ENFORCING THE LAWS ON INTERNET PHARMACEUTICAL SALES: WHERE ARE THE FEDS?

HEARING

BEFORE THE

SUBCOMMITTEE ON
OVERSIGHT AND INVESTIGATIONS

OF THE

COMMITTEE ON COMMERCE
HOUSE OF REPRESENTATIVES

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ENFORCING THE LAWS ON INTERNET PHARMACEUTICAL SALES: WHERE ARE THE FEDS?

THURSDAY, MAY 25, 2000

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

The subcommittee met, pursuant to notice at 10 a.m., in room 2125, Rayburn House Office Building, Hon. Fred Upton (chairman) presiding.

Members present: Representatives Upton, Burr, Ganske, Bryant, Bliley (ex officio), Klink, Green, Strickland, and DeGette.

Staff present: Lori Wall, majority counsel; Amy Davidge, legislative clerk; and Chris Knauer, minority investigator.

Mr. UPTON. Good morning everyone. Here I am a little bit late. My second-grader is an author, and they had a little presentation at the school. So I needed to be there. I have a tape for anyone who wants to watch it.

The asteroid.

Today this subcommittee will hold its second hearing on the issue of Internet sales of prescription drugs. Since we met almost 1 year ago, we have continued our review of this important issue. This review has focused not only on domestic sales of pharmaceutical drugs over the Internet, but also international sales of pharmaceutical products.

Domestically, States have taken the lead in enforcement activities. State Attorneys General met just last week in Michigan to look at a number of issues related to Internet sales, including the sale of prescription drugs. The National Association of Attorneys General has established the Online Sales of Drugs Working Group to address issues related to Internet pharmacies and has had success in implementing cost-effective means to take action.

I have been impressed with the level of coordination and cooperation between States on this issue. However, as we have heard from Carla Stovall, Attorney General of the State of Kansas, at our hearing last July, States are still limited in their ability to protect consumers. With the borderless nature of the Internet, States will need additional tools to increase their effectiveness beyond their State lines.

In the coming weeks, I plan to introduce legislation that would give States the ability in appropriate circumstances to go into Federal court to more effectively protect its citizens. This will allow the

good work of a number of States to have an impact in ensuring consumer safety nationwide.

Unfortunately, the Federal Government has not been as effective in dealing with this issue. Despite several working groups charged with studying this issue at the Federal level, little has changed in the past year.

Despite the fact that the FDA devoted more than 30,000 staff hours in the first quarter of fiscal year 2000 alone to investigate hundreds of Internet sites, not a single arrest or conviction has occurred with respect to Web sites offering to sell prescription drugs. I want the FDA to explain today this failure to enforce the law.

As I stated earlier, our investigation has also focused on drugs being shipped into the U.S. from foreign Web sites. As part of our review, committee staff have visited several U.S. Customs mail facilities. At these facilities, staff have witnessed significant quantities of pharmaceutical products being sent into the United States, many arriving in plastic ziploc bags with nothing indicating the bags' content, dosage instructions, warnings of potential side effects or possible drug interactions.

I was troubled to learn that despite guidance issued by the FDA defining what pharmaceutical products will be allowed into the U.S. under the FDA's personal importation policy, in most instances this Guidance is being applied piecemeal or not at all.

Clearly, FDA's policy in allowing certain personal importations of pharmaceutical products into this country is valid—what is troubling is that this policy is being exploited by foreign Web sites selling pharmaceutical products in the U.S. without even requiring a prescription from the person who purchased the drug.

Evidence of the increase in pharmaceutical products being seized at our borders is clear. In 1999, almost 2 million pills mailed from overseas were seized by the Customs Service—more than 2.5 times the number confiscated in 1998, an increase that Customs attributes to foreign-based Internet pharmacies. In addition to prescription drugs, controlled substances and scheduled drugs such as GHB and Rohypnol, common date rape drugs, which that is Congress has now banned, are also being sent into country.

I would encourage FDA and Customs to work together in stopping the flow of potentially dangerous drugs into this country. I pledge to continue my review of this issue and welcome our witnesses here today.

I now yield time to Mr. Klink, ranking member of the subcommittee.

Mr. KLINK. Thank you Mr. Chairman for your vigilance in this matter and for holding this hearing.

For the past 18 months, this subcommittee has looked into a range of activities related to online pharmacies, including how they operate; where they get their drugs from; what potential benefits and what potential threats they pose, and most importantly, who's overseeing them.

Indeed, we know that responsible sites operate online, and offer beneficial services to the public. But that is not what this hearing is about. Instead, today, we focus on what the Federal Government is doing to protect consumers from the "rogue" sites, or those sites

that offer prescription drugs in violation of both State and Federal law, possibly at the expense of public health and safety.

During our investigation, we have met with a number of Federal authorities and repeatedly we have sought detailed information on what is being done to address these concerns. Yet, with significant time having elapsed since our last online pharmacy hearing, and after numerous document requests and interviews, I believe we still lack a suitable approach for protecting the public.

Since last July's hearing, the number of sites selling prescription drugs seems to have increased, not decreased. Moreover, the list of drugs offered by some sites seems to be growing. For example, in response to a February 28, letter I sent to Customs seeking information on the types of drugs they are finding being sent to the U.S.—many of which they believe are linked to Internet sites—they're reporting the following: Diazepam; various painkillers with codeine; Xanax; Codigesic; Lorazepam; Fenfluramine; and Rohypnol, the date rape drug that the Chairman mentioned. This agency also reports that they have experienced a significant increase in the amount of pharmaceuticals that are being shipped to our shores. Last year alone, Customs had a more than 400 percent increase over the previous year. Much of this increase they believe is linked to online pharmacies. At this pace, we have to wonder what next year will look like?

These statistics, Mr. Chairman, suggest the problem is getting worse, not better. Yet today, still no Federal authority can explain who is coordinating this effort, what agency or Department is in charge. And I ask, why is that? We all appreciate the complexity of this problem. But with almost a year since our last hearing, it is not even clear what the two main agencies on this front—the Department of Justice and the Food and Drug Administration—are accomplishing.

Here's an example: On February 1 I wrote to the FDA Commissioner Henry asking answers to these questions. After months of delay, I then had to send a second letter demanding answers to my first letter, I finally got a response on the March 23. FDA reported that during the 6-month period ending at the end of January 2000, they had spent more than 39,520 hours on this matter. That's very impressive. But when I asked if any prosecutions during that period of time as a result of this effort, they said: "FDA is not aware that any Federal prosecutions or convictions for Internet pharmacy violations have occurred at this time." Again, I'll remind you that March 23, the date of that letter, was only 2 months ago.

I'm confused. This is not a new issue or one we don't know anything about. We've heard all the stories about people that have been able to obtain drugs online when posing as cats, dogs, dead people, young children, or as patients with contra-indicated conditions. What we don't hear is how the Federal Government is aggressively attacking this problem.

To their credit, many of the States—with far fewer resources and limited jurisdiction have attempted to curtail the activities of some rogue sites. But why aren't we doing the same at the Federal level? The FDA and DOJ repeatedly tell us, either "we're working on it," or "it's an active criminal investigation, and therefore we can't tell you anything."

Staff from DOJ said they were "chomping at the bit" to get these cases referred from the FDA whom they call the "foot soldier" on the front. FDA tells us that they have referred the cases to Justice. But where are the indictments and where are the prosecutions?

Mr. Chairman, buying drugs online can be the health care equivalent of trick-or-treating in a bad neighborhood. Counterfeit or adulterated drugs can find their way into the U.S. via rogue sites, with potentially devastating results of potentially catastrophic proportions.

We've seen reports of arrests that were made for smuggling in fake Viagra. We've seen accounts of arrests being made for the selling of fake Xenical, made from only starch and a small amount of an anti-asthmatic drug. We've even seen reports of fake ampicillin and AZT made from cassava starch and anti-mold powder. How prevalent are these bogus drugs? We don't know. But if we don't get some control over the rogue Internet sites, we may find out the hard way.

Now we've heard talk about self-regulation when it comes to this Industry. In fact, last July when we had our last hearing on this matter, the two companies representing legitimate online pharmacies made commitments to this subcommittee that they would have online pharmacy summits to discuss how to address these problem. At that time, and even to this day, many believe that the National Association of Boards of Pharmacy's VIPPS program is the most suitable approach for doing this. I generally applaud the concept and the sincerity of that program. But, again, after almost a year, only five sites have bothered to obtain a VIPPS seal. Does this mean that only a tiny fraction are willing to play by these rules? Should consumers feel safe shopping online when the vast majority of sites don't have a VIPPS seal? In what other industry would such a low compliance rate be tolerated? In other words, is that system working?

Mr. Chairman, the U.S. has a very strict law on how drugs can and cannot be dispensed by doctors and pharmacists. It is a good system that has generally served us well for decades. Yet many online pharmacies have managed to turn this system on its head. A patient in State (A) has his prescription written by a mystery doctor they've never seen they've never met. We don't even know if they're a doctor. Their drugs are then sent by somebody—who may not even be a licensed pharmacist—from a source that may or may not even be located in the U.S. Is that what we envision as sound public health policy? Is it illegal. I'm hard pressed—or is it legal rather. I'm hard-pressed to believe that it is.

In the near future, Mr. Chairman, for some segments of our population, online pharmacies could significantly affect how drugs are ultimately sold and purchased. So far, we've seen a generally narrow range of drugs—mostly lifestyle drugs—sold through the Internet and mostly at similar prices. But in the future, there will be price competition. Some citizens already head to Mexico and Canada to buy their drugs, even though that practice is not without risk. What makes us think people won't buy from cheaper Internet sites that don't require a doctor or pharmacist, once they begin to offer their drugs? What then? Will the Internet become a global flea-market for those who can't afford today's high-priced prescrip-

tions, or for those looking for drugs of abuse? Will we be comfortable with such system? We need to think about this, because that is what may be on the horizon.

And, finally, Chairman, we have the question of what role the drug companies should be playing in this area. For the most part, they've remained oddly quiet. We have not heard much from the drug manufacturers. Should they be quiet? Should they be participating? After all, it is their products that are being offered by many of these rogue sites. Are they comfortable with that? What do we as policymakers think they should be doing and why? Are we prepared to ask them? At the very least, should these companies post consumer information on their official promotional sites—such as www.viagra.com, www.propecia.com, or www.xenical.com—warning patients about the potential risks of buying online? What about providing a link to FDA's web site where an in-depth discussion on this matter can already be found? Because, this could be done almost immediately, it would cost almost nothing, and I am hereby asking each major drug company with a promotional site for drugs frequently being sold over the Internet to do this immediately. Why not? Rather than using these sites only to promote their drugs, what about using them also to help consumers make safer decisions about buying their drugs, their products online? Be responsible.

Mr. Chairman, I conclude again by thanking you for holding this hearing and being vigilant on this subject. As you clearly understand, the online pharmacy world is already and will continue to challenge our public health policies. While these sites offer many potential benefits, the potential downside and risks are very real. We must begin to formulate a comprehensive strategy to this matter before people get hurt or killed. So far, I don't believe that the Federal Government has lived up to this task. I once again look forward to hearing from the people who are here in the hearing room today as to how they intend to proceed, and I thank you, Mr. Chairman.

Mr. UPTON. Thank you, Mr. Klink.

Mr. Bliley.

Chairman BLILEY. Thank you, Mr. Chairman.

For more than a year this committee has looked at the issue of Internet pharmacy sales. Since our investigation began, much has changed. We have seen a dramatic increase in the number of Web sites selling pharmaceutical products. Most sites appear to operate legally and provide convenient, affordable service to millions of Americans.

However, there are also Web sites that appear to be violating the law. More troubling is there appears to be an increase in Web sites outside the United States that are dispensing medications to consumers in the U.S. even without a prescription.

Our hearing today will examine what efforts Federal and State agencies have taken in order to address this issue and enforce the laws that currently govern pharmacies and doctors on the Internet.

As this committee has studied this issue over the last 18 months, it has become clear that Federal enforcement and coordination on this issue have fallen short. At the last hearing this subcommittee held on the topic of Internet pharmacies in July 1999, I called on

the President to establish a joint Federal-state Task Force to coordinate current law enforcement efforts and to assess whether they are adequate to protect consumers.

Following the hearing, on August 5, 1999, the President established by Executive Order a Federal Working Group on unlawful conduct on the Internet, including prescription drugs.

Although I supported the creation of this Working Group and its underlying principles, I was disappointed the President chose not to include State regulatory and enforcement groups as part of this Working Group. Since the practice of medicine and pharmacy have traditionally been regulated at the State level, I believed it was imperative that they be included.

To date, States have led the way in enforcing the law against illegal actions taking place on the Web. State Attorneys General across the country met just last week to discuss illegal Internet sales of prescription drugs and more than 20 States have brought actions against pharmacies and doctors violating their laws. Because the Internet knows no boundaries, States have a harder time stopping bad actors.

Because of this, I join Chairman Upton in announcing a proposal to empower State Attorneys General by granting them authority in appropriate cases to obtain equitable relief under Federal law in Federal court. Chairman Upton and I plan to jointly introduce such legislation in the coming weeks. This legislation will allow State Attorneys General to continue their good work in making the Internet safe for all.

Unfortunately the strides made by many States to enforce the law have not been made at the Federal level. In fact, just the opposite has occurred. This committee has witnessed not a single enforcement action by the Federal Government related to illegal sales of prescription drugs on the Internet.

Today, the FDA has submitted testimony stating there have been 43 arrests and 22 convictions resulting from FDA investigations involving products over the Internet. Not a single one of those arrests or convictions were related to Internet prescription drugs being sold over the Internet. Despite no record of stopping illegal prescription drug sales, the Administration proposes giving the FDA even more authority in the area of Internet pharmacies.

Moreover, the Administration continues to ignore the biggest problem we face—foreign Web sites shipping drugs into the United States.

Today, we will hear from the U.S. Customs Service who have documented a 450 percent increase in seizures of pharmaceuticals in only 1 year. While the President has called for additional regulations to govern domestic Web sites selling pharmaceuticals, he has all but ignored the problem we are facing at our borders.

While the President has talked a big game about Internet pharmacies, not one arrest or conviction related to Internet prescription drug sales has taken place since this subcommittee last met on this issue almost 1 year ago.

While States across the country with fewer resources than the FDA or the DOJ have been proactive, the Federal Government has been silent in the area of enforcement.

I will continue to be vigilant in looking at this issue and am devoted to holding additional hearings if need be. I look forward to hearing from our witnesses today and thank you all for joining us.

Mr. UPTON. Thank you, Mr. Chairman.

Ms. DeGette.

Ms. DEGETTE. Thank you, Mr. Chairman. I would like to join with my colleagues in thanking you or holding this hearing on this important issue.

This is, as you've just heard from the Chairman, this is the second hearing we've had on this topic; the last one was in July of last year. And the Chairman is right, much has changed in the last year but there is something that has not changed, and the thing that has not changed is we still have not had one prosecution by the Federal Government for these often illegal sales. And so I would echo the concerns expressed by my ranking member and by those on the other side of the aisle about this issue.

The good news is, the Internet has opened up a whole new world of convenience. We can research any topic, we can chat with somebody a half a world away, we can purchase anything. But, as we know, hazards exist as well. In the last hearing we had on this issue we talked about the benefits of pharmaceutical sales on the Internet. And it's true that convenience of shopping on the Internet for prescriptions is undeniable for some patients. But there are still some problems that are dangerous and perhaps even deadly.

As the co-chair of the Congressman Diabetes Caucus, I know, for example, many individuals with chronic illnesses like diabetes benefit enormously from being able to buy their supplies on the Internet. But if we don't have adequate oversight, there can be improper and even illegal dispensing of drugs over the Internet and we've got to address this. On some Internet pharmaceutical sites we've removed both the doctor's role in prescribing drugs and the pharmacist's role in reducing adverse effects and providing the patient yet another source of medical advice.

We've seen these sites. We saw them last year and I've looked at them since. A few clicks of the mouse on an online questionnaire must never be a substitute for medical treatment. I don't think that an Internet pharmacy should be a way to skirt professional medical practices by allowing individuals to access inappropriate and perhaps even illegal drugs.

And I will also, by the way, join with the Chairman in my view that simply that the Federal Government can't simply buck their responsibility by saying that oversight of the medical and pharmaceutical professions have traditionally been a State and local role. The Internet is a national and international phenomenon and has to be dealt with in a national manner.

I've got a study right here from the Institute of Medicine called, "To Err is Human, Building a Safer Health System." In that report it was estimated that between 44,000 and 98,000 people die annually as the result of medical errors. According to the report, "A good deal of research has identified medication error as a substantial source of preventable error." The report continues, "Because the burden of harm to patients is great, the cost to society is large, and knowledge of how to prevent the most common kinds of errors is

well known." The committee singles out medication safety as a high priority area for all health care organizations.

Well, if we have problems with medication error with folks that are actually under medical care, imagine the medication error you can get when people are just clicking on a computer screen before they get their medications.

I can't help but remember the lady who was able to get Viagra prescribed for both her dead father and her dog. And this is a real concern, I think, for this committee, and I know for all of us in the medical and pharmaceutical communities as well.

One of the recommendations of the report is that patients should tell physicians about all medications they are taking and ask for information in terms that they understand before accepting medications. Clearly that won't happen if people are ordering their own medications on line through simple questionnaires or worse.

We are going to hear testimony today, and I know our ranking member referred to this, that the FDA has devoted over 40,000 staff hours to this important issue, but I'm very concerned that the FDA can't point to one single prosecution or conviction for Internet pharmacy violations as late as March of this year. And I would like to know if any of the witnesses or anyone on the committee can point to some changes that we make. I have some ideas of my own of how we can perhaps increase the commitment both of the Federal agencies and also streamline some of the rules and legislation to allow these prosecutions to occur.

Finally, I would like to commend our ranking member representative Klink for his outstanding leadership on this issue and his continued diligence. I look forward to working on both sides of the aisle to see how we can begin to resolve this problem, intercept these drugs, and have some more prosecutions.

I yield back the balance of my time.

Mr. UPTON. Thank you.

Dr. Ganske.

Mr. GANSKE. Thank you, Mr. Chairman. I'm going to listen with interest to the testimony today. Let me just throw another angle into this issue. I got this letter from a constituent. It was actually addressed to Senator First and he sent a copy to me. He said, "I enjoyed your response to President Clinton's speech last evening. As a retired hospital administrator and someone involved in fundraising, I would like to make a suggestion needing investigation."

"For senior citizens, the best thing Congress can do is to help with medicine costs, not to pay medical costs, but to make the costs fair. Let me give you an example."

"After completing a University of Iowa Study on Celebrex, 200 milligrams for arthritis I got a prescription from my M.D. and picked it up at the hospital pharmacy. My cost was $2.43 per pill with, 'A volunteer discount.' Later on the Internet I found the following. I can order through"—and I'll leave out the company—"in Geneva, Switzerland after paying either of two American doctors $70 for a phone consultation at a price of $1.05 per pill, plus handling and shipping."

"I can order through a Canadian pharmacy if I use a doctor certified in Canada or my doctor can order it on my behalf through his office for 96 cents per pill plus shipping."

"I can send $15 to a Texan and get a phone number at a Mexican pharmacy who will sell it without a prescription. A friend now in Texas priced them at $52.50 per 100 pills in Progresso, Mexico."

"After the Federal Government gives funds for research and development and then gives tax breaks to pharmaceutical companies via write offs and depreciation, why are Americans raped on pharmaceutical costs?"

Well, I think that we're going to see a lot of senior citizens like my constituent making purchases through the Internet, Mr. Chairman, and from overseas because there's a huge cost differential. And the thing that I hear most about the pharmaceutical problem is that there is an inequity between drugs that are sold in Canada and Mexico, for instance and what their costs are in the United States.

So one of the things we ought to think about on this is, are we going to have increased enforcement so that senior citizens who may try to take advantage of these decreased costs will find that the FDA, for example, is acting as the policemen preventing them from getting their drugs at a reduced price. Or, are there problems with verification of the medicines that they're actually receiving. That's the line of questioning that I want to take in this hearing. And I yield back. Thank you.

Mr. UPTON. Mr. Green.

Mr. GREEN. Thank you, Mr. Chairman. I would like to ask unanimous consent for my full statement to be placed in the record. And following up my Iowa colleague, coming from Houston, Texas, I can relate to and I know very well where Progresso, Mexico is, along with every other border crossing. And the success my constituents have had driving 6 hours to fill prescriptions at one time. They would fill them for their neighbors, and because of the effort at the border now, it's only them and their own prescriptions and a 90-day supply.

My concern though is the quality and the purity of the pharmaceuticals, whether we get it from Thailand or Mexico or anywhere else. And, again, I'm concerned about the costs and hopefully Congress will address that this year. And sooner or later, although hopefully sooner, but I hope this hearing will talk about the quality and the purity of those pharmaceuticals from around the world to see if people are really purchasing what they think they are.

So with that, Mr. Chairman, I'll just put the remainder of my statement in the record.

Mr. UPTON. Without objection all members will be able to have the opportunity to put their entire statement into the record.

[The prepared statement of Hon. Gene Green follows:]

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

Mr. Chairman, I would like to start by thanking you for holding this important hearing.

While the growth over the past several years in e-commerce has been a positive experience for both consumers and retailers alike, this Committee has tried to look at ways to balance the right of open access to the Internet with responsible safeguards to protect consumers from online predators and scams.

To ensure this continued growth and prosperity, we need to provide appropriate safeguards to protect consumers. An emerging area of concern is the growth of online pharmacies who operate without regard for standard practices of medicine.

While this Congress is attempting to reduce the cost of prescription drugs for seniors, we have a responsibility to ensure that the cheaper alternatives are safe and effective.

Currently, the FDA has the authority to protect consumers against the importation, sale or distribution of illegal, unapproved or counterfeit drugs, while the FTC has jurisdiction to protect consumers from unfair or deceptive acts or practices, including the false advertisement of drugs.

Despite this authority, these agencies have been slow to act against Web sites selling prescription drugs illegally. This gap has been filled, to a certain extent, by the states. Action by the FDA and FTC, however, is still necessary.

Additionally, as the number of Internet sites outside the U. S. has grown, the role of the Customs Service has expanded as well. The number of seizures at Customs mail branches has increased dramatically, and Customs has worked closely with authorities in other countries to combat illicit Internet pharmacies. However, without assistance from the FDA, the Customs Service cannot be effective in stemming the flood of drugs being shipped into this country from abroad.

We need to encourage state and local authorities to continue their efforts against online pharmacies, encourage the FDA and FTC to join in those efforts where feasible, and push the, FDA to work more closely with Customs to stem the tide of drugs flowing in from outside our borders.

Thank you for the time, Mr. Chairman, and I look forward to the testimony of the witnesses.

Mr. UPTON. Mr. Bryant.

Mr. BRYANT. Mr. Chairman, I too thank you for this follow-up hearing that you're holding today and I think just about everything that could be said about this issue this semi-informed panel has been said, and I am going to yield back my time. I am anxious to hear from the people who are perhaps a little more knowledgeable on this.

Mr. UPTON. Mr. Burr.

Mr. BURR. No opening.

Mr. UPTON. Welcome. The panel this morning includes Mr. William Hubbard, Senior Associate Commissioner for Policy, Planning and Legislation at the Food and Drug Administration; Mr. Ethan Posner, Deputy Associate Attorney General from the Department of Justice; Ms. Betsy Durant, Director, Office of Trade Programs, U.S. Customs Service; and The Honorable Carla Stovall, Attorney General, State of Kansas. Welcome back.

As you all know we have had a long tradition in this subcommittee of taking testimony under oath. Do any of you have objection to that?

[No response.]

Mr. UPTON. If not, we also have, under the committee rules, you're entitled to counsel. Do any of you desire counsel?

[No response.]

Mr. UPTON. If you would all stand and raise your right hands.

Do you swear to tell the truth, the whole truth, and nothing but the truth, so help you God?

[Chorus of ayes.]

Mr. UPTON. Thank you. You are now under oath. Your statements in their entirety are part of the record. We have a little clock up here. We would like to limit your remarks, if we can, your opening statements to 5 minutes.

Mr. Hubbard, we will begin with you.

TESTIMONY OF WILLIAM K. HUBBARD, SENIOR ASSOCIATE COMMISSIONER FOR POLICY, PLANNING AND LEGISLATION U.S. FOOD AND DRUG ADMINISTRATION; ETHAN M. POSNER, DEPUTY ASSOCIATE ATTORNEY GENERAL, U.S. DEPARTMENT OF JUSTICE; BETSY DURANT, DIRECTOR, OFFICE OF TRADE PROGRAMS, U.S. CUSTOMS SERVICE; AND HON. CARLA J. STOVALL, ATTORNEY GENERAL, STATE OF KANSAS

Mr. HUBBARD. Thank you, Mr. Chairman. I have a written statement for the record, but I'll just make a few opening remarks.

While the Agency has been very aggressive in going after unapproved drugs on the Internet, we have also, of course, been looking at the issue of approved drugs being sold through these online questionnaires, and we've learned a lot since last year's hearing.

We've learned that most of these web sites actually have licensed pharmacists and licensed physicians at the other end; and that most of the drugs are not diverted; they're being purchased through normal channels. We also know that the States do not in most cases have laws to adequately address this sort of problem.

There is a gap between Federal and State law that falls in there that you suggested that you have some ideas for; and thus the cases are harder to make and we certainly can talk about it more today. But we have been very active. We have done many things. We have set up an education program to tell people that this is a potentially dangerous practice and to understand how to order drugs over the Internet, because there are, of course, good sites. But then there are sites that are not so good.

We have partnered quite a bit with not only the States, but with other Federal agencies. We've done a lot in enforcement. We have used search engines and new technology to look at the sites that are out there. We have developed the case assessment process to follow the leads that come our way. We have redeployed personnel in this area. We have given the Congress a budget request for next year that would increase our efforts here and would evaluate over 400 web sites.

On the civil side, Mr. Chairman, we have taken action already on more than 50 web sites and we have 54 more under investigation. And as part of that we have issued 38 warning letters, 17 so-called "cyber letters" to foreign countries, five injunctions have been sought, or have been done, 12 seizures of drugs have occurred, 11 recalls have occurred, 18 voluntary destructions of shipments of drugs have occurred, and 17 import alerts have occurred.

On the criminal side, we have 132 investigations underway; 86 are full-blown, open criminal investigations and 46 more preliminary ones that are moving in that direction. Of those, 49 are the sorts of online pharmacy that use questionnaires and 83 are those that are selling unapproved drugs. And, as you noted, that results in 43 arrests and 22 convictions, and we've also referred at least 11 cases to the States who are independently taking action.

There is a difficulty, though, in winning these cases with these online questionnaires for the approved drugs; it's logistically difficult. We have to track down the site, the domain, the true business owner. In many cases there are multiple sits being operated by one entity. We have to find them and their operator. That's a lot of work.

But then beyond that, when we find that the site exist and is selling a drug through a licensed pharmacy and a licensed physician, and if the State cannot tell us that that prescription being written is not valid, we have a great deal of difficulty making a successful case. I'm sure we will be talking about that more today, Mr. Chairman.

Thus, we believe legislation is needed in this area. We prepared a legislative bill that is, I believe, before the Congress. It requires State licensure of these online pharmacies that would build upon Mr. Klink's concepts last year of disclosure which were, I think, universally accepted as a good idea. That would ask or declare that they are in compliance. In other words, it gives the consumer some sort of declaration that this is a site that meets the requirements of State law, as opposed to one that would not have that.

We would ask that the site notify us when they beginning to operate to understand if there are some skeptical activities going on. We have asked for civil money penalties the deter some of these activities. And most importantly, as you yourself have acknowledged, we believe there needs to be a State cause of action. Because, in the end, States are most responsible for the regulation of pharmacy and medicine and we believe giving the States the cause of action would greatly enhance their ability to work, to go into Federal court on these cases.

And, last, I believe, Mr. Chairman, that the noose is slowly tightening over these domestic sites. The States are changing their laws, investigations are under way. Progress is being made even though we're not seeing the convictions you're asking about. But I believe we can get these domestic sites under control. The issue will, I think, be, as you're saying today, these foreign sites; what can we do about them.

And one item that we have that we would like to urge you to consider is that in our bill we would have a site that's legitimate, have some sort of declarational seal identifying a legitimate site so at least a consumer, when he's surfing through the web, and sees a site that has that declaration, he'll know there is a legitimate, licensed, pharmacist at the other end; he can call him on the phone, he can talk to him, he's a real person there. He's not some guy in a garage in some third-world country.

So with that, Mr. Chairman, I'll end my testimony.

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

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

INTRODUCTION

Mr. Chairman and Members of the Committee, I am William K. Hubbard, Senior Associate Commissioner for Policy, Planning and Legislation at the Food and Drug Administration (FDA or the Agency). I am pleased to come before the Subcommittee to discuss with you the benefits and risks of pharmaceutical sales over the Internet and what the Agency has been doing to address these issues since your hearing last year. The sale of consumer products over the Internet has grown rapidly, including the sale of drugs. The growth in online drug sales by reputable pharmacies is a trend that can provide significant benefits to consumers. On the other hand online drug sales also present risks to purchasers and some unique challenges to regulators, law enforcement officials and policy makers. FDA is concerned about the public health implications of Internet drug sales, and we are responding to these con-

cerns as part of our overall goal of developing and implementing risk-based strategies to protect public health and safety.

Although other products regulated by the Agency, such as medical devices, medical test products, foods, dietary supplements and animal drugs also are sold online, this testimony will focus on online drug sales. We will discuss the advantages and risks of online drug sales, outline FDA's authority and enforcement activities in this area, and describe new initiatives we are taking to better respond to the regulatory challenges we face.

In the context of prescription drug sales over the Internet, the private sector has an important role to play in promoting consumer education and in providing assurance to consumers about the quality of products and services. Our challenge is to make sure that the same safety net that protects the consumer who purchases prescription drugs at the corner store is just as strong when the click of a mouse is used to purchase from a venue in cyberspace. Rapid technological developments have changed the nature of the challenges we face today and we must be flexible in developing solutions that are appropriate to meeting these challenges. As electronic commerce embraces global markets, we should strive for consistent principles across State, national, and international borders that promote safety and efficacy, regardless of the jurisdiction in which a particular buyer or seller resides.

BENEFITS OF ONLINE DRUG SALES

The use of the Internet by our nation's citizens, from school age children to seniors, has opened up vast new opportunities for the exchange of information and for enhancing commerce in all types of consumer products. Electronic mail and chat groups have dramatically facilitated communications. Information gathering that once took hours or days of research, whether for a student's homework assignment or to look up information on the medical condition of a family member, can now be accomplished in minutes.

The Internet is rapidly transforming the way we live, work, and shop in all sectors of the economy. In the health sector, tele-medicine allows people in remote areas to access the expertise of doctors in the nation's finest academic health centers. The Internet permits an increasing number of individuals to obtain a plethora of medical information that often helps them to understand health issues and treatment options. In fact, more than 22 million Americans used the Internet last year to find medical information, either in documentary resources or through online discussions with health professionals. According to Investor's Business Daily, 43 percent of web surfers access health care data online each year. Conducting research regarding their health concerns is the sixth most common reason that people use the Internet, and according to the market research firm, Cyber Dialogue Inc. The number of persons accessing health care data is growing by 70 percent a year.

Prescription drug sales on the Internet can provide tremendous benefits to consumers. These benefits are many and include: access to drugs for the disabled or otherwise home-bound, for whom a trip to the pharmacy can be difficult; the convenience of shopping 24 hours a day; an almost unlimited number of products for customers; and privacy for those who don't want to discuss their medical condition in a public place. Hyperlinks and search programs provide online customers with written product information and references to other sources of information much more easily than in the traditional storefront. Finally, as the use of computer technology to transmit prescriptions from doctors to pharmacies expands, a reduction in prescription errors may be possible.

While online pharmaceutical sales will be important for some customers, it must be noted that the traditional "brick and mortar" pharmacy offers benefits or services that are often not available through the Internet, such as immediate access to prescription drugs needed for immediate treatment. These pharmacies will undoubtedly remain an essential component in the delivery of effective health care.

The challenge for government at both the State and Federal level is to pursue policies that will allow legitimate electronic commerce to flourish but provide that safety is assured. Consumers will have confidence in the quality of the medical prescription and in the medicine delivered because the protection for online consumers is equivalent to the safeguards of the traditional local pharmacy and the practice of medicine and pharmacy.

CONCERNS ABOUT ONLINE SALES

As beneficial as this new technology can be, the Internet also creates a new marketplace for activity that is already illegal, such as the sale of unapproved new drugs, prescription drugs dispensed without a valid prescription, or products marketed with fraudulent health claims. As FDA considers the issues related to online

drug sales, we recognize that there are various types of websites used for drug sales. Many sites focus on selling prescription drugs and have been referred to by some as "Internet pharmacies." These sites offer for sale either FDA-approved prescription drug products, or in some cases, unapproved, illegal versions of prescription drugs. The sales sites of legitimate, properly licensed pharmacies provide benefits to consumers, however, those that are unlicensed or otherwise engaged in the illegal dispensing of prescription drugs pose a serious threat to the health and safety of American citizens. Other drug sales sites offer for sale unapproved drug products, products making fraudulent health claims, or drugs for recreational use. Examples of these sites are those that sell products containing gamma hydroxy butyrate (GHB), an unapproved drug used recreationally, for body building and for incapacitating the victims of sexual assaults, or sites that offer unproven cancer therapies. It should be noted that with regard to GHB, early this year the President signed legislation, which originated in this subcommittee, placing GHB in Schedule 1 of the Controlled Substances Act. While the increase in "Internet pharmacy" sites engaged in illegal sales is seen by some as a particularly potent threat, FDA believes that the non-pharmacy sites are harmful, or in some cases more so, and we have moved aggressively against those that operate unlawfully.

The unique qualities of the Internet, including its broad reach, relative anonymity, and ease of creating new websites or removing old ones, pose new challenges for the enforcement of existing laws. FDA has found that most drug sale websites are actually made up of multiple related sites and links, thereby making investigations much more complex and resource intensive. The global nature of the Internet creates particular problems for effective law enforcement. Different approaches to drug approval and marketing in foreign countries further complicate law enforcement issues for United States' (U.S.) officials. FDA and other U.S. government agencies need to work closely with foreign governments to share information and to develop mechanisms for cooperative law enforcement.

FDA Authority

As you know, the establishment of FDA as it exists today grew out of a time early in the century when consumers were victimized by dishonest purveyors of fraudulent potions and compounds that were ineffective, dangerous, or both. A system of drug regulation was established in this country that has served us well. Under this system, FDA reviews new drugs to assess their safety and efficacy. In addition, certain types of drugs must be prescribed and dispensed only by licensed health care professionals. The prescribing requirement is based on the principle that certain drugs have risks of such significance associated with them that they should be administered only under the supervision and recommendation of a "learned intermediary"—that is, a licensed practitioner with the education and training necessary to oversee the administration of potentially harmful drug products. Similarly, these products may only be dispensed by a licensed professional that can help to assure proper dosing and administration and can provide important information on the drug's use to patients. These requirements are crucial components of the risk management system for drugs in the U.S.

The types of unlawful conduct involving online drug sales that FDA has identified are similar to unlawful activities that occur in other sales contexts. Under the Federal Food, Drug, and Cosmetic (FD&C) Act, FDA has the legal authority to take action against:

- the importation, sale, or distribution of an adulterated or misbranded drug;
- the importation, sale, or distribution of an unapproved new drug;
- illegal promotion of a drug;
- the sale or dispensing of a prescription drug without a valid prescription; and,
- counterfeit drugs.

When the Internet is used for an illegal sale, FDA, working with the Department of Justice (DOJ), must establish the same elements of a case, develop the same charges, and take the same actions as it would if another medium, such as a storefront or a magazine, had been used. FDA has investigated and referred cases for criminal prosecution and initiated civil enforcement actions against online sellers of drugs and other FDA-regulated products, particularly sellers of drugs not approved by the Agency. As will be described later, FDA has significantly expanded its enforcement activities during this past year with regard to online drug sales.

State Regulation of Practice of Medicine, Pharmacy and Dispensing of Drugs

The States have enacted laws regulating the practice of pharmacy and the practice of medicine in order to protect patients from harm resulting from the use of unsafe drugs, counterfeit drugs, and the improper practice of medicine and pharmacy. Under many of these laws, to receive a prescription drug for the first time,

a patient generally must be physically examined by a licensed health care practitioner who determines the appropriate treatment and issues a prescription for an FDA-approved drug. The patient then has the prescription filled by a registered pharmacist working in a licensed pharmacy that meets state practice standards.

Use of the Internet to Bypass the Regulatory System

Even with these Federal and State systems in place, there are those who try to circumvent established safeguards, and the Internet provides them with new opportunities for doing so. It is fair to say that the speed and ease of ordering products on the Internet that attracts consumers can likewise entice unscrupulous sellers to use the Internet as their new medium of choice. Individuals not licensed to sell prescription drugs can easily create websites that appear to represent legitimate pharmacies. The fact that operators can easily change the location and appearance of their Internet sites makes enforcement all the more difficult. Unlike most other forms of electronic commerce, the unauthorized sale of prescription and unapproved drugs poses a potential threat to the health and safety of consumers.

Patients who buy prescription drugs from an illegitimate site are at risk of suffering adverse events, some of which can be life threatening. These risks include potential side effects from inappropriately prescribed medications, dangerous drug interactions or contaminated drugs, as well as the possible ill effects of impure or unknown ingredients found in drugs manufactured under substandard conditions. Further risk to patients is posed by their inability to know what they are really getting when they buy some of these drugs. Although some patients may be purchasing genuine product, some may unknowingly be buying counterfeit copies that contain inert ingredients, outdated legitimate drugs that have been diverted to illegitimate resellers, or dangerous sub-potent or super-potent versions that were improperly manufactured. Moreover, consumers who are desperate for a cure to a serious medical problem may be more susceptible to purchasing an unapproved product.

FDA is concerned about the proliferation of sites that substitute a simple online questionnaire for a face-to-face examination and patient supervision by a health care practitioner. According to the American Medical Association, a health care practitioner who offers a prescription for a patient they have never seen before, based solely on an online questionnaire, generally does not meet the appropriate medical standard of care. Just last month, the Federation of State Medical Boards received the report of its Special Committee on Professional Conduct and Ethics, which found that "Prescribing of medications by physicians based solely on an electronic medical questionnaire clearly fails to meet an acceptable standard of care and is outside the bounds of professional conduct." This finding is especially important in light of the primary responsibility of States in regulating the practice of medicine. Additionally, FDA is concerned that the use of such questionnaires may jeopardize the privacy of a patient's medical records. We will continue to play a role in the Administration's efforts with the private sector to implement appropriate protections for patient's medical information. We also will continue to distinguish legitimate online communications from unlawful conduct that increases patient risk.

The Agency is equally concerned that in some Internet transactions, there is an apparent absence of any health professional/patient relationship. This is a particular concern where the prescription involves a first-time use by a patient or where the patient may be taking other medications. FDA is concerned that the selection of prescription drug products or treatment regimens for a particular patient should be made with the advice of a licensed health care practitioner familiar with the patient's current health status and past medical history. In situations where a customary physician-patient relationship does not exist, the patient may be essentially practicing self-diagnosis. Consequently, the risk of negative outcomes such as harmful drug interactions, contraindications, allergic reactions or improper dosing is greatly magnified.

Jurisdictional Issues

In addition to magnifying existing problems by reaching potentially millions of consumers worldwide, online drug sales create unique issues for regulatory and law enforcement bodies at the State, Federal and international level. Internet technology can obscure the source of the product as well as provide some degree of anonymity to persons responsible for making and shipping the product. The participants in a transaction can be widely dispersed geographically (in different States or countries) and they may never meet. Thus, the regulatory issues cross traditional regulatory boundaries as well as Federal and State jurisdictional lines. If one or more participants in the transaction are located outside of the U.S., the task of regulating the activity is further complicated.

The sale of drugs to U.S. residents via foreign websites is an extremely challenging area. Some medications sold on the Internet may be legal in foreign countries but not approved for use in the U.S., and some products may include addictive and dangerous substances. Products not approved for sale in the U.S. often do not conform to the good manufacturing practice and quality assurance procedures required by U.S. laws and regulations, and it is illegal for a foreign pharmacy to ship such drugs into the U.S. Foreign sales pose the most difficult challenge for U.S. law enforcement because the seller is not within U.S. boundaries. Although FDA has jurisdiction over a resident in a foreign country who sells to a U.S. resident in violation of the FD&C Act, from a practical standpoint, the Agency is hard pressed to enforce the law against foreign sellers. FDA confronts the same obstacles facing other U.S. regulatory and law enforcement agencies seeking to hold foreign actors accountable for violations of Federal law. FDA efforts are mostly limited to requesting the foreign government to take action against the seller of the product, or asking the U.S. Customs Service (USCS or Customs) to stop the imported drug at a U.S. port-of-entry.

Foreign governments are also struggling with how to address the problem of illegal drug sales over the Internet. For instance, pharmaceutical industry officials in Italy are recommending that the issue be addressed by the European Community as a whole.

The New Zealand Health Ministry has begun to look at options to prevent pharmaceuticals from being dispensed from New Zealand to overseas consumers without a prescription, after a court decision revealed a loophole that prevents regulators from preventing the practice.

FDA'S INTERNET DRUG SALES ACTION PLAN

Over the past several years, FDA has sharpened its focus on the issue of Internet promotion and sale of drugs as online activity has expanded. In the fall of 1996, FDA held a public meeting on the use of the Internet to promote drug products at which we heard from consumers and health professionals on this emerging issue. In February 1999, the Agency hosted a meeting with representatives of health professional organizations to look at the prescribing and dispensing of drugs on the Internet.

In July 1999, FDA adopted, and has since been implementing, an Internet Drug Sales Action Plan to expand and improve the activities of the Agency in addressing the unlawful sale of drugs over the Internet. This plan is based on internal deliberations, meetings with Federal and State regulatory and law enforcement bodies, as well as organizations representing consumers, health care practitioners, and the pharmaceutical and pharmacy industries. Details of the action plan's elements and FDA's activities in implementing them are as follows.

Engage in Public Outreach

At a minimum, every drug sale involves at least a purchaser and a seller. Consumers buy drugs on the Internet for different reasons, and some may be targets of unscrupulous business practices, such as the selling of unsafe, unapproved, expired, counterfeit or otherwise illegal drugs. Public outreach offers one mechanism by which the Agency can help protect consumers from dangerous or inappropriate drugs. FDA is expanding its public outreach to inform the public about dangerous practices involving Internet purchases and to explain what compliance and enforcement actions we already have taken. This outreach effort includes FDA *Talk Papers*; articles in the FDA Consumer Magazine; and information on FDA's website to help educate consumers about safely purchasing drugs online and provide consumers with an opportunity to submit to the Agency information on sites that may be violative.

This year, FDA has launched a new media campaign about safe ways to purchase pharmaceutical products over the Internet. The campaign includes placing advertisements on health related websites; taping public service announcements for distribution to television and radio stations nationwide; and developing a "safety checklist" to be posted online and distributed through health care providers and consumer advocacy organizations.

The Agency will keep working with consumer groups, health care practitioner organizations, and industry to encourage these parties to keep their constituents and the public informed about safe practices for purchasing drugs online.

Engage in Professional Outreach and Partnering

At the February 1999 meeting with health professional organizations, FDA, the Federation of State Medical Boards of the United States, the National Association of Boards of Pharmacy (NABP), the American Medical Association and the Associa-

tion of Food and Drug Officials discussed the roles that each organization plays in regulating prescribing and dispensing on the Internet and how the various roles could better compliment each other. At that meeting, the NABP announced its program to verify the legitimacy of Internet sites dispensing prescription drugs. The program, known as the Verified Internet Pharmacy Practice Sites, or VIPPS, provides a NABP "seal of approval" to sites meeting State licensure requirements and NABP's standards. Over time, this seal of approval may help to assure consumers that the designated sites are offering FDA approved pharmaceuticals. The VIPPS program is voluntary.

FDA continues to meet with organizations representing State regulatory and law enforcement bodies, consumers, health care practitioners and industry. The purpose of these meetings are to gather information on: 1) how issues relating to online drug sales should be addressed, 2) who should regulate and how they should regulate; 3) whether and what changes to the current law should be enacted; and 4) when to develop partnering arrangements. These organizations 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 Pharmaceutical Association,
- the American Association of Retired Persons,
- the National Consumers League,
- the American Society of Health-Systems Pharmacists,
- the National Association of Chain Drug Stores,
- the National Community Pharmacists Association, and,
- the Pharmaceutical Research and Manufacturers Association.

Coordinate Activities with other State and Federal Agencies

Several Federal agencies, as well as the States, have the authority to regulate and/or enforce U.S. laws related to the sale of drug products online. Due to the growth of potential cases involving the Internet, there are instances when working with another agency or State could result in a more effective enforcement action. Working closely with the States is essential to effectively regulate the domestic sale of both approved and unapproved drugs, as well as the sale of prescription drugs without a valid prescription over the Internet. FDA has established partnership agreements with several State bodies, including the National Association of Boards of Pharmacies and the Federation of State Medical Boards, to coordinate Federal and State activities aimed at questionable practices associated with the selling and prescribing of prescription drugs. Additionally, we are talking with the National Association of Attorneys General about a possible agreement.

FDA has increased its coordination of efforts with other governmental bodies and has met several times over the past year with Federal agencies and State officials to share information, discuss the roles and responsibilities of the parties regarding online drug sales and identify opportunities for partnering in enforcement actions. FDA has established cooperative working relationships with the Department of Justice (DOJ), including the Drug Enforcement Administration (DEA) and Federal Bureau of Investigation (FBI), the U.S. Postal Inspection Service, USCS and other appropriate Federal and State law enforcement and regulatory agencies. FDA believes an important area where cooperation among federal agencies is critical is the sale of drugs to U.S. residents by foreign sellers. The USCS, the U.S. Postal Service, FDA, and the DEA all play important roles in taking action against the illegal importation of drugs.

Generally, determinations of when and with whom FDA would engage in joint enforcement is based on the kinds and severity of violative conduct identified through Internet monitoring. Although FDA is expanding its own Internet monitoring capabilities, the Agency also is developing partnerships in this area with other agencies. In addition, FDA was a participant in the Administration's Working Group on Unlawful Conduct on the Internet, which issued its report to the President this past March. In its analysis of the problems associated with online drug sales, the report calls for legislation requiring online pharmacies to disclose certain information to consumers and for a system of assurance that they comply with appropriate Federal and State requirements.

Cooperate Internationally

Because FDA and the other Federal agencies possess limited investigatory jurisdiction over sellers in foreign countries, we must work with foreign governments to bring action against such individuals. Internet crime and the practice of online pharmacy are a growing concern throughout the international law enforcement com-

munity. FDA's Office of Criminal Investigations (OCI), maintains ongoing liaison with numerous government agencies in Canada, the United Kingdom, Spain, Germany, Belgium, the Netherlands, Ireland, Brazil, Singapore and others.

An example of this cooperation involved OCI contact with authorities in a Pacific Rim country where a website operator alleged that he used the services of two legitimate doctors to review his online questionnaire. Through our foreign counterparts, we were able to have the doctors interviewed. Both denied any involvement in the scheme, thus exposing the operator to possible mail and wire fraud or other charges.

In another case, OCI made an undercover purchase of drugs from a site operating out of a European country. The site made no pretense of a medical review. OCI was looking for a domestic connection for charges in the U.S. While none was found, ourcontacts with the health authorities in that country resulted in their initiation of an criminal investigation. Finally, OCI is involved in two cases with USCS overseas offices regarding foreign websites selling prescription and controlled pharmaceuticals. Enforcement activity by Customs resulted in numerous arrests and the seizure of over 1.5 million pills and several computers.

Customize and Expand Enforcement Activity

FDA's emerging role in regulating online drug sales is consistent with its traditional regulatory role. Existing approaches to enforcement, including close cooperation with State agencies, are being adapted to focus more effectively on the problems posed by online drug sales. An effective Internet enforcement process requires establishing priorities, identifying and monitoring potentially violative websites and making appropriate referrals for criminal prosecution and/or civil enforcement actions. FDA is enhancing its enforcement efforts by undertaking the following actions:

Establishing Priorities—FDA has initially focused its online drug sales-related enforcement activities to the following areas, particularly where there is a significant public health risk: [1]

- Unapproved new drugs,
- Health fraud, and
- Prescription drugs sold without a valid prescription.

Improving Data Acquisition—FDA has increased its capability to monitor the Internet and identify potentially violative sites through the use of various search tools and by upgrading its data handling capabilities. This is helping the Agency to better understand the kind and extent of unlawful conduct on the Internet and to more accurately assess whether its enforcement efforts have had an impact on illegal Internet behavior.

In an attempt to better comprehend the universe of websites selling drugs, OCI reviewed thousands of websites early this year and identified approximately 326 websites involved in the sale of drug products. This review was based on a search of websites performed by Internet search software, which was followed by a manual review of sites that appeared to involve the sale of drug products. Because new websites are put up everyday and old ones are taken down, the total number of these sites is subject to change and will not be consistent over time. Additionally, because OCI's technology and methodology probably differs from those used in studies by other organizations, the results of this study are not directly comparable to other studies.

Coordinating Case Assessment—In June 1999, FDA established a case assessment, or "triage" team with representatives from the Office of Enforcement and OCI within the Office of Regulatory Affairs (ORA), the Center for Drug Evaluation and Research (CDER), the Office of the Chief Counsel (OCC) and the Office of Policy. Under the triage process, FDA obtains leads on potentially violative sites from internal Internet monitoring activity, State, other Federal or foreign law enforcement agencies, consumers, Congress, and the press. The triage team evaluates the leads and decides whether they should initially be pursued through a civil or criminal investigation. Priority is given to cases involving unapproved new drugs, health fraud, prescription drugs sold without a valid prescription and products with the potential for causing serious or life-threatening reactions. The triage team makes referrals, when appropriate, to FDA's civil and criminal enforcement units for follow-up.

The triage process results in a better coordination of criminal and civil enforcement actions at the appropriate Agency components and reduces overlapping effort. This process better ensures that decisions are made in a timely way, with an appropriate balance in terms of achieving a maximum deterrent effect while taking ac-

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[1] *A significant public health risk* exists when a consumer is at risk for harm (1) from the use of the product, (2) as the result of not taking approved drugs for a specific disease or condition, or (3) by delaying medical treatment recognized as safe and effective for a specific disease or condition.

tion, if needed, to remove harmful products from the market. The team will continue to oversee Internet-related enforcement activities while they are being investigated and will ensure that they are brought to appropriate completion. In addition, the scope of this group is being broadened to include all FDA-regulated products.

Enhancing Enforcement Resources—In general, FDA's investigative and enforcement activity regarding Internet drug sales has been accomplished by re-deploying FDA personnel, which necessarily results in a reduction of investigation and enforcement activity in other areas. The Agency has drawn from existing resources to increase its current enforcement efforts because we believe that illegal online drug sales pose a significant public health risk. As explained in more detail later, the President has requested $10 million in additional funding for Internet enforcement activities in the Fiscal Year (FY) 2001 budget.

Results to Date—Using information generated by Internet searches, as well as leads from all parts of the Agency, other State and Federal law enforcement units, and the public, FDA has performed at least cursory reviews of thousands of websites related to drug sales. FDA (the offices of ORA, CDER Compliance, OCC and OCI) has evaluated well over 400 websites for possible regulatory or criminal action and has taken enforcement action on many of those sites, as follows: Currently, FDA has 54 sites under active review for possible regulatory or civil action. Regulatory action has been taken on more than 50 sites as follows. Thirty-eight (38) warning letters have been sent by the Office of Compliance to domestic online sellers. A warning letter is a written communication from FDA notifying an individual or firm that the Agency considers one or more products, practices, processes, or other activities to be in violation of the FD&C Act, or other relevant statutes, and that failure of the responsible party to take appropriate and prompt action to correct and prevent any future repeat of the violation may result in administrative and/or regulatory enforcement action without further notice.

Additionally, OCC has sent seventeen (17) "cyber letters" to operators of foreign-based Internet sites offering to sell online prescription drugs. These sites may be engaged in illegal activity such as offering to sell prescription drugs to U.S. citizens without valid (or in some cases without any) prescriptions. Cyber letters, which are sent over the Internet to the suspect websites, warn these operators that they may be engaged in illegal activities, and informs them of the laws that govern prescription drug sales in the U.S. FDA has received seven responses from "cyber" letter recipients and FDA is continuing to monitor these sites.

Other civil and regulatory actions include the following. In cooperation with DOJ, two preliminary injunctions have been imposed on the sale of a illegal products—one marketed as a weight-loss aid that contains a potent thyroid hormone, which could cause heart attacks or strokes, and the other an unapproved cancer therapy. FDA and DOJ are pursuing an additional injunction against the sale of another unapproved cancer therapy over the Internet. Additionally, twelve (12) product seizures, eleven (11) product recalls, and the voluntary destruction of eighteen (18) violative products have been achieved, generally pertaining to unapproved new drug products including GHB, gamma butyrolactone (GBL), Triax, 1,4 butanediol, and laetrile. Seventeen (17) import alerts have been issued targeting products offered by foreign online drug sellers.

OCI, working with OCC, is responsible for investigations of pharmacy sites and other Internet drug sites whose operations involve potential criminal activity. The information collected by OCI headquarters is analyzed by the Investigative Analysis Branch. After the suspect sites are researched they are sent to the OCI field offices for investigative work, which often includes undercover buys. Further investigation determines the bona fides of the pharmacy and doctor(s), and looks at the relationship between the patient and doctor and the doctor and pharmacy. OCI has ongoing cooperative relationships with the USCS, DEA, FBI, the Postal Inspection Service and appropriate State law enforcement and regulatory agencies, and this has enhanced their investigative capabilities with regard to Internet drug sales.

Currently, OCI has 132 Internet related investigations underway, including 86 open criminal investigations and 46 preliminary investigations. Of these 132 investigations, 49 cases are investigations of sites selling prescription drugs, while 83 cases are related to various types of health fraud, or unapproved drug products such as GHB or other illegal drug sales. Forty-three (43) arrests and twenty-two (22) convictions have resulted from OCI investigations involving products being sold over the Internet.

THE ADMINISTRATION'S FISCAL YEAR 2001 BUDGET REQUEST AND PROPOSED INITIATIVE

On December 28, 1999, the Administration announced a new initiative to protect consumers from the illegal sale of pharmaceuticals over the Internet. The initiative

includes a $10 million request in the President's FY 2001 budget to enhance FDA's enforcement capabilities, and called for legislation to help ensure that Internet pharmacies comply with State and Federal laws.

Budget Request

The Administration's FY 2001 budget request contains a new $10 million investment to take action against those who engage in illegal drug sales over the Internet. The funding would be used to identify, investigate, and prosecute operators of websites selling prescription drugs without a valid prescription, unapproved new drugs, counterfeit drugs, and expired or illegally diverted pharmaceuticals. This funding initiative will also help crack down on the marketing of products based on fraudulent health claims.

The $10 million appropriation would be used primarily to sustain the number of investigative and enforcement personnel we are currently investing in this area. FDA will continue to employ Internet hardware and software to identify suspect websites, and will use the additional personnel resources to investigate and take enforcement action against the operators of these sites. To date, FDA's enforcement activity on Internet drug sales has been accomplished by re-deployment of existing personnel resources, which necessarily results in a reduction of investigations in other areas.

Enactment of the $10 million request would allow FDA to re-direct its currently re-deployed resources back to other enforcement priorities and establish a significant, permanent presence on Internet pharmacy enforcement. In addition, the requested funding would help FDA step up efforts to educate consumers about the risks involved online and what types of sites or practices they should avoid.

Drugs marketed and sold illegally over the Internet present real risks for the American consumer. Enforcement activities targeting these sites have been made a budget priority for FY 2001.

LEGISLATIVE PROPOSAL

On May 2, 2000, Secretary Shalala sent to Congress the Administration's proposed legislation, the "Internet Prescription Drug Sales Act of 2000". The Administration's objective in developing this legislation is to protect the health of consumers by providing them with a level of protection equivalent to that enjoyed by customers of traditional "brick and mortar" pharmacies without hindering the enormous potential benefit of the Internet. We see this proposal as a first step in the process of developing appropriate protections for online consumers of drugs, and we look forward to working with the members of this subcommittee and others in the Congress on this important matter.

The bill is also designed to enhance the effectiveness of the Federal-State partnership in regulating prescription drugs and recognize the importance of the States' traditional role in regulating the practice of medicine and pharmacy. Accordingly, the bill would support and strengthen the States' authority to enforce applicable laws within their borders, while providing enhanced Federal authority to monitor the multi-state and interstate aspects of Internet prescription drug sales. By filling gaps in Federal and State authority, the bill seeks to curb illegal sales of prescription drugs and to ensure that consumers are receiving safe and effective drugs prescribed by licensed health care professionals, and dispensed by pharmacies that are properly licensed, and in compliance with, all applicable State and Federal laws.

Specifically, the bill would require online pharmacies to be licensed in each State in which they operate or to which they deliver prescription drugs. They would have to comply with all applicable Federal and State laws governing the practice of pharmacy which include, among others, requirements for proper storage and handling of prescription drugs, record keeping, and other consumer protections including safeguards on patient privacy and confidentiality of medical records.

The online pharmacy would be required to provide to the Secretary and relevant State boards of pharmacy, prior to launching an online site, a notification containing the information required to be posted on the site and assurances of compliance with the requirements of the bill. The online pharmacy also would be required to post on its website a declaration that this notification has been made and to post information about the business, including the name of the pharmacy as it appears on its State license(s), the street address of its principal place of business, the name and licensing information of the pharmacist in charge, and a phone number where consumers can contact a pharmacist with questions or concerns.

If the online pharmacy failed to comply with any requirement, the Secretary, after providing notice and an opportunity for a hearing, could prohibit the pharmacy from displaying the declaration. Violators would be subject to substantial civil money

penalties. Finally, States would be authorized to bring civil actions against online pharmacies for violations of these requirements.

This bill would fill gaps in current consumer protection and enforcement authority. The compliance and disclosure requirements for online pharmacies would afford substantial public health benefits and provide enhanced tools for law enforcement. Legitimate online pharmacies could be much more easily distinguished from illegal online pharmacies. Consequently, enactment of this bill would enhance consumer safety and confidence in the Internet, and level the playing field for legitimate online pharmacies by reducing illegal competition.

CONCLUSION

Mr. Chairman, online shopping for pharmaceutical products clearly provides many benefits for consumers, however, it also has a number of significant risks. Additionally, the nature of Internet technology presents law enforcement and policy makers with unique challenges. FDA is grappling with the challenges posed by online drug sales and with our need to carefully balance consumer access to information and products with protecting the public health. We are adapting our compliance and enforcement techniques to the new electronic marketplace and we will continue to evaluate what changes in our procedures, regulations, or the law might be appropriate. We want to ensure, as much as possible, that the protections afforded to consumers who purchase drugs from their corner drugstore are extended to consumers in the electronic marketplace.

We look forward to working further with Congress on this important issue, and I would be happy to answer any questions you may have.

Mr. UPTON. Thank you.

Mr. Posner.

TESTIMONY OF ETHAN M. POSNER

Mr. POSNER. Mr. Chairman and members of the subcommittee, good morning. On behalf of the Department of Justice, I appreciate the invitation to appear today and address the important issue of online drug sales.

In approaching this issue and in enforcing the law in this area, the Department has tried to strike a balance between protecting the public from the dangers of online drug sales without undermining the benefit the Internet provides to consumers.

In my opening statement I will briefly highlight some of the Department's accomplishments in this area over the past 12 months.

Mr. Chairman, first, we have, just in the last 12 months, filed at least ten cases involving online drug sales, seven criminal and three civil. Two of these criminal cases very recently resulted in convictions. Both involved the sale of prescription drugs online.

In the first case, prosecuted by our United States Attorneys Office in Tampa, a jury just yesterday convicted two individuals of distributing and conspiring to distribute Depranol without a prescription and with the intent to defraud or mislead. This prescription drug was sold on web sites and by mail in the United States and abroad. The jury found multiple violations of the Federal Food, Drug, and Cosmetics Act and other Federal laws.

In the second case, the United States Attorneys Office for the District of Hawaii obtained a guilty plea from an individual for selling Viagra, a prescription drug, over the Internet without a prescription. This guilty plea was obtained exactly 1 month ago.

In addition to these two convictions, we have at least five other indicted criminal cases in various stages involving online drug sales. Some cases have been indicted recently, another case is in the middle of trial as we speak. These cases involve the sale of prescription drugs and controlled substances on the Internet. The

drugs involved range from Fen-Phen to GBL and GHB, the so-called "sex drug," to unapproved dietary supplements, to marijuana, to nitrous oxide.

In addition to the criminal cases, Mr. Chairman, we have filed at least three civil cases in the last year involving the sale of online drugs. In addition to the cases we have filed in court, we have opened at least 30 criminal investigations involving the sale of drugs on the Internet; approximately 20 of these cases involve the sale of prescription drugs by online pharmacies. These 20 cases, which encompass at least 60 different web sites, were all opened in the past 12 months.

In addition to bringing criminal and civil cases, and supervising active investigations, the Department of Justice has spent considerable time in the past year analyzing the law as applied to online drug sales, building the blocks for future convictions and future prosecutions.

We have held training sessions for our prosecutors and agents on Internet crimes generally and Internet drug cases in particular. We have continued to train our agents on how to investigate computer crimes, including online drug sales, again, building the blocks for future cases and future convictions. Also in the past year we have coordinated and reached out to other Federal and State agencies regarding online pharmacy cases. We have hosted interagency coordination meetings on this issue. We have met with State medical pharmacy boards, we have met with State prosecutors. We have entered into alliances with State prosecutors. We have worked with State enforcement authorities to make arrests, execute search warrants, and seize dangerous and unlawful products that were being sold on the Internet.

We have sent enforcement alerts on at least two occasions to the National Association of Attorneys General regarding online drug sales. We have offered the assistance of the Drug Enforcement Agency, the Federal Bureau of Investigation and our own prosecutors to prosecute these cases and we have done all of that in the past 12 months.

We have also begun to address the difficult issues associated with drug sales by foreign web sites. We have increased our efforts to cooperate with authorities abroad regarding the global problems associated with the use of the Internet to sell prescription drugs and controlled substances.

And, Mr. Chairman, we have a suggestion we hope to discuss with Members of the committee on how current law can be amended to give the Department additional authority to enjoin and stop the transfer and dissipation of funds to and from those who operate illegal foreign and domestic online pharmacy sites.

In short, Mr. Chairman, although there is much to be done, the Department of Justice has made considerable progress on this issue in the past year. We are bringing cases, we are obtaining convictions, we are investigating cases, and we look forward to working with our investigative partners at the States, at FDA, at DEA, and Customs to bring more cases in the future.

Thank you for the opportunity to present the views of the Department on this important topic. We look forward to working with you on this issue.

[The prepared statement of Ethan M. Posner follows:]

PREPARED STATEMENT OF ETHAN M. POSNER, DEPUTY ASSOCIATE ATTORNEY GENERAL, U.S. DEPARTMENT OF JUSTICE

Mr. Chairman and Members of the Subcommittee, Good Morning. I am Ethan Posner, Deputy Associate Attorney General at the Department of Justice. On behalf of the Department, I appreciate the invitation to appear today and describe the many efforts underway at the Department to address the sales of pharmaceuticals and other drugs on the Internet.

Like the Subcommittee and the other agency representatives who appear before you today, the Department of Justice recognizes that online drug sales present many important questions for enforcement authorities. On the one hand, Internet prescription drug sales have the potential to provide significant societal benefits, particularly to those such as the elderly and those living in rural communities who have difficulty going to traditional "brick and mortar" pharmacies. Online sales of prescription medications also may foster price competition, again to the benefit of consumers. On the other hand, the risks posed by online drug sales are obvious. First, online pharmacy sites often circumvent the traditional protections built into the doctor-patient relationship, such as a diagnosis based on a physical examination. Second, consumers may not be able to confirm the legitimacy of online pharmacies, many of which might be located overseas, increasing the risk that the drugs are mislabeled or counterfeit. Therefore, the Department of Justice has attempted, in establishing its enforcement strategy, to set a course that will protect the public from the dangers of online drug sales without undermining the benefits the Internet provides to consumers.

A. THE ROLE OF THE DEPARTMENT OF JUSTICE IN INTERNET DRUG SALES

The Department of Justice—through its Civil and Criminal Divisions, local United States Attorney's Offices, the Federal Bureau of Investigation, and other components—enforces numerous consumer protection statutes for which the primary regulatory authorities are administrative agencies such as the Food and Drug Administration (FDA), the Drug Enforcement Administration (DEA), and the Federal Trade Commission (FTC). Over the past year, the Department has analyzed carefully the application of these statutes to online drug sales.

1. Legal Theories: Enforcement under the Food, Drug, and Cosmetic Act

The Food, Drug and Cosmetic Act (FDCA) generally prohibits the manufacture and distribution of misbranded and adulterated drugs, thus requiring drugs to be labeled accurately and handled in ways that prevent them from becoming contaminated or misused. In 1951, to protect the public from abuses arising from the sale of potent prescription drugs, and to relieve retail pharmacists from burdensome and unnecessary restrictions on the dispensing of over-the-counter drugs, Congress established the system that currently governs the sale of prescription drugs. *See* 21 U.S.C. § 353(b)(1). Under that system, Congress relied on two health professionals—the patient's physician and pharmacist—to protect patients from the knowing or accidental misuse of medicines that are toxic or that have the potential for causing harm.

Accordingly, drugs that are considered prescription drugs under the FDCA may be distributed only with a valid prescription under the professional supervision of a licensed practitioner. *See* 21 U.S.C. § 353. A prescription drug is considered "misbranded" if it is not dispensed pursuant to a valid prescription in accordance with 21 U.S.C. § 353(b). Introduction or distribution of misbranded drugs into interstate commerce violates the FDCA. 21 U.S.C. § 331(a). An online pharmacy that provides prescription drugs without a prescription would therefore be in violation of this requirement. Legal action to curtail such conduct may be brought criminally or civilly. For a felony conviction, the government must establish that the defendant acted with an intent to defraud or mislead either the consumer or the government, or that the defendant is a repeat offender. Civil cases and misdemeanor prosecutions do not require proof of an intent to defraud or mislead.

For online pharmacies that offer online diagnosis, prescription, and distribution of medication, the issue is whether the online interaction results in a valid "prescription" under 21 U.S.C. § 353(b). This is a significant issue for online prescription drug sales based solely or primarily on an online questionnaire completed by the consumer. The legality of this practice often will turn on whether the relevant state law considers such a sale a valid prescription. If not, the online pharmacy may be found to be distributing "misbranded" medication in violation of the FDCA. In this regard, it is significant that Kansas, Maryland, and Washington have taken legal

action against doctors, websites, and pharmacies that dispense prescription drugs over the Internet based upon an online questionnaire. We also recognize that the State Federation of Medical Boards has adopted the position that the "[p]rescribing of medication by physicians based solely on an electronic medical questionnaire clearly fails to meet an acceptable standard of care and is outside the bounds of professional conduct."

2. Other Enforcement Theories

Apart from enforcement under the FDCA, the Department can rely on other legal authorities. For instance, the Controlled Substances Act prohibits the dispensing of a controlled substance without a valid prescription. *See* 21 U.S.C. §§ 822, 829, and 841. A regulation issued by DEA defines "prescription" in a way that may exclude "prescriptions" for controlled substances that are obtained through an online questionnaire. Relying on these statutes, a grand jury in Maryland last year returned a 34-count indictment against a physician for dispensing several controlled substances, including phentermine and fenfluramine, without a legitimate medical purpose.

Another potential avenue for enforcement is the Federal Trade Commission Act (FTC Act), 15 U.S.C. § 45 *et seq*., under which the Department is authorized to proceed with a civil enforcement action in conjunction with the FTC. The FTC Act protects consumers from unfair or deceptive acts or practices. Many online pharmacies operate by making important representations to consumers. For example, the FTC has found websites that advertise that a physician reviews each application to purchase prescription medications. To the extent these representations are false or deceptive, or if a website operator sells prescription drugs and represents that the drugs are safe and effective without disclosing their possible adverse effects, then such operators may be engaging in unfair or deceptive trade practices.

Indeed, some online pharmacies may suggest that completion and analysis of an online medical questionnaire is the equivalent of a visit to a doctor's office. In our view, in almost all circumstances, that is not the case. In fact, some prescription drugs, such as Viagra, have package insert labeling that recommends that a physical examination be performed before prescribing. Because some of these websites appear to provide deceptive information, these sites may violate the FTC Act, and thereby subject the website operator to a civil enforcement action.

The Department can also pursue similar theories under the federal mail and wire fraud statutes whenever an online or other pharmacy defrauds consumers in any way. Whether such a suit would be criminal or civil, under 18 U.S.C. §§ 1341, 1343, or 21 U.S.C. § 332, would depend on the precise facts of the case and the evidence of fraudulent intent. Schemes involving the sale of drugs or health products over the Internet may violate other related federal criminal laws. Some websites offer to bill private or public health care programs or insurers for a "doctor's" advice or for the price of the drug or product itself. If any false representations are made to the insurer to obtain payment, violations of a number of federal criminal laws may occur, and the civil fraud laws also may be implicated.

3. The Department's Experience In Related Areas

Although the Internet and online prescribing are recent phenomena, the Department has prosecuted similar conduct perpetrated using different media. In the 1950's, for example, the Department prosecuted doctors and pharmacists who sold prescription and other drugs by mail or to undercover agents without any prior examination or diagnosis. We have also brought many cases over the years against doctors and veterinarians for dispensing drugs without a valid prescription. More recently, the Department prosecuted several cases in which doctors prescribed and distributed anabolic steroids to athletes and entertainers. The evidence showed that they distributed steroids not to treat medical conditions, but for purely cosmetic purposes, and that they did not examine the patients before dispensing the steroids. In these cases, we argued successfully that under section 353(b) of the FDCA, one may distribute prescription drugs only if (1) there is a bona fide doctor-patient relationship, and (2) the distribution is pursuant to a course of individualized treatment for a legitimate medical purpose.

B. CURRENT DOJ ENFORCEMENT ACTIVITY, TRAINING, AND COORDINATION

1. Indictments, Investigations

Just in the past year, the Department of Justice, working with its investigative partners at DEA, FBI, and FDA, has filed several cases involving sales of drugs on the Internet. In addition to the cases we have filed in court, the Department has opened, again in the past year, approximately 30 cases involving the sale of drugs on the Internet, of which approximately 20 involve the sale of prescription drugs by

online pharmacies. Those 20 investigations encompass at least 60 different web sites.Our filed cases include:

- In July 1999, the United States Attorney's Office in Maryland obtained the indictment of former Internet diet doctor Pietr Hitzig on 34 counts of illegal drug distribution. The indictment charges that between 1996 and 1998 Hitzig ran a Baltimore-based Internet practice through which he provided controlled substances such as phentermine and fenfluramine to patients worldwide based on their e-mail requests alone.
- On September 30, 1999, a grand jury in the Middle District of Florida returned a thirty-one count indictment against Jose A. Perez Menchaca, Paul Cabaniss, and Bondtech-Klebrig Corporation alleging Internet sales of the unapproved drug gamma butyrolactone (GBL), an ingredient of Gamma hydroxy butyrate (GHB). A co-conspirator pled guilty to related charges last December.

  GHB is a black-market drug sold illicitly throughout the country for its alleged ability to cause euphoria, induce sleep, increase sexual arousal, and increase muscle mass. GHB consumption has caused serious adverse health effects, including vomiting, sudden and uncontrollable onset of sleep, uncontrollable shaking, coma, convulsions, and death. The indictment charges that Menchaca sold "GHB kits" from 1996 to October 1998. The criminal schemes were allegedly facilitated by computers through electronic communications and the Internet: According to the indictment, the defendants used a website to both advertise and solicit orders from customers within the United States and from around the world; used various aliases to pose as a "satisfied" customer while touting their GHB kits on computer "newsgroups;" and used email to communicate with each other and to advise international customers how to avoid detection of the kits' contents by foreign Customs.
- On December 9, 1999, the United States Attorney's Office in Hawaii charged Kent Aoki Lee with one count of selling Viagra over the Internet. The indictment also charged the defendant with unrelated fraudulent activity. The defendant offered Viagra for sale through a website in the Japanese language. He did not require any form of prescription. On April 25, 2000, the defendant pled guilty to one count of wire fraud and one count of dispensing a misbranded drug.
- On December 10, 1999, the Department filed a civil action to enjoin a purported dietary supplement manufacturer from distributing products that are actually promoted for the cure or treatment of disease. *United States v. Lane Labs-USA, Inc., and Andrew J. Lane,* No. 99-5782 (D.N.J.). The products, including shark cartilage "dietary supplement," a glycoalkaloid skin cream, and a rice bran extract "dietary supplement," are promoted through Internet links and other sources as being effective in treating or preventing cancers and HIV infection. The complaint seeks to enjoin the defendants from engaging in interstate commerce in these products, or any other products containing the same or similar ingredients, unless and until they are approved as drugs by the FDA.
- On February 11, 2000, the United States Attorney's Office in the Eastern District of Louisiana obtained an indictment in a case involving the Internet distribution of marijuana. *United States v. Aronov and Arizona Company Medical.* Indictment followed a DEA investigation into the illegal sale of "medical marijuana" by Michael David Aronov via the Internet. Aronov and his business, Arizona Company Medical, were indicted on 7 drug distribution counts and 1 count of placing a written advertisement in a publication, the Internet, for the purpose of seeking, or offering illegally to receive, or distribute marijuana.
- On March 2, 2000, the Federal District Court for the Eastern District of Missouri entered a preliminary injunction barring Syntrax Innovations, Inc., from manufacturing or distributing any product containing the thyroid hormone tiratricol. Prior to this order, the company had been marketing over the Internet a tiratricol-containing product called "Triax" as a dietary supplement for weight loss. The use of tiratricol can cause hyperthyroidism, which can lead to hypertension, insomnia, nervousness, cardiac arrhythmia, heart attacks, and strokes. The preliminary injunction bars Syntrax from selling any tiratricol products during the pendency of the litigation.
- On April 20, 2000, the Department obtained a preliminary injunction against Christian Bros. Contracting Corp. and its president, Jason Vale, prohibiting them from making or distributing amygdalin, Laetrile, "Vitamin B-17," or apricot seeds during the pendency of the action. We brought suit after learning that the defendants were defrauding thousands of vulnerable cancer victims by advertising and selling apricots seeds and Laetrile products as a cure for cancer through numerous Web sites and millions of "spam" e-mails. On April 24, the *Wall Street Journal* discussed the impact this ruling may have on other Inter-

net purveyors of unapproved drugs, in an article entitled "Judge Orders Online Laetrile Vendor to Quit Business, Signaling U.S. Stance."

- On May 17, 2000, the proprietor of an Internet-based "virtual" retail business was indicted by a federal grand jury in Roanoke, Virginia, for the interstate marketing of the misbranded drug, nitrous oxide, a substance blamed for the death of a Virginia college student. The grand jury charged the defendant (of Tempe, Arizona) with selling nitrous oxide to customers in the Western District of Virginia via the web site BONGMART.com, which the defendant operates. The web site sold nitrous oxide and other drug paraphernalia.
- Currently, a case involving individuals who solicited customers to buy unapproved drugs over the Internet is on trial in Baltimore. This case, which was indicted in June 1999, is likely to go to the jury soon.
- Just yesterday, a jury in the Middle District of Florida convicted two individuals of distributing prescription drugs in interstate commerce without a prescription with the intent to defraud and mislead. One individual was also convicted of distributing deprenyl, a misbranded prescription drug. The product "Liquid Deprenyl Citrate" was offered for sale on the Internet as a "fountain of youth" drug and for a long list of other diseases.

2. Training and Education

With the array of new and challenging issues posed by unlawful conduct on the Internet, it is critical to educate and train our prosecutors and agents about the applicable legal principles and the techniques and tools required to investigate unlawful online conduct. When someone sells drugs on the street corner, law enforcement is familiar with the steps required to investigate the crime. Similarly, when someone promises in a newspaper advertisement that he has the cure for cancer or AIDS, law enforcement typically know how to identify the responsible individual or entity. But when a web page makes similar claims, the methods for determining who is making the claim, where that person might be located, and how to obtain and preserve evidence present new challenges to law enforcement. For this reason, the Department of Justice has embarked on an active and wide-ranging training and education program. As part of our effort, computer crimes specialists and coordinators have been designated in each United States Attorney's Office. Other activities include:

- In December 1999, the Department's Office of Legal Education conducted an Internet Fraud Seminar. This seminar, presented jointly with the National District Attorneys Association, addressed such topics as investigative approaches to Internet fraud, obtaining electronic evidence (for example, search warrants and the Electronic Communications Privacy Act), the online investigative principles and their application to Internet fraud investigations, and likely defenses in Internet fraud prosecutions.
- In February 2000, the Department's Office of Legal Education sponsored a Computer Crimes and Electronic Evidence Seminar. This seminar, which will be repeated in July, assists attorneys in the prosecution of information technology crimes. Topics covered include telephone networks and telephone switching, investigative approaches to computer crimes, obtaining and using electronic evidence, Electronic Communications Privacy Act, data forensics and analysis, and online investigations.
- In February 2000, the Department's Office of Legal Education also sponsored a presentation on Internet Prescription Sales at the Advanced Health Care Training seminar for experienced Assistant United States Attorneys. This course instructed prosecutors on how to investigate an Internet pharmacy case, how to charge an Internet pharmacy case, how to structure the agent's investigation, how to analyze the evidence, and what specific charges could be filed against rogue Internet pharmacies, web-sites, and prescribing professionals.

On several occasions in the past year, the Department, acting through the Executive Office for United States Attorneys, has alerted our 94 United States Attorney's Offices about online drug sales. We have also provided legal support about online drug sales to these offices. The Department also educates its attorneys and agents through the Health Care Fraud Working Group, which consists of experienced health care fraud specialists from the FBI, United States Customs Service, State Attorneys General Offices, the Department of Health and Human Services, and Assistant United States Attorneys from across the country.

3. Coordination with Other Federal and State Agencies

One of the most significant challenges we face in this area is coordination of enforcement policies and initiatives among a variety of federal, state, and other entities. We rely heavily, for example, on the hard work and dedication of federal and

state investigating agencies such as the FDA. For this reason, just in the past year, we have hosted meetings of the Online Sales of Drugs and Medical Products Interagency Working Group, which has convened at least three times in the past year. That group consists of representatives from DOJ, DEA, FBI, FDA, the Customs Service, the Postal Inspection Service, the Department of Health and Human Services, the Department of Defense and the Defense Criminal Investigation Service, the National Association of Attorneys General, the Attorney General's offices of Kansas and Pennsylvania, and the Texas Department of Health. We have also hosted meetings of a subgroup of that Working Group to more closely coordinate law enforcement actions.

Finally, the Department coordinates with state law enforcement agencies and investigators. Just in the past six months, we have discussed online pharmacy enforcement issues with representatives from State Boards of Medicine and Pharmacy in Arizona, California, Texas, Virginia, North Carolina, and Ohio. Last month, we sent an online pharmacy "alert" to the Attorneys General of all 50 states, the National Association of Attorneys General (NAAG), the National District Attorney's Association, the National Sheriff's Association, and the International Association of Chiefs of Police. That alert highlighted the Department's concerns over online drug sales and offered the assistance of the Drug Enforcement Administration and the Department of Justice in investigating and prosecuting such cases. Department lawyers also participate in the NAAG working group that deals with online pharmacy issues.

This federal-state coordination recently led to a very successful crackdown on the "date rape" drug GHB, which was added as a "List I Chemical" under the Controlled Substances Act by the Hillory J. Farias and Samantha Reid Date-Rape Drug Prohibition Act of 1999. In February 2000, the California Department of Justice sought assistance in an investigation of the sale of GBL, a key GHB ingredient, via the Internet to persons in California. The Department of Justice, DEA, and the California Department of Justice combined resources to investigate an individual in Arizona who allegedly marketed GBL on the Internet under the name "Inova Products." On March 15, two days after the federal scheduling of GHB, the subject's premises were searched under a federal search warrant. The individual was arrested, extradited to California, and is being held in state custody. Inova allegedly sold GBL in 55-gallon drums that contained more than 98,000 doses each, with a street value of $5 per dose, or a value of almost $500,000 per drum. On March 15 and 16, 2000, California agents made controlled deliveries of 55-gallon drums of GBL to persons located in Orange County and San Mateo County, California. Two suspects were arrested and charges are pending. On March 28, federal agents arrested another Inova customer, a registered sex offender, after he accepted a controlled delivery of a 55-gallon drum of GBL in Florida. In April 2000, California agents arrested five additional Inova customers. Thus far, this effort has resulted in the seizure of more than 400 gallons of GBL and the identification of six GHB labs in three states.

Another example of federal and state coordination is the alliance entered into recently by the Kansas Attorney General's Office and the U.S. Attorney's Office for the District of Kansas. In addition to these two offices, the alliance includes representatives from the Kansas Pharmacy Board, Kansas Board of Healing Arts, Consumer Protection Division, the Medicaid Fraud and Abuse Division, and the Food and Drug Administration's Office of Criminal Investigations. In this coalition, state authorities have taken the lead in dealing with online pharmacies that may not satisfy state regulations but are attempting to offer legitimate pharmaceutical services. The Kansas authorities have found that these entities will generally conform their conduct to satisfy state regulations after notification. For its part, the U.S. Attorney's Office is assisting the state with the identification of individuals, including doctors responsible for illegal online pharmacy sites. In turn, Kansas authorities are taking legal action against doctors, websites, and pharmacies that dispense prescription drugs over the Internet in violation of state law on grounds that "prescriptions" issued based on online interaction are not valid.

C. THE INTERNET PRESCRIPTION DRUG SALES ACT OF 2000

The Department of Justice supports the Internet Prescription Drug Sales Act of 2000, transmitted by Secretary Shalala to Speaker Hastert on May 2, 2000. As the FDA explains in its testimony, the Act would do the following:

- require online pharmacies to be licensed in each State in which they operate or to which they deliver prescription drugs;

- require compliance with all applicable Federal and State laws governing the practice of pharmacy, including those laws that require proper storage and handling of prescription drugs, proper record keeping, and other consumer protections;
- require online pharmacies to post on their web site a notice of their physical location, a list of States in which the online pharmacy is licensed to dispense prescription drugs and a list of applicable license numbers, the name, degree, and license of the pharmacist in charge; a telephone number for contacting a licensed pharmacist associated with the website, and a statement that the online pharmacy shall dispense prescription drugs only upon a valid prescription by a licensed practitioner.

Under the Act, if the online pharmacy fails to comply with these requirements, the FDA could seek to prohibit the pharmacy from selling drugs online, after providing notice and opportunity for a hearing. Also, the Justice Department could seek criminal sanctions, civil money penalties, or an injunction from a federal court. The Act also provides the Justice Department with subpoena authority to obtain important records in connection with investigations into violations of the Act. Finally, the states are also authorized to bring civil actions against online pharmacies for violations of the Act.

In addition, the Act would provide consumers with the same level of protections they enjoy in traditional "brick and mortar" pharmacies. When an offline consumer walks into a traditional pharmacy, for example, he or she can readily identify the location of the pharmacy and the name(s) and license(s) of the pharmacist(s), all of which help to assure the consumer that the pharmacy satisfies the relevant health and safety requirements. Under the Act, online pharmacies will have to provide the same information to consumers and investigators.

Like the FDA, the Department of Justice believes that the Act fills an important gap in current regulatory and enforcement authority. One of the most significant regulatory and investigative challenges in this area is the difficulty in identifying the name and location of the online pharmacy, a telephone number where the operator or pharmacist can be reached, and the State licensure information of the pharmacist in charge. The compliance requirements of the Act would require that online pharmacy sites provide this critical information under threat of civil or criminal sanction, benefitting both consumers and enforcement authorities.

D. THE CHALLENGE OF FOREIGN ONLINE PHARMACY SALES

An increasing percentage of online drug distribution is conducted by firms operating outside of the United States. Some of these off-shore sites sell prescription drugs approved by the FDA without a prescription; some sites sell drugs that have not been approved for sale in the U.S.; and other sites sell drugs that are classified as Controlled Substances in the United States.

Under U.S. law, it is illegal for a foreign-based online pharmacy to sell prescription drugs to consumers in the U.S. without a prescription. Prescription drugs dispensed within the U.S. without a valid prescription are misbranded under the FDCA. It is also illegal for a domestic or foreign online pharmacy to sell drugs not yet approved by the FDA. Likewise, it is illegal for an off-shore web site to sell controlled substances to consumers in the United States. Indeed, the foreign sale of pharmaceutical controlled substances to U.S. consumers via the Internet violates the United Nations Convention Against Illicit Traffic in Narcotics and Psychotropic Substances. Similarly, it is illegal under U.S. law for a consumer to order or obtain a controlled substance from an off-shore pharmacy for delivery in the U.S. If the operator of an off-shore online pharmacy that illegally sold controlled substances or unapproved drugs to U.S. residents enters the United States, he or she could be prosecuted in the U.S.

The difficulties inherent in any investigation and prosecution of an online pharmacy are magnified when the web site, the dispensing pharmacy, and the operator(s) are located overseas. But there are several actions that government agencies are taking and can take to address the investigative challenges posed by off-shore sales of drugs through the Internet.

First, the United States must continue to obtain the cooperation of foreign governments in reducing the use of the Internet to commit illegal activity. The United States already is working with other nations to address this problem. With the support and encouragement of the United States, the Council of Europe is drafting a Cybercrime Convention, which will define cybercrime offenses and address such topics as jurisdiction, international cooperation, and search and seizure. The Group of Eight ("G-8") nations are also working to enhance the abilities of law enforcement to investigate and prosecute computer and Internet-facilitated crimes; a G-8 working group recently established a 24-hour/7-day-a-week network of high-tech points of

contact in each of the G-8 nations and in a number of non-G-8 nations. These and other instances of international cooperation will benefit the investigation and prosecution of many international cybercrimes, including those involving off-shore Internet pharmacies.

Next, the Justice Department and other enforcement authorities can work with American financial institutions to reduce the flow of money to these foreign web sites and their operators. Like domestic online pharmacies, off-shore online pharmacies often rely on credit card transactions processed by U.S. banks and credit card networks. Federal agencies already work cooperatively on occasion with financial institutions and credit card companies to investigate transactions that are made in furtherance of illegal activity. If enforcement agencies and financial institutions can stop even some of the credit card orders used for the illicit sale of controlled substances or prescription drugs, then the operations of some of these "rogue" online pharmacies may be disrupted significantly.

To enhance the Department's ability to act effectively in this area, it is important for prosecutors to have the option of seeking injunctive relief from a court. Under 18 U.S.C. § 1345, the Department has the authority to seek injunctive relief against "any person" who withdraws, transfers, removes, or dissipates any property (including money) traceable to a violation of a defined list of banking law and health care fraud offenses. *See* 18 U.S.C. § 1345(a)(1)-(a)(2)(B). The Department has relied on section 1345 to enjoin the dissipation of assets from particular bank accounts or other types of accounts. We recommend that 18 U.S.C. § 1345 (and the Administration's online pharmacy bill) be amended so that the Department can, where appropriate, seek to enjoin certain financial transactions traceable to unlawful online drug sales. Such an amendment would provide the Department with an important weapon to combat the harms posed by off-shore (and domestic) online pharmacies. We would be happy to work with Members of Congress on drafting such an amendment. We would also welcome the opportunity to work with Congress to formulate additional strategies to address the problem of violative off-shore (and domestic) Internet pharmacies.

Mr. Chairman, thank you for the opportunity to present the views of the Department of Justice on this important topic. I would be pleased to answer any questions that you might have.

Mr. UPTON. Thank you very much and thank you for that offer to help as well.

Ms. Durant.

TESTIMONY BETSY DURANT

Ms. DURANT. Thank you, Mr. Chairman and members of the subcommittee. I appreciate the opportunity to present U.S. Customs' efforts to prevent illegal importation of pharmaceuticals and other dangerous drugs into the U.S. via the Internet.

I brought with me today a sample on the table and some pictures of pharmaceutical seizures made at our international mail branches. Before I begin to explain what Customs does to combat the importation of illicit pharmaceuticals, I believe it's important to relate Customs' core mission activities. The U.S. Customs Service is the protector of our Nation's borders. We are vigilant against the ever-present threats of narcotics smuggling, money laundering, and unwarranted threats against American industry.

On a typical day, Customs officers process 1.3 million passengers and nearly 350,000 vehicles at ports and border crossings around the country. They seize nearly 4,000 pounds of narcotics and about a million dollars in ill-gotten proceeds. Customs also protects domestic industries from unfair competition; keeps tainted and spoiled products from making their way to consumers; and defends intellectual property rights and deters the corrosive effects of economic fraud.

To this end, U.S. customs understands the dangers of unregulated and illicit pharmaceuticals entering our Nation. Not only is

there a potentia danger to those ingesting these drugs, but there is a clear and economical danger to the domestic pharmaceutical industry. Many of the pharmaceuticals that are smuggled into our Nation lack the quality control that most Americans rely upon.

The numbers of pharmaceuticals seized by U.S. Customs entering the U.S. are staggering. In 1999, seizures soared from 2,139 in 1998 to nearly 10,000 in 1999, an increase of 450 percent. Fiscal year 2000 seizures are on pace to equal or surpass 1999 levels.

The Customs Service has recognized the unique challenges of enforcement that comes with the information age. Customs has recently transferred ten special agents from the field to the Customs CyberSmuggling Center in Fairfax, Virginia. The CyberSmuggling Center was established in 1997 primarily to combat online child pornography and coordinate computer forensic examination. However, the Internet is now being used to facilitate a variety of crimes investigated by Customs including intellectual property rights, illegal sale of cultural property, and importation of a variety of prohibited merchandise including pharmaceuticals.

In July 2000 the CyberSmuggling Center will establish a Cyber crimes unit to compliment the existing international child pornography unit and computer forensic unit. The CyberSmuggling Center, C3, can play a significant role in addressing this issue. Upon the establishment of it, the C3 will proactively search the Internet to identify foreign-based targets marketing prohibited drugs to the U.S. Agents will use a variety of investigative techniques unique to Internet investigation to identify individuals and businesses utilizing the Internet web sites or e-mail to sell prohibited drugs.

The U.S. Customs Service staffs 14 international mail branches at various postal facilities. These international mail branches are located at various ports or entry with high volumes of cargo. Customs' 14 facilities process hundreds of millions of flats and parcels per year. With less than 220 Customs personnel, personnel available at these facilities, we, as with all shipments, must take a risk management approach. Resources are such that we must make conscious decisions to look at some mail, but not all mail. Most often this is done by choosing to inspect mail from countries that provide a higher threat for illegal activity.

Customs feel that our current manual targeting is a catch as catch can approach and provides little assurance that we can successfully achieve our enforcement mission with respect to the interdiction of prohibited pharmaceuticals. Customs also has several ongoing investigations involving U.S. persons operating foreign pharmaceutical web sites. All of these investigations are being worked jointly with the Food and Drug Administration's Office of Criminal Investigation.

The CyberSmuggling Center participates with FDA, DEA, and the Postal Service in an informal working groups to work together on these issues.

To make the most of this enforcement loop, it is imperative that the Federal agencies responsible for stopping the importation of pharmaceuticals, namely Customs and the Food and Drug Administration, work closely together at the point of entry.

For example, often pills being smuggled into the U.S. have been stripped of all packaging and labeling, to enable them to be con-

cealed in innocuous items. Upon discovery, it can be difficult to identify whether or not the pills are prohibited. The multi-agency effort to identify and determine admissibility needs to be accomplished with speed, so that if necessary, further enforcement action such as controlled deliveries can take place.

Very recently executives and managers from the Food and Drug Administration and U.S. Customs met to discuss how together we can streamline our enforcement and interdiction efforts of illegal pharmaceuticals. In this meeting FDA promised that they would provide us with uniform guidance that will assist our field offices in dealing with this difficult aspect of our mission.

Customs is also working with the Food and Drug Administration to ensure that as the Internet grows, as a means for conducting business, the Government will be able to provide a responsive and effective enforcement Internet driven—enforcement of Internet driven illicit trade. With the proper tools interagency cooperation and resources Customs can facilitate legal international trade and stand poised at America's frontline, protecting our citizens and Nation's borders. Thank you, Mr. Chairman.

[The prepared statement of Betsy Durant follows:]

PREPARED STATEMENT OF BETSY DURANT, DIRECTOR, OFFICE OF TRADE PROGRAMS, UNITED STATES CUSTOMS SERVICE

Good Morning Chairman Upton, Ranking Member Klink and Members of the Subcommittee. Thank you for the opportunity to present US Customs' efforts to prevent the illegal importation of pharmaceuticals and other dangerous drugs into the US via the internet.

Before I begin to explain what Customs does to combat the importation of illicit pharmaceuticals, I believe it is important to relay Customs core mission activities. The U.S. Customs Service is the protector of our Nation's borders. We are vigilant against the ever-present threats of narcotics smuggling, money laundering, and unwarranted threats against American industry. On a typical day, Customs officers process 1.3 million passengers and nearly 350,000 vehicles at ports and border crossings around the country. They seize nearly 4,000 pounds of narcotics and about a million dollars in ill-gotten proceeds. Customs also protects domestic industries from unfair competition; keep tainted and spoiled products from making their way to consumers; and defend intellectual property rights and deter the corrosive effects of economic fraud.

To this end, US Customs understands the dangers of unregulated and illicit pharmaceuticals entering our Nation. Not only is there a potential danger to those ingesting these drugs but also there is a clear and economical danger to the domestic pharmaceutical industry. Many of the pharmaceuticals that are smuggled into our Nation lack the quality control that most Americans rely upon.

The numbers of pharmaceuticals, both scheduled and non-scheduled seized by U.S. Customs entering the US are staggering. In 1999, seizures soared from 2,139 seizures in 1998 to 9,725 in 1999, an increase of 450%. Most of these seizures involved controlled substances. Fiscal year 2000 seizures are on pace to equal or surpass 1999 levels.

There is no doubt that the internet is playing a major role in the increase in illegal pharmaceutical imports. Many web sites offer assistance on how to order prescription drugs without a doctor's prescription. Typically these sites, for a fee, provide publications that list foreign pharmacies in Central & South America, Asia and Europe that allegedly will ship prescription drugs to the US. In addition, some overseas individuals advertise in news groups and conduct their business via Email. A curious consumer who sends an email will receive an auto-reply price list and information on how to order. In addition, there are online pharmaceutical web sites that allow for direct ordering of drugs.

Customs faces many significant interdiction challenges at the point of entry, primarily in our international mail facilities. The growth of this challenge is commensurate with the phenomenal growth of the small package delivery industry. The Express Consignment Industry, comprised of companies such as FedEX, UPS and DHL, to name a few, has enjoyed huge growth in their markets since its inception.

The Postal Service also has seen significant increases in the use of its Express Mail service. Today, the industry sees a continuation for further growth, not only domestically, but also in the global marketplace. Much of this growth can be attributed to e-commerce. The consumer is now able to purchase goods directly from overseas manufacturers or suppliers via the Internet. As a result, the number of individual shipments sent through Express Consignment Operators and the U.S. Postal Service will increase dramatically.

With the shift in this industry, Customs has found itself wrestling with the way it handles the processing of international mail and express consignment shipments so that it can provide efficient entry of legal shipments, while maintaining a strong and effective contraband interdiction capability.

Customs is under continuing pressure to move shipments quickly, yet our ability to maintain control of these small parcels is vastly different between the postal and express consignment environments. The express industry, with its requirements to provide manifest information, present outbound shipments for examination, and to reimburse us for costs of service have enabled us to respond to this growth while preserving our enforcement mission. However, the lack of this capability and authority in the Postal setting has hindered meeting our enforcement goals.

The Customs Service has recognized the unique challenges of enforcement that comes with the information age. Customs has recently transferred 10 Special Agents from the field to the Customs CyberSmuggling Center in Fairfax, Virginia. The CyberSmuggling Center was established in 1997 primarily to combat online child pornography and coordinate computer forensic examinations. However, the internet is now being used to facilitate a variety of crimes investigated by Customs including Intellectual property rights, illegal sale of Cultural property and the importation of a variety of prohibited merchandise including pharmaceuticals. In July 2000, the CyberSmuggling Center will establish a Cyber Crimes Unit to compliment the existing International Child Pornography Unit and Computer Forensics Unit.

The CyberSmuggling Center (C3) can play a significant role in addressing this issue. Upon the establishment of the Cyber Crimes Unit, the C3 will proactively search the internet to identify foreign based targets marketing prohibited drugs to the US. Agents will use a variety of investigative techniques unique to internet investigations to identify the locations, individuals and businesses utilizing internet web sites or e-mail to sell prohibited drugs.

In 1999, Thailand emerged as one of the most prolific source countries for illegal pharmaceutical seizures. Controlled deliveries, whereby an undercover agent poses as a delivery person, of Thai origin mail seizures, by the Office of Investigations, often resulted in the subject admitting to buying the drugs from Thai Web Sites. US Customs brought this problem to the attention of Thai authorities who upon looking into the matter discovered that most of the Thai online pharmacies were violating a variety of Thai laws including, exporting pharmaceuticals with out an export license and dispensing unauthorized drugs. In January 2000, Customs agents from the Customs CyberSmuggling Center and the Customs Attache in Bangkok provided technical assistance to Thai authorities in the execution of search and arrest warrants against 7 online pharmacy sites. In all, 22 Thai citizens were arrested and 2.5 million pharmaceutical dosage units were seized. As a result, Thai seizures have decreased dramatically.

Despite this, analysis of seizure volumes for the first half of this fiscal year indicate that the overall 1999 figures were not a short term variance; the problem is persistent. While the highly successful Thai operation did result in an initial drop in seizures, data for the past three months indicates that seizures are again on the rise, mirroring the FY 1999, pre-Thai rate. This only highlights the very power and problem, of the Internet. Electronic Commerce is essentially borderless, and web sites can be closed down and reopened in very short order and with very little difficulty. Countering this aspect of Internet crime at the point of entry requires three critical elements: automation, consistent and uniform interagency action, and resources.

The U.S. Customs Service staffs 14 International Mail Branches at various Postal facilities across the United States. These International Mail Branches are located at ports of entry with high volumes of cargo, and service more than one mode of transportation. Customs' 14 facilities process hundreds of millions of flats and parcels per year. With less than 220 Customs personnel at these facilities, we, as with all shipments, must take a risk management approach to our day to day operations. Resources are such that we must make conscious decisions to look at some mail, but not all mail. Most often this is done by choosing to inspect mail from countries that provide a higher threat for illegal activity. While the Postal Service is required to present all the international mail to Customs, the selection or targeting process for mail is entirely manual.

Customs does not encounter the same enforcement difficulties with the Express Consignment Operators. In exchange for reimbursed expedited clearance during non-traditional business hours and at locations where we would not ordinarily provide service, the couriers agreed to regulations that require them to integrate sophisticated automation systems into their daily operations. Furthermore, advance manifest information is required for all Express Consignment shipments so that Customs may pre-screen these shipments before arrival. The availability of advance, automated manifest information allows Customs to both expedite the automatic release of lower risk shipments, and at the same time to maximize the effectiveness of our targeting of higher risk shipments. Specifically, the availability of such data allows Customs to capitalize on intelligence developed by our Office of Investigations and other members of the domestic and international law enforcement community, knowledge of past transgressors, and analyses of smuggling trends and shipment patterns.

Conversely, over 95 percent of the Postal Service's international mail parcels are not individually manifested. By law, Express Consignment Operators are required to maintain extensive records for each shipment or transaction solely for Customs review, whereas the Postal Service is under no such obligation to keep these records.

Prevention and point of entry interdiction aspects of the Internet pharmaceutical issue are inextricably linked. Seizures generate intelligence used by investigators in their prevention efforts, and intelligence generated by investigators may be used to assist in interdiction.

Customs also has several ongoing investigations involving US persons operating foreign pharmaceutical web sites. All these investigations are being worked jointly with the Food and Drug Administration's (FDA) Office of Criminal Investigation. The Customs Office of Investigations has a great working relationship with FDA investigators. The CyberSmuggling Center participates with FDA, DEA and Postal in an informal working group that meets on a monthly basis to discuss on going investigations and other related topics.

To make the most of this enforcement loop, it is imperative that the Federal agencies responsible for stopping the importation of prohibited pharmaceuticals, namely Customs and the FDA, work closely together at the point of entry. For example, often the pills being smuggled into the U.S. have been stripped of all packaging and labeling to enable them to be concealed within innocuous items. Upon discovery, it can be difficult to identify whether or not the pills are prohibited. The multi-agency effort to identify and determine admissibility needs to be accomplished with speed, so that if necessary, further enforcement action such as controlled deliveries can take place.

Very recently, executives and managers from the Food and Drug Administration and U.S. Customs met to discuss how together we could streamline our enforcement and interdiction efforts of illegal pharmaceuticals. In this meeting, FDA promised they would provide us with clearer guidance that will assist our field offices in dealing with this difficult aspect of our mission. We also discussed additional education and training efforts. Clear guidance, which can lead to more consistent application of enforcement policy, is critical to the point of entry interdiction effort

Lastly, to effectively enforce the laws governing the importation of pharmaceuticals, it is imperative that the resources needed to effectively meet these responsibilities are available to Customs. While the importation of prohibited pharmaceuticals is prevalent in any mode of transport that focuses on small parcel delivery, it is manifested primarily in the international mail operating environment. Customs currently provides clearance of international mail at little or no expense to the Postal Service. The Postal Service does not reimburse Customs for expenses incurred to examine inbound international mail.

On the other hand, Express Consignment Operators are required by statute to fully reimburse Customs for the processing of their shipments. This includes all expenses associated with the Customs operations within the Express Consignment facility. By regulation, Customs office space, personnel and equipment are all paid for by the Express Consignment operator.

As I stated earlier, with automated, parcel level manifest information provided to Customs in advance of shipment arrival, Customs can greatly increase its targeting capabilities and its ability to capitalize on intelligence information. The Postal Service is working to develop electronic messaging data sets that would support such a badly needed automated system. This would be similar to the level of data that the Express Consignment Operators are currently providing Customs; Customs desperately needs this information. A cooperative initiative with the European Community began in April of this year to develop an international electronic message that will provide uniform information for mail shipments for the European Community,

the United States, Canada, and possibly Australia. Customs has been invited to serve as a technical advisor to the European Community on this project. The successful results of this initiative would greatly increase Customs capability to interdict prohibited pharmaceuticals in our International Mail Branches.

In summary, Customs believes that the manual nature in which mail arrives and is entered into the United States, severely inhibits our ability to interdict prohibited pharmaceuticals. We believe that we need to work with the Postal Service to change the standards for processing Postal Service shipments. Doing so will decrease the vulnerability our Nation currently faces with respect to pharmaceutical smuggling, and the smuggling of other forms of contraband.

Customs is also working with the Food and Drug Administration to ensure that as the Internet grows as a means for conducting business for a fast paced U.S. economy, the government will be able to provide responsive, effective enforcement of Internet driven, illicit trade. With the proper tools, interagency cooperation, and resources, Customs can both fairly facilitate legal international trade, and yet enable us to stand poised as America's frontline, protecting our citizens and Nation's borders. We are cognizant of the dangers that these unauthorized drugs pose to our citizens. We stand ready to work with the Congress and other Executive agencies to fully ensure that these smuggled items never harm our citizens and the legitimate pharmaceutical industry.

Mr. Chairman, this concludes my written statement. I will be happy to answer any questions that you or any other Members may have.

Mr. UPTON. Thank you.

Ms. Stovall.

TESTIMONY OF THE HON. CARLA J. STOVALL

Ms. STOVALL. Thank you very much, Mr. Chairman, and members of the committee for the opportunity and the invitation to come and update you on what States have done since the last time we were gathered to talk about this topic. We always appreciate the opportunity to be able to visit about what we've done. We share the committee's concern about the illegal sites. Obviously there are some good sites, legitimate sites that are conducting business appropriately, and we think the convenience to consumers, to patients, the privacy, the cost savings that can result from, that is important. And so we always want to be very clear that there are good sites and we certainly approve those and would like to facilitate their operation.

It is the roughly 400 web sites, though, that are not legitimate that give us great concern. The AMA and then recently the Association of State Medical Boards has voted to say that prescribing online was out at a prior position paper relationship is not consistent with the standards of professional conduct and that is from where Attorneys General derive the authority, in our opinion, to classify these actions as violative of the Consumer Protection Acts. That to sell prescription drugs without valid prescriptions is unconscionable. And that's where AGs have stepped in and used their Consumer Protection Act to be the basis for the lawsuits we have filed.

As many of you know, because you've mentioned in your comments, States have been very active in this area. Many States have sued a total of 54 entities and/or individuals have been sued by States as a result of prescribing unlawfully on line.

We see, most of the time, when the State of Kansas, for example, would sue a particular illegitimate pharmacy, we'll get an injunction against it and so it will then stop prescribing or stop distributing those drugs within our State.

What our hope always had been is that there could be national injunctive relief and the proposed legislation that Chairman Upton and Congressman Bliley talked about. We would hope we would have something like that in it for us so that there would be the opportunity to maximize resources, so that when I sue a company, not only do they stop selling to Kansas citizens, but they stop selling to citizens around the country as well. And that would allow the very minimal resources that State Attorneys General have to be maximized.

In my office we have—I'm quite proud to say that we have taken the lead on this issue, but we have only one attorney working on this. And so that's the way it is in many AG offices around the country. There just are not very many resources. So if we can maximize by getting injunctive relief, nationally, it would add a tremendous benefit to the resources that we are able to devote to it.

NAG, the National Association of Attorneys General, as some of you have mentioned, have monthly conference calls. We have a task force set up to deal with this regularly so that we can try to coordinate activities and coordinate enforcement action and keep track of one another.

The conference that we had just last week apparently got lots of recognition by Congress because several of you mentioned that we are very proud of the attendance and think that the information provided there really helps train assistant attorneys general around the country to be able to continue this work in the most effective way possible.

We welcome the opportunity to continue to work with this committee, other Members of Congress, as well as the Federal agencies, to try to get a handle on what is a great public health concern to citizens of our country. We share your concern with that as well, and we appreciate the opportunity to come and be a part of these discussions.

Thank you.

[The prepared statement of Hon. Carla J. Stovall follows:]

PREPARED STATEMENT OF CARLA J. STOVALL, KANSAS ATTORNEY GENERAL

Chairman Upton, Ranking Member Klink, members of the Subcommittee, thank you for the invitation to testify today on the important issues the Subcommittee is considering.

Beginning with Kansas' lawsuit in February, 1999, six States have filed a total of 18 lawsuits, eight administrative actions, and nine notices of intended action against more than 54 individuals, pharmacists, pharmacies, doctors, and other entities who participated in the online prescribing, sale and dispensing of prescription drugs to our States' citizens. None of them required any in-person examination or consultation prior to prescribing and dispensing those drugs, using instead the "online application" method.

Ohio has criminally indicted a doctor for drug trafficking as a result of this practice, and his trial is scheduled for June 12, 2000. That same doctor is also being pursued civilly by at least three other States, and he has filed his own civil suit against the State of Ohio.

Approximately fifteen additional States are investigating sites with a review toward litigation, investigations which are not yet public.

In most of the Kansas cases, we are in the process of negotiating settlements, with provisions not to engage in the practice of online prescribing and to comply with the laws and regulations of our State before dispensing drugs to our citizens. We have settled with one defendant, and have filed an action requesting the court enforce the settlement agreed upon in another case.

Most of the entities sued by the States are in the process of negotiating settlements, but a few continue to hide from us. It is worth noting one case where the Defendants are not only *not* hiding, they are actively pursuing the State. Attorney General Jennifer Granholm of Michigan has been sued in the Federal District Court in Virginia by one of the Defendants in a case that she filed earlier this year. The Defendants are claiming the Michigan Attorney General has, among other things, unreasonably burdened interstate commerce by requiring pharmacies and pharmacists to be licensed in Michigan before they distribute the drugs in Michigan. That case has not yet been docketed for hearing.

In general, however, most websites sued or notified by the States are voluntarily not shipping to consumers in all States that have brought action against *any* site. Additionally, the publicity from these actions has helped boost our consumer education campaigns regarding the dangers of buying prescription drugs from sites that sell without the benefit of a valid prescription. There is no way to confirm the number of sites offering drugs for sale in this manner has changed, however, we know several of the sites that have been sued have gone out of business, and many of the doctors have ceased practicing in this dangerous manner.

I have submitted with my testimony a summary of the cases filed by the States—and legislation proposed in State legislatures. I ask that this summary be included in the hearing record.

In each of these cases, it is clear our law enforcement actions are aimed at stopping the *illegal* Internet sale of drugs to our citizens—more appropriately named "online prescribing." We are not interested in shutting down websites operating in compliance with all licensing and registration laws and regulations in the State to where they dispense the medication. We certainly have no problem with the legitimate pharmacies that utilize the Internet as an effective mode of communication with their patients.

"Online pharmacies" should not be treated differently than traditional, "brick and mortar" pharmacies. The standards should be the same. If a pharmacy wants to transact business in a certain State, then it should submit to the laws and regulations of that State.

That is the basic theory of our cases: by prescribing drugs to citizens in our States, the pharmacy, pharmacist, prescribing physician and website are practicing and operating within our States' jurisdiction and are subject to our States' laws. If they do not have the legal authority to dispense these drugs, they are breaking our laws.

All the Defendants in the lawsuits filed by the States have one thing in common—they did not require a valid physician-patient relationship to prescribe and to dispense prescription-only drugs. These Defendants merely asked their customers to fill out a questionnaire about their health and claimed that a physician would review the application and prescribe the drug if appropriate. In all of our cases, however, it was apparent that if a physician reviewed the application, it was a feckless review indeed. A 16-year-old boy in Kansas ordered and received Viagra, a medication for erectile dysfunction, as well as Meridia and Phentermine, both controlled substances, even though he entered his true date of birth on the online order applications. No company asked for parental consent before sending drugs to that minor. The ease with which these drugs, especially the controlled substances, were distributed without an exam, without even a conversation with the recipient, is shocking and should be terrifying to those invested in public health—and especially as children's access to these drugs is unfettered.

Additionally, we have found many more problems than just the licensing issues. These sites use unconscionable tactics to lure consumers and to mislead them about the drugs they are buying and their rights in the transaction. For example, many of these sites require the consumer to accept a waiver before they will ship the medication. These waivers purport to exonerate the physician who writes the prescription, the pharmacy that fills it, and the website and its operators who coordinate the transaction from **all** liability. The violations of State consumer protection laws the States have seen are too numerous for me to list here. Requiring a licensure verification will not erase all the problems inherent in the "rogue online pharmacy" industry.

The National Association of Attorneys General (NAAG) is coordinating a united effort among the States to combat these problems, and that has served all of our citizens well. NAAG has established the Online Pharmacy Working Group to address the issues surrounding Internet pharmacies, and I am proud to say that Kansas has led the effort. The group has accomplished a great deal by implementing simple, cost-effective ideas which allow the most expedient action to be taken. For example, the members of the group have established a procedure to notify the State medical board where a defendant doctor is licensed or the board of pharmacy where

a defendant pharmacy is located after a lawsuit is filed. Each State licensing entity can use the information to conduct its own investigation, if appropriate, and take any action it deems necessary, which can result in license suspension.

As a direct result of this interstate cooperation, the State of Washington summarily suspended one doctor's license to practice medicine. This Washington doctor prescribed Viagra to a 16-year-old boy in Kansas, without ever seeing or talking to him. This boy was truthful about his age in his "online questionnaire," yet that doctor prescribed and the company dispensed and shipped the drug directly to his home. My office coordinated with Attorney General Gregoire's office, and not only were we able to enjoin this company from selling to Kansans, the State of Washington was able to prevent him from prescribing to anyone online, pending the outcome of their licensing action.

A carefully organized and unified campaign of both State and Federal resources will be the most effective way to attack this dangerous practice of dispensing potentially dangerous drugs without a valid prescription. Kansas can't stop this practice alone, nor can Illinois, Missouri, or Michigan. But all States working together with the Federal government can make the cost of operating illegal online pharmacies so high as to price the bad actors out of this business.

Efforts in the direction of State and Federal coordination have already begun. On its March conference call, the NAAG Online Pharmacy Working Group included representatives from several Federal agencies, including the Department of Justice, Food and Drug Administration, and the Federal Trade Commission. The cooperative relationships that have developed between the States and between the State and Federal representatives as a result of this group have been extremely productive.

At the most recent annual meeting of The National Association of Attorneys General, my colleagues and I adopted a resolution calling for cooperative federalism in addressing Internet issues. A copy of that resolution is attached and I ask that it be incorporated into the record for this hearing.

As applied to online pharmacies, we have two substantive recommendations for any federal proposal:

First, respect the States' historical role in setting substantive requirements for the regulation of doctors and pharmacies that operate within our borders. States are the primary enforcers of laws relating to the health of their citizens, and we should continue that tradition in this important issue.

Second, the most important tool the Federal government can give the States is nationwide injunctive relief. Several States' Attorneys General have filed suit against the same companies and the same doctors. Because each State only has the power to obtain a restraining order under its own State law, it is only operable in that particular jurisdiction. To simply prevent those actors from doing business in their State, each Attorney General has to file an action in his or her State court. This duplication of effort drains our resources. We obtained a temporary injunction preventing the Defendants in our cases from doing business in Kansas, pending the outcome of the litigation. Five other cases were filed by other States against some of the same Defendants—essentially duplicating our efforts but because no nationwide injunctive relief is currently available, this replication is required to adequately protect all our citizens. Had we been able to file our cases in Federal court under a statute that allowed an injunction to apply nationwide, those States' citizens would have been protected from those entities and their practices, and their Attorneys General could have used their resources to file actions against different offenders. Since the States' most important goal in this area is to prevent these businesses from harming our citizens, this simple tool would allow each State to help protect all the citizens of this nation.

The States advocate a regime modeled on the federal telemarketing statute that would allow State Attorneys General to take action in Federal court to curb online pharmacies. This arrangement would allow States to obtain an injunction effective nationwide, and yet not prohibit any State from filing an action in its State court, based on State law. Therefore, the first State suing an entity could obtain an injunction effective in every State and prevent harm to citizens in the entire nation, yet other States could still seek restitution for their State's consumers and seek penalties and fees in their own State courts. In crafting this relief, we ask that any legislation recognize the unique qualities of the Internet and clearly state both the nationwide nature of the relief and that the jurisdiction to act is based upon the location of the consumer at the time that the transaction takes place.

In addition, I emphasize the need for an effective national registration or disclosure requirement for entities that sell prescription medications across State borders. One of the most difficult challenges in the States' prosecutions has been finding the companies and people responsible for selling these drugs to consumers in our States. We all had to sort through multiple shell corporations, addresses that turned out

to be mail drops, overlapping physical and Internet addresses shared by different entities, and similar evasive tactics. Companies selling dangerous drugs across State lines should be required to maintain current, accurate, accessible information about their principals, their physical addresses, and their identities. We should not have to struggle to find them. The National Association of Boards of Pharmacy has established an excellent system for certifying these online pharmacies. We encourage you to use their program, the Verified Internet Pharmacy Practice Sites, VIPPS™, as a model. We strongly support the VIPPS™ program and believe mandating it would not only provide the information Attorneys General want displayed on the websites, but would also obviate the need for a second and federal disclosure scheme.

What role do the States want the Federal government to take? Most importantly, the Federal government should continue the effort at consumer education. The Food and Drug Administration and Federal Trade Commission have both begun campaigns to inform the public of the dangers of essentially writing your own prescription over the Internet. We applaud their programs but respectfully submit that it is not enough. The States would welcome federal resources to provide information to our citizens at our local hospitals, doctors' offices, even our State fairs! We would like to see a nationwide campaign including Public Service Announcements, brochures at Veterans' Administration hospitals and federal social service agencies, and model education campaigns for schoolchildren. Just weeks ago, a preteen character on the television show "ER" ordered growth hormone via the Internet and suffered significant health effects—hence, the need for the emergency room! Such an incident is not, unfortunately, limited to television fiction. Art, in this case, has imitated life. Our children are much more sophisticated in their use of computers and the Internet than most of us are, and they need to know about these dangers.

Another important place for federal involvement is in combating the problem of off-shore sites. A commonly held fear is that the States' actions will merely force these companies out of the country, where laws are less stringent and enforcement frequently non-existent. But because of the borderless Internet, these rogue companies still can get their products to our consumers—and we have no reasonable method to stop them. The FDA's recent "cyber" letter-writing campaign is an encouraging step, and we would like to see the Federal government focus more of its efforts on these type of companies. The Department of Justice has recently designated contacts within the Drug Enforcement Administration to work with the States. Both of these steps recognize the need for the States to look to their Federal law enforcement partners in addressing the threat from entities in other countries.

Just last week, NAAG hosted a conference in Ann Arbor, Michigan, to discuss issues arising from State Regulations and e-commerce. Both State and Federal representatives met to discuss issues such as investigative techniques, protecting consumers from online fraud, how to effectively present a case at trial, and interagency cooperation. Training sessions such as this are absolutely crucial if we as law enforcement want to stay ahead of the bad actors.

Kansas has led the cooperative effort among the States, with the continued support of the National Association of Attorneys General. We welcome a partnership with Federal agencies to solidify our enforcement of the laws of our States.

Thank you.

NATIONAL ASSOCIATION OF ATTORNEYS GENERAL

ADOPTED

SPRING MEETING, MARCH 22-24, 2000, WASHINGTON, D.C.

RESOLUTION

In Support of Legislation Encouraging Cooperative Federalism to Protect Consumers on the Internet

WHEREAS, fraud, which continues to victimize consumers across state lines, has expanded from telephone lines to cyberspace; and

WHEREAS, Congress in the last decade has recognized that it is neither desirable nor cost-effective for the federal government to pursue all forms of consumer fraud that cross state lines; and

WHEREAS, State Attorneys General have had an ongoing, longstanding, and valuable partnership with federal agencies in protecting consumers nationwide; and

WHEREAS, joint state-federal initiatives, including sweeps and Internet "surfs" targeting false health claims, fraudulent business opportunities, fraudulent invest-

ment opportunities, and fraudulent online sales are helping to protect the consumers; and

WHEREAS, as a result of Congressionally-enacted legislation, State Attorneys General have gone into federal court for nationwide equitable relief using vehicles such as the Telemarketing Sales Rule, and this has proven highly effective; and

WHEREAS, a joint enforcement approach has been effective because it complements and enhances, rather than preempts, state consumer protection enforcement, allowing state officials the option to determine which law and relief is appropriate, as well as allowing a consultive process with federal enforcers; and

WHEREAS, authorizing the State Attorneys General to proceed in federal court would further protect citizens from fraud which "knows no boundaries," eliminate the need for wasteful duplication of state and federal resources, and promote closer state-federal relations;

NOW, THEREFORE, BE IT RESOLVED THAT THE NATIONAL ASSOCIATION OF ATTORNEYS GENERAL:

1. Supports federal legislation that would grant authority to State Attorneys General to obtain nationwide equitable relief in federal court to combat unfair and deceptive acts or practices occurring over the Internet; and
2. Supports federal legislative efforts to ensure that state consumer protection laws are not preempted; and that states have the option to enforce both federal and state consumer protection laws in federal court; and
3. Authorizes the Executive Director and General Counsel to transmit these views to Congress, the Federal Trade Commission, the Department of Justice, and other interested parties.

Abstain: Attorney General John Cornyn

Mr. UPTON. Thank you very much, all of you.

We are now going to proceed to the stage where I am sure that we will have a couple of rounds of questions, and because we have so many members here, I'm going to try to maintain strict control of the 5-minute rule for us beginning now.

Mr. Hubbard, under the Food, Drug, and Cosmetic Act, the FDA has the legal authority to take action against the importation, sale, or distribution of a misbranded drug, the importation, sale, or distribution of an unapproved new drug, illegal promotion of a drug, the sale or dispensing of a prescription drug without a valid prescription, and obviously counterfeit drugs as well. What enforcement actions has the FDA taken under any of the above-mentioned legal authorities related to prescription drugs?

Mr. HUBBARD. I think you're talking about approved drugs from a pharmacy. As I said, we have 132 investigations underway now and in the criminal area about 50 of which are dealing with the sorts of online pharmacies that offer drugs to patients via a questionnaire. Patients just ask a few questions, sometimes more, sometimes less and then the patient sends the questionnaire back to the site along with a credit card number and the site at the other end in most cases apparently has a physician and a pharmacist. The physician then reads the questionnaire, determines that patient who wants that drug, and perhaps the patients ask for that drug, say Viagra, by name, writes the prescription and the site which may be a pharmacy or may be associated with a pharmacy will take the prescription and fill it and then drop the drug into the mail and mail it back to the patient.

Now, the medical profession had said, I think, uniformly that is bad medicine. The patient is not seen, there is no medical history taken, there is no physical examination. There's no question of things such as, in the case of Viagra, for instance, does the patient have a pre-existing heart condition. And in that case the patient

should not take Viagra because it could be a lethal drug in that circumstance.

What FDA has done in those circumstances and in a number of these sites out there, we go in and we find a site, we trace it to its ISP source, then we attempt to trace it to the actual individual or storefront or the business or whatever the location is, and then we make purchases over the Internet. We use a dummy credit card; I won't go too much into investigative procedures, but we do make purchases. And then the drug is mailed to us. At that point this site is selling a drug and so we are well on our way.

Mr. UPTON. At that point do you alert the Justice Department?

Mr. HUBBARD. No, not usually at that point.

Mr. UPTON. You do everything on your own?

Mr. HUBBARD. Usually at that point.

Mr. UPTON. Okay.

Mr. HUBBARD. We try to work the case up, as it were, into a case with all the pieces of evidence. In a criminal case then we go to the appropriate U.S. attorney in whatever State or region it is. Now, a civil case would go to the Office of Civil Litigation at the Department of Justice here in Washington. So we now have a case in which we have gotten the evidence we need, that there is a site offering the drug, selling the drug, we have made purchase of the drug, and the key piece at that point is, is it a valid prescription.

And the way it would work is, if we go into court, the State official there, the State Medical Board would be asked to come testify and say, whether this is a valid prescription in your State. If that State individual says yes, we're done. If he says, no, we have no valid prescription, it's a violation of the Food, Drug, and Cosmetic Act and we can bring criminal action. And we could bring civil action. This would all be done through Justice, of course, but there could be an injunction, there would be a seizure, there could be a number of activities.

Mr. UPTON. Let me just—I am watching my clock. According to your budget request for 2001 you indicated that you had devoted more than 30,000 staff hours to investigate the Internet illicit sales which I presume is under the scenario that you just described. So you spend 30,000 hours—time hours on that—identifying cases, and yet the Justice Department has had what, two, three convictions? How many? You have a few more now in the pipeline, but until recently, there were none.

Mr. HUBBARD. I believe we referred 33 cases to the Justice Department.

Mr. UPTON. Is that based on 30,000 hours of checking these out?

Mr. HUBBARD. That is actually over only 6 months. We've actually devoted on the annual basis more like 80,000.

Mr. UPTON. It just seems like 80,000 hours coming up with——

Mr. HUBBARD. Well, first of all, many of those resources have gone into the unapproved drugs and we have many arrests, prosecutions, convictions, injunctions, seizures, many, many different things are done. On the approved drugs, those investigations have not ripened to the point of a prosecution yet. Because of the problem that I've explained to you about the valid prescription, if a State official cannot attest that that is an invalid prescription in that State, it's not a violation of the Food, Drug and Cosmetic Act.

Mr. UPTON. If I am going to maintain the relevance of this clock I have to obey it myself. But I am going to come back.

Mr. Klink.

Mr. KLINK. I would start, if I can, with Mr. Posner.

I mentioned this in my opening statement. It is my understanding that in a meeting with the subcommittee staff that the Department of Justice reported the Justice Department was chomping at the bit to receive online pharmacy referrals from the FDA. The Department of Justice was waiting to get some of these cases to really jump on; is that an accurate description?

Mr. POSNER. Well, the Department is certainly very interested in prosecuting these cases. We have gotten a couple dozen referrals from the FDA over the last year. A couple of them have resulted in convictions.

You know, we remain ready and eager to work these cases, but Mr. Hubbard quite accurately summarizes the difficulty and the length involved in investigating these cases. The Chairman asked a very good question which is, when do you come to the Justice Department with these cases and Mr. Hubbard answered quite correctly, well, really at the end. You've got to do a lot of work first. And even when the first referral is made, frequently more work needs to be done. Sometimes the FDA will decide maybe they will take it to the State prosecutor because the facts and the law in that particular case justify that. That happens all the time with a range of substantive areas the Department is involved with.

But, Congressman Klink, we are quite eager to take these cases. The U.S. Attorneys are quite eager to take these cases, and our prosecutors in the Office of Consumer Litigation, our experts in criminal cases under the FDCA, and they are ready to take cases as well.

Mr. KLINK. Of the cases then referred to DOJ by the FDA, the so-called "foot soldiers" in this whole thing, do they have the necessary elements to go forward? Are these good cases? What can you tell us about the referrals after these tens of thousands of hours, whatever it is, of manhours and womanhours that have been put into this research by FDA. What happens then when DOJ gets it. What sort of shape are you in on making these cases?

Mr. POSNER. Well, I want to steer a little clear from actual cases, but I can tell you what we have. I say we have 30 active criminal investigations, 20 involving prescription drugs. But it is not like we are ready to go to trial at that point. That means that the investigative agent has done a lot of work, has prepared a case, but it will depend on the facts and the law and the judgment of the prosecutor as to whether the case is ready for indictment, ready for a search warrant, what have you. Sometimes the cases aren't ready. Prosecutors—I know we have at least one former U.S. Attorney on the committee. Prosecutors make decisions every day about whether something is ready for a search warrant or an indictment or what have you, sometimes the cases are ready, sometimes they are not.

All I can say here is we have a number of active grand jury investigations in online prosecution drug cases.

Mr. KLINK. What I cannot understand, let me jump back to Mr. Hubbard for a second, if I heard your testimony right, you said that

initially when you began this investigation as determining who is operating the site, where the site is being operated from, kind of getting some formation out of what is jello. Why would not the FDA fully be behind the bill that we offered a year ago on disclosure and force these sites—wouldn't that be a way—at least if you're a police officer and a car is driving down the street and it doesn't have a license plate it lets you know it is something that you ought to check. At least if we had some kind of disclosure like you display a license a lot of these questions would be answered for you right away, or at least if they didn't answer them for you by having that accurate information, you would know those are the sites you have to look at.

And, yet, I will tell you, I am very dismayed that this bill that you mentioned that FDA and the administration has come forward with, you didn't work with us on it. We want to be partners in this, we don't want to be advocates. I do not believe that you work with the majority or the minority in putting this together, and quite frankly the disclosure in your bill was much weaker than that that we put forward in our bill in the beginning. So if this is such a problem why don't you at least want some strong disclosure laws on this?

Mr. HUBBARD. I think we absolutely support your disclosure provisions, Mr. Klink, and did include them in our bill.

Mr. KLINK. Doctors in your bill do not have to do any disclosure at all. We do not know who is doing the prescription.

Mr. HUBBARD. We had a concern that without any teeth behind it could lead to people disclosing things that were not truthful.

Mr. KLINK. Should doctors have to disclose who they are and whether or not they have the authority and the education to be prescribing these medications; is that something that should be done to protect the public?

Mr. HUBBARD. We saw that bill as the beginning of a process and we would very much like now to engage the committee on what the right ideas are. But we are hoping this bill is a point of departure for discussion.

Mr. KLINK. If it is a point of departure for discussion, why did we not work together on this from a year ago? Why was there not some coordination between the people at FDA and our staff? You knew we had an interest in this, yet you kind of thrust this—well, I got a phone call the day you were releasing the bill. That's not a way to cooperate with us, to have a dialog on how we are going to solve this problem, but I think it is potentially a difficult problem.

Mr. HUBBARD. Well, first of all, this bill was not totally driven by FDA. It was an administration bill and I believe——

Mr. KLINK. Whose bill was it?

Mr. HUBBARD. Well, I think it was a joint effort with the Electronic Commerce Working Group at the White House, with the Department of Justice, with FDA.

Mr. KLINK. Everybody but the Members of Congress.

Reclaiming my time for just one moment. I understand I'm running over.

General Stovall, do you think disclosure is an important part in this process giving you the tools to know automatically if we know

who this person is, if we know if they have the authority of the licensure where they're operating from, is that important to you?

Ms. STOVALL. We think that is absolutely, incredibly important. That was the most difficult task that all the States face in bringing the litigation was to be able to find out who it was that we could bring action against. So that was important.

Mr. KLINK. So, then, Chairman, I think what we have gotten out of this from General Stovall who has really been on the frontline in this, if we put together a bill that has disclosure and injunctive relief, we are on our way; is that right?

Ms. STOVALL. Absolutely. Absolutely.

Mr. KLINK. Thank you, Mr. Chairman.

Mr. UPTON. Thank you. Dr. Ganske.

Mr. GANSKE. Thank you, Mr. Chairman.

Let us think about the elderly widow who is existing on her Social Security as her only source of income. She also has significant pharmaceutical costs. She is forced to make a decision between paying her rent and picking which one of her pharmaceuticals not to purchase for the month. So she has a friend in AARP who has a computer who can get on the internet and can order through PharmaWorld in Geneva, Switzerland after paying either of two American doctors $70 for a phone consultation and get her medication at one half the cost it would cost her in her local pharmacy.

I would like a response from each of you as to is this lady doing something illegal, is it safe, what would you recommend to her? Let's start with Mr. Hubbard.

Mr. HUBBARD. Under the law as currently written, it is illegal to bring a drug in from another country that's not approved by the FDA. So in that case if she goes to a foreign web site and makes such a purchase of the drug whether it be a completely unapproved drug or a foreign version of an approved drug, she is violating the law. And FDA is empowered to stop that drug and not let it in. The practical reality has been somewhat different because there is an intent to show some compassion in some circumstances, but this is a very vexing problem in which more and more seniors are seeing less expensive drugs in other countries, going to those other countries, more often in our experience by traveling to those such as to Canada and Mexico and then bringing them back in. And that is a very difficult problem because we are not inclined to board a bus and go through the purses of little old ladies and take their prescriptions away from them.

However, technically she's doing two things; she has violated a law and second she is taking risks that she may get a drug that's a real drug or a counterfeit drug or a subpotent drug, or a superpotent drug, or anything else. And we cannot guarantee that she is getting the real drug, but she is probably saving money in many cases.

Mr. GANSKE. Let's say that she goes through a group called "Canada Prescriptions" a group of retail pharmacies in Canada. How big a risk is she taking?

Mr. HUBBARD. Well, obviously I don't know anything about that group, but any time you get outside the system, you're taking a risk.

Mr. GANSKE. Are we talking about a 5 percent risk if she goes through this group PharmaWorld? While I understand you do not know the specifics about some of these cases, what can you tell this elderly person? What is it? Is it a 50 percent risk that she may not be getting the drugs she's supposed to be getting? How would she distinguish which of these overseas places might be reputable and which would not be?

Mr. HUBBARD. She is totally incapable of doing that. And I believe the FDA is totally incapable of doing that.

Mr. GANSKE. And so let us say that she orders this and pays for it by MasterCard and this drug is coming into the United States. Ms. Durant, are you going to confiscate that medicine?

Ms. DURANT. If it does not meet the legal detainment for the FDA petition. If it does not meet the guidance that we have from the FDA. Now, if she is coming over the border, we have guidance from the FDA on the amount of dose, et cetera, and we generally do not detain those from Canada and Mexico. We do have guidance from the FDA on this. So in the mail however our experience has been that that is generally not the kind of drugs we are finding and seizing.

Mr. GANSKE. In other words, you wouldn't be so concerned about a drug like Celebrex? I mean, you are really looking at some other types of drugs?

Ms. DURANT. Correct. Correct. But we do take our guidance from the FDA and we have received complaints from members, from the constituents on some seizures that we have made and, again, we work closely with the FDA to take this practical approach to those situations and have guidance——

Mr. GANSKE. Do any of the panel members have any idea of the type of volume that we are talking about for this type of practice for senior citizens? Do any of you have any ideas?

Mr. HUBBARD. Anecdotally we understand that people are increasingly traveling by car or bus or whatever to Canada and Mexico to make these purchases. We are not seeing big increases in the common carriers. There are increasing amounts of some drugs, I believe, that Customs is seeing, but they tend to be more of these sorts of products you have here today, the steroids and the control substances that are regulated by the Drug Enforcement Administration, not by the FDA.

Mr. GANSKE. I wonder if Ms. Stovall would have a comment on this as it relates to citizens in Kansas who may be struggling with paying for their drugs and are looking at the Internet and saying, gee, I can send $15 to a Texan and get a phone number at a Mexican pharmacy and I can get that pill for one-fourth of what I have to pay for it in Kansas.

Ms. STOVALL. We understand and are empathetic with that. The safety concern is paramount though. We have a drug approval system in this country for a reason, and that is to be sure that consumers get the drug that they think they're getting and so that would be our great concern with getting drugs from overseas when they have not been approved. We do not know what they are——

Mr. GANSKE. So is the State of Kansas looking at intercepting those medications as they're coming into the State?

Ms. STOVALL. We do not have the resources to do that.

Mr. GANSKE. Do you think you should?

Ms. STOVALL. It absolutely is not a priority frankly. We do not—in a perfect world, yes, we would be able to protect our consumers from getting drugs overseas and know what the quality of them—of those drugs were. But we don't have the resources to do that. We have just concerns about the convenience of the Internet and we think that the valid pharmacies operating over the Internet are wonderful and if we can give some seal of approval to the pharmacies that are legitimate so that consumers know the good ones to buy from, the hope is they get cost savings there as well and don't have to risk their health.

Mr. GANSKE. Okay. I guess my time is up. Thank you.

Mr. UPTON. Ms. DeGette.

Ms. DEGETTE. Thank you, Mr. Chairman. I think we are all struggling with the same issue here today and that issue is, what is going to be the most effective approach to stop the online pharmacies from inappropriately and illegally selling prescription drugs. So let me try to get a little bit better handle here.

As I understand it, Mr. Hubbard, the FDA, has identified potentially up to maybe 400 of these online pharmacies that are inappropriately——

Mr. HUBBARD. We evaluated 400 sites, yes.

Ms. DEGETTE. Yes. And the reason I was confused is I have this March 23, 2000 letter from the FDA to this committee which says that the FDA is not aware of any Federal prosecutions or convictions for Internet pharmacy violations that have occurred at this time. Mr. Posner has updated us and apparently there have been a couple since this letter and there is more in the pipeline. But here is my concern, we have maybe 400 of these pharmacies and I used to practice law myself, so I know, particularly for cases like this, it can be very difficult to collect evidence that will make a criminal prosecution stick. And I do empathize with that. But here's the thing I'm struggling with and I would like to hear your comments on it.

First of all, Mr. Hubbard, how many States—you say you refer a lot of these cases to the State prosecutors, how many of these cases have actually resulted in convictions at the State level, if you know?

Mr. HUBBARD. I know of at least 11 where the State has not so much prosecuted criminally, but has issued a cease and desist order for the pharmacy.

Ms. DEGETTE. So as far as you know there are no State criminals?

Mr. HUBBARD. No, no, I believe the States are pursuing——

Ms. DEGETTE. No, no, do you know of any though?

Mr. HUBBARD. I believe we do. I can't name them here. I could certainly get that for you for the record.

Ms. DEGETTE. Wait a minute.

Mr. Chairman, with unanimous consent, can I ask that they supplement their response and if you can please let us know, have your staff let us know how many actual State convictions there have been.

Mr. HUBBARD. There have been—about half the States are being active in this area.

Ms. DEGETTE. Okay. What I want to know is criminal prosecutions and convictions. Because here's the other thing, what I am wondering is currently these prosecutions as I understand, Mr. Posner, are misdemeanor prosecutions at the Federal level; is that right?

Mr. POSNER. The jury in Florida yesterday convicted on felony counts.

Ms. DEGETTE. They did. What was that felony?

Mr. POSNER. I believe it was felony FDCA counts. It might have been a felony false statement count. It might have been a felony conspiracy count. There were multiple counts and I think at least one of the defendants was convicted on multiple felony counts. The plea last month in Hawaii was to a misdemeanor charge that the United States brought as a misdemeanor charge——

Ms. DEGETTE. Okay. But are most of these cases brought as misdemeanor cases and being investigated as misdemeanor cases or are they being investigated as felonies?

Mr. POSNER. I think most of them are filed criminal cases but charge felony violations. Obviously, in the investigations underway now, if the prosecutor determines that the facts and the law support a felony charge, the Department could seek that. And the Department is looking at an array of very serious charges. I don't want to get into what we're thinking about in particular matters, but it would be fair to say that the Department is considering felony charges in a number of online prescription——

Ms. DEGETTE. Okay. So you one of your suggestions would be we need to look at legislation to give a more serious designation to some of these crimes? Would that help? Because practically speaking, I know when you have limited resources you're going to generally pursue felonies versus misdemeanors.

Mr. POSNER. Well, the Department is very interested in these cases and we will pursue a misdemeanor if that's what the facts and the law support in this particular case. I think our view is that the penalties are generally adequate, we are very supportive of the administration's bill, the disclosures and all that, but I think that we are certainly satisfied with the penalties of the FDCA.

Ms. DEGETTE. All right. Now, you referred in your testimony today and you talked about it in your written testimony to a suggestion that you folks have that could help in the civil arena. Could you talk just briefly about that?

Mr. POSNER. I will. Under 18 U.S.C. Section 1345, the Attorney General can seek civil injunctive relief to stop disposition of assets that are traceable to a violation of the banking laws and a defined array of health care fraud offenses. That's what Section 1345 currently says.

We recommend adding violations of perhaps the FDCA and also the Administration's Online Pharmacy Bill to that list of defined——

Ms. DEGETTE. I see. And do you think that would help you then in your ability to get civil injunctive relief against these folks?

Mr. POSNER. Yes, certainly, Congresswoman, but I think it will also help along with the subpoena power the Department has in the new bill. When you take those two things together, we believe that we may be able to stop some of the money from United States

consumers flowing to foreign sites. That is, I think, a creative and potentially quite useful way of combatting the problem of foreign sites. And obviously you do that with domestic sites as well.

So the answer to your question is yes.

Ms. DEGETTE. Thank you.

Mr. UPTON. Mr. Burr.

Mr. BURR. Thank you, Mr. Chairman.

Let me, Mr. Hubbard, go back to the lady that Dr. Ganske was talking about. She fills her prescription via an Internet pharmacy—online pharmacy. You said that if the drug were not approved by the FDA or was manufactured out of the country, that that would be illegal. How about if the drug were manufactured in this country?

Mr. HUBBARD. I think the big issue there would be—you're talking about a foreign Internet site?

Mr. BURR. Correct.

Mr. HUBBARD. This committee led the way to legislation about 15 years ago that would prohibit the reimportation of drugs exported from the United States. The problem that the committee found at the time was that drugs were going offshore, expiring or otherwise being contaminated or having problems and then being reimported into the United States and that became very problematic. So the Congress enacted legislation under this committee's auspices called the Prescription Drug Marketing Act that would make that particular practice illegal.

Mr. BURR. So what you're saying to us is that there is no international online pharmacy that has a product that can legally be shipped into this country; is that correct?

Mr. HUBBARD. There may be some exception, but generally, a drug brought in from another country that is not subject to a specific FDA approval would be violative, and, of course, both those would come in, in commercial shipments to the manufacturer and then the manufacturer would distribute them to a wholesaler and then to a pharmacy to dispense them to a patient.

Mr. BURR. Mr. Posner, is that also the U.S. code that allows pharmaceutical companies and manufacturers here under patent protection the ability to refuse for a reimportation?

Mr. POSNER. I don't—are we still on the hypothetical with the——

Mr. BURR. I think we're down to reality now. I mean, Mr. Hubbard just said——

Mr. POSNER. Right.

Mr. BURR. [continuing] under the current rules maybe there's an exception out there and I grant him that leeway, there's not an international online pharmacy that it could be legal to sell products here because they might not be approved by the FDA, not manufactured in this country and for those that are manufactured in this country, there is a law that says it's illegal to reimport them to this country. There is also an additional U.S. code that allows manufacturers of patented goods to deny their re-entry into this country after they've been manufactured here and shipped somewhere else and then tried to ship back to the U.S.

Mr. POSNER. I think I generally agree with the FDA's position. I am hesitant to offer a definitive legal opinion on a set of facts.

Mr. BURR. Well, since you quoted U.S. Code, I thought you might be familiar with that about patent protection.

Mr. POSNER. I'm not——

Mr. BURR. So let me go to Ms. Durant, if I can. Does that mean that the U.S. Customs is in fact stopping every shipment that comes into the United States from an international online firm?

Ms. DURANT. No, the U.S. Customs Service does not have the resources.

Mr. BURR. Has the FDA ever shared with you that their opinion is that anything that is shipped from an international online pharmacy into this country would be breaking the law?

Ms. DURANT. We have some rules from the FDA on circumstances——

Mr. BURR. Is this the first time you have ever heard Justice or the FDA say that any product, any pharmaceutical product shipped internationally back into this country in fact breaks either FDA regulations or U.S. law?

Ms. DURANT. This is the first time that I have personally heard that.

Mr. BURR. We are making tremendous progress today.

Which I would say for the purposes of everybody's testimony which I believe without exception they had it in there, this paragraph on cooperation. I would tell you that we still have something to strive for as it relates to the communication between all the entities.

Mr. Posner, let me go to you for two quick questions. In March of this year the Department of Justice released a report on the President's Working Group on unlawful conduct and the Internet. The report of the Department of Justice concluded, "existing Federal law appears generally adequate to encompass the unlawful sale of prescription drugs over the Internet." However, the Administration recently released their draft proposal to impose new Federal regulations on the Internet. How do you explain the inconsistency with the Department of Justice's conclusion and what the proposal of the Administration currently was?

Mr. POSNER. Well, Congressman, we don't see an inconsistency. What we testified actually in the committee last year was that we said that——

Mr. BURR. Let me read you a quote, if I could, one more time, and you tell me where I've misunderstood it. And I quote, "Existing Federal law appears generally adequate to encompass the unlawful sale of prescription drugs over the Internet."

Mr. POSNER. That's right. Existing substantive laws generally are adequate, although we say in the report that there were a lot of different investigatory issues. And what we said last year and what we say in the Administration's report is that you need to match up the offline world and the online world. That is, disclosure in the offline world, you walk into a CVS on Wisconsin Avenue and there is an array of disclosure for you, pharmacy license with names, addresses, phone numbers, all of that. That's what you see in the offline world. So it's critical to match up the disclosures in the online world. That's why that bill is, in our view, perfectly consistent with the Administration's report which calls for consistency because it requires all that disclosure to match offline pharmacies.

Mr. BURR. One of the challenges that we deal with is the consistency of what you tell us and what it is next month. And in this particular case in March you made a statement and here at the first of May we get a bill that basically says everything that you told us that everything wasn't adequate.

Let me just ask this last question, I know with the committee's indulgence. Also in the President's Working Group the report said that the U.S. continues to seek and obtain cooperation from foreign governments with regard to foreign web sites illegally importing drugs into the United States. I think we would all conclude today that is now defined as 100 percent of the foreign sites that ship into the United States.

What type of cooperation is the U.S. seeking and have we had meetings with foreign governments on this topic?

Mr. POSNER. Congressman, the Department is involved in a range of negotiations, the Department and other Federal agencies, Customs, FDA, and others, the State Department, involved in a range of discussions about cyber crimes committed internationally. These are very significant issues. They cut across a lot of substantive areas. There are a number of international agreements in place, there will be more international agreements in place.

I mean, Customs can speak to a very successful story about international cooperation resulting in arrests and seizures in Thailand. There is more and more of that international cooperation, particularly involving the Internet which obviously presents global problems. There is a lot of activity in that area as to cyber crime generally and as to online pharmacies specifically and I think we are beginning to see quite tangible results including convictions and arrests.

Mr. BURR. I thank you for your thoroughness in that answer and have also been informed that in the proposal that was recently sent to Congress that the bill also contains the administrative subpoena power and civil monetary penalties that do not exist in the offline world. So if we are trying to reach a point of equity between the online and offline, the pendulum might have gone too far.

I haven't had an opportunity to sit down and read the proposal word-for-word, but I assure you that I will and I think that from Mr. Klink's comments, we're all interested in playing a part of whatever the solution is. I am amazed to find out that today is the first day that we've all realized that international sites based upon any criteria that we choose would be illegal for a shipment to come to the United States. And I hope that in fact Ms. Durant carries that back to the Customs because I don't think she was aware of it based upon her testimony. I thank the Chair and I thank the members.

Mr. UPTON. The gentleman yields back the balance of his time.

Mr. Hubbard, according to your testimony the FDA has sent 17 cyber letters to operators of foreign-based Internet sites offering to sell online prescription drugs; what has happened?

Mr. HUBBARD. I understand——

Mr. UPTON. Did they stop? Did you scare them?

Mr. HUBBARD. One of them notified us that they had ceased immediately. Two others agreed to stop selling Viagra, but were con-

sidering other drugs and I don't believe we heard from the others. These are not orders, because these are sites in foreign countries.

Mr. UPTON. How long ago did you send them?

Mr. HUBBARD. Oh, I think a month ago——

Mr. UPTON. Could you keep us posted on the response?

Mr. HUBBARD. Sure.

Mr. KLINK. Would the Chairman yield for just one follow up?

Mr. UPTON. Sure.

Mr. KLINK. When you sent those letters did you coordinate with the Department of Justice or Customs to make sure that notifying these people they were under investigation didn't interfere with other actions that other Federal agencies are taking?

Mr. HUBBARD. I understand while we did not do that in advance, we've obviously shared them at the time we sent them and I understand that there were no problems there.

Mr. KLINK. Do you know that for sure?

Mr. HUBBARD. I asked that question specifically and was told by investigators that that was the case. But I did not personally talk to Customs.

Mr. UPTON. Ms. Durant, is that answer——

Ms. DURANT. We were notified. It was after the fact and there were no problems.

Mr. UPTON. Mr. Posner, how are you coordinating with the State enforcement agencies? And I want to get Ms. Stovall's response to that as well. I want to hear a little bit about the conference and how you all are interacting between the States.

Mr. POSNER. Well, I know that our prosecutors both in Washington and in U.S. Attorneys Offices around the country have been in a number—I mean, we've all had plenty of interagency meetings on this. The State AG's are quite involved in this. We sent at least two notifications to NAAG, I think in the last year about our interest and said here's a contact and a phone number at DEA, here is a contact and a phone number for a prosecutor in Washington.

My understanding, it's in my prepared remarks is that we have a pretty good working relationship, an alliance between the U.S. Attorney's office in Kansas, and Ms. Stovall's Office. She can obviously speak to that in more detail as could our Kansas prosecutor. But we have alliances with State prosecutors and we have a lot of defined, longstanding, and ongoing relationships with State prosecutors in a number of the substantive areas and we use that with this subject matter as well.

Mr. UPTON. Ms. Stovall?

Ms. STOVALL. In terms of the cooperation there is a Federal group that was put together, a Federal/State working group and it meets about quarterly and AGs have been invited to participate in that. I'm not aware of specific examples of times that we have called upon the U.S. Attorney in Kansas although the U.S. Attorney is an outstanding individual, and I know would be ready to help if we were to ask. But I'm not aware of particular examples where we have asked for that to occur.

Mr. UPTON. Ms. Durant, Mr. Posner referenced the working relationship with Thailand.

Ms. DURANT. Yes.

Mr. UPTON. What other relationship—that has been fairly successful by I think everyone's admonition. What other countries are you trying to build a similar relationship with?

Ms. DURANT. We have not proceeded as dramatically as we have with our Thailand attache's office. We are looking forward to making that success in Thailand a model when the CyberSmuggling Center adds these ten agents in July to the Cyber Crimes Unit that we're forming in Customs.

But the way we do that is through our attache's office. Customs has attaches overseas and they work with the foreign governments to provide technical assistance to the foreign governments which is what happens in Thailand such that they shut down the Thai Government, seven online sites.

Mr. UPTON. This subcommittee's investigative staff has spent a little time at a couple of different facility sites and they noted that the customs officials were applying different standards in determining the pharmaceutical products that would be allowed into the United States. And I would just note that there is some cue perhaps in terms of the allowance of drugs from other countries in we have a guidance sheet here that—maybe we can make copies of this and share with you now, but can you explain, Ms. Durant, why a Customs official might apply a different standard depending on where the mail facility that a package might go through?

Ms. DURANT. We stress uniform application of our guidance through our field offices.

Mr. UPTON. San Diego, right, and San Francisco, and Oakland, and Los Angeles. Dramatically different procedures as you identified products that were coming in from whether it would stored, whether it would be sent back, how long you would have it, whether it would be sent along to the individual that it was addressed to. It was remarkable the differences that were——

Ms. DURANT. We do have some differences. Some of those differences frankly stem from guidance that we get from FDA at the various FDA locations in the field. We do take our guidance there. There are some variances we've been working with the FDA to get a uniform policy and they, I believe, are issuing some fairly strident instructions to their field offices not to deviate from the national guidance.

Having said that, we need to work as well with our mail branches to make sure that they too are following the guidance and not deviating from that guidance. Part of the problem, frankly, is just the overwhelming amount of mail and this manual targeting that we're forced to use. We have only the country information, X-rays and some dogs in our mail units to be able to select those articles. We are fairly overwhelmed in the mail in terms of our ability to cope with what is coming at us. Be we are working with the FDA and working with our own mail branch to make sure they follow the guidance that they're given.

Mr. UPTON. Mr. Klink?

Mr. KLINK. I want to follow up on that, Mr. Chair. It was a good line of questioning and it's the direction I wanted to go. But before I do that, I had mentioned in my opening statement, we see these promotional web pages, Mr. Hubbard, for some of the drugs that are most frequently sold on these rogue sites and I mentioned

Propecia, Xenical, Viagra, and I've got copies of them here. And I will tell you if you will accept my word for it, there is nothing on these sites that jumps out front as to where or where not to buy these. It does not really lead you to the FDA where you could give some warning, and I understand your site gives some warning as to these drugs. Does it make good sense to you that these companies should be encouraged to at least post certain basic consumer information at their promotional web site talking about where or where not to buy these drugs and there is safety and risk to associated purchasing these on line?

Mr. HUBBARD. These are by the manufacturer of the drug or by the——

Mr. KLINK. The promotional site done by the manufacturer; yes.

Mr. HUBBARD. Right. That is an issue, Mr. Klink, and I think it's an important one. We have told companies that their promotional material on these sites is subject to FDA regulation. We have sent warning letters on that, we are monitoring those because there is a real potential for abuse and you're absolutely correct.

Mr. KLINK. So what we're saying, these are promotional sites that talk about these drugs, obviously very popular drugs like Propecia, Xenical, and Viagra, and we're simply saying if a company, and not to pick on any one of them, but they should have something on that web site that would lead to the FDA or say, look, obviously they list the risks associated with the drug, but also there should be something on there that would say where it's safe to buy this or where not to buy it?

Mr. HUBBARD. I think that's good advice, Mr. Klink. I'm not sure we can require that. We do, however, require that if they promote the drug that they must have balanced information about risks and contraindications and other problems with the drug or what we call "fair balance".

Mr. KLINK. I don't think that I'm making myself clear. You've got at the FDA this online pharmacy facts——

Mr. HUBBARD. Yes.

Mr. KLINK. [continuing] and tips and warnings for consumers.

Mr. HUBBARD. Right.

Mr. KLINK. If, for example, and I'll use Propecia, for example, and this is Merck, if at Merck they had a place to click here——

Mr. HUBBARD. I think that's a good idea, Mr. Klink.

Mr. KLINK. [continuing] but not to require them, but to encourage them to say, why don't you click on FDA and when you do, you're going to be at least——

Mr. HUBBARD. That is a very reasonable suggestion, Mr. Klink. Let me take that back and see if we can look at that.

Mr. KLINK. I would like the FDA to join us in encouraging these pharmaceutical companies—we have a lot of pharmaceutical people I've noticed in the room today. I don't know why they would want to be here, but we would encourage them to take that message back and act responsibly in that issue.

I want to follow up, if I can on this whole issue of because I agree with Mr. Burr, and it has been my supposition that these illegal—that the shipping in of these drugs from overseas sights is illegal from the very beginning and that is why we wanted to deal with a disclosure bill. I have a copy of the FDA's personal use importa-

tion guidance and Mr. Hubbard, I would like you to walk me through it and explain exactly how FDA intends this policy to be applied by U.S. Customs agents and inspectors at the mail facilities. We think there is a great discrepancy in how they are interpreting this. In other words, how should they determine if a package of pills or something that looks like pills should be released to the addressee?

Now, would you say here that the general guidance section states that FDA should consider not taking enforcement action against such importation when No. 1, the intended use of the drug is unapproved for serious conditions for which effective treatment may not be available domestically either through commercial or clinical means?

Mr. HUBBARD. First of all remember all of these imported drugs are illegal. This policy was derived with compassion in mind, that if a person with a serious or life threatening illness cannot get a therapy in this country because there is nothing here, and they travel to another country to get treatment or they order a drug over the Internet or mail to get treatment, unapproved drugs for a serious condition, we have adopted an enforcement discretion policy that says if the patient is aware that they are bringing in unapproved illegal drugs, if there is a physician here that is going to monitor their use of it, we will let small amounts of it, personal use amounts, in.

Mr. KLINK. Well, let me jump in because I'm going to run out of time here. The question here is—and I just want to read through this real quick—the other two points is there are is no known commercialization or promotion to a person residing in the U.S. by those involved in the distribution of the product at issue, the product is considered not to represent an unreasonable risk, and the individual seeking to import those products affirms in writing that it is for the patient's own use generally not more than 3 months supply and provides the name and address of the doctor that's licensed in the U.S. for his or her—is responsible for his or her treatment with the product or provide evidence that the product is for continuation of treatment begun in a foreign country.

So the question here is, what criteria should they use? Because we have visited different sites with the people in Customs. They are confused, and I think rightfully so. They don't understand or if they're not confused they are interpreting this all differently.

So we have to make a determination as to how this gets done and there really needs to be coordination with FDA. We are hearing from some Customs people they pull these drugs off to the side and nobody from FDA ever shows up and then it goes back to the addressee. So the question I would ask, Ms. Durant very quickly, what percentage of the mail packages that your inspectors stop actually meet all or even a majority of the criteria as outlined by the FDA in the guidance document; do you have any idea?

Ms. DURANT. I don't know.

Mr. KLINK. We are told very little.

Ms. DURANT. Very little, very little. In fact, in the mail what we are seeing, we do see these quantities coming over under this guise, it's more on the border with accompanying passengers, but not so much in the mail shipments. Most of the mail shipments

and the seizures that we are making and the detentions we are making are for illegal drugs, but very little. Most of it and the way the inspectors recognize that it doesn't meet any of this criteria in terms of labeling, prescriptions accompany, et cetera.

Mr. KLINK. So as a result of the clarification of Mr. Burr's questioning earlier and this questioning now, we should eventually be very close to almost drying up entirely the amount of pharmaceutical products that U.S. Customs finds coming through unless it clearly meets the majority——

Ms. DURANT. The criteria.

Mr. KLINK. [continuing] of these criteria; is that correct?

Ms. DURANT. Correct. That is correct.

Mr. KLINK. So these or whatever drugs are coming through right now, after this hearing it should be very clear working with FDA and the Department of Justice, we should not have a vast amount of drugs or vast quantity of drugs coming through U.S. Customs either by the mail or being carried by individuals; would that seem to be correct?

[Simultaneous conversation.]

Mr. KLINK. Or to rework the policy with the FDA and Justice.

Ms. DURANT. We are working with the FDA so that we have very clear policy on what is allowed and what we should be detaining. I am hesitant to say that we won't have illegal drugs coming through the mail.

Mr. KLINK. Mr. Chairman, I would like to know if we could as the three agencies that are represented here within a 2-week period of time to report back to this subcommittee as to the manner in which they will be developing a clarified policy in how this will be done, what criteria will be used as far as personal exemptions. I think your concerns under your line of questioning were the same. Clearly there needs to be a process set in place immediately where these three agencies are working together and I would ask unanimous consent that this subcommittee make that request of the DOJ, the FDA, and Customs.

Mr. UPTON. Without objection.

Mr. KLINK. Thank you.

Mr. UPTON. Dr. Ganske?

Mr. GANSKE. Well, Mr. Chairman, I want to follow up on this because I think I'm reading from the same document that Mr. Klink has, subchapter and coverage of personal implications and under "general guidance" it says, "FDA's personnel may use their discretion to allow entry of shipments of violative FDA regulated products when the quantity and purpose are clearly for personal use and the product does not represent an unreasonable risk to the user. Even though all products that appear to be in violation of statutes administered by FDA are subject to refusal. FDA personnel may use their discretion to examine the background risk and the purpose of the product before making the final decision. Although FDA may use discretion to allow admission of certain violated items, this should not be interpreted as a license to individuals to bring in such shipments."

Mr. Hubbard, is that correct?

Mr. HUBBARD. Yes, that's right.

Mr. GANSKE. And that is FDA policy?

Mr. HUBBARD. Yes, it is policy. It is a form of enforcement discretion.

Mr. GANSKE. My point would be that I think when Congress looks at the issue of prescription drug benefits we will want to examine the inconsistancies in place between countries and the fact that I think that we are going to see a big increase in the shipments as our senior citizens start using that Internet more. And I think we would need more information on this. We need to know how much is going on. You know you could get on the Internet and go to a site in the United States and order a prescription drug and but what you get back might not necessarily be the drug that you ordered and which was part of your potential problem in getting it from a foreign source.

I mean, when we go to a pharmacist we are pretty certainly that the pharmacist has gotten the drug from the pharmaceutical manufacturer. There aren't too many places where somebody is going to see a lot and take off the cellophane, substitute a drug, put it back on—reseal it or something like that. But I think that there is a potential for more abuse through an Internet site than not.

I want to finish by just asking this, we are not here saying that you cannot order drugs over the Internet in the United States, i.e., we all see advertisements in the newspapers for Viagra, etc. What is the legal and proper procedure for a citizen to order a drug like Viagra through the Internet?

Mr. HUBBARD. I will be glad to answer that. It is to go to your physician and give a history and be examined and be determined that Viagra is appropriate for your condition and also that you don't have heart disease or other reasons not to be given it. The physician would then write the prescription. You go online to an Internet site, give your name and address and other necessary information, and then you would probably mail in the prescription, although a physician could fax it. Then that online site would mail you your drug and it would arrive 2 or 3 days later. That is perfectly legitimate and legal practice and, if anything, we encourage it.

Mr. GANSKE. Ms. Stovall, is it legal for somebody to go on the Internet to a site for Viagra and then interact on the Internet with a physician that's employed by that Internet pharmaceutical and get the prescription; is that legal or illegal?

Ms. STOVALL. You maintain that's a violation of the law. That it is not a valid physician/patient relationship and it is violative under the Consumer Protection Act.

Mr. GANSKE. And Mr. Hubbard, do you agree with that?

Mr. HUBBARD. Yes, if there is no valid relationship then there is no valid prescription. But we have relied upon the States to tell us within that State whether the valid prescription exists.

Mr. GANSKE. I thank you.

Mr. UPTON. Ms. DeGette?

Ms. DEGETTE. Thank you, Mr. Chairman. I would like to follow up briefly on my previous questioning. Mr. Posner, in listening to all of this, it seems to me that the criminal prosecutions are because of the proof issue very time consuming to investigate at the FDA level and then once they get to the prosecutor still more investigation is needed. And I'm sitting here wondering if maybe you

can talk briefly about whether we should be focusing our efforts more on the civil injunctive end. For example, passing legislation that Ms. Stovall is advocating, talking about the legislative improvements you are talking about. I mean, certainly there is always going to be an egregious example where you need to use the criminal statute, but wouldn't we be better off right now really focusing on injunctive efforts to put these online pharmacies out of business?

Mr. POSNER. Well, the enforcement of criminal laws is important. I mean, we are——

Ms. DEGETTE. We all agree with that.

Mr. POSNER. [continuing] violation so we obviously need to continue that. We do have several civil injunctions in cases that have been filed and that are under investigation.

I would say, though, that it is still time consuming to work up a civil injunctive case. I mean, these are complex cases and you have got some different ens rea requirements for the civil side, that's true, but you still need the identities and the numbers and we need to understand conduct and we need to understand State law. We need to understand a lot of things. It is fairly time consuming to put together a civil——

Ms. DEGETTE. Right. But if you put together the civil case then you can get an injunction stopping them from sending this to anybody, whereas the criminal case is going to be sometimes a little more attenuated. And also I'm concerned because I know that Ms. Stovall did a wonderful job and some of the other AGs too, but when you rely completely on States for either criminal or civil injunctive relief, you're going to have a spotty result. And, of course, these pharmaceuticals are coming into every State.

So you know, in Kansas it may be a great enforcement effort particularly on the civil end, but in Wyoming it might not be.

Mr. POSNER. We are very eager to do civil cases. We have a unit in Washington, the Office of Consumer Litigation that does both criminal and civil cases. We would encourage FDA to look to them for many cases. We are ready and eager to do a lot of these cases.

Ms. DEGETTE. And I guess that brings me to kind of the ultimate question which is, it doesn't seem to me that we have a lead agency or a point person coordinating what our strategy is on this to identify both legislative issues and administrative issues, and I am wondering, Mr. Hubbard and Ms. Posner, if that wouldn't be a good idea to figure out and then to pursue aggressively?

Mr. HUBBARD. I would note on the legislation I think there was a very coordinated effort among the——

Ms. DEGETTE. No, I know, but who is in charge? Do you know exactly who is in charge?

Mr. HUBBARD. Well, I think for the legislation I would say that the Electronic Commerce Working Group at the White House.

Ms. DEGETTE. Okay. But what about in terms of enforcement both criminal and civil? Who is in charge of coordinating that effort?

Mr. HUBBARD. We have a working group——

Ms. DEGETTE. No, but who is in charge?

Mr. HUBBARD. There has not been a designated lead agency on that.

Ms. DEGETTE. And do you not think that would be helpful to figure our strategy, Mr. Posner?

Mr. POSNER. You raise a very good question. The States have a very important role here and they are very active and have longstanding expertise in a lot of these areas. The Federal Government also has a role. This comes up in a number of different subject matters.

Ms. DEGETTE. Right.

Mr. POSNER. Because the State and the Federal Government and then within the Federal Government there are obviously multiple agencies that have a role.

Ms. DEGETTE. Right.

Mr. POSNER. And it is frequently difficult to just put somebody in charge. What you want to do is obviously have effective cooperation and coordination, but I am not sure at this point you can just say somebody is in charge when all of the State and Federal Governments have very important roles to play.

Ms. DEGETTE. Exactly. And I would never disagree with that coming out of the State legislature myself. But, you know, we have many, many very effective State and Federal working groups and agreements and it would seem to me you want someone to be the lead agency in helping coordinate. Because when no one is in charge, what happens is everybody is running around pursuing often less effective solutions. So I would really urge you to look at that.

And one last question which is related to this, we heard from Ms. Durant about the international side and it seems to me that there is no interagency cooperation being discussed on the international side. I don't know if you would agree with that or not?

Mr. POSNER. I think the international—there are a lot of challenges, challenges to domestic sites are magnified through international operations. That's been part of the discussions in all the agencies and State/Federal cooperation, that's always a part of the discussion. Obviously Customs has the lead there, the FDA plays a very important role in that and our DEA obviously is very on top of the controlled substances. So, yes, that is a part of the interagency cooperation, but there have been a lot of challenges.

Ms. DEGETTE. I mean, it would seem to me, and I would ask you to look at this, it would probably be really useful, the recently released legislation didn't address this international site at all and it might be very useful for you folks to figure out how that fits in and whether we can put some legislative—on that end as well?

Mr. POSNER. The only thing I would say about the legislation there is that we do have a suggestion on an amendment as I discussed earlier that may help us on the foreign sites.

Ms. DEGETTE. Okay. Thank you.

Thank you, Mr. Chairman.

Mr. UPTON. Thank you. I have just a statement, no further questions on my part. You know, I just want to say this has been a very instructive hearing and I am encouraged, always have been encouraged by the amount of bipartisan thought and commitment we have not only on this panel, but on the committee as well, and I certainly look forward to working with Mr. Klink and Ms. DeGette and others on drafting legislation to solve a problem that really is

out there. And I hope this doesn't open maybe a can of worms, but as I have been listening to your testimony, and some of your thoughts with regard to guidance—the policy guidance that you have particularly in personal use, drugs that perhaps have not been approved by the FDA, and often life threatening illnesses and our hearts extend to all those individuals that are those cases that are not so often unique, but something that you've arrived for some guidance and flexibility, I guess you could say in where the law actually is. I'm not sure what gives you—not being a lawyer myself, I'm not sure what precisely gives you the authority to bend the law to allow those things to happen.

But as we look at legislation that may move into our committee and get to the floor, I will be most interested to see what thoughts, particularly from Justice, and FDA, in terms of what leeway language we might include that would in your best judgment allow us to in fact give you that leeway when you think that it's necessary. And, again, it would be a very difficult thing for us to take up, but clearly one that is in practice has been going on for some time and allows us to be responsive to the needs of those that are suffering life threatening diseases when in fact they think that those that particularly drugs may in fact extend their quality of life in a meaningful way.

So that being said, I just want to appreciate your testimony this morning. We may have additional questions for you by all members of this panel and if that happens, if you would respond quickly to those, that would be appreciated. I also would ask unanimous consent that letters and other things, periodicals that were mentioned from us can be inserted into the record by unanimous consent.

I will yield to Mr. Klink.

Mr. KLINK. Yes. Mr. Chairman, I just want to again compliment you. This was a good hearing. I think by my count we come out with at least three action items. One is that we do want to draft a bill which would include this merger and injunctive relief and we look forward to working—and, again, I would say to the FDA and to Justice and to Customs and to the Attorneys General, we want to work together on this and we want to be a part of the discussion. This disclosure the bill has been out there for a long time and we could use some support in that language. If it's wrong, tell us what is wrong with it, and let's go on with it. Let's get it done.

I think also I agree with the Chairman, in regarding this whole issue of personal use exemption. I know it is intended to be humane, but it is like a screen door on a submarine, you are protecting someone who has got a life threatening illness or that has got a problem; we are allowing other drugs to come through that could cause the problem. Because it, again, has less substance than Jello that hasn't set yet. No one really has an idea on the front lines, I think, exactly how they are supposed to deal with it. So we would like to know within 2 weeks how the agencies are going to work together to resolve this issue, how that is going to be done.

That is extremely important to us and I also would like to hear from the FDA that we take a manner of encouragement to the drug companies to see that they post some kind of or that we encourage them—obviously we can't require them—we would encourage them to be good corporate citizens and to have information on their prod-

uct web sites that would lead to the FDA warning sites, I think that that is a minimum step that would begin to solve the problem if indeed they are concerned about their products are being used in a manner which would be adverse to public health and would risk potentially human life. And I am sure that the drug companies are concerned about that so I know that they will take our suggestion very seriously and will comply.

And with that, Mr. Chairman, again, thank you for the courtesy and thanks for the witnesses today.

Mr. UPTON. Ms. DeGette, do you have further questions?

Ms. DEGETTE. No.

Mr. UPTON. Mr. Strickland?

Mr. STRICKLAND. No. Thank you, Mr. Chairman.

Mr. UPTON. Thank you to everyone.

[Whereupon, at 12:01 p.m., the subcommittee was adjourned.]