, Chairman of the Board
Ronald J. Streck, President & CEO

PHARMACEUTICAL DISTRIBUTORS PLEDGE TO PROTECT SUPPLY CHAIN FROM COUNTERFEIT DRUGS

FOR IMMEDIATE RELEASE
June 24, 2003

CONTACT: Jennifer Fortney
(703) 787-0000

RESTON, VA – In an aggressive effort to protect the integrity of the pharmaceutical supply chain, the Healthcare Distribution Management Association (HDMA), whose membership represents more than 90 percent of the nation's pharmaceutical distribution sales, today adopted a new, voluntary consumer safeguard program that will help keep counterfeit drugs out of the marketplace.

"The problem of counterfeit drugs is alarming to pharmaceutical distributors who are dedicated to product integrity, patient safety and to distributing approved medications that help ease pain, improve the quality of life and cure diseases," said Ronald J. Streck, president and CEO of HDMA. "Because product integrity is vital, the HDMA is today announcing a program to combat counterfeit drugs, working closely with the U.S. Food and Drug Administration (FDA) and pharmaceutical manufacturers."

Under the program, HDMA member companies pledge to notify the FDA Office of Criminal Investigations and the manufacturer within five working days of discovery of a suspicious product. The program goes beyond our nation's borders, and includes counterfeit drugs that could be brought into the United States from foreign countries. The voluntary reporting program goes into effect July 1, 2003.

The program is the latest step in HDMA's and its member's strong commitment to ensure compliance with federal and state laws and regulations pertaining to prescription drugs and pharmaceutical distributors. Pharmaceutical distributors in the U.S. are highly regulated with strong oversight from both federal and state government agencies. The Prescription Drug Marketing Act (PDMA) enacted by Congress and signed into law in 1988 established the national standards for the storage and distribution of pharmaceutical products in the U.S.

"HDMA members support safe medicines for all consumers," Streck concluded. HDMA also supports vigorous enforcement of existing laws to crack down on criminals who are violating the public trust.

# # #

HDMA's mission is to secure safe and effective distribution of healthcare products, create and exchange industry knowledge affecting the future of distribution management, and influence standards and business processes that produce efficient healthcare commerce.

Addendum to June 24 HDMA Press Release

Under the Prescription Drug Marketing Act (PDMA), 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:
. Maintenance of all purchase and sales records for three years including pedigrees
· 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
. Security against theft

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