SAFETY OF IMPORTED PHARMACEUTICALS: STRENGTHENING EFFORTS TO COMBAT THE SALES OF CONTROLLED SUBSTANCES OVER THE INTERNET

HEARING

BEFORE THE

SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS

OF THE

COMMITTEE ON ENERGY AND COMMERCE
HOUSE OF REPRESENTATIVES

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SAFETY OF IMPORTED PHARMACEUTICALS: STRENGTHENING EFFORTS TO COMBAT THE SALES OF CONTROLLED SUBSTANCES OVER THE INTERNET

TUESDAY, DECEMBER 13, 2005

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

The subcommittee met, pursuant to notice, at 1:05 p.m., in Room 2123, Rayburn House Office Building, Hon. Ed Whitfield [chairman of the subcommittee] presiding.

Members present: Representatives Whitfield, Stearns, Ferguson, and Stupak. Also present, Representative Norwood.

Staff Present: Mark Paoletta, Chief Counsel for Oversight and Investigations; Alan Slobodin, Deputy Chief Counsel for Oversight and Investigations; Clayton Matheson, Analyst; Michael Abraham, Legislative Clerk; and Chris Knauer, Minority Investigator.

MR. WHITFIELD. The committee will come to order.

I want to thank all of you for being here today, and particularly our witnesses for today's hearing, and apologize. We're just a few minutes behind schedule, but with travel arrangements and everything else, I'm sure you all understand how that goes.

The hearing today is on the safety of imported pharmaceuticals and strengthening the effort to combat sales of controlled substances over the Internet. Today's hearing will focus on the effort to combat the sale of controlled substances over the Internet. Prescription drugs with wide appeal and popularity such as Percoset, Vicodin, Darvon, anabolic steroids, and Valium are just a few examples of drugs that are being sold over the Internet.

As you know, this committee is committed to protecting the safety of Americas' pharmaceutical supply, but, unfortunately, with the advent of the Internet, obtaining controlled substances illicitly online has become too convenient and can be obtained without a valid prescription.

Now the Government Accountability Office will be testifying at today's hearing, and they will talk about some of their findings. But they recently found that, although there is no systematic collection of data on

the volume of controlled substances encountered at mail and carrier facilities, we know without question that the volume is substantial. For example, according to the FDA/Customs blitz which was conducted in the summer of 2003 at the Miami, New York, San Francisco, and Carson, California international mail facilities, of the imported pharmaceutical products found, 28 percent of the drugs tested were controlled substances, representing over 25 different controlled substances. Based on the JFK estimate by senior Customs officials that 40,000 parcels contained drugs imported through that airport on a daily basis and extrapolating those figures, as many as 11,200 drug parcels containing controlled drug substances are imported daily through JFK alone.

A February 2004 study by the National Center on Addiction and Substance Abuse, in partnership with a private investigative firm, documented the availability of controlled prescription drugs on the Internet; and they found that of the 495 websites offering Schedule II through IV controlled prescription drugs identified in the study, only a third of those, of the 495, or 157, were "anchor" sites where consumers actually purchased the drug, but 90 percent of those sites did not require a prescription. Now the remaining 68 percent of the 495 were portal sites simply acting as a conduit to other websites, including anchor sites which sell the drugs.

I have already mentioned GAO will be testifying today; and they also, as I said, will be discussing their recent report that documents these highly addictive controlled substances being readily available.

All of us are concerned about our young people. The February 21, 2005, issue of U.S. News & World Report pointed out the concern of prescription drug abuse among our teenagers. One in 10 high school seniors have tried the painkiller Vicodin without a prescription and 1 in 20 have taken the potent pill OxyContin.

For young people in particular, online pharmacies are especially seductive. We know, for example, that on February 21, 2001, a young teenager named Ryan Hate died at the age of 18 of an overdose after mixing morphine and two prescription antidepressants with Hydrocodone, a potent and highly addictive painkiller that he bought from an Internet pharmacy in Oklahoma. And on June 7, 2001, the parents of Todd Rhodie told our subcommittee about finding their son dead in his apartment; and, according to the medical examiner, Todd's death was caused by a massive overdose of controlled substances that he had ordered from a foreign Internet pharmacy.

DEA has testified that its investigations have discovered over 14 deaths of overdoses and 15 people who have entered treatment or sustained injuries from drugs obtained over the Internet.

IntegriChain will be testifying today. They are out of Princeton, New Jersey. It's a firm doing investigative work on Internet pharmacies. They provided a briefing to our subcommittee last July, and as a result of that briefing I requested as a test of their investigative capabilities that IntegriChain gather intelligence on a series of websites selling these controlled substances identified by the majority and the minority staff, and the results of that work will be presented publicly for the first time at this hearing. This white paper will provide more details for consideration on how to strengthen efforts to combat sales of controlled substances over the Internet.

I might also say that most of us are critical of what we view as the inability of the Federal agencies to really get a control of this issue. We have a right to be critical I think in many instances, but I also think it's important to look at some of the accomplishments of the agencies.

Last September, for example, the DEA announced a new virtual enforcement initiative, part of which included Operation CYBERx. That investigation led to the arrest of 17 people who operated rogue Internet pharmacies that took orders for controlled substances over the Internet and then shipped those products to U.S. citizens without a valid prescription. Those arrested included the ringleader of more than 4,600 rogue Internet pharmacy websites.

Then on July 15, 2005, the Attorney General of the State of Florida announced the State's largest prosecution of an organized filling Internet orders for controlled substances. These arrests in this operation resulted from an investigation involving a task force involving the DEA.

Then last April the DEA led Operation Cyber Chase which resulted in more than 20 arrests in eight U.S. cities and four foreign countries, shutting down an organization that ran over 200 websites illegally selling what were identified as controlled substances.

In September 2004, the Bureau of Customs and Border Protection implemented a national policy for processing controlled substances, Schedules III through V, imported through the mail and carrier facilities. Under this new policy, packages containing controlled substances in Schedules III through V are no longer transferred to FDA for disposition, released to the addressee, or returned to the sender. Instead, Customs can now hold these packages as unclaimed or abandoned property as an alternative to seizure. And, according to the GAO, Customs recently reported to this committee that a full year of this new policy resulted in over 72,000 interdictions, with almost all of the parcels abandoned and disposed.

Now we're also going to be looking at some ways to hopefully deal with this problem from a legislative standpoint or to make some suggestions; and we have identified several ideas worthy, though, of

consideration. First, the July 2005 National Center on Addiction and Substance Abuse report specifically recommended that Congress should clarify Federal law to prohibit sale or purchase of controlled prescription drugs on the Internet without an original copy of a prescription issued by a licensed DEA certified physician licensed in the state of purchase based on a physical examination and evaluation and to impose higher penalties for illegal sale to minors. That's one recommendation.

Congress should also, it has been suggested, consider increasing penalties for Schedule III drugs. We know that penalties are much more severe for I and II, and they seem to be having some impact there, so that's one thing that we could look at. But, more important, we want to explore everything to come up with the best solutions we can that are reasonable.

So I want to thank all the witnesses for being with us today and those members of the subcommittee as well; and now, at this time, I'd like to recognize our ranking member, my friend, Congressman Bart Stupak of Michigan.

[The prepared statement of Hon. Ed Whitfield follows:]

PREPARED STATEMENT OF THE HON. ED WHITFIELD, CHAIRMAN, SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS

Today's hearing focuses on strengthening the efforts to combat the sales of controlled substances over the Internet. What are these controlled substances of concern? Prescription drugs with wide appeal among drug abusers such as Percoset, Vicodin, and Darvon, anabolic steroids, and Valium.

We at this Committee have long been interested in and committed to protecting the safety of America's pharmaceutical supply. The Committee has played a key role in the enactment of the Prescription Drug Marketing Act in 1987, and the Bioterrorism Preparedness Act in 2002. To that end, this Subcommittee has held a number of hearings related to the safety of imported drugs over the last seven years. However, today's hearing focuses on a subset of imported drug concerns: the particular problem of controlled substances sold over the Internet by rogue pharmacies. Unfortunately, with the advent of the Internet in the last few years, obtaining controlled substances illicitly online has become too convenient. Most illicit Internet pharmacies offer controlled substances without valid prescriptions. Many of these sites substitute a simple online questionnaire for a face-to-face examination of the patient by a physician.

While the Government Accountability Office (GAO) recently found that there is no systematic collection of data on the volume of controlled substances encountered at mail and carrier facilities to establish an exact measurement, the federal authorities do not dispute that this volume is substantial and have undertaken actions to curb this problem. Available information documents a growing and serious public health priority justifying the actions already undertaken as well as other possible future actions. For example, according to the FDA/Customs blitz conducted in the summer of 2003 at the Miami, New York (JFK Airport), San Francisco, and Carson, CA international mail facilities, of the imported pharmaceutical product found, 28 percent of the drugs tested were controlled substances, representing over 25 different control substances. Based on the JFK estimate by senior Customs officials that 40,000 parcels containing drugs are imported through that airport on a daily basis, as many as 11,200 drug parcels containing controlled

substances are imported daily through JFK.

A February 2004 study by the National Center on Addiction and Substance Abuse in partnership with a private investigative firm documented the availability of controlled prescription drugs on the Internet. It is important to note that it is difficult to ascertain the exact number of these Internet pharmacies. Of the 495 websites offering Schedule II-V controlled prescription drugs identified in the study, only about a third (157) were "anchor" sites, where consumers actually purchase the drugs. 90% of these sites did not require a prescription. 47% of these sites disclosed that the drugs would be coming from outside the United States and 25% gave no indication where the drugs would be coming from. The remaining sixty-eight percent of the 495 total websites were portal sites. Portal sites do not sell drugs but act as a conduit to other websites, including anchor sites, which sell the drugs. The report also found that 73% of drugs offered on these websites were Schedule II and III controlled substances. Only 6% of the websites in the study required a prescription in order to purchase drugs. About half of the sites offered only an online "consultation," a practice that the American Medical Association has found not to meet appropriate standards of medical care.

Likewise, we will hear testimony from the GAO about its recent report that also documented the wide availability of highly addictive controlled substances over the Internet. And as the GAO notes in its report, both the Drug Enforcement Administration (DEA) and the Office of National Drug Control Policy (ONDCP) have found that the easy availability of controlled substances directly to consumers over the Internet has significant implications for public health, given the opportunities for misuse and abuse of these addictive drugs.

According to an article in the February 21, 2005 U.S. News and World Report, although prescription-drug abuse is rising among all age groups, law enforcement officials are especially concerned about abuse among teenagers: One in 10 high school seniors has tried the painkiller Vicodin without a prescription, and 1 in 20 has taken the potent pill OxyContin. For young people in particular, online pharmacies seem especially seductive. For this generation, the Internet is a familiar medium and it feels safe. Controlled substances are easily sold over the Internet by not attracting attention and looking legitimate. Postings skillfully blend these drugs with other apparently legal or "lifestyle" drugs. The seduction and convenience of the Internet coupled with the wide availability of controlled substances raises a disturbing prospect of many young people hooked on drugs with the ease of logging on to a computer.

The convenience and seductiveness of the Internet and the wide availability of controlled substances over the Internet has already had tragic consequences. On February 21, 2001, Ryan Haight died at the age of 18 of an overdose after mixing morphine and two prescription antidepressants with Hydrocodone, a potent and highly addictive painkiller that he bought from an Internet pharmacy in Oklahoma. Ryan was 17 and complaining of back and joint pain when he started ordering prescription painkillers from Internet pharmacies. On June 7, 2001, the parents of Todd Rode (pronounced RO-DEE) told this Subcommittee their heart-wrenching story of finding their son dead in his apartment. According to the medical examiner, Todd's death was caused by a massive overdose of controlled substances that Todd ordered from a foreign Internet pharmacy. Last year, DEA testified that its investigations have discovered 14 deaths or overdoses and 15 people who have entered treatment or sustained injuries from drugs obtained over the Internet.

Moreover, in the course of its oversight work, the Committee has become acquainted with ICG, Inc. of Princeton, New Jersey and its investigative work on Internet pharmacies. Last July, ICG provided a briefing I convened for the Subcommittee members. As a result of that briefing, I requested as a test of its investigative capabilities that ICG gather intelligence on a series of websites selling controlled substances identified by the Majority and Minority Committee staff. The results of that work as well

as other investigations of websites marketing controlled substances will be presented publicly for the first time at this hearing. This White Paper will provide more details for consideration in how to strengthen efforts to combat sales of controlled substances over the Internet. In addition, at the invitation of the Majority and Minority Committee staff, ICG last week briefed representatives from credit card companies, consignment carriers, and the Internet community. That meeting has already led to beneficial exchanges of information and may lead to constructive and proactive working relationships in the private sector.

While we note the growing problem of controlled substances over the Internet and consider additional new approaches to curb the sales of these products, we will also examine what the federal agencies have accomplished, especially during the last year.

For example, last September, the DEA announced a new "Virtual Enforcement Initiative," part of which included Operation CYBERx. That investigation led to the arrests of 17 people who operated rogue Internet pharmacies that took orders for controlled substances over the Internet and then shipped these products to U.S. citizens without a valid prescription. Those arrested included the ringleaders of more than 4,600 rogue Internet pharmacy websites. On July 15, 2005, the Attorney General of the State of Florida announced the state's largest prosecution of an organization filling Internet order for controlled substances. These arrests in this operation resulted from an investigation involving a collaborative task force involving the DEA. Last April, the DEA led Operation Cyber Chase, which resulted in more than 20 arrests in eight U.S. cities and four foreign countries, shutting down an organization that ran over 200 web sites illegally selling what were identified as controlled substances such as Ritalin, Xanax, and Valium.

In September 2004, the Bureau of Customs and Border Protection ('Customs") implemented a national policy for processing controlled substances, schedule III through V, imported through the mail and carrier facilities. Under this new policy, packages containing controlled substances in schedules III through V are no longer transferred to FDA for disposition , released to the addressee, or returned to the sender. Instead, Customs can now hold these packages as unclaimed or abandoned property as an alternative to seizure. According to the GAO, Customs reported that the recent policy improved their ability to quickly process the volume of this category of packages. Customs recently reported to this Committee that a full year of this new policy resulted in over 72,000 interdictions, with almost all of these parcels abandoned and disposed, and only 120 individuals electing to pursue a formal seizure proceeding. As the GAO noted, with Customs implementing this new policy, a more reliable and systematic approach to data gathering could result by using information collected by Customs and FDA at various field locations, including the number of packages deemed abandoned by CBP. Finally, the GAO notes that working groups of a federal interagency task force are working cooperatively with the carriers, credit card companies, and Internet businesses to develop more policy solutions relevant to the imported controlled substances problem.

I personally have been very interested in the safety of imported drugs, and in particular, the problem of controlled substances. The people in my homestate of Kentucky have been significantly harmed by prescription drug abuse, including the misuse of controlled drugs containing hydrocodone. In light of this concern, I am pleased to say that the State of Kentucky recently enacted a new law this year, and effective this past June, that law makes it illegal to ship a prescription drug to a pharmacy or a pharmacist not registered with the Kentucky State Board of Pharmacy. As a result of this law, under the auspices of the Kentucky Bureau of Investigation, UPS and FedEx have worked successfully to intercept illegal shipments. I realize the issue under examination today is a national problem concerning a global threat of controlled substances sold over the Internet. I am not suggesting that the Kentucky law is instructive as a particular policy solution to controlled substances over the Internet. But the positive developments in Kentucky remind me of what America can accomplish in solving a problem when we

are all united, focused, and supportive of efforts to combat a prescription drug abuse problem.

I believe this is a crucial time for the U.S. Congress to send a unified, bipartisan, unmistakable message about stopping the illicit sales of controlled substances over the Internet. That clear, unified message will have a tremendous impact in providing further support to the Executive Branch and the private sector to intensify the focus of the laser beam against illicit sales of controlled substances over the Internet.

Already, in preparing for this hearing, I can identify several ideas worthy of legislative consideration in addressing this issue. First, the July 2005 National Center on Addiction and Substance Abuse report specifically recommended that Congress should clarify federal law to prohibit sale or purchase of controlled prescription drugs on the Internet without an original copy of a prescription issued by a licensed, DEA-certified physician, licensed in the state of purchase, based on a physical examination and evaluation, and to impose higher penalties for illegal sale to minors. That is a recommendation that I will explore at this hearing. Second, Congress should consider increasing penalties for Schedule III drugs. Why is it that there do not appear to be websites explicitly marketing heroin or cocaine? There may be several reasons, but one factor may be the harsher penalties. The penalties for crimes involving Schedule III drugs are substantially less than for those in Schedules I and II. We should consider increasing penalties for Schedule III drugs illicitly marketed over the Internet. Third, we should consider extending the coverage of forfeiture authority for Customs from not just Schedule I and II drugs but also to Schedule III drugs. Information and testimony gained today may help determine whether Congress pursues these proposals, and other measures. I invite Congressman Stupak, the Ranking Member, to join with me as a bipartisan team to spearhead Congressional action on this front.

I am hopeful that today we will learn much more about the nature of the problem, the actions taken to combat it, and what actions could be taken to help aid the effort, including legislation. I thank all of the witnesses for testifying today and look forward to their testimony. I now recognize my friend, Congressman Bart Stupak, the Ranking Member, for his opening statement.

MR. STUPAK. Mr. Chairman, before I start, I'd like to make special mention this will be the last hearing a good friend to this committee, Ms. Dot Riley, will be participating in. Dot retires on the 30th of this month and has served the Federal government at Customs for more than two decades. She's been a friend to this committee and helped us on a broad range of very important Homeland Security matters.

Dot, I realize that working with this subcommittee has often been on the enjoyment scale of a root canal, but we'll sorely miss you and thank you for all the work you have done for us.

Mr. Chairman, if I may, I would like to revise and extend my opening statement and submit supporting documents. I also ask that members who are not present at this time be allowed to submit their opening statements with exhibits.

MR. WHITFIELD. So ordered.

MR. STUPAK. Thank you, Mr. Chairman.

Mr. Chairman, by my count this will be the fifth hearing this subcommittee has had on the issue of dangerous drugs entering the United States via the mail facilities and express consignment carriers and

how the Internet drives much of that traffic. While today's hearing is on the aspect of dangerous controlled substance being sold on the Internet, as opposed to prescription drugs generally, if you examine those earlier hearing transcripts you will fine nothing but promises and assurances from many of the witnesses today about how they're working to eradicate this problem. Unfortunately, what we will hear again today is virtually the same thing we hear every year on this matter, which is that nobody is really in charge, that the problem is only getting worse, and that the steps everybody is taking appear not to be working.

Sad to say, Mr. Chairman, I do not believe we're any closer to solving this problem now than we were a half decade ago when myself, Mr. Dingell, and Mr. Klink wrote the very first Internet pharmacy bill. Then there were only 25 active sites selling drugs on the Internet. Those seemed to be offering Propecia, Xanacal, and Viagra. Almost no sites could be found offering the dangerous controlled substances that we are seeing entering the U.S. such as those depicted in the posters taken last year by Senate staff at the JFK mail facility or our staff at the Miami facility.

Since our first hearing on this matter, we have only watched the volume of dangerous drugs explode. Indeed, the record of these earlier hearings regarding Internet drugs, including controlled substances, are replete with promises from DEA, Customs, and FDA about how they're putting together a special interagency task force or how they're working closely with shippers and credit card companies to eradicate this problem, yet today there appears to be little new data to guide us on what policies are most effective, nor are there any new approaches to tackling this problem.

DEA, like they were years ago, is working off an ineffective model of attempting to put people in jail, as opposed to rapidly frustrating the ability for rogue sites to do business. While it's admirable to bring prosecutions, the fact is that those behind these sites proliferate much quicker than DEA can bring such actions. Indeed, DEA's formal approach takes months if not years of efforts to shut down a rogue Internet site. By the time one is removed, many others are allowed to open for business. The trend of new rogue sites selling controlled substances is heading upwards. Today, hundreds of sites are selling or offering to sell controlled substances to almost anybody without a prescription, and there appears nothing on the horizon to reverse that trend.

The credit card companies and shippers will testify again today that they, too, are aggressively working on shutting down or decoupling their services from these dangerous sites. Nevertheless, what is known is exactly what impact -- what is not known, I should say, is exactly what

impact, if any, this is having on the problem, whether this activity is being coordinated with other formal activities or how many stand-alone sites have been permanently blocked from doing business.

In correspondence to Mr. Dingell, DEA has told us that they are working aggressively with shippers and credit card companies, but we have no idea what such an effort really entails nor what is being accomplished. In fact, we will hear from GAO controlled substances continue to enter the United States through mail facilities and express consignment carriers and the problem appears to be getting worse. Moreover, as GAO will tell us, the approach to this problem by key agencies is still uncoordinated and ineffective.

Why, Mr. Chairman? Countless letters have been sent by members of this committee to key agencies responsible for prosecuting this mess for years. Here is a group I have over the last two years. What we appear to be doing is spinning our wheels on the same patch of mud year after year.

I'm particularly disappointed the administration has not taken a more proactive and aggressive approach to address this public health crisis by asking for new tools from Congress, particularly given now that prescription drugs are abused at even a greater rate than Schedule I drugs. In fact, earlier this year Mr. Dingell and I sent a letter to Secretary Levitt that once again lists the many concerns we have with imported pharmaceuticals.

This is what the letter said in part. It was a July 20, 2005 -- we've pointed out repeatedly that significant amounts of controlled substances are now entering the United States from foreign sources. Recently, a report by the National Center on Addiction and Substance Abuse at Columbia University noted that Americans are now abusing prescription drugs more than cocaine, hallucinogens, inhalants, and heroin combined. That report also found that the abuse rate of prescription drugs by teenagers has increased substantially in just the past decade. One reason cited for the recent increase in abuse rates is the easy access of prescription drugs purchased through the Internet. Our investigation has repeatedly demonstrated the ease at which foreign purchased prescription drugs can enter the United States with the click of a mouse, and anybody who has visited an international U.S. mail facility would understand that the Internet is a source of many of these drugs.

Mr. Chairman, even though HHS has neither responded to this letter of July nor asked for any new authorities from Congress to allow them to more effectively target this problem, I would nonetheless like to place this correspondence in the record. It's just one more example that we're serious about solving this dangerous and growing threat to public health and we continue to remind key agencies of our concerns.

So I move for admission of these documents, Mr. Chairman.

MR. WHITFIELD. Without objection.

MR. STUPAK. Thank you.

[The information follows:]

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DAN R. BROUILLETTE, STAFF DIRECTOR

October 20, 2003

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Commissioner
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Alexandria, Virginia 22301

Dear Commissioners Bonner and McClellan and Administrator Tandy:

For the past fifteen years, we have been actively investigating a range of issues related to the sale and distribution of prescription drugs entering the United States from foreign sources. As part of this effort, we have directed Committee staff to visit various border crossings and international mail-branch facilities (including major consignment carriers) to investigate what types of drugs are entering the U.S. and in what volume.

We are troubled by the amount of controlled substances that now routinely enter the U.S. via the international mail-branch facilities, and through various consignment carriers. Recent information from the National Institute on Drug Abuse (NIDA) suggests that the abuse of prescription drugs -- in particular scheduled drugs -- has increased dramatically in the past half-decade. According to NIDA, this continues to be a major public health challenge today. More recently, news surrounding talk show host Rush Limbaugh's addiction to pain killers underscores that this is a serious problem.

We have long believed the increase in prescription drug abuse is attributable in part to the ease of access created by the Internet. And today's excellent article in The Washington Post reaffirms the connection. A simple search of websites will show numerous sites offering a range of scheduled drugs, many offering a choice between the U.S. mail, or express delivery, such as Federal Express or United Parcel Service. With the mere click of a mouse, consumers can now access a vast array of scheduled drugs, and in sizable quantities. Many websites offer these powerful drugs without regard to the patient's need, or even require a prescription. Such sites have replaced the corner street dealer, and potentially place a seller in every household having a computer connected to the Internet.

That unregulated prescription drugs (including controlled substances) are entering the U.S. through numerous mail-branch facilities in vast quantities has been well documented by staff in the past decade. In one recent visit to the Miami international mail-branch facility, for example, staff was told by officials of the Bureau of Customs and Border Protection (Customs) that approximately 30,000 shipments of prescription drugs enter that facility each day. Most of these drugs are routinely passed to the public without scrutiny. Yet in general, of the shipments that are entering these facilities, an alarming amount now appear to be scheduled drugs.

For example, when staff visited the Miami facility in March 2003, two massive bins containing hundreds and perhaps thousands of individual shipments of diazepam, purportedly from Central America, were being detained by Customs (please see attached photos; a full report is on the Minority website). On a subsequent visit to that facility additional bins containing approximately 5,000 individual shipments of what purportedly were also diazepam were observed.

The entry of drugs such as these have been witnessed by staff at these facilities for years. Yet there are a number of troubling aspects regarding the way key federal agencies are addressing the problem. For example, at the Miami facility, staff was told by Food and Drug Administration (FDA) officials that they instruct Customs to examine and detain only "large" parcels that appear to contain drugs. This raises the obvious question about how it is that Customs and FDA know what kinds of drugs are contained in the smaller parcels that routinely go out the door. FDA's instructions at this facility (and others) are not well defined.

Another troubling aspect of this problem involves Customs' detention procedures. At various mail facilities visited by staff (including New York, Los Angeles, Oakland, and Miami), staff has been told that it takes approximately 30 minutes to "process" a single shipment containing a controlled substance. Given that hundreds and perhaps thousands of parcels are entering these facilities each week, it remains unclear how Customs has the manpower to dispose of these drugs.

Consider for example the approximately 5,000 shipments of diazepam mentioned above. A single inspector working full-time to process these shipments must spend more than a year to accomplish this task. Yet, while this processing occurs, additional new shipments arrive, compounding the workload. Therefore, while Customs clearly appears capable of intercepting a reasonable percentage of controlled substances entering these facilities, the internal procedures that must be followed to "dispose" of such shipments appear out of sync with reality.

Another concern is the role the Drug Enforcement Agency (DEA) is playing regarding controlled substances being sold on the Internet. During the most recent visit to the Miami facility, staff learned that DEA was rarely present at this facility to investigate the kinds of entries witnessed (despite the fact that this facility appears to be a major entry point for scheduled drugs). Because the volume of scheduled drugs entering the U.S. through the mail-branch facilities and consignment carriers is growing, DEA's present efforts to coordinate with Customs and FDA to address this threat appear lacking. More resources and better coordination appear essential if meaningful progress is to be realized.

The ease of entry of controlled substances through these facilities is understood and well documented. Nonetheless, it is unclear whether DEA, Customs, or FDA has a sufficient, coordinated plan to address this threat. Because the jurisdiction of this matter is shared by all three agencies, and because each should be actively involved in protecting the public from this growing scourge, we are requesting that you coordinate amongst yourselves to address the following:

1. Do Customs, DEA, and FDA have an estimate of the quantity of controlled substances that are now entering the U.S. each month via (1) the U.S. mail facilities and (2) the major consignment carriers? If so, please provide those statistics. If not, please explain why such statistics are not gathered.

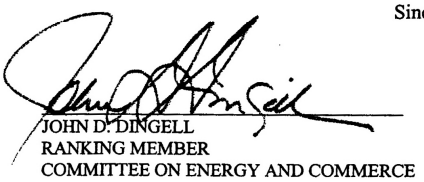
2. Do DEA, FDA, and Customs have a coordinated comprehensive written plan to address what is clearly a growing threat to the public health? If so, please provide that plan. If not, please explain why no such plan exists or whether such a plan is being prepared.

3. Does Customs have the ability to change its internal "processing" procedures with respect to personal (or small) shipments of controlled substances (Schedules II - V) entering the U.S. via the U.S. mail, and the major consignment carriers? Is it planning to do so? Also, please also provide (1) the approximate number of man-hours expended each year at each of the 13 mail facilities to process controlled substances, and (2) the average time it takes an inspector to process a single package containing a controlled substance?

4. What specific plans do DEA, FDA, and Customs have to coordinate and address the problem of the many Internet sites that purportedly appear to be both advertising and shipping illegal controlled substances into the U.S. via Federal Express, United Parcel Service (and all other relevant consignment carriers)?

Thank you very much for your assistance in addressing this extremely important public health matter. If you have any questions about this request, please contact us or have your staff contact Christopher Knauer of the Committee on Energy and Commerce Democratic staff at (202) 226-3400.

Sincerely,



JOHN D. DINGELL
RANKING MEMBER
COMMITTEE ON ENERGY AND COMMERCE

PETER DEUTSCH
RANKING MEMBER
SUBCOMMITTEE ON OVERSIGHT
AND INVESTIGATIONS

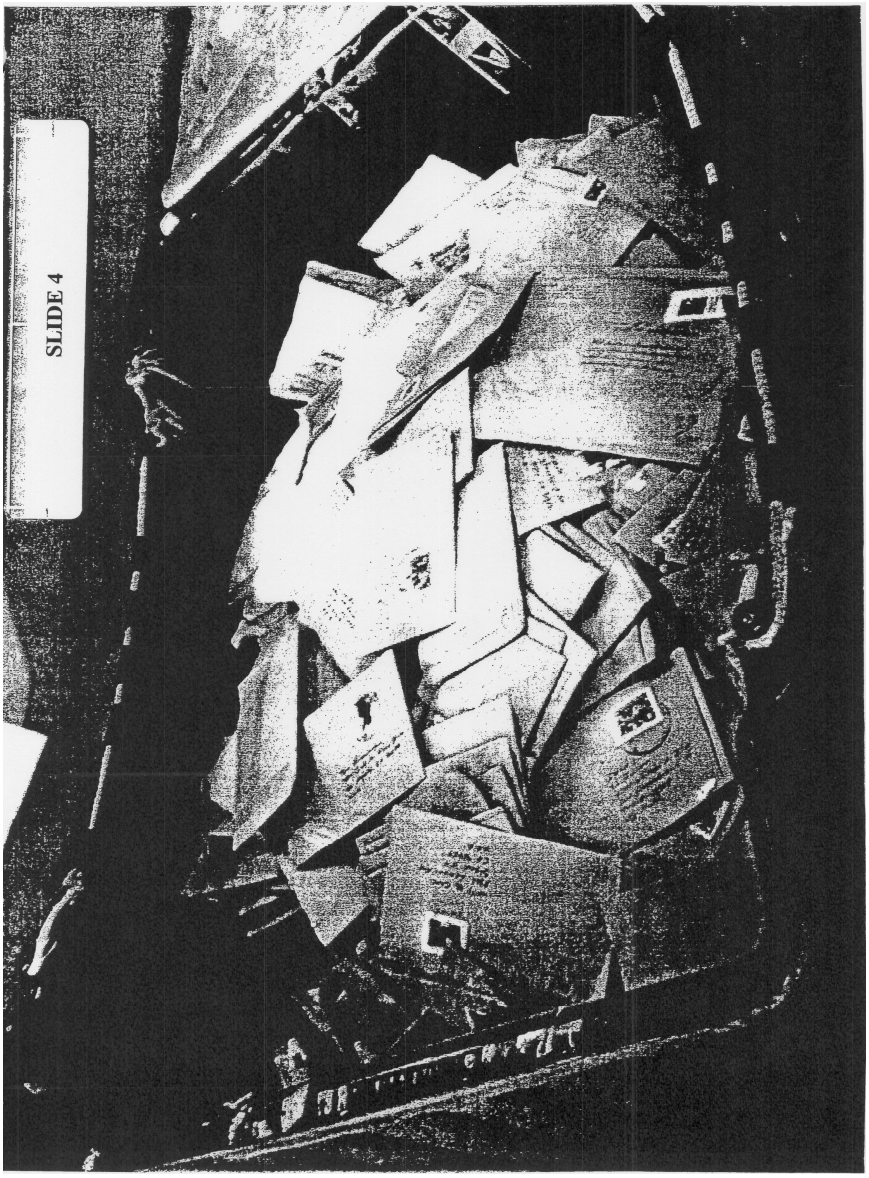
cc: The Honorable W. J. "Billy" Tauzin, Chairman
Committee on Energy and Commerce

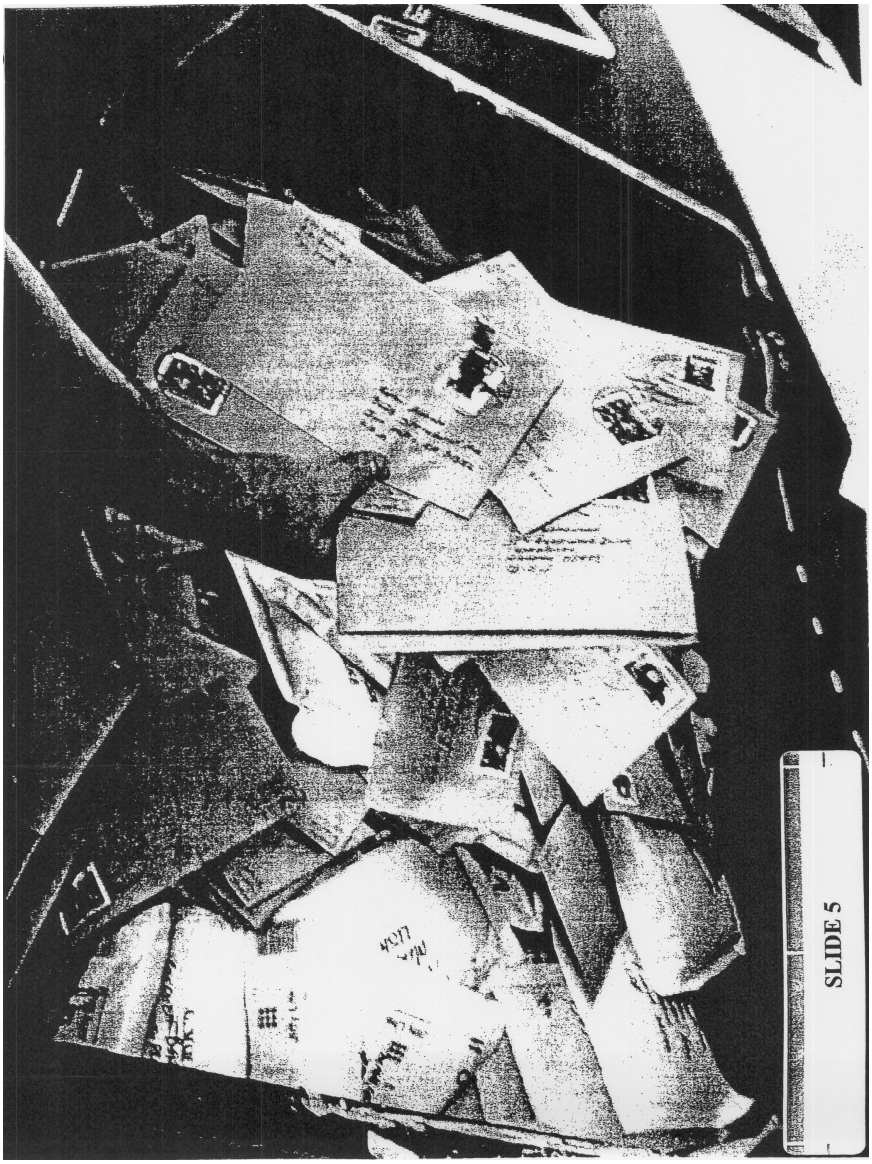
The Honorable James C. Greenwood, Chairman
Subcommittee on Oversight and Investigations

The Honorable Tommy G. Thompson, Secretary
Department of Health and Human Services

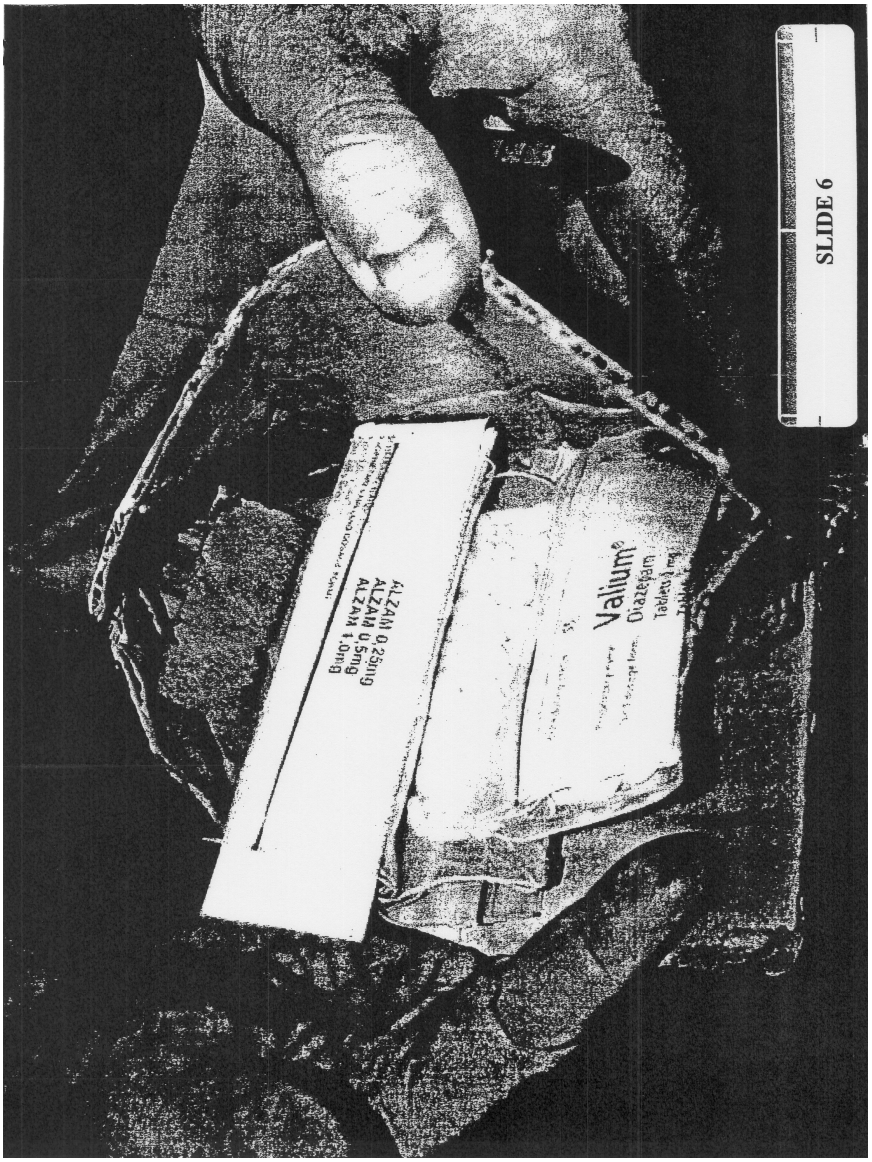
Nora D. Volkow, M.D., Director
National Institute of Drug Abuse

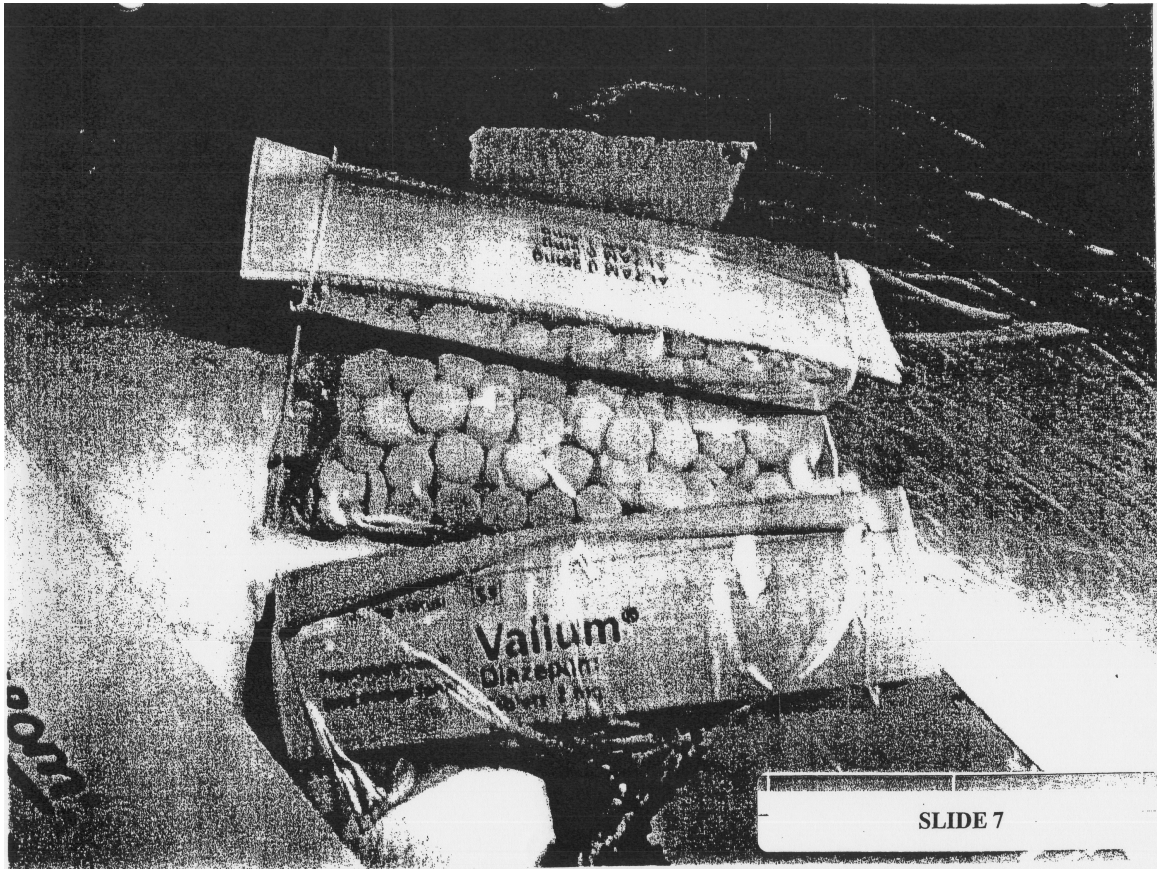
Mr. John P. Walters, Director
Office of National Drug Control Policy


SLIDE 4



SLIDE 5


ALZAM 0.25mg
ALZAM 0.5mg
ALZAM 1.0mg
Valium®
Diazepam
SLIDE 6



SLIDE 7

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JOE BARTON, TEXAS
FRED UPTON, MICHIGAN
CLIFF STEARNS, FLORIDA
PAUL E. GILLMOR, OHIO
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ONE HUNDRED EIGHTH CONGRESS

U.S. House of Representatives
Committee on Energy and Commerce
Washington, DC 20515–6115

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DAN R. BROUILLETTE, STAFF DIRECTOR

November 13, 2003

The Honorable David M. Walker
Comptroller General
U.S. General Accounting Office
441 G Street, N.W.
Washington, D.C. 20548

Dear Mr. Walker:

Recently, The Washington Post published a compelling series of excellent articles outlining the continuing degradation of the prescription drug supply in the United States. These articles covered many issues that I have been concerned about for almost twenty years. One more recent issue in particular concerns the ever-increasing sale of dangerous drugs via the Internet. Numerous hearings held by the Committee on Energy and Commerce, and many letters sent to key federal agencies responsible for regulating this activity, including the Food and Drug Administration (FDA), the Bureau of Customs and Border Protection (Customs), the Drug Enforcement Agency (DEA), and the Department of Health and Human Services (HHS), have not led to sufficient action.

Unapproved, misbranded, counterfeit, and adulterated prescription drugs from across the globe continue to flood unabatedly into the United States at staggering (and increasing) rates, through U.S. mail facilities and major consignment carriers (whose services are directly advertised on a number of drug websites). Nonetheless, key federal agencies remain in a state of regulatory paralysis even as FDA claims to be moving aggressively. The system now used by FDA and Customs to review, process, and detain the multitude of dangerous drugs now entering the U.S. daily has essentially collapsed.

A cursory search of drug websites today will show that hundreds are offering a range of inherently dangerous drugs such as Accutane, fentermine, ciprofloxin, and a host of controlled substances. With the click of a mouse, consumers (including children) can now have a wide range of drugs delivered to their door with no regulatory scrutiny. Many sites offer these drugs without regard to patient need, without requiring a prescription, or without providing any doctor or pharmacist supervision in their use. With near certainty, most drugs ordered this way will be delivered. The chances that a shipment will be stopped, examined, and detained are slight.

Committee staff has documented substantial amounts of unregulated prescription drugs entering the U.S. via these channels in vast quantities. In a recent visit to the Miami international mail-branch facility, for example, staff was told by Customs inspectors that approximately 30,000 shipments of prescription drugs are entering that facility each day. The vast majority of these drugs are routinely passed to the public with no review from FDA, DEA, or any other regulatory agency, nor is there any proof that a doctor or pharmacist will supervise their use.

Many of the dangerous drugs entering are scheduled drugs. In the most recent visit to the Miami facility, for example, staff witnessed several bins containing thousands of shipments of diazepam. According to Customs officials interviewed by staff, this and other branch facilities routinely find controlled substances, and in ever-increasing numbers.

There are a number of troubling aspects regarding the way key federal agencies are addressing the problem. At the Miami facility, staff was told by FDA officials that they instruct Customs to examine and detain only "large" parcels that appear to contain drugs. Yet FDA field staff had no definition of what a large package was, nor was it clear why the smaller packages were somehow viewed as safe as they routinely left the facility with no examination. Moreover, because FDA's detention process now takes approximately two hours to detain even a single package, it is unrealistic to believe this system has any material application as thousands of shipments are entering this (and other) facilities each day. FDA's instructions and processing procedures have become meaningless in the field. They are vague, devoid of reality, and cannot be expected to serve as a regulatory tool of any consequence.

Another troubling aspect of this problem involves Customs' detention procedures for controlled substances. At various mail facilities visited by staff (including New York, Los Angeles, Oakland, and Miami), staff has been told that it requires approximately 30 minutes to "process" a single shipment containing a controlled substance. Given that hundreds and perhaps thousands of parcels containing controlled substances are entering these facilities each week, it remains unclear how Customs has the manpower to dispose of these drugs. Consider the example of the thousands of shipments of diazepam Committee staff witnessed that had entered the Miami mail facility. A single inspector working full-time to process these shipments must spend more than a year to accomplish this task. Yet, while this processing occurs, additional new shipments arrive, compounding the workload. Therefore, while Customs clearly appears capable of intercepting a reasonable percentage of controlled substances entering these facilities, the internal procedures that must be followed to "dispose" of such shipments appear unrealistic.

DEA's role regarding controlled substances being sold on the Internet is also worrisome. During the most recent visit to the Miami facility, staff learned that DEA was rarely present at this facility to investigate the kinds of entries witnessed (despite the fact that this facility appears to be a major entry point for scheduled drugs). Because the volume of scheduled drugs entering the U.S. through the mail-branch facilities and consignment carriers is growing, DEA's present efforts to coordinate with Customs and FDA to address this threat appear lacking. More resources and better coordination appear essential if meaningful progress is to be realized.

The ease of entry of dangerous drugs -- including controlled substances -- through these facilities is understood and well documented. Nonetheless, it is unclear whether the agencies responsible for this matter have a sufficient, coordinated plan to address this threat. Therefore, I am requesting that GAO conduct a review of existing laws, regulations, and procedures related to this matter to assess how effective these agencies are in dealing with this growing threat. Specifically, I request that you address the following questions:

1. Do DEA, FDA, and Customs have a coordinated comprehensive written plan to address what is clearly a growing threat to the public health? If so, please describe and assess that plan. If not, please explain why no such plan exists, and whether such a plan is being prepared.

2. Does Customs have the ability to change its internal "processing" procedures with respect to personal (or small) shipments of controlled substances (Schedules II - V) entering the U.S. via the U.S. mail, and the major consignment carriers? Is it planning to do so? Also, please describe (1) the approximate number of man-hours expended each year at each of the 13 mail facilities to process controlled substances; and (2) the average time it takes a Customs inspector to process a single package containing a controlled substance.

3. Does FDA have the ability to change its internal "processing" procedures with respect to personal (or small) shipments of non-scheduled prescription drugs to allow the system to become more efficient? If so, is it planning to do so? Also, please describe (1) the approximate number of man-hours expended each year at each of the 13 mail facilities to process non-controlled prescription drugs; and (2) the average time it takes a FDA inspector to process a single package containing a controlled substance.

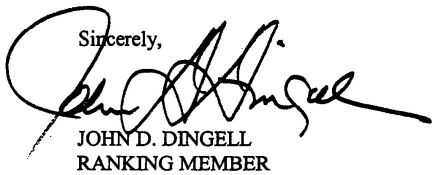
4. How rapidly is the quantity of unregulated dangerous drugs entering the U.S. via mail, and mail-related channels, growing? Do Customs, DEA, and FDA have estimates of the quantity of prescription drugs that are now entering the U.S. each month via (1) the U.S. mail facilities and (2) the major consignment carriers? Are they collecting meaningful data on this problem, and if so, in what form? If not, why are such statistics not gathered?

5. Do DEA, FDA, and Customs need to coordinate to address the problem of the many Internet sites that purportedly appear to be both advertising and shipping illegal controlled substances into the U.S. via Federal Express, United Parcel Service, and all other relevant consignment carriers?

6. What role do the major credit card companies (such as Visa and Master Charge) and underwriting banks play in selling dangerous drugs – such as controlled substances – via the Internet? Are they self-policing the websites to which they are offering their services? If not, should they be required to do so?

Thank you for your assistance in addressing this extremely important public health matter. If you have any questions about this request, please contact me or have your staff contact Christopher Knauer of the Committee on Energy and Commerce Democratic staff at (202) 226-3400.

Sincerely,



JOHN D. DINGELL
RANKING MEMBER

cc: The Honorable W. J. "Billy" Tauzin, Chairman
Committee on Energy and Commerce

The Honorable James C. Greenwood, Chairman
Subcommittee on Oversight and Investigations

The Honorable Peter Deutsch, Ranking Member
Subcommittee on Oversight and Investigations

The Honorable Tommy G. Thompson, Secretary
Department of Health and Human Services

The Honorable Karen Tandy, Administrator
Drug Enforcement Agency

The Honorable Robert C. Bonner, Commissioner
United States Customs Service

Mark B. McClellan, M.D., Commissioner
Food and Drug Administration

Nora D. Volkow, M.D., Director
National Institute of Drug Abuse

Mr. John P. Walters, Director
Office of National Drug Control Policy

Congress of the United States
House of Representatives
Washington, DC 20515

February 24, 2004

The Honorable Karen Tandy
Administrator
U.S. Drug Enforcement Administration
2401 Jefferson Davis Highway
Alexandria, Virginia 22301

Dear Administrator Tandy:

As you know, the Committee on Energy and Commerce has been investigating the illegal sale and distribution of controlled substances purchased through the Internet. These drugs are often sent via U.S. mail or through consignment carriers (such as the United Parcel Service and Federal Express) and involve the use of major credit cards (such as Visa and MasterCard). Over the years, letters have been sent to your agency and others detailing the growing severity of this problem, and the lack of progress in stemming it. This matter has also been the subject of numerous Congressional hearings and press accounts. I believe that the Drug Enforcement Administration (DEA) can take prompt action to address one aspect related to these illegal sales: the fact that legitimate businesses are involuntarily facilitating these transactions.

Over the past several weeks, staff have met with officials from Federal Express, UPS, MasterCard, and Visa to discuss this problem. On all occasions, officials from each of these companies emphatically underscored their disdain for this illegal behavior. Moreover, each said that they have had (and continue to have) discussions with DEA to offer assistance, which they believe would be significant, in terminating this activity.

In a recent conversation with officials from one major credit card company, for example, Committee staff was told that any purchase made via a website using its services would allow it to locate both the merchant bank, and other detailed information on the seller. Moreover, at a minimum, this company suggested that it could quickly terminate the relationship with any vendor if such activities are illegal. I believe that such action would greatly frustrate this type of dangerous activity. This would require that DEA conduct "buys" of the product from these websites so that the merchants and underwriting banks connected to this activity could be traced. Because purchasing a controlled substance through the mail from a foreign location is illegal under current U.S. law, it is even possible that minimal or no expenses would be incurred by the Federal Government if using a major credit card, because the charges could technically be reversed.

The Honorable Karen Tandy
Page 2

Similar offers of assistance have apparently been made by officials from each of the companies named in this letter. Given what appear to be substantive offers of cooperation from the principal credit card companies and shippers in this public health matter, it remains unclear what steps DEA is taking to aggressively attack this problem. Perhaps even more troubling is that these companies are limited by law in taking action on their own. Each company told staff that, according to DEA, they would not be allowed to conduct their own Internet purchases in order to self-police their credit card networks or shipping routes.

It is clear that action by DEA is critical to solving the growing health threat of illegal Internet purchases of scheduled drugs. I therefore request a detailed briefing for staff by senior DEA officials to discuss how it plans to confront this growing health threat and also how it will use the many offers of services available. I ask that your staff contact Christopher Knauer of the Committee on Energy and Commerce Democratic staff at (202) 226-3400 at your earliest possible convenience to schedule this briefing.

Sincerely,

JOHN D. DINGELL
RANKING MEMBER
COMMITTEE ON ENERGY AND COMMERCE

cc: The Honorable James C. Greenwood, Chairman
Subcommittee on Oversight and Investigations

The Honorable Peter Deutsch, Ranking Member
Subcommittee on Oversight and Investigations

The Honorable Tommy G. Thompson, Secretary
Department of Health and Human Services

Mark B. McClellan, M.D., Commissioner
Food and Drug Administration

The Honorable Robert C. Bonner, Commissioner
United States Customs Service

Nora D. Volkow, M.D., Director
National Institute of Drug Abuse

Mr. John P. Walters, Director
Office of National Drug Control Policy

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BUD ALBRIGHT, STAFF DIRECTOR

ONE HUNDRED EIGHTH CONGRESS

U.S. House of Representatives
Committee on Energy and Commerce
Washington, DC 20515–6115

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CHARLES A. GONZALEZ, TEXAS

May 5, 2004

The Honorable Karen Tandy
Administrator
Drug Enforcement Administration
2401 Jefferson Davis Highway
Alexandria, Virginia 22301

Dear Administrator Tandy:

I am writing to you because of the failure of the Drug Enforcement Administration (DEA) to address adequately the continuing and increasing problem posed by the thousands of illegal controlled substances now entering the United States each day through the consignment carriers and the many international mail branch facilities. Both the scale and the diversity of controlled substances now entering the U.S. through various mail systems have grown exponentially over the last five years.

The issue of controlled substances entering the U.S. via the consignment carriers and international mail facilities has been a concern of mine for years. Moreover, it has also been the subject of numerous hearings held before the Committee on Energy and Commerce (at which DEA, Customs, and FDA have all provided testimony). To this latter point, I am attaching a copy of the relevant pages of a hearing held July 30, 1999, before the Subcommittee on Oversight and Investigations of this Committee. These passages are important because they represent the testimony of FDA and the Department of Justice regarding their plan to address this problem almost five years ago.

The central themes of this previous plan, however, appear largely identical to the proposals now being discussed by your agency, as evident in a recent briefing given to Committee staff by senior DEA and Department of Justice officials. The individuals at that briefing told staff of a "strategic plan" to have a functioning "webcrawler" and the formation of a new interagency "task force" to coordinate how to best approach this issue. Yet this "new" task force (made up of the very agencies that have been involved in previous task forces on this matter -- namely FDA, Customs, and DEA) appears strikingly similar to the task force of the late 1990s.

Moreover, according to your senior staff, this new task force is to develop strategies for the use of information gleaned from the new webcrawler to then shut down foreign rogue sites and offending shippers. But the formation of a special webcrawler was the centerpiece of the strategic plan of 1999, and that earlier task force and the earlier webcrawler failed to make a dent in this problem. And DEA officials at this latest briefing were not even aware that an earlier webcrawler had been developed and deployed by FDA.

DEA lawyers and operational managers at the briefing offered the same tactics and procedures that have so far proved completely ineffective in dealing with this matter. Those tactics are based largely on the traditional narcotics enforcement model which, unfortunately, appears to have little realistic application to the problem of individual imports of schedules II-V drugs ordered over the Internet, which are often comprised of relatively small shipments going to individuals. DEA officials informed staff that upon the identification of these foreign traffickers, DEA field offices (in the counties from where drugs were sent) would be supplied this information and then asked to procure the assistance of foreign governments to halt such shipments (and then presumably apply whatever criminal sanctions were available under the foreign law). When asked how often this model has, over the past five years, resulted in shutting down illegal websites and shippers sending drugs to the U.S., no estimates could be obtained from DEA. To my recollection, in the past five years, this approach has only resulted in shutting down a single website (after substantial work with the government of Thailand). Of course, hundreds of websites are currently offering dangerous drugs for sale to U.S. residents. Given the time involved in shutting down this single site, it is unrealistic to expect this model to have any measurable impact on the broader problem.

Some apparently believe this ineffectual model must be followed in order to avoid contaminating potential criminal prosecutions or compromising the rights of the traffickers. There might be some justification for this position regarding domestic internet sites operated by U.S. citizens. It is clear, however, that regardless of the effectiveness of the new webcrawler, this model will result in few (if any) criminal prosecutions of foreigners involved in foreign websites. Nonetheless, the DEA apparently refuses to consider alternative means of stopping these shipments.

On February 24, 2004, I sent you a letter which described a potential solution to this burgeoning problem. DEA was informed that at least one, and probably all, major credit card companies and at least one, and probably all, major consignment carriers were prepared to work with the DEA to cut off the credit and the shipping rights of anyone using their cards or shipping services to traffic controlled substances into the United States. Because such imports are illegal, several of these firms were told by your agency that they were not permitted to make the "buys" necessary to identify which of their customers are violating U.S. law. Our discussions, however, have produced assurances that these private sector firms would act unilaterally and quickly deny the banking services necessary to facilitate these shipments. This would require that DEA conduct the necessary foreign "buys" so that the scofflaw sites could be identified, something I see no evidence DEA is doing.

Because these offers of private sector assistance were made to Congressional staff, it would appear that DEA would have little trouble working out an acceptable program that would at least assure a substantial dent in this form of drug dealing. Not only could some Internet sites be shut down quickly, but the increase in uncertainty of receiving the ordered contraband from any Internet site would presumably deter adolescents and other U.S. customers of these drugs from placing orders at all. While your agency provided some vague concerns about various court rulings on this matter, neither DEA nor the DOJ staff provided any formal analysis or opinion as to whether this was feasible.

DEA, of course, is only part of the problem. Customs has failed to modernize its regulations dealing with an important administrative roadblock caused by the sheer volume of these illegal imports. Specifically, Customs requires a strict accounting of the receipt and disposition of all imports that violate the Controlled Substances Act. This would appear appropriate as a means of assuring that these dangerous but valuable street drugs do not get lost or stolen in the interdiction and destruction process. This is arguably necessary when dealing with tons of marijuana, and kilos of cocaine, but dangerously inefficient in the processing of thousands of relatively smaller shipments of schedules II-V substances. For example, Customs field officials have repeatedly told staff that they spend between 30 minutes to more than an hour to seize (e.g., process paperwork) a single shipment of a controlled substance that arrives in a mail facility. When hundreds if not thousands of shipments may arrive weekly, this is clearly untenable. Customs has undoubtedly been informed of these inefficiencies from its inspectors at the international mail facilities. Additionally, Customs officials have been informed in private briefings, and public hearings, of our concerns for at least the past four years. Clearly, some provision must be made to deal with bulk-drug custody (and accounting) and subsequent destruction. But, to my knowledge, this critical bottleneck has not been alleviated, nor has DEA exerted any leadership or initiative to rectify this failure.

In conclusion, I remain highly skeptical that a new webcrawler, a new task force, working closely with foreign countries to seek criminal prosecutions of offending shippers, and sending cease and desist letters -- tactics which have all been tried in the past -- will help significantly. New approaches are clearly needed. Moreover, until FDA deploys more inspectors at the mail facilities (which it has not asked for) and DEA, Customs, and FDA obtain the tools they need to rapidly seize and destroy the illegal and dangerous substances entering these facilities (which will require new legislation, yet to be proposed), the flood of illegal controlled substances will only worsen.

Please reexamine the adequacy and effectiveness of your agency's policies and procedures. As part of that review, please respond to the following questions:

1. Does DEA have a coordinated comprehensive written plan to address what is clearly a growing threat to the public health? If so, please provide that plan. If not, please explain why no such plan exists and/or whether such a plan is being prepared.

2. Has DEA determined whether Customs has the ability to change its internal "processing" procedures with respect to personal (or small) shipments of controlled substances (Schedules II-V) entering the U.S. via the U.S. mail, and the major consignment carriers? Is it planning to do so? Also, please describe (1) the approximate number of man-hours expended each year at each of the 13 mail facilities to process controlled substances; and (2) the average time it takes a Customs inspector to process a single package containing a controlled substance.

3. How rapidly is the quantity of unregulated dangerous drugs entering the U.S. via mail, and mail-related channels, growing? Does DEA have estimates of the quantity of prescription drugs that are now entering the U.S. each month via (1) the U.S. mail facilities and (2) the major consignment carriers? Are they collecting meaningful data on this problem, and if so, in what form? If not, why are such statistics not gathered?

4. Does DEA have a plan to address the problem of the many Internet sites that purportedly appear to be both advertising and shipping illegal controlled substances into the U.S. via Federal Express, United Parcel Service, and all other relevant consignment carriers? If so, please describe that plan in detail and how it has changed since the late 1990s. Does DEA believe that the consignment companies are adequately policing the activities of the vendors using their services? Does DEA have any estimates on the amount of money that consignment carriers are making as a result of these illegal drug transactions?

5. What role does DEA believe that the major credit card companies (such as Visa and Master Charge) and underwriting banks are playing in selling controlled substances via the Internet? Does DEA believe that these credit card companies are adequately policing the activities of the vendors using their services? Does DEA have any estimates on the amount of money that credit card companies are making as a result of these illegal sales?

6. What additional legal authority is needed? I note that informal requests from Congressional staff for comments on draft language have gone unanswered. Have you considered whether new laws are needed? What was your conclusion, and why?

Thank you for your assistance in addressing this extremely important public health matter. If you have any questions about this request, please contact me or have your staff contact Christopher Knauer or David Nelson of the Committee on Energy and Commerce Democratic staff at (202) 226-3400.

Sincerely,

JOHN D. DINGELL
RANKING MEMBER

cc: The Honorable Joe Barton, Chairman
Committee on Energy and Commerce

The Honorable James C. Greenwood, Chairman
Subcommittee on Oversight and Investigations

The Honorable Peter Deutsch, Ranking Member
Subcommittee on Oversight and Investigations

The Honorable Tommy G. Thompson, Secretary
Department of Health and Human Services

The Honorable Robert C. Bonner, Commissioner
United States Customs Service

Lester M. Crawford, D.V.M., Ph.D, Acting Commissioner
Food and Drug Administration

Nora D. Volkow, M.D., Director
National Institute of Drug Abuse

Mr. John P. Walters, Director
Office of National Drug Control Policy

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ONE HUNDRED EIGHTH CONGRESS

U.S. House of Representatives
Committee on Energy and Commerce
Washington, DC 20515–6115

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September 22, 2004

The Honorable David M. Walker
Comptroller General
Government Accountability Office
441 G Street, N.W.
Washington, D.C. 20548

Dear Mr. Walker:

I am writing to thank you for your ongoing work on the entry of controlled substances into this country through mail and consignment delivery, and to provide you with additional information. Attached is a response from the U.S. Drug Enforcement Agency (DEA) dated July 26, 2004, to my letter of May 5, 2004, to DEA Administrator Karen Tandy (also attached). My original correspondence underscored a number of concerns repeatedly voiced to DEA regarding the growing flow of controlled substances entering the United States through the international U.S. mail facilities and the express consignment carriers (such as Federal Express and United Parcel Service). Unfortunately, the vagueness of the responses to my questions continues to convince me that neither the DEA nor the Bureau of Customs and Border Protection (Customs), has a workable strategy on how to effectively confront the growing problem of controlled substances entering the U.S. through these facilities. Moreover, nothing in this correspondence suggests that DEA is making progress at a rate even closely approximating the dimensions of this problem.

Significant quantities of scheduled drugs are continuing to enter this country. Customs inspectors continue to be overwhelmed by both the volume and the antiquated system used to seize and process inbound drugs. Inconsistencies on how to handle large shipments of dangerous drugs (e.g., known counterfeit or controlled substances) are apparently still occurring from facility to facility. There is no indication that a meaningful strategy exists on how to effectively work with the credit card companies and the express consignment carriers, both of which are being used by rogue drug peddlers to circumvent U.S. law. In short, DEA's response to this problem continues to appear outdated, unrealistic, and notably unsuccessful.

The Honorable David M. Walker
Page 2

On November 13, 2004, I wrote you to request that GAO examine how DEA, Customs and FDA are addressing the growing problem of controlled substances entering the U.S. via these mail facilities. The attached correspondence from DEA should help in your ongoing work, and also raises the following questions:

1. DEA mentions that the President has put forward a comprehensive written plan in the National Drug Control Strategy. Does this plan adequately address the multitude of issues repeatedly observed at various airport mail facilities by our respective staff?

2. Is DEA making significant progress in shutting down those purveyors who are illegally shipping controlled substances into the U.S.? Does the Agency have any measures to demonstrate what progress is being made? If not, why not, and how is DEA assessing its progress in addressing this growing threat to public health?

3. Does DEA's plan to undertake a comprehensive approach to working with the express consignment carriers and credit card companies seem effective? Specifically, what is that plan and how much work has been done by DEA to create a methodology that will include these entities? Have these plans been shared with the Department of Justice (DOJ)? Moreover, has DEA asked DOJ to conduct the requisite legal analysis to understand what the agency can or cannot do in terms of conducting "controlled purchases" of scheduled drugs from foreign web sites working with the credit card companies?

4. Reference is made in the attached DEA correspondence that DOJ is in the process of reviewing legislative proposals to provide "enhanced authorities to address the problem of 'rogue' internet pharmacies." What are these proposals and specifically what agencies are working on them? I have heard vague references to such proposals for years, and nothing of significance has come from either the DOJ or the DEA on this matter. Are these new proposals and have they been turned over to GAO for any review?

GAO's evaluation of the efforts by both DEA and Customs to stem the growing tide of controlled substances entering the U.S. via the mail from foreign sources will be of great use to the Congress, and it would be very helpful if the GAO's ongoing work could address these additional issues. If you have any additional questions on this matter, please have your staff contact Christopher Knauer, Minority Investigator with the Committee on Energy and Commerce, at 202-226-3400.

Sincerely,

JOHN D. DINGELL
RANKING MEMBER

cc: The Honorable Joe Barton, Chairman
Committee on Energy and Commerce

The Honorable Norm Coleman
United States Senate

The Honorable Carl Levin
United States Senate

The Honorable Karen Tandy, Administrator
Drug Enforcement Administration

The Honorable Robert C. Bonner, Commissioner
United States Customs Service

Lester M. Crawford, D.V.M., Ph.D, Acting Commissioner
Food and Drug Administration

AUG 0 4 2004

U. S. Department of Justice
Drug Enforcement Administration

www.dea.gov

Washington, D.C. 20537

JUL 2 6 2004

The Honorable John D. Dingell
Ranking Minority Member
Committee on Energy and Commerce
United States House of Representatives
Washington, D.C. 20515

Dear Congressman Dingell:

Thank you for your letter of May 5 to Administrator Tandy reiterating your concerns with respect to the problem of illegal entry of controlled pharmaceuticals into the United States by mail resulting from illegal sales over the internet. I apologize for the delay in this response.

The President's National Drug Control Strategy for 2004, issued on March 1 of this year, set forth a comprehensive and coordinated national plan to deal with the problem of illegal diversion and abuse of prescription drugs, including the proliferation of "rogue" internet pharmacies. For our part, the Drug Enforcement Administration ("DEA") has been working to implement the enforcement initiatives outlined in Administrator Tandy's January 14, 2004 letter to you, including improved capacity to identify illicit internet pharmacy operations, increased DEA staffing and resources dedicated to the problem of diversion over the internet, and closer cooperation with organizations inside and outside the government on related matters. The online investigations system you discussed in your letter is now operational and providing investigative information.

We appreciate your continued comments, suggestions and questions on these initiatives and will continue to take them into account in addressing the problem of "rogue" internet pharmacies. Specifically, you asked us to address the following questions:

1. Does DEA have a coordinated comprehensive written plan to address what is clearly a growing threat to the public health? If so, please provide that plan. If not, please explain why no such plan exists and/or whether such a plan is being prepared.

As I mentioned earlier, the President put forward a comprehensive written plan in the National Drug Control Strategy for his Administration to address the problem of illegal diversion and abuse of prescription drugs as a whole. A summary of the relevant portion of the Strategy is enclosed for your information.

2. Has DEA determined whether Customs has the ability to change its internal "processing" procedures with respect to personal (or small) shipments of controlled substances (Schedules II-V) entering the U.S. via the U.S. mail, and the major consignment carriers? Is it planning to do so? Also, please describe (1) the approximate number of man-hours expended each year at each of the 13 mail facilities to process controlled substances; and (2) the average time it takes Customs inspector to process a single package containing a controlled substance.

I am unable to respond to questions regarding internal procedures of another federal agency, but the DEA is not aware of any specific changes that have taken place with respect to handling small packages containing controlled substances at international mail facilities. We are continuing to work closely with the Bureau of Customs and Border Protection ("CBP") and the Food and Drug Administration ("FDA") to review and streamline relevant procedures. The DEA does not maintain specific statistics regarding time expended by Customs personnel on inspections or processing of incoming shipments of controlled substances, but we are certainly aware that the volume of such parcels is significant and must be addressed as a priority.

3. How rapidly is the quantity of unregulated dangerous drugs entering the U.S. via mail, and mail-related channels, growing? Does DEA have estimates of the quantity of prescription drugs that are now entering the U.S. each month via (1) the U.S. mail facilities and (2) the major consignment carriers? Are they collecting meaningful data on this problem, and if so, in what form? If not, why are such statistics not gathered?

The DEA does not specifically estimate the quantity of illegal imports of pharmaceutical controlled substances entering the United States through the mail and by private carriers. This is because CBP has primary responsibility for illegal entries at U.S. ports of entry. Again, however, we are aware that the volume is significant and must be addressed as a priority.

4. Does DEA have a plan to address the problem of the many Internet sites that purportedly appear to be both advertising and shipping controlled substances into the U.S. via Federal Express, United Parcel Service, and all other relevant consignment carriers? If so, please describe that plan in detail and how it changed since the late 1990's. Does DEA believe that the consignment companies are adequately policing the activities of the vendors using their services? Does DEA have any estimates on the amount of money that consignment carriers are making as a result of these illegal drug transactions?

The National Drug Control Strategy directs federal agencies to enlist the support of responsible businesses affiliated with online commercial transactions, including credit card companies, shippers, and Internet service providers. These legitimate businesses will be asked to alert law enforcement officials to suspicious or inappropriate activities, while ISP and credit card companies will be requested to require internet pharmacies to display on their websites the physical street address of their primary business locations.

Officials from the DEA have already held several meetings with both Federal Express (FedEx) and United Parcel Service (UPS) on this issue and have also visited the FedEx Mail Hub in Memphis, Tennessee to evaluate the processing of international parcels. Both FedEx and UPS continue to support

DEA investigative informational requests and are aware that their businesses are being exploited for illegal purposes. DEA has no overall estimate of the profit these companies are generating from individuals exploiting their businesses to facilitate illegal imports.

Our investigations related to the internet have significantly increased since the late 1990s, when it became clear that internet drug sales were undergoing a transition from "lifestyle" drugs (such as Propecia and Xenical) to controlled pharmaceutical substances.

5. What role does DEA believe that the major credit card companies (such as Visa and MasterCard) and underwriting banks are playing in selling controlled substances via the Internet? Does DEA believe that these credit card companies are adequately policing the activities of the vendors using their services? Does DEA have any estimates on the amount of money that credit card companies are making as a result of these illegal sales?

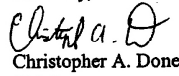
One of the key elements of Administrator Tandy's vision for the DEA is to renew a significant emphasis on taking away the proceeds of all illicit drug trade. Accordingly, DEA officials have met with both Visa and Master Card. Both companies are aware that their businesses are being exploited for illicit purposes and are willing to assist in investigations. It is important to note, however, that legal and operational issues may bear on a case-by-case basis on the ability to cut off accounts used by illicit internet pharmacy sites. The DEA does not have a reliable estimate of the amount of money that is flowing as a result of these illegal sales.

6. What additional legal authority is needed? I note that informal requests from Congressional staff for comments on draft language have gone unanswered. Have you considered whether new laws are needed? What was your conclusion, and why?

The Department of Justice is in the process of reviewing legislative proposals to provide enhanced authorities to address the problem of "rogue" internet pharmacies. We appreciate your interest and support on this issue and will provide additional information as soon as it is available.

We look forward to continuing to work with you on this important matter. Please let my office know whenever we may be of assistance.

Sincerely,



Christopher A. Donesa
Chief
Congressional and Public Affairs

Enclosure

REDUCING PRESCRIPTION DRUG ABUSE

Non-medical use of addictive prescription drugs has been increasing throughout the United States at alarming rates. According to the National Survey on Drug Use and Health, in 2002, an estimated 6.2 million Americans reported past month use of prescription drugs for non-medical purposes. Nearly 14 percent of youth between the ages of 12 and 17 have used such drugs, which include pain relievers, sedatives/tranquilizers, or stimulants, for non-medical purposes at some point in their lives. Emergency room visits associated with narcotic pain relievers have increased 163 percent since 1995.

The President's National Drug Control Strategy engages Federal, state, and local officials; the medical community; and businesses working in the area of Internet commerce to prevent and stop the illegal sale, diversion, and abuse of prescription pshychotherapeutic drugs.

The Strategy focuses on three core tactics for reducing prescription drug abuse:

- ☑ Business outreach and consumer protection
- ☑ Investigation and enforcement against the illegal sale and diversion of prescription drugs
- ☑ Education and training of physicians and consumers

☑ **Business Outreach and Consumer Protection:** The Food and Drug Administration (FDA) will work to ensure product labeling that clearly articulates conditions for the safe and effective use of controlled substances so that commercial advertising fully discloses safety issues associated with the drug's use. Specific examples include labeling that properly identifies patients for whom these products are appropriate and that recommends a "stepped care" approach to the treatment of chronic pain, in accordance with treatment guidelines.

- ➢ FDA will consider Risk Management Programs (RiskMAPs) during the approval process for Schedule II opiate drug products. RiskMAPs help ensure the safe prescription and use of these drugs through identification of appropriate patients and monitoring for adverse outcomes.
- ➢ FDA, the Drug Enforcement Administration (DEA), and the White House Office of National Drug Control Policy will work with physician organizations to encourage comprehensive patient assessment prior to prescription of opiate therapy. Identification of persons at risk for opiate abuse and addiction will help their medical caretakers to more effectively monitor for signs of abuse.
- ➢ Federal agencies are enlisting the support of responsible businesses affiliated with online commercial transactions. Such businesses include credit card companies, shippers, and Internet Service Providers (ISP). These legitimate businesses will be asked to alert law enforcement officials to suspicious or inappropriate activities, while ISP and credit card companies will be requested to require Internet pharmacies to display on their websites the physical street address of their primary business locations.

☑ **Investigation and Enforcement:** The Internet is one of the most popular sources of diverted prescription drugs. An increasing number of rogue pharmacies – or "pill mills" – offer controlled substances and other prescriptions direct to consumers online. These unscrupulous entities are often foreign-based and undermine state licensing systems, exposing consumers to potentially counterfeit, adulterated, and contaminated products.

- ➢ The FDA's Office of Criminal Investigations (OCI) and DEA work together on criminal investigations involving the illegal sale, use, and diversion of controlled substances, including illegal sales over the Internet. Both FDA and DEA have utilized the full range of regulatory, administrative, and criminal investigative tools available, as well as engaged in extensive cooperative efforts with local law enforcement groups, to pursue cases involving controlled substances.

Investigation and Enforcement (continued):

- DEA will deploy sophisticated web crawler/data mining technology to generate investigative leads that could lead to enforcement actions against illegal pill mills.
- ONDCP and DEA will work with state officials to expand the number of Prescription Monitoring Programs (PMPs) and to facilitate information sharing among jurisdictions. Currently, 20 states have PMPs to identify individuals who attempt to fill multiple prescriptions from numerous doctors ("doctor shopping"). This information can help reputable physicians and pharmacies prevent illegal diversion of controlled substances.
- FDA and U.S. Customs and Border Protection (CBP), with assistance from DEA, continue to do spot examinations of mail and courier shipments for foreign drugs to U.S. consumers to help FDA and CBP target, identify, and stop illegal and potentially unsafe drugs from entering the U.S. from foreign countries via mail and common carriers.

☑ **Education and Training:** One potential means of preventing diversion and abuse of prescription drugs is wider dissemination of continuing medical education programs for physicians and other health professionals regarding pain management. These programs will seek to balance the legitimate needs of patients against the risk of diversion and abuse.

- The DEA, with support from the FDA, is working to consult with medical associations to identify existing best practices in physician training in the field of pain management. The agencies plan to develop a mechanism to support the wider dissemination and completion of approved Continuing Medical Education (CME) courses for physicians who prescribe controlled substances. The curriculum will educate doctors on the appropriate medical use of opioids as well as the risks of abuse and addiction.
- ONDCP, DEA, and FDA will develop public service announcements that appear automatically during Internet drug searching to alert consumers to the potential danger and illegality of making direct purchases of controlled substances online. Currently, FDA, along with its sister agency, the Substance Abuse and Mental Health Services Administration (SAMHSA), have jointly developed a public service announcement campaign to better educate consumers on the abuse of prescription pain killers.

☑ **Protecting Safe and Effective Use of Medications:** Some estimate that more than 10 million Americans suffer from chronic pain. The efforts outlined in the National Drug Control Strategy to prevent and reduce the diversion and abuse of prescription drugs will help to ensure that patients have full and appropriate access to the medications that best meet their needs and that their healthcare providers are informed and trained to effectively manage pain while limiting potential for misuse, abuse, and addiction.

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July 20, 2005

The Honorable Michael O. Leavitt
Secretary
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Secretary Leavitt:

For the past fifteen years, the Committee on Energy and Commerce has been actively investigating a range of issues related to the sale and distribution of prescription drugs entering the United States from foreign sources. As part of this effort, we have directed minority staff to visit various border crossings, international mail-branch facilities, and major consignment carriers to examine the types and amounts of unapproved prescription drugs entering the United States. The Committee has had numerous hearings documenting the dubious nature of these drugs. In particular, these hearings have extensively examined the problem of rogue Internet pharmacies and how the drugs sold on these Web sites enter the U.S. through the U.S. international mail facilities and express consignment carriers, such as FedEx, UPS, and DHL.

Through these hearings and repeated correspondence, we have provided extensive input into how and why current policies adopted by the key agencies responsible for combating this problem -- namely, the Drug Enforcement Administration (DEA), the Bureau of Customs and Border Protection (Customs), and the Food and Drug Administration (FDA) -- are ineffective. We have suggested possible solutions, both legislative and regulatory in nature. It remains clear to us that the unabated flow of unregulated drugs entering the U.S. poses a growing threat to the Nation's public health. The nature of online pharmacies and the inability of key agencies to provide even rudimentary controls over rogue Internet pharmacies is producing measurable harm. For example, it is likely that at least some of the unregulated drug flow that we have documented entering the U.S. from foreign sources is finding its way into the wholesale chain, and even onto pharmacy shelves.

We have also pointed out repeatedly that significant amounts of controlled substances are now entering the U.S. from foreign sources. Recently, a report by the National Center on Addiction and Substance Abuse at Columbia University noted that Americans are now abusing

prescription drugs more than cocaine, hallucinogens, inhalants, and heroin combined. That report also found that the abuse rate of prescription drugs by teenagers has increased substantially in just the past decade (*see* "Under the Counter: The Diversion and Abuse of Prescription Drugs in the U.S.," National Center on Addiction and Substance Abuse at Columbia University, July 2005). One reason cited for the recent increase in abuse rates is the easy access of prescription drugs purchased through the Internet. Our investigation has repeatedly demonstrated the ease at which foreign-purchased prescription drugs can enter the U.S. with the click of a mouse, and anybody who has visited an international U.S. mail facility would understand that the Internet is the source of many of these drugs. We believe that the failure to deal with the inflow of non-controlled prescription drugs is also causing an inflow of controlled substances and that the two problems are closely linked: Web sites that sell non-scheduled prescription drugs often offer controlled substances as well.

It is no surprise that prescription drug abuse is rapidly increasing and that some of this increase is linked to online pharmacies. In June of 2003, majority and minority staff issued an investigative memorandum regarding a series of visits to just one international mail entry point, the international U.S. mail facility in Miami. That memo showed that thousands of shipments of controlled substances (and other forms of unregulated prescription drugs) were arriving weekly at that facility. The memo also reported that the volume of such entries were overwhelming all efforts to adequately process or deny entry to the bulk of these drugs. While Customs and the FDA were making some attempts to stop a portion of these drugs (mostly the controlled substances), after the purposeful release of hundreds of packages of counterfeit Sildenafil, it became evident through visits to other mail facilities that the entire screening system had collapsed. In short, the system used by Customs and FDA was no longer capable of addressing this problem. The memo also pointed out that both senior FDA and Customs management had been aware of the deteriorating situation at this and other facilities for nearly half a decade. Nonetheless, at this time no meaningful proposals have been enacted to effectively address this problem.

Some attempts were made by FDA officials to make some constructive changes to this problem. At a June 7, 2001, hearing before the Subcommittee on Oversight and Investigations of this Committee, for example, FDA's Senior Associate Commissioner for Policy and Planning, Mr. Bill Hubbard, testified that the agency was recommending a straightforward denial of entry policy for the massive amounts of unregulated and suspect drug products that were entering the mail facilities each day. He offered the following potential fix:

> ". . . we have been examining [the issue of foreign drugs entering the mail facilities], Mr. Chairman. We have been surveying the drugs that come in. We have been consulting with our sister agencies, and we have been carefully considering what to do about this. The inescapable conclusion for us is that these drugs are virtually all unapproved in the United States. They are provided without proper manufacturing controls. They often lack instructions for safe use, and they

> may be counterfeit, or worse. These factors, combined with the rapid increase in the Internet that's caused the explosion of these things, leads us to believe that they pose a risk to our citizens that must be reduced. So, accordingly, we have recommended to Health and Human Services Secretary Thompson that he approve our recommendation to request that the Customs Service deny entry of all of these drugs, and to return them to their sender . . ."

Secretary Thompson later testified before the Subcommittee on Health on March 13, 2002, that the Department "should have at least the authority to reject these [drugs], and be able to send them back to the manufacturer, instead of sending them on" (*see* Printed Hearing No. 107-100, p. 43). But no legislative proposals on this matter have been forthcoming from the Administration. Since those hearings, in fact, we believe that the problem of unregulated prescription drugs (including controlled substances) has only grown and continues to overwhelm U.S. mail facilities. We believe that much of this is caused by rogue Internet sites.

We are pleased that you already appear to understand the potential dangers online pharmacies present, as underscored in your recent comments that appeared in an interview with Morton Kondrocke, Executive Editor of Roll Call Newspaper. You responded to a question on reimportation with the following comment:

> ". . . You could go onto your internet service provider, go to your search engine and put in 'Canadian drugs,' it would pull up a number of different sites. You will see one, I saw one the other day called the Canadian Generics. And it offered name brand drugs and generic drugs. FDA tracked it down to look at it; they found out that the Internet service provider was in China. They found that the Web site was managed out of Belize. They found that the check we sent them to buy drugs was cashed in St. Croix. And the postmark was in Dallas. We got the drugs, and the first box I looked at was impeccably counterfeited. It looked exactly like one that would come from a manufacturer. But when you tested the fluid that was in the syringe that it packaged, it was tap water. When you tested the chemical compound that made up the medications, it had the right ingredients, but they were just in the wrong proportion. Some of them were as high as 200 percent of what was supposed to be there. Some of them were as little as 50 percent. . . . I think drug safety is going to become a much bigger problem." (*See* Roll Call, "The Health of Our Nation," July 11, 2005.)

Nonetheless, each day thousands of potentially dangerous packages -- perhaps like the very one you describe above -- enter the U.S. via the mail facilities and the express consignment carriers without any FDA scrutiny or review. This is largely taking place because of failed FDA policies and the inability of the Administration to pursue effective policies that provide affordable drugs to those that are otherwise forced to take such risks. Americans are using these drugs daily, and at ever-increasing rates. They are risking their health in doing so. And while

this Committee has repeatedly pointed out to your Department that there are almost no controls surrounding those drugs that are entering the U.S. through these channels, no effective actions have been pursued to address this dangerous situation. Therefore, we are now asking whether you believe FDA's earlier recommendation, as cited above -- or some form of that recommendation -- should be enacted. At a minium, we request that you respond to the following questions:

1. What is the status of the recommendation made by FDA to HHS (as cited above from the hearing held before our Committee more than four years ago)? Please explain how HHS has examined that recommendation.

2. What is HHS's current position on this matter? Does it differ since you assumed your position and if so, how? Does HHS still believe that new legislation is needed to allow FDA to expeditiously return these unregulated drugs to the original sender, or even to rapidly destroy such products? If so, please describe your plan. If additional tools are not required by FDA, please describe what evidence you have that FDA and Customs officials are no longer inundated by unregulated drugs at these facilities.

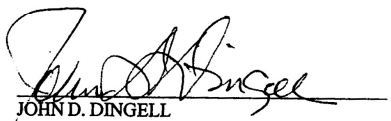
3. Does the Department intend to offer any legislation to provide controls over the present situation at the express consignment carriers and the mail-branch facilities that handle most of the Nation's inbound U.S. mail and parcels? If so, please explain those proposals.

4. If HHS does not intend to propose any legislation, does HHS support any existing legislation or proposals currently under consideration? If so, which ones?

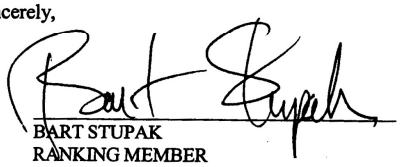
5. Does HHS have any plan to oversee the credit card companies, express consignment shippers, and search engines that are essentially the "infrastructure" for these Internet Web sites? If so, please describe that plan.

We look forward to working with you on this major public health challenge. We would appreciate answers to these questions by no later than Monday, August 22, 2005. If you have any questions about this request, please do not hesitate to contact us, or have your staff contact Christopher Knauer of the Committee Democratic staff at (202) 226-3400.

Sincerely,



JOHN D. DINGELL
RANKING MEMBER
COMMITTEE ON ENERGY AND COMMERCE



BART STUPAK
RANKING MEMBER
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS

The Honorable Michael O. Leavitt
Page 5

cc: The Honorable Joe Barton, Chairman
Committee on Energy and Commerce

The Honorable Ed Whitfield, Chairman
Subcommittee on Oversight and Investigations

MR. STUPAK. Mr. Chairman, let me say something about the border issue, the broader issue of importation. Some will try to argue the administration hasn't been more aggressive in stopping controlled substances from being sold online because Congress and others have sent mixed messages regarding the whole online pharmacy problem. Quite frankly, I believe the importation debate is a ruse and that those agencies should not be allowed to hide behind it.

While indeed many advocate finding ways to allow U.S. consumers to safely purchase drugs on the Internet, I can't think of anyone in this Congress who openly advocates the purchasing of illegal controlled substances from Internet sites without a prescription. Quite frankly, I believe that for too long key agencies have been allowed to duck behind the smokescreen while not getting the job done.

Mr. Chairman, I started my opening by thanking you for having this hearing; and I say this with some hesitation because each time we have this hearing my level of frustration grows a bit greater. This subject has become the public health version of the movie Ground Hog Day. The same promises keep being made, the same task forces, the same strategic plans, and the same Web crawlers. Much of what we will hear today we have heard many times in the past. But, like in the movie, nothing seems to ever change and nothing new seems to be added in terms of what the agencies will do differently to effectively address the serious problem.

So as we proceed forward let me make the following suggestions. If as a committee we really do expect to see some meaningful progress, then we must make certain agencies are accountable for solid and specific action plans. The fact of the matter is that neither DEA nor FDA appear to have at all affected the flow of controlled substances entering the United States with the approaches they've taken over the last six years. Why?

We must answer the following questions:

Number one, what are the various agencies doing that is effective and what are they doing that is ineffective? Do we know the difference between the two? I believe much more data needs to be forthcoming from DEA in particular on how they are approaching this issue.

Secondly, we also need to know from the administration, if the current model is not working, what new tools are needed. Do we need a change in regulations or statutory changes to give DEA, Customs, or FDA something new they currently do not have? So far, we have almost no useful guidance in this regard from the administration.

The administration must also be held accountable in this regard. We must understand what roles are the credit card companies, the shippers, the Web hosts, and the search engines. They're among the key actors. Should they be playing a role to eradicate this problem? To date, we have no idea if success lies more in attacking the credit card part of the problem or going after the domain names of the rogue sites.

Fourth, we can't evaluate if FedEx or UPS are doing enough to police their systems because we don't know if their systems hold the keys to solving this problem. We can't evaluate who we should be working with more closely and with whom because no one seems to have any decent data on where best to place limited resources to be effective. This is a failure by the Federal government, and this should change immediately.

Mr. Chairman, in short, we need to formally measure who is doing what and then measure what impact it is having on the problem. If we do not start holding agencies seriously accountable for either solving this problem or at least coming up with new ideas on how to approach this problem, then I fear that sometime next year we will be having our seventh or eighth hearing on the subject, and the problem will be greater. I'll look forward to hearing what this witnesses say today. I'll try to remain open minded, but if suddenly I hold up a ground hog to see its shadow, you'll know why.

One more quick note, if I may. The posters we have here -- I know you have been involved in this and I have for the last six years -- this is just from JFK International. That's the mail branch room. If you look, a lot of this came from the Netherlands; and if you go down to the third one just in the picture the day we were there we had about 20,000 boxes of suspended mail from JFK. And in Miami Airport where I mentioned in my opening, it's the same.

You can go out here to Dulles. You'll see just shipments and shipments illegally coming into the United States containing who knows what. As I said, this problem is only getting greater and greater each and every day. As these pictures show us, if you have been out there, whether Dulles, JFK, or Miami, it's a whole roomful of drugs coming

into these country by the click of a mouse; and we have done nothing to stop its trend.

So with that, Mr. Chairman, I'll yield back to you and thank you for your extended time.

MR. WHITFIELD. Mr. Stupak, thank you very much and I appreciate those pictures as well because all of us have been at those sites and hopefully we can get some good information from our witnesses today.

At this time, I recognize the gentleman from Florida for his opening statement.

MR. STEARNS. Thank you, Mr. Chairman; and let me echo my colleague's comment. It's an important issue. It's an important issue, and I heard Mr. Stupak, and I have heard him speak on this eloquently before. I'm hoping that our panel will help educate us some more on what laws are currently being broken and perhaps what we in Congress should do to draft legislation.

It's my understanding that the drugs being discussed today are mostly those controlled substances classified as Schedule II or III by the DEA under the guidelines of the Controlled Substances Act. Obviously, these drugs are highly addictive in nature and require monitoring by a licensed physician to prevent complications.

When it comes to the latter, I harbor particular concerns. As chairman of the Subcommittee on Commerce, Trade, and Consumer Protection, I have been active in legislative efforts to clean up illicit steroid use in sports leagues. It has culminated in a bill in the subcommittee and the full committee, the Drug-free Sports Act, H.R. 3084. Not only do young, impressionable schoolchildren see these idolized athletes take steroids to enhance their performance, and sometimes these athletes lie about it, and then are able to easily purchase steroids themselves over the Internet. That's a doubleheader of a problem here.

We have here a good example here in this Google presentation that the staff has shown that you can go to Google, put in steroids, go next to buying steroids online, and then, step three, we have that the FDA and others have some advertising saying that these drugs could be dangerous and they need a prescription and should be very careful.

Further study by the National Center on Addiction and Substance Abuse found that of the 165 websites they found that sold Schedule II and III drugs, almost 90 percent of them did not require a prescription. That's hard to believe. Many of these sites also substituted an online questionnaire for the face-to-face consultation by a physician, which the American Medical Association has deemed below acceptable standards of care. So what kind of doctor can think that a cursory online checklist substitutes for a thorough examination? I wonder.

These illegal pharmaceutical websites sell these dangerous drugs to people of all ages. According to a report by the U.S. News & World Report, 1 in 10 high school seniors have tried Vicodin without a prescription and one in 20 has taken OxyContin. Additionally, the National Institute on Drug Abuse monitoring the future report for trends in the years 1975 to 2004, the majority of students reported that it was fairly easy or very easy to obtain these controlled substances, and children as young as in fourth grade have sampled them.

Controlled substances have their place in America's medicine cabinets, we all agree, for controlling pain, sedating nerves, preventing seizures. Of course, there is no substitute. However, the ideal practice is to obtain a prescription by your personal physician and go to your local pharmacist to get it filled and not through a cursory filling out of a questionnaire and getting it through the Internet.

So I appreciate your having this hearing, Mr. Chairman; and I look forward to some of the remedies. I yield back.

MR. WHITFIELD. Thank you, Mr. Stearns.

At this time, I recognize the gentleman from New Jersey, Mr. Ferguson.

MR. FERGUSON. Thank you, Mr. Chairman.

I appreciate you holding this hearing, and I share some of the frustrations of my friend from Michigan. I would simply remind him he's been here a long time and he knows sometimes government doesn't work as quickly as we would like. I would just remind him that Ground Hog Day did have a happy ending, and I would hope certainly that as we continue to investigate and try to take action on this very serious subject that this situation would also have a happy ending.

Mr. Chairman, I think today we're taking another important step toward uncovering a growing problem in our country and one that many people are simply not aware of, certainly not aware of in terms of its scope or in terms of the growing threat that it poses to American's health. Today we have mayors and county officials and even governors of some states who are explicitly supporting Internet purchasing of drugs from Canada. They're essentially lulling Americans to sleep, making them think that pharmaceuticals and drugs purchased from other countries over the Internet are perfectly safe. The facts say very clearly that this is not the case.

According to a July 2004 FDA analysis of three commonly prescribed drugs purchased from a website advertised as Canadian, all three so-called Canadian generic drugs were fake, substandard, and potentially dangerous. The products purchased were so-called generic versions of Viagra, Lipitor, and Ambien. None of these products have a generic version that are approved for use in the United States.

The FDA stated, and I quote, the test results of our analyses offer proof positive that buying prescription drugs online from unknown foreign sources can be a risky business. As was the case here, even where a website looks legitimate, FDA has clear evidence that the website is dispensing misbranded drugs that are not the same quality as those approved by the FDA for sale in the United States. Close quote.

The FDA findings have also cited pharmacies posing as being located in states like Arizona but in reality were fronts for selling drugs originating in countries like India.

For today's hearing, we're looking into the dangerous unregulated availability of controlled substances over the Internet. The GAO recently documented the wide availability of highly addictive controlled substances over the Internet; and, as the GAO notes in its report, both the DEA and the Office of National Drug Control Policy have found that the easy availability of controlled substances directly to consumers over the Internet has significant implications for public health, given the opportunities for misuse and abuse of these addictive drugs.

Last July, IntegriChain Inc., who is represented here in a second panel, a firm which is just outside of my district in Princeton, New Jersey, provided a briefing for the subcommittee members. IntegriChain investigates Internet pharmacies, and after the briefing the majority and minority staffs of the subcommittee asked the company to provide a review of a few websites selling controlled substances. I'm looking forward to the IntegriChain report and hearing about its findings.

But what does this report and the questionable integrity of foreign Internet pharmacies say about this dangerous cottage industry? How can we trust nameless, faceless doctors and pharmacists to distribute controlled substances over the Internet? How can we trust them to get us other drugs and medication? The answer very simply is that we can't, and at this hearing we hope to shine light on this very important and growing problem.

Thank you, Mr. Chairman. I yield back.

MR. WHITFIELD. Thank you, Mr. Ferguson.

We have with us today Dr. Charlie Norwood, who is a member of the full Energy and Commerce Committee and serves on the Health Subcommittee, among others. Although he's not a member of Oversight and Investigations, this is a subject matter that we are discussing today that he has a particular interest in; and I would like to ask unanimous consent that Mr. Norwood be able to make an opening statement and ask questions if he so desires.

So the gentleman is recognized.

MR. NORWOOD. Thank you, very much, Mr. Chairman, for allowing me the privilege of sitting in on this what I consider extremely important hearing.

I know my colleagues on the Commerce Committee have heard me say this before, but I just really need to say it again: We in this country do not do a good enough job addressing the needs of patients with chronic pain, yet over 45 percent of us will experience chronic pain at some point in our lives. Prescription medications are an important part of pain therapy. Unfortunately and sadly, we have allowed a few bad actors to jeopardize a doctor's ability to offer pain care to their patients out of fear of patient abuse or diversion.

I am encouraged by some of Congress's recent efforts to address pain care. However, if we don't tackle prescription drug abuse, no bill expanding access is going to make any difference at all. We need a comprehensive strategy that removes bad actors. NASPER legislation that the Chairman and I offered encouraging state prescription drug monitoring programs, that's a good first step. However, we must address what is perhaps one of the biggest barriers to improving legitimate pain care therapy, and that is Internet pharmacies.

The addiction community tells me that these sites represent one of the easiest ways to access controlled substances. Even children and teenagers can easily order an addictive controlled substance without a prescription. Worse yet, Internet pharmacies often fill the e-mail boxes of those trying to beat the addiction with advertisements for their goods.

The number of Internet pharmacies grew from zero in the mid-1990s to roughly a thousand in 2003, to who knows how many today. It would be one thing if these pharmacies were operating under the same standards as traditional pharmacies, but most don't. Of 157 Internet pharmacies identified by the Center for Addiction and Substance Abuse, 90 percent, 90 percent did not require prescription. It boils down to this: Right now, I could go on the Internet and buy a controlled substance by pointing and clicking two things: I need the drug, and I'm not lying.

This problem isn't restricted to certain low-grade painkillers. An Internet search for OxyContin yields several hundred thousand websites, many of which can be used to get it and other powerful painkillers without a prescription. If you take a careful look at these sites, you will find many based abroad, but some are right here in the United States. These sites have become a problem as they grow in number, market aggressively, and lack proper regulation.

Don't get me wrong. There are good, legitimate Internet pharmacies, but rogue pharmacies that sell prescription drugs without a prescription have to change the way they do business. I will soon introduce a bill to target these rogue Internet pharmacies by requiring a prescription for

controlled substance. We can provide effective protections against Internet pharmacy abuse while ensuring that chronic pain patients receive the care that they desperately need.

Mr. Chairman, I look forward to hearing from your witnesses today.

MR. WHITFIELD. Mr. Norwood, thank you very much; and I would also ask unanimous consent that any member that desires to do so may submit his opening statement for the record.

[Additional statements submitted for the record follow:]

PREPARED STATEMENT OF HON. JOE BARTON, CHAIRMAN, COMMITTEE ON ENERGY AND COMMERCE

Mr. Chairman, I strongly support this hearing. The fact that these rogue Internet pharmacies are easily selling highly addictive, dangerous controlled substances without a valid prescription to American citizens, especially teenagers, is an outrage. Republicans and Democrats disagree on many issues. But this is an issue on which we can all work together.

The sale of controlled substances such as Vicodin, Percoset, and steroids to our kids must be stopped. Immediate action needs to be taken to drive these operations off the Internet and put the bad actors in jail. There has been understandable frustration that the Federal government has not found a silver bullet strategy to solve the problem. The challenge of these rogue Internet pharmacies is that their operations may involve several countries and the bad actors behind these operations can easily conceal their identities and activities. For those reasons, it has been difficult to obtain the kind of data about the bad actors to enable the federal government to design an effective, comprehensive strategy to stop these rogue Internet pharmacies.

With today's hearing, this Subcommittee can help the public and private players achieve significant results in solving this problem. As we have learned from fighting terrorism, a part of the solution is about gaining more detailed intelligence about these rogue pharmacies and the bad actors behind them. We will hear testimony from a private investigative firm about the results of their work in probing about 180 websites that have controlled substances available for purchase. In particular, by focusing on controlled substances, particularly the Schedule 2 and 3 drugs offered on the Internet, the public and private sectors can concentrate on getting comprehensive information about the limited number of Internet operations selling controlled substances. With this better intelligence, they have an opportunity to take more effective actions to stop these transactions that pose a serious public health threat.

The people on the frontlines of federal and state law enforcement combating this problem should be commended for their efforts in dealing with this highly challenging and complicated threat. What I am very interested in learning about today is what we in the Congress can do to help law enforcement by giving them more authority and perhaps more resources.

I also want to express appreciation to the private industries represented at today's hearing. While they should not be confused with law enforcement agencies, these private companies have been working cooperatively with the government, are taking steps to address this issue, and are an essential part of the solution.

Easy Internet access to controlled substances is a dangerous reality, one that today's hearing will show must be addressed immediately, legislatively if necessary. With unified, bipartisan leadership from this Committee, we can help the public and private sector act against an illegal industry that makes it possible to do drugs and get them without a prescription.

I thank the witnesses and look forward to the testimony.

MR. WHITFIELD. Before I introduce the witnesses, one other sort of milestone I would like to recognize today is John Dingell, who served as chairman of the full Energy and Commerce Committee for many years and certainly was also chairman of the Oversight and Investigations Subcommittee, is celebrating his 50th year in the Congress today. He was sworn in on December 13, 1955, and I guess is the third-longest serving member, Mr. Stupak. So we all congratulate him for his distinguished service in the Congress.

Once again, I want to welcome those of you on the first panel. We genuinely appreciate your time in being here to help address this serious issue.

On the first panel today, we have Mr. Richard Stana with the GAO; we have Mr. Joseph Rannazzisi, who is the Deputy Assistant Administrator, Office of Diversion Control, at the DEA; we have with us Mr. Jayson Ahern, who's the Assistant Commissioner, Office of Field Operations, for the Bureau of Customs and Border Protection; and then we have Dr. Robert Meyer, who is the Director, Office of Drug Evaluation, at the Food and Drug Administration.

So thank you very much for being here.

As you're aware, the Committee on Oversight and Investigations is holding an investigative hearing; and when doing so it has been our practice of asking that people testify under oath. Do any of you have any objection to testifying under oath? Do any of you have any attorneys with you today that will be representing you, giving you advice?

Okay. In that case, if you would stand and raise your right hand, I'd like to swear you in.

[Witnesses sworn].

MR. WHITFIELD. Thank you. You're now sworn in.

TESTIMONY OF RICHARD STANA, DIRECTOR, HOMELAND SECURITY AND JUSTICE ISSUES, GOVERNMENT ACCOUNTABILITY OFFICE; JOSEPH RANNAZZISI, DEPUTY ASSISTANT ADMINISTRATOR, OFFICE OF DIVERSION CONTROL, AND DEPUTY CHIEF, OFFICE OF ENFORCEMENT OPERATIONS, DRUG ENFORCEMENT ADMINISTRATION; JAYSON AHERN, ASSISTANT COMMISSIONER, OFFICE OF FIELD OPERATIONS, BUREAU OF CUSTOMS AND BORDER PROTECTION; AND, ROBERT MEYER, M.D., DIRECTOR, OFFICE OF DRUG EVALUATION II, OFFICE OF NEW DRUGS, CENTER FOR

DRUG EVALUATION AND RESEARCH, FOOD AND DRUG ADMINISTRATION

MR. WHITFIELD. Mr. Stana, we'll call on you for your five-minute opening statement.

MR. STANA. Thank you Mr. Chairman, Mr. Stupak and members of the subcommittee.

I appreciate the opportunity to discuss Federal agencies' efforts to interdict and inspect millions of packages of prohibited prescription drugs imported for personal use through the 14 international mail and 29 private carrier facilities. Since early 1999, online Internet pharmacies have enabled American consumers to order a range of prescription drugs over the Internet. These drugs include noncontrolled prescription drugs like those to combat baldness, impotence and obesity, but also include controlled substances like Valium and anabolic steroids.

There's growing concern that purchasing prescription drugs from Internet pharmacies is risky because these drugs may be compromised or not the authentic product customers intended to purchase. Another concern is that consumers might also be violating the law, unknowingly or intentionally, by having these drugs shipped into the country.

U.S. Customs and Border Protection and the FDA are responsible for interdicting and inspecting incoming packages at U.S. mail and private carrier facilities. DEA, the Postal Service, ONDCP, and U.S. Immigration and Customs Enforcement are involved in efforts to inhibit the importing of prescription drugs.

My prepared statement summarizes our recent report on Federal efforts to address the illegal importation of prescription drugs through the international mail and carrier facilities. In my oral statement I'd like to focus on efforts to address the illegal importation of illegal controlled substances and make three main points.

First, drugs purchased over the Internet from foreign sources are largely outside the U.S. regulatory system, which can present safety and quality and law enforcement problems. Of particular concern is easy access to highly addictive controlled substances which can be imported by consumers of any age, sometimes without a prescription or consultation with a physician. Recently, GAO investigators easily obtained anabolic steroids without a prescription through the Internet. After conducting Internet searches we found hundreds of websites offering anabolic steroids commonly used by athletes and bodybuilders for sale. Our investigators then used an e-mail account in a fictitious name to place 22 orders. From these orders, we received 10 shipments of anabolic steroids, all from foreign sources. Obviously, obtaining such drugs and taking them without medical supervision is not only illegal but

risky. The officials we spoke with told us the Internet is the most widely used means of buying and selling anabolic steroids illegally. Law enforcement actions require extensive time and resources, and sentences for illegal steroid traffic are relatively low.

Second, the large volume of packages containing prescription drugs that arrive at international mail and private carrier facilities is straining CBP's and FDA's limited resources. Despite changes in both FDA and CBP handling procedures, large numbers of packages continue to be released to addressees, with or without inspection.

In August, 2004, FDA issued procedures to standardize CBP's selection of packages forwarded to FDA, FDA's inspection of these packages, and FDA's admissibility determinations. However, even with these new procedures, many packages containing prescription drugs prohibited for import continue to be released to addressees. For example, packages forwarded by CBP to FDA but not processed by FDA inspectors by the end of each workday are returned to the Postal Service for delivery to the addressee. If the results of recent enforcement sweeps are typical, some of these release packages likely contained controlled substances.

With respect to controlled substances, last year CBP implemented a new policy to expedite its handling of drugs in Schedules III through V that are detected in its inspection process. The new policy reduces the information to be recorded about the drugs and enables CBP to destroy the drugs 30 days after notifying the addressee that the drugs would be treated as abandoned property if not claimed. CBP officials told us that an inspector at a mail facility could now process a package in about one minute, versus one hour under the old seizure and forfeiture system. CBP reported it destroyed about 72,000 packages in the first year of implementation, but no one knows whether the new policy has deterred individuals from importing controlled substances, and packages containing these drugs continue to flow into the country.

My last point is that concerns about illegal importation are not new and past actions to mitigate the problem have had only limited success. Most recently, CBP is leading an interagency task force that includes CBP, FDA, DEA, ONDCP, ICE, and DOJ attorneys. To date, this task force has undertaken multiagency enforcement operations and promoted increased public awareness of potential dangers of imported drugs, among other things. While this was a step in the right direction, we recommended that a broader strategic framework be adopted that commits governmental and private organizations to better define the nature and scope of the illegal importation problem, establish objectives, milestones and performance measures to gauge results, determine the number and types of resources needed to address the problem, and

evaluate progress and barriers to successful resolution. We believe that a strong strategic framework would provide direction, coordination and accountability needed to address the law enforcement and safety challenges we identified.

This concludes my oral statement, and I'd be happy to address any questions the subcommittee may have.

MR. WHITFIELD. Thank you, Mr. Stana.

[The prepared statement of Richard Stana follows:]

PREPARED STATEMENT OF RICHARD STANA, DIRECTOR, HOMELAND SECURITY AND JUSTICE ISSUES, U.S. GOVERNMENT ACCOUNTABILITY OFFICE

United States Government Accountability Office

GAO

Testimony

Before the Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, U.S. House of Representatives

For Release on Delivery
Expected at 1:00 p.m. EST
Tuesday, December 13, 2005

PRESCRIPTION DRUGS

Enhanced Efforts and Better Agency Coordination Needed to Address Illegal Importation

Statement of Richard M. Stana, Director
Homeland Security and Justice Issues

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GAO-06-175T

December 2005

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Highlights

Highlights of GAO-06 175T, a testimony before the Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, U.S. House of Representatives

PRESCRIPTION DRUGS

Enhanced Efforts and Better Agency Coordination Needed to Address Illegal Importation

Why GAO Did This Study

This testimony summarizes a GAO report on federal efforts to address the importation of prohibited prescription drugs through international mail and carrier facilities for personal use. U.S. Customs and Border Protection (CBP), in the Department of Homeland Security (DHS), and the Food and Drug Administration (FDA), in the Department of Health and Human Services (HHS), work with other federal agencies at international mail and express carrier facilities to inspect for and interdict these drugs. This testimony addresses (1) available data about the volume and safety of these drugs, (2) the procedures and practices used to inspect and interdict them, (3) factors affecting federal efforts to enforce the laws governing these drugs, and (4) federal agencies' efforts to coordinate enforcement of the prohibitions on personal importation of these drugs.

What GAO Recommends

GAO recommends that (1) CBP and other task force agencies develop a strategic framework to enhance their enforcement efforts and (2) HHS assess the effect of modifying the requirement that FDA notify addressees about unapproved drug imports. DHS and most task force agencies generally supported the idea of a strategic framework. HHS agreed to assess modifying the notification requirement, and the U.S. Postal Service said that any proposal should consider international postal obligations.

www.gao.gov/cgi-bin/getrpt?GAO-06-175T-.

To view the full product click on the link above.
For more information, contact Richard Stana at (202) 512-8777 or StanaR@gao.gov.

What GAO Found

The information currently available on the safety of illegally imported prescription drugs is very limited, and neither CBP nor FDA systematically collects data on the volume of these imports. Nevertheless, on the basis of their own observations and limited information they collected at some mail and carrier facilities, both CBP and FDA officials said that the volume of prescription drugs imported into the United States is substantial and increasing. FDA officials said that they cannot assure the public of the safety of drugs purchased from foreign sources outside the U.S. regulatory system.

FDA has issued new procedures to standardize practices for selecting packages for inspection and making admissibility determinations. While these procedures may encourage uniform practices across mail facilities, packages containing prescription drugs continue to be released to the addressees. CBP has also implemented new procedures to interdict and destroy certain imported controlled substances, such as Valium. CBP officials said the new process is designed to improve their ability to quickly handle packages containing these drugs, but they did not know if the policy had affected overall volume because packages may not always be detected.

GAO identified three factors that have complicated federal enforcement of laws prohibiting the personal importation of prescription drugs. First, the volume of imports has strained limited federal resources at mail facilities. Second, Internet pharmacies can operate outside the U.S. regulatory system and evade federal law enforcement actions. Third, current law requires FDA to give addressees of packages containing unapproved imported drugs notice and the opportunity to provide evidence of admissibility regarding their imported items. FDA and HHS have testified before Congress that this process placed a burden on limited resources. In May 2001, FDA proposed to the HHS Secretary that this legal requirement be eliminated, but according to FDA and HHS officials, as of July 2005, the Secretary had not responded with a proposal. FDA officials stated that any legislative change might require consideration of such issues as whether to forgo an individual's opportunity to provide evidence of the admissibility of the drug ordered.

Prior federal task forces and working groups had taken steps to deal with Internet sales of prescription drugs since 1999, but these efforts did not position federal agencies to successfully address the influx of these drugs imported from foreign sources. Recently, CBP has organized a task force to coordinate federal agencies' activities to enforce the laws prohibiting the personal importation of prescription drugs. The task force's efforts appear to be steps in the right direction, but they could be enhanced by establishing a strategic framework to define the scope of the problem at mail and carrier facilities, determine resource needs, establish performance measures, and evaluate progress. Absent this framework, it will be difficult to oversee task force efforts; hold agencies accountable; and ensure ongoing, focused attention to the enforcement of the relevant laws.

Mr. Chairman and Members of the Subcommittee:

I appreciate the opportunity to provide a summary of our recent report on federal agencies' efforts to address the importation of prohibited prescription drugs through international mail and carrier facilities.[1]

The advent of online Internet pharmacy services in early 1999, enabled American consumers to order over the Internet a range of prescription drugs from controlled substances,[2] such as Valium, to noncontrolled prescription drugs intended to improve an individual's quality of life by addressing non-life-threatening conditions such as baldness, impotence, and obesity. The broad reach and access of the Internet allow the easy creation of online pharmacies that anonymously traverse state and national borders to prescribe, sell, and dispense prescription drugs without complying with traditional state or federal regulatory safeguards.

Under current law, the importation of prescription drugs, both controlled and noncontrolled, for personal use is illegal, with few exceptions. In

[1]See GAO, *Prescription Drugs: Strategic Framework Would Promote Accountability and Enhance Efforts to Enforce the Prohibitions on Personal Importation*, GAO-05-372 (Washington, D.C.: September 8, 2005).

recent years, Congress and others have debated whether Americans should be allowed to purchase drugs from pharmacies located in foreign countries. However, currently, consumers could be violating federal law, unknowingly or intentionally, by having drugs shipped, in effect, imported, into the United States through the international mail and private carriers. Two acts specifically regulate the importation of prescription drugs into the United States. That is, all prescription drugs offered for import must meet the requirements of the Federal Food, Drug, and Cosmetic Act, and those that are controlled substances also must meet the requirements of the Controlled Substances Import and Export Act. Prescription drugs imported for personal use generally do not meet these requirements.

Several federal agencies have responsibility for regulating the importation of prescription drugs through the international mail and private carriers. They include the Department of Homeland Security's (DHS) U.S. Customs and Border Protection (CBP), which can inspect international mail and packages for potentially illegal drugs entering the United States through the U.S. Postal Service's (USPS) international mail facilities or private carriers; the Department of Health and Human Services' (HHS) Food and

[2]The Controlled Substances Act establishes a classification structure for certain drugs and chemicals that are designated as controlled substances. This structure places such substances in one of five schedules, based on their medicinal value, risk to public health, and potential for abuse and addiction, among other factors. Schedule I is reserved for the most dangerous drugs that have no currently accepted medical use, such as heroin and ecstasy. Controlled substances that may be prescribed by a physician or used in medical facilities fall in schedules II through V (e.g., Valium). For certain law enforcement purposes, however, schedule II drugs are treated more like schedule I drugs.

Drug Administration (FDA), which is responsible for ensuring the safety, effectiveness, and quality of domestic and imported drugs; the Department of Justice's Drug Enforcement Administration (DEA), which regulates controlled substances; and the Department of Homeland Security's U.S. Immigration and Customs Enforcement (ICE), which has law enforcement responsibilities that include investigations of prescription drugs coming into the United States through the mail and express carriers. Also, the Office of National Drug Control Policy (ONDCP) formulates the nation's drug control strategy and addresses policy issues concerning the illegal distribution of controlled substances, as its authority does not extend over noncontrolled substances.

This statement presents a summary of our latest work on federal efforts to enforce prohibitions on personal importation of prescription drugs through the international mail and carrier facilities, which was requested by the Chairman of the Senate Permanent Subcommittee on Investigations, Committee on Homeland Security and Governmental Affairs and the Ranking Minority Member of the House Energy and Commerce Committee. My testimony today, requested by the Chairman of this Subcommittee, provides a summary of our report and will focus on the following issues:

- what available data show about the volume and safety of prescription drugs imported into the United States for personal use through the international mail and private carriers,
- what procedures and practices are used at selected facilities to inspect and interdict prescription drugs unapproved for import,
- what factors affect federal agency efforts to enforce the prohibition on prescription drug importation for personal use through international mail and carrier facilities, and
- what efforts federal agencies have undertaken to coordinate the enforcement of the prohibitions on personal importation of prescription drugs.

Summary

Our report on illegal prescription drug importation notes that the information currently available on the safety of illegally imported prescription drugs is very limited, and neither CBP nor FDA systematically collects data on the volume of these imports. Nevertheless, on the basis of their own observations and limited information they have collected at some mail and carrier facilities, both CBP and FDA officials said the volume of prescription drugs imported into the United States is substantial. For example, a December 2004 HHS report states that approximately 10 million packages containing prescription drugs enter the United States annually from all over the world. However, this estimate has limitations, being partially based on extrapolations from limited FDA

observations at international mail branch facilities. Without reliable estimates of the volume of importation of prescription drugs, federal agencies cannot determine the full scope of the importation issue, which is of particular concern because of access to potentially unsafe or risky drugs, including highly addictive controlled substances. With regard to safety, the FDA officials told us that they cannot assure the public of the safety and quality of drugs purchased from foreign sources that are largely outside the U.S. regulatory system. Consistent with these concerns, in June 2004, we reported that a sample of drugs purchased from some foreign-based Internet pharmacies posed safety risks for consumers.[3]

Regarding the practices used at the mail and carrier facilities we visited to inspect packages and interdict prohibited prescription drugs, our report states that both FDA's and CBP's procedures are evolving. FDA issued procedures in August 2004 to standardize the selection of packages by CBP and the forwarding of them to FDA for inspection. These procedures include guidelines for inspecting the packages and making admissibility determinations. However, under the current procedures, similar to previous practices, many packages that contain prescription drugs prohibited for import are released to addressees. For example, packages

[3]See GAO, *Internet Pharmacies: Some Pose Safety Risks for Consumers*, GAO-04-820 (Washington, D.C.: June 17, 2004) and GAO, *Internet Pharmacies: Some Pose Safety Risks for Consumers and Are Unreliable in Their Business Practices*, GAO-04-888T (Washington, D.C.: June 17, 2004).

that contain prescription drugs prohibited for import that have not been processed by FDA inspectors at the end of each workday are returned by FDA for delivery by USPS to the recipient. CBP has also implemented a new policy to expedite its handling of schedule III through V controlled substances imported as prescription drugs. Until recently, CBP was required to seize and begin forfeiture proceedings on packages of such controlled substances it detected—a process CBP considered to be time-consuming given the volume of controlled substances entering some facilities. In September 2004, CBP determined it could treat schedule III through V controlled substances as abandoned property, thereby (1) reducing the amount of information recorded about the drugs and (2) enabling CBP to destroy the drugs 30 days after notifying the addressee that the drugs would be treated as abandoned property if not claimed.

In our report, we also identify three factors beyond inspection and interdiction issues that have complicated federal efforts to enforce laws prohibiting the importation of prescription drugs for personal use. First, the volume of importation has strained federal resources at the mail and carrier facilities. According to officials we contacted, agencies have multiple priorities, which can constrain the resources they are able to allocate to the inspection and interdiction of prescription drugs and controlled substances imported through mail and carrier facilities. Second, the attributes of Internet pharmacies have posed challenges to law

enforcement efforts for multiple reasons. For example, Internet sites can be installed, moved, or removed in a short period of time, making it difficult for law enforcement agencies to identify, track, monitor, or shut down those sites that operate illegally. Additionally, legal and practical considerations can limit the nature and extent to which commercial firms (e.g., Internet providers and credit card organizations) can assist in federal law enforcement actions. Third, the notification process in current law requiring FDA to hold packages containing items that appear unapproved for import and give the addressee the opportunity to provide evidence of admissibility is, according to FDA officials, time-consuming — taking up to 30 days per import — and can hinder their ability to quickly process packages containing potentially unapproved prescription drugs. FDA and the Secretary of Health and Human Services have expressed concerns about this process during testimony before Congress. However, FDA officials told us that any legislative change might necessitate consideration of some complicated issues, including whether the government would want to forgo an individual's opportunity to provide evidence of admissibility for the drug(s) that had been ordered, or what imported prescription drugs and other imported products within FDA's jurisdiction should be covered by the new law. In addition, USPS indicated that any discussion of options to expedite the processing and disposition of

prescription drugs should consider international postal obligations established by the Universal Postal Union (UPU).[4]

We also report that CBP has organized a task force to coordinate the activities of federal agencies responsible for enforcing laws prohibiting the personal importation of prescription drugs. Among other things, the task force has performed joint operations to gather data on the type and source of unapproved drugs entering international mail facilities and developed public service campaigns to inform the public about the risks of buying prescription drugs from Internet providers in foreign countries. Although the task force appears to be a step in the right direction, efforts to address many of the challenges facing these agencies could be further enhanced if the task force established a strategic framework to promote accountability and guide resource and policy decisions. Our past work has shown that a strategic framework is particularly useful in addressing problems, such as prescription drug importation, that are national in scope and involve multiple agencies with varying jurisdictions. Without such a strategic framework, it will be difficult for agency officials and congressional

[4]UPU is a specialized agency of the United Nations governing international postal services. According to the USPS, the Universal Postal Convention establishes a general rule that undeliverable items are to be returned to sender. UPU regulations provide that where an item can neither be delivered to the addressee nor returned to the sender, the Postal Service must notify the postal administration of origin of how the item was dealt with, including indicating the prohibition under which the item falls. USPS noted that this is particularly important with respect to registered or insured mail for which the Postal Service can be held financially responsible if it is not delivered or returned.

decision makers to oversee the overall federal effort, hold agencies accountable for their individual efforts, adjust to changing conditions, and ensure consistent and focused attention to the enforcement of prescription drug importation laws.

Accordingly, our report recommends that the CBP Commissioner, in concert with other agencies responsible for enforcing these laws, develop and implement a strategic framework that, at a minimum, includes establishing an approach to more reliably estimate the volume of prohibited prescription drugs imported through international mail and carrier facilities; determine resource needs and target resources based on priorities; establish performance measures and milestones; and evaluate progress, identify barriers to achieving goals, and suggest modifications. DEA and ONDCP generally agreed with this recommendation. DHS generally agreed with the contents of our report and said that CBP is convening a task force meeting to discuss it. While generally concurring with this recommendation, HHS questioned the need to include an approach to estimate the volume of unapproved drugs entering the country, believing its current estimates to be valid. We believe that developing more systematic and reliable volume estimates might position agencies to better define the scope of the problem so that decision makers can make informed choices about resources. Considering FDA's continuing concern about the statutory notification requirement, we also

recommend that the Secretary of HHS assess the ramifications of removing or modifying the requirement, report the assessment results, and, if appropriate, recommend changes to Congress. HHS generally agreed with this recommendation; USPS noted that discussions of such options must consider international postal obligations.

Background

All international mail and packages entering the United States through the U.S. Postal Service and private carriers are subject to potential CBP inspection at the 14 USPS international mail facilities and 29 express consignment carrier facilities operated by private carriers located around the country. CBP inspectors can target certain packages for inspection or randomly select packages for inspection. CBP inspects for, among other things, illegally imported controlled substances, contraband, and items—like personal shipments of noncontrolled prescription drugs—that may be inadmissible. CBP inspections can include examining the outer envelope of the package, using X-ray detectors, or opening the package to physically inspect the contents. Each year the international mail and carrier facilities process hundreds of millions of pieces of mail and packages. Among these items are prescription drugs ordered by consumers over the Internet, the importation of which is prohibited under current law, with few exceptions.

Two acts—the Federal Food, Drug, and Cosmetic Act and the Controlled Substances Import and Export Act—specifically regulate the importation of prescription drugs into the United States. Under the Federal Food, Drug, and Cosmetic Act, as amended, FDA is responsible for ensuring the safety, effectiveness, and quality of domestic and imported drugs and may refuse to admit into the United States any drug that appears to be adulterated, misbranded, or unapproved for the U.S. market as defined in the act.[5] Under the act and implementing regulations, this includes foreign versions of FDA-approved drugs if, for example, neither the foreign manufacturing facility nor the manufacturing methods and controls were reviewed by FDA for compliance with U.S. statutory and regulatory standards. The act also prohibits reimportation of a prescription drug manufactured in the United States by anyone other than the original manufacturer of that drug. According to FDA, prescription drugs imported by individual consumers typically fall into one of these prohibited categories. However, FDA has established a policy that allows local FDA officials to use their discretion to not interdict personal prescription drug imports that do not contain controlled substances under specified circumstances, such as importing a small quantity for treatment of a

[5]An unapproved drug includes one that has not been demonstrated to be safe and effective and for which the manufacturing facility, methods, and controls have not been shown to meet FDA standards. Failure to meet other statutory and regulatory standards relating to labeling, handling, and packaging may result in a drug being considered adulterated or misbranded. See 21 U.S.C. §§ 351, 352, 355.

serious condition, generally not more than a 90-day supply of a drug not available domestically.[6] The importation of prohibited foreign versions of prescription drugs like Viagra (an erectile dysfunction drug) or Propecia (a hair loss drug), for example, would not qualify under the personal importation policy because approved versions are readily available in the United States.

In addition, the Controlled Substances Import and Export Act, among other things, generally prohibits personal importation of those prescription drugs that are controlled substances, such as Valium. Under the act, shipment of controlled substances to a purchaser in the United States from another country is only permitted if the purchaser is registered with DEA as an importer and is in compliance with the Controlled Substances Import and Export Act and DEA requirements. As outlined in the act, it would be difficult, if not impossible, for an individual consumer

[6]According to the policy, other conditions should be met as well, such as (1) provision of the name and address of the doctor licensed in the United States responsible for the importer's treatment with the product or evidence that the product is for continuation of treatment begun in a foreign country and (2) the absence of any known commercialization or promotion to persons residing in the United States by those involved in the distribution of the product at issue. Alternatively, in the case of a drug that is not for a serious condition, the policy also permits FDA officials to use their discretion to allow importation of that drug if the intended use is identified and the product is not known to represent a significant health risk. A complete description of FDA's personal importation policy can be found in chapter 9 of FDA's *Regulatory Procedures Manual,* which is available on the agency's Web site.

seeking to import a controlled substance for personal use to meet the standards for registration and related requirements.[7]

CBP is to seize illegally imported controlled substances it detects on behalf of DEA.[8] CBP may take steps to destroy the seized and forfeited substance or turn the seized substance over to other federal law enforcement agencies for further investigation.[9] CBP is to turn over packages suspected of containing prescription drugs that are not controlled substances to FDA.[10] FDA investigators may inspect such packages and hold those that appear to be adulterated, misbranded, or unapproved, but must notify the addressee and allow that individual the opportunity to present evidence as to why the drug should be admitted into the United States.[11] If the addressee does not provide evidence that overcomes the appearance of inadmissibility, then the item is refused admission and returned to the sender.

[7]The act and implementing regulations permit an individual traveler under certain circumstances to carry a personal use quantity of a controlled substance (except a substance in schedule I) across the U.S. border, but they do not make a similar exception for importation by mail or private carrier.

[8]See 19 U.S.C. § 1595a(c)(1)(B); 19 C.F.R. §§ 162.23, 145.59, 145.58, 12.36. Controlled substances in schedules I and II are subject to summary forfeiture without notice, but those in schedule III through V are not.

[9]See 19 C.F.R. §§ 162.31, 162.32, 162.45, 162.45a, 162.46, 162.47, 162.63.

[10]See 21 U.S.C. § 381(a); 19 C.F.R. §§ 12.1(a), 145.57; see also Chapter 9 of FDA's *Regulatory Procedures Manual*, Subchapter Coverage of Personal Importations, "Mail Shipments" http://www.fda.gov/ora/compliance_ref/rpm_new2/ch9pers.html.

[11]See 21 U.S.C. § 381(a); 21 CFR §1.94.

Investigations that may arise from CBP and FDA inspections may fall within the jurisdiction of other federal agencies. DEA, ICE, and FDA investigators have related law enforcement responsibilities and may engage in investigations stemming from the discovery of illegally imported prescription drugs. Although USPS's Inspection Service does not have the authority, without a federal search warrant, to open packages suspected of containing illegal drugs, it may collaborate with other federal agencies in certain investigations. Also, ONDCP is responsible for formulating the nation's drug control strategy and has general authority for addressing policy issues concerning the illegal distribution of controlled substances. ONDCP's authority does not, however, include prescription drugs that are not controlled substances.

The Volume of Prescription Drug Imports Is Unknown but Believed to Be Substantial, and the Safety of These Drug Imports Is Not Assured

My statement will now focus on what the available data show about the volume and safety of prescription drugs imported into the United States for personal use through the international mail and private carriers.

CBP and FDA Do Not Know the Scope of Prohibited Prescription Drug Importation, but They Believe it to Be Substantial

In our report, we state that CBP and FDA do not systematically collect data on the volume of prescription drugs and controlled substances they encounter at the mail and carrier facilities. CBP and FDA officials have said that in recent years they have observed increasingly more packages containing prescription drugs being imported through the mail facilities, but neither agency has complete data to estimate the volume of importation. FDA officials told us that CBP and FDA currently have no mechanism for keeping an accurate count of the volume of illegally imported drugs, because of the large volume of packages arriving daily through the international mail and carriers. Furthermore, FDA officials told us that FDA did not routinely track items that contained prescription drugs potentially prohibited for import that they released and returned for delivery to the recipient. However, they said that FDA had begun gathering from the field information on the imported packages it handles, but as of July 2005, this effort was still being refined.

We also report that CBP and FDA, in coordination with other federal agencies, have conducted special operations targeted to identify and tally the packages containing prescription drugs imported through a particular facility during a certain time period and to generate information for possible investigation. The limited data collected have shown wide variations in volume. For example, at one mail facility CBP officials estimated that approximately 3,300 packages containing prescription

drugs entered the facility in 1 week and at another mail facility CBP officials estimated that 4,300 such packages entered the facility in 1 day. While these data provide some insight regarding the number of packages containing prescription drugs at a selected mail facility during a certain time period, the data are not representative of other time periods or projectable to other facilities.

Our report also notes that during congressional hearings over the past 4 years, FDA officials, among others, have presented estimates of the volume of prescription drugs imported into the United States through mail and express carrier facilities ranging from 2 million to 20 million packages in a given year. Each estimate has its limitations; for example, some estimates were extrapolations from data gathered at a single mail facility. More recently, a December 2004 HHS report stated that approximately 10 million packages containing prescription drugs enter the United States—nearly 5 million packages from Canada and another 5 million mail packages from other countries.[12] However, these estimates also have limitations, being partially based on extrapolations from limited FDA

[12]HHS Task Force on Drug Importation, *Report on Prescription Drug Importation*, Department of Health and Human Services, December 2004.

observations at international mail branch facilities.[13] Without an accurate estimate of the volume of importation of prescription drugs, federal agencies cannot determine the full scope of the importation issue.

The Safety of Prescription Drug Imports Is Not Assured

Regarding the safety of prescription drug imports, we report that FDA officials have said that they cannot provide assurance to the public regarding the safety and quality of drugs purchased from foreign sources, which are largely outside of their regulatory system. FDA officials also said that consumers who purchase prescription drugs from foreign-based Internet pharmacies are at risk of not fully knowing the safety or quality of what they are importing. While some consumers may purchase genuine products, others may unknowingly purchase counterfeit products, expired drugs, or drugs that were improperly manufactured.

In addition, we report on CBP's and FDA's limited analysis of the imported prescription drugs identified during special operations. The results of these efforts have raised questions about the safety of some of the drugs.

[13]FDA officials told us that FDA developed its estimate for Canadian drugs entering the country using (1) IMS Health estimates (IMS Health is a management consulting firm that provides information to pharmaceutical and health care industries) that 12 million prescriptions sold from Canadian pharmacies were imported into the United States in 2003 and (2) FDA's experience during special operations at various locations from which it concluded that there appeared to be about 2.5 prescriptions in each package. According to FDA officials, the estimate for other countries was an extrapolation using the estimated 5 million packages from Canada in conjunction with FDA's observations, likewise made during special operations, that 50 percent of the mail packages enter from countries other than Canada.

For example, during a special operation in 2003 to identify and assess counterfeit and potentially unsafe imported drugs at four mail facilities, CBP and FDA inspected 1,153 packages that contained prescription drugs.[14] According to a CBP report, 1,019, or 88 percent, of the imported drug products were in violation of the Federal Food, Drug, and Cosmetic Act or the Controlled Substances Import and Export Act.

Consistent with these concerns, we report on the findings of our June 2004 report in which we identified several problems associated with the handling, FDA approval status, and authenticity of 21 prescription drug samples we purchased from Internet pharmacies located in several foreign countries—Argentina, Costa Rica, Fiji, Mexico, India, Pakistan, the Philippines, Spain, Thailand, and Turkey.[15] Our work showed that most of the drugs, all of which we received via consignment carrier shipment or the U.S. mail, were unapproved for the U.S. market because, for example, the labeling or the foreign manufacturing facility, methods, and controls were not reviewed by FDA. We observed during the site visits undertaken for our current report that in addition to some prescription drugs imported through the mail and carrier facilities not being shipped in protective

[14]According to CBP officials, packages shipped through four mail facilities were examined over a 3-day period. Approximately 100 parcels (each of which may have contained multiple drug products) per day per facility were selected based upon their country of origin and CBP's historical experience.

[15]GAO-04-820 and GAO-04-888T.

packages, some drugs also lacked product identifications, directions for use, or warning labels. Furthermore, for some drugs, the origin and contents could not be immediately determined by CBP or FDA inspection.

Highly Addictive Controlled Substances Are Widely Available via the Internet

Our report also noted that federal agencies and professional medical and pharmacy associations have found that consumers of any age can obtain highly addictive controlled substances from Internet pharmacies, sometimes without a prescription or consultation with a physician. Both DEA and ONDCP have found that the easy availability of controlled substances directly to consumers over the Internet has significant implications for public health, given the opportunities for misuse and abuse of these addictive drugs. In addition, the American Medical Association recently testified that Internet pharmacies that offer controlled substances without requiring a prescription or consultation with a physician contribute to the growing availability and increased use of addictive drugs for nonmedical purposes.

Some Targeted Packages Containing Prescription Drugs Are Interdicted, but Many Others Are Not

My statement will now focus on the procedures and practices used at selected facilities to inspect and interdict prescription drugs unapproved for import.

New Procedures Should Encourage Uniform Practices, but They Still Allow Many Packages Containing Prescription Drugs to Be Released

With regard to procedures and practices used at selected facilities to inspect and interdict prescription drugs unapproved for import, our report cites our July 2004 testimony in which we reported that CBP and FDA officials at selected mail and carrier facilities used different practices and procedures to inspect and interdict packages that contain prescription drugs.[16] While each of the facilities we visited targeted packages for inspection, the basis upon which packages were targeted could vary and was generally based on several factors, such as the inspector's intuition and experience, whether the packages originated from suspect countries or companies, or were shipments to individuals. At that time, we also reported that while some targeted packages were inspected and interdicted, many others either were not inspected and were released to the addressees or were released after being held for inspection. FDA officials said that because they were unable to process the volume of targeted packages, they released tens of thousands of packages containing drug products that may violate current prohibitions and could have posed a health risk to consumers.

In August 2004, FDA issued standard operating procedures outlining how FDA personnel are to prioritize packages for inspection, inspect the packages, and make admissibility determinations of FDA-regulated

[16]See GAO, *Prescription Drugs: Preliminary Observations on Efforts to Enforce the*

pharmaceuticals imported into the United States via international mail. Under the procedures, CBP personnel are to forward to FDA personnel any mail items, from FDA's national list of targeted countries and based on local criteria,[17] that appear to contain prescription drugs. Deviations from the procedures must be requested by facility personnel and approved by FDA management. According to FDA officials, these procedures have been adopted nationwide. While the new procedures should encourage processing uniformity across facilities, many packages that contain prescription drugs are still released. Specifically, according to the procedures, all packages forwarded by CBP but not processed by FDA inspectors at the end of each workday are to be returned for delivery by USPS to the recipient. However, according to the procedures, packages considered to represent a significant and immediate health hazard may be held over to the next day for processing.

Our report cites CBP and FDA officials at two facilities who told us that the new procedures resulted in an increase in the number of packages CBP personnel refer to FDA. Officials at one facility estimated that CBP referrals have increased from approximately 500 to an average of 2,000 packages per day. The FDA officials noted that the procedures did not resolve the heavy volume of prescription drug importation or FDA's ability

Prohibitions on Personal Importation, GAO-04-839T (Washington, D.C.: July 22, 2004).

[17]Local criteria can include other targeted countries and additional intelligence.

to deal with the volume, nor were they designed to do so. While the packages that are not targeted are released without inspection, so are many packages that are targeted and referred to FDA personnel. At one facility, FDA officials estimated that each week they return without inspection 9,000 to 10,000 of the packages referred to them by CBP. They said these packages were given to USPS officials for delivery to the addressee.

New CBP Controlled Substances Policy May Improve Interdiction Efforts, but Impact on Importation Is Unclear

Regarding the procedures and practices used to inspect and interdict certain controlled substances, our report cites our July 2004 testimony in which we reported that CBP officials were to seize the illegally imported controlled substances they detected.[18] However, at that time, some illegally imported controlled substances were not seized by CBP. For example, CBP officials at one mail facility told us that they experienced an increased volume of controlled substances and, in several months, had accumulated a backlog of over 40,700 packages containing schedule IV substances.

According to our report, CBP field personnel said they did not have the resources to seize all the controlled substances they detected. Officials said that the seizure process can be time-consuming, taking approximately

[18]GAO-04-839T.

1 hour for each package containing controlled substances. According to CBP officials, when an item is seized, the inspector records the contents of each package—including the type of drugs and the number of pills or vials in each package. If the substance is a schedule I or II controlled substance, it is to be summarily forfeited without notice, after seizure. However, if it is a schedule III through V controlled substance, CBP officials are to notify the addressee that the package was seized[19] and give the addressee an opportunity to contest the forfeiture by providing evidence of the package's admissibility and trying to claim the package at a forfeiture hearing.[20]

Our report goes on to say that to address the seizure backlog and give CBP staff more flexibility in handling controlled substances, in September 2004, CBP implemented a national policy for processing controlled substances, schedule III through V, imported through the mail and carrier facilities. According to the policy, packages containing controlled substances should no longer be transferred to FDA for disposition, released to the addressee, or returned to the sender. CBP field personnel are to hold the packages containing controlled substances in schedules III through V as unclaimed

[19]The seized package could also be submitted to ICE for possible investigation of the addressee and the sender.

[20]Since schedule I and schedule II controlled substances are subject to summary forfeiture without notice, there is no opportunity to contest the forfeiture of these drugs.

or abandoned property as an alternative to a seizure.[21] According to a CBP headquarters official, processing a controlled substance as abandoned property is a less arduous process because it requires less information be entered into a database than if the same property were to be seized. Once CBP deems the controlled substance to be unclaimed property, the addressee is notified that he or she has the option to voluntarily abandon the package or have the package seized. If the addressee voluntarily abandons the package or does not respond to the notification letter within 30 days, the package will be eligible for immediate destruction. If the addressee chooses to have the package seized, there would be an opportunity to contest the forfeiture and claim the package, as described above. CBP also instituted an on-site data collection system at international mail and express carrier facilities to record schedule III through V controlled substances interdicted using this new process.[22] CBP reported that from September 2004 to the end of June 2005, a total of approximately 61,700 packages of these substances were interdicted,

[21]Under the policy, unless accompanied by a valid DEA Import Permit or DEA Declaration, schedules I and II controlled substances are to be seized pursuant to 19 U.S.C § 1595a(c)(1)(B) and processed in accordance with established seized asset procedures.

[22]CBP officials emphasized that these data only include schedule III through V controlled substances interdicted through its new process and do not include those schedule III through V controlled substances seized. According to a CBP headquarters official, the number of interdictions made using the controlled substance policy implemented on September 1, 2004, refers to single packages, because these detentions are almost all personal use quantities. In contrast, CBP seizure data for schedules III, IV, and V controlled substances are most likely commercial shipments and, therefore, could include multiple packages.

about 61,500 at international mail facilities and 200 at express carrier facilities.

We report that generally, CBP officials we interviewed told us that the recent policy improved their ability to record information about and destroy schedule III through V controlled substances they detected. A CBP official at one facility said that the abandonment process is faster than the seizure process, as it requires much less paperwork. A CBP headquarters official told us that the abandonment process takes an inspector at a mail facility about 1 minute to process a package. He added that the new policy was intended to eliminate the backlog of schedule III through V controlled substances at the facilities. However, we also report that CBP officials in the field and in headquarters said that they do not know whether the new policy has had any impact on the volume of controlled substances illegally entering the country that reach the intended recipient. Generally, CBP officials do not know the extent of packages that contain controlled substances that are undetected and released. For example, CBP officials at one facility told us that they used historical data to determine the countries that are likely sources for controlled substances and target the mail from those countries. They do not know the volume of controlled substances contained in the mail from the nontargeted countries. A CBP official at another facility said that he believed the volume of controlled

substances imported through the facility had begun to decrease, but he had no data to support his claim.

Packages Containing Prescription Drugs Can Bypass FDA Review at the Carrier Facilities

According to our report, packages containing prescription drugs can also bypass FDA inspection at carrier facilities because of inaccurate information about the contents of the package. Unlike packages at mail facilities, packages arriving at carrier facilities we visited are preceded by manifests, which provide information from the shipper, including a description of the packages' contents. While the shipments are en route, CBP and FDA officials are to review this information electronically and select packages they would like to inspect when the shipment arrives. FDA officials at two carrier facilities we visited told us they review the information for packages described as prescription drugs or with a related term, such as pharmaceuticals or medicine. CBP and FDA officials told us that there are no assurances that the shipper's description of the contents is accurate. The FDA officials at the carrier facilities we visited told us that if a package contains a prescription drug but is inaccurately described, it would not likely be inspected by FDA personnel.

Factors beyond Inspection and Interdiction Complicate Efforts to Enforce the Prohibitions on Personal Importation of Prescription Drugs

My statement will now focus on the three factors that our report identified as affecting federal agency efforts to enforce the prohibition on prescription drug importation for personal use through international mail and carrier facilities.

The Volume of Imports Can Strain Federal Resources

In our report, we state that the current volume of prescription drug imports, coupled with competing agency priorities, has strained federal inspection and interdiction resources allocated to the mail facilities. CBP and FDA officials told us that the recent increase in American consumers ordering drugs over the Internet has significantly contributed to increased importation of these drugs through the international mail. CBP officials said that they are able to inspect only a fraction of the large number of mail and packages shipped internationally. FDA officials have said that the large volume of imports has overwhelmed the resources they have allocated to the mail facilities and they have little assurance that the available field personnel are able to inspect all the packages containing prescription drugs illegally imported for personal use through the mail. In addition, agencies have multiple priorities, which can affect the resources they are able to allocate to the mail and carrier facilities. For example, FDA's multiple areas of responsibility include, among other things,

regulating new drug product approvals, the labeling and manufacturing standards for existing drug products, and the safety of a majority of food commodities and cosmetics, which, according to FDA officials, all go to FDA's mission of protecting the public health while facilitating the flow of legitimate trade. CBP's primary mission is preventing terrorists and terrorist weapons from entering the United States while also facilitating the flow of legitimate trade and travel. DEA's multiple priorities include interdicting illicit drugs such as heroin or cocaine, investigating doctors and prescription forgers, and pursuing hijackings of drug shipments.

We also report on HHS and CBP assessments of resources needed to address the volume of illegally imported drugs coming into the country. In a 2004 report on the importation of prescription drugs, the Secretary of HHS stated that substantial resources are needed to prevent the increasing volume of packages containing small quantities of drugs from entering the country.[23] The Secretary found that despite agency efforts, including those with CBP, FDA currently does not have sufficient resources to ensure adequate inspection of the current volume of personal shipments of

[23]HHS Task Force on Drug Importation, *Report on Prescription Drug Importation*, Department of Health and Human Services, December 2004. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 directed the Secretary of Health and Human Services, in consultation with appropriate government agencies, to conduct a study of the importation of drugs into the United States, including, according to the conference report for the legislation, a review of the adequacy of federal agency resources to inspect and interdict drugs unapproved for import, and submit a report to Congress. Pub. L. No. 108-173, § 1122, 117 Stat. 2066, 2469 (2003), H.R. Conf. Rep. No. 105-39, at 833-34 (2003).

prescription drugs entering the United States. CBP is also in the early stages of assessing the resources it needs at the mail facilities to address the volume of controlled substance imports. However, CBP officials admit that an assessment of resource needs is difficult because they do not know the scope of the problem and the impact of the new procedures. A CBP official told us that CBP has a statistician working on developing estimates on the volume of drugs entering mail facilities; however, he was uncertain whether this effort would be successful or useful for allocating resources. Likewise, in March 2005, FDA officials told us that they had begun to gather from the field information on the imported packages it handles, such as the number of packages held, reviewed, and forwarded for further investigation. However, as of July 2005, they could not provide any data because, according to the officials, this effort was new and still being refined.

Internet Pharmacies Challenge Law Enforcement Efforts

According to our report, Internet pharmacies, particularly foreign-based sites, which operate outside the U.S. regulatory system, pose a challenge for regulators and law enforcement agencies. In an earlier 2004 report, we described how traditionally, in the United States, the practice of pharmacy is regulated by state boards of pharmacy, which license pharmacists and pharmacies and establish and enforce standards. To legally dispense a prescription drug, a licensed pharmacist working in a licensed pharmacy must be presented a valid prescription from a licensed health care

professional. The Internet allows online pharmacies and physicians to anonymously reach across state and national borders to prescribe, sell, and dispense prescription drugs without complying with state requirements or federal regulations regarding imports.

In addition, we report that the nature of the Internet has challenged U.S. law enforcement agencies investigating Internet pharmacies, particularly foreign-based sites. Internet sites can easily be installed, moved, or removed in a short period of time. This fluidity makes it difficult for law enforcement agencies to identify, track, monitor, or shut down those sites that operate illegally. Moreover, investigations can be more difficult when they involve foreign-based Internet sites, whose operators are outside of U.S. boundaries and may be in countries that have different drug approval and marketing approaches than the United States has. For example, according to DEA officials, drug laws and regulations regarding controlled substances vary widely by country. DEA officials told us their enforcement efforts with regard to imported controlled substances are hampered by the different drug laws in foreign countries. Internet pharmacy sites can be based in countries where the marketing and distribution of certain controlled substances are legal. Steroids, for example, sold over the Internet may be legal in the foreign country in which the online pharmacy is located. Federal agencies can also face challenges when working with foreign governments to share information or develop mechanisms for

cooperative law enforcement. For example, FDA officials have testified that they possess limited investigatory jurisdiction over sellers in foreign countries and have had difficulty enforcing the law prohibiting prescription drug importation when foreign sellers are involved. A DEA official told us that it was difficult to convince some foreign governments that the illegal sale of prescription drugs over the Internet is a global problem and not restricted to the United States.

In our report, we also note that FDA and DEA officials told us that they work with commercial firms, including express carriers, credit card organizations, Internet providers, and online businesses to obtain information to investigate foreign pharmacies, but these investigations are complicated by legal and practical considerations. FDA and DEA officials said that the companies have been willing to work with government agencies to stop transactions involving prescription drugs prohibited from import, and some have alerted federal officials when suspicious activity is detected. However, officials also identified current legal and practical considerations that complicated obtaining information from organizations, such as credit card organizations. For example, according to FDA, DEA,

and ICE officials, credit card organizations[24] and banks and other financial institutions[25] that issue credit cards will not provide to the agencies information about the parties involved in the transaction without a subpoena. Representatives from the credit card companies we contacted explained that these issues generally are resolved if the agency issues a properly authorized subpoena for the desired information.[26]

The Notification Process Challenges Enforcement Efforts

We also report that FDA headquarters officials said that packages that contain prescription drugs for personal use that appear to be prohibited from import pose a challenge to their enforcement efforts because these packages cannot be automatically refused. Before any imported item is refused, the current law requires FDA to notify the owner or consignee that the item has been held because it appears to be prohibited and give the product's owner or consignee an opportunity to submit evidence of admissibility. If the recipient does not respond or does not present enough

[24]Two types of credit card organizations handle the four major U.S. credit cards. Credit card associations, such as Visa and MasterCard, license their member banks to issue bank cards, authorize merchants to accept those cards, or do both. In contrast, full-service credit card companies, such as American Express and Discover, issue their own brands of cards directly to customers and authorize merchants to accept those cards. See also GAO, *Money Laundering: Extent of Money Laundering through Credit Cards Is Unknown*, GAO-02-670 (Washington, D.C.: July 22, 2002), and *Internet Gambling: An Overview of the Issues*, GAO-03-89 (Washington, D.C.: December 2, 2002).

[25]When banks and financial institutions, rather than the credit card company, have the direct relationship with the merchants and credit cardholders, the former are the primary source of transactional information needed for law enforcement purposes.

[26]According to a DEA official, the majority of Internet drug sites used the payment systems of the two associations we contacted.

evidence to overcome the appearance of inadmissibility, then the item can be returned to the sender, or in some cases destroyed.

FDA officials told us that this requirement applies to all drug imports that are held under section 801(a) of the Federal Food, Drug, and Cosmetic Act. Nonetheless, they said that they believe this notification process is time consuming because each package must be itemized and entered into a database; a letter must be written to each addressee; and the product must be stored. The process can take up to 30 days per import—and can hinder their ability to quickly handle packages containing prescription drugs prohibited from import. According to FDA investigators, in most instances, the addressee does not present evidence to support the drugs' admissibility, and the drugs are ultimately provided to CBP or the U.S. Postal Service for return to sender. FDA headquarters officials told us that the Standard Operating Procedures, introduced in August 2004 and discussed earlier in this report, were an attempt to help FDA address the burden associated with the notification process because the procedures were designed to focus resources on packages containing drugs considered to be among the highest risk.

Our report further indicates that FDA and the Secretary of HHS have raised concerns about FDA's notification process, noting that it is time-consuming and resource intensive, in testimony before Congress, but did

not propose any legislative changes to address the concerns identified. In May 2001, FDA's Acting Principal Deputy Commissioner wrote a memorandum to the Secretary of HHS expressing concern about the growing number of drugs imported for personal use and the dangers they posed to public health. The memorandum explained that because of the notice and opportunity to respond requirements, detaining and refusing entry of mail parcels was resource intensive. The Acting Principal Deputy Commissioner proposed, among other things, the removal of the requirement that FDA issue a notice before it could refuse and return personal use quantities of FDA-regulated products that appear violative of the Food, Drug, and Cosmetic Act. He noted that removal of the notification requirement would likely require legislation, but without this change, FDA could not effectively prohibit mail importation for personal use. As of July 2005, according to FDA officials and an HHS official, the Secretary had not responded with a specific legislative proposal to change FDA's notification requirement. FDA officials said that there are some complicating issues associated with eliminating the notification requirement; for example, the importance of providing due process, which basically gives individuals the opportunity to present the case as to why they should be entitled to receive the property (e.g., prescription drugs that they ordered from a foreign source), and/or the extent the law should be changed to cover all imported prescription drugs and other products. In

addition, USPS indicated that any discussion of options to expedite the processing and disposition of prescription drugs must consider international postal obligations, specifically the requirements of the Universal Postal Union (UPU). FDA officials said that currently, the notification requirement also applies to large commercial quantities of prescription drugs and other nonpharmaceutical products for which the requirement is not a problem. They said it has become a burden only because FDA and CBP are overwhelmed with a large volume of small packages.

Furthermore, we report that FDA officials said that they have considered other options for dealing with this issue, such as summarily returning each package to the sender without going through the process. However, they said that the law would likely need to be changed to allow this, and, as with the current process, packages that are returned to the sender could, in turn, be sent back by the original sender to go through the process again. They said that another option might be destruction, but they were uncertain whether they had the authority to destroy drugs FDA intercepts; they indicated that the authority might more likely lie with CBP. Regardless, FDA officials said that whatever approach was adopted, FDA might continue to encounter a resource issue because field personnel would still need to open and examine packages to ascertain whether they contained unapproved prescription drugs.

Federal Efforts to Coordinate Law Enforcement Activities Could Benefit from a Strategic Framework

My statement will now focus on efforts federal agencies have undertaken to coordinate the enforcement of the prohibitions on personal importation of prescription drugs.

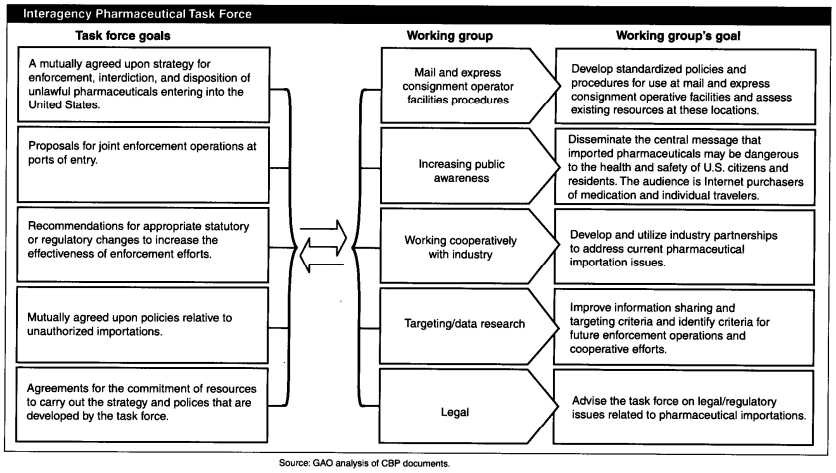
Federal Agencies Have Recently Begun to Coordinate Efforts to Focus on Prescription Drugs Imported for Personal Use

According to our report, since 1999, federal law enforcement and regulatory agencies have organized various task forces and working groups to address issues associated with purchasing prescription drugs over the Internet; however, recent efforts have begun to focus particular attention on imported prescription drugs. For example, according to an FDA official, many of FDA's efforts, started in 1999, focused on Internet pharmaceutical sales by illicit domestic pharmacies and the risks associated with purchasing those drugs, rather than drugs that are being imported from foreign countries. As our report discusses, more recent efforts have focused on prescription drugs entering international mail and express carrier facilities.

In January 2004, the CBP Commissioner initiated an interagency task force on pharmaceuticals, composed of representatives from CBP, FDA, DEA, ICE, and ONDCP as well as legal counsel from the Department of Justice. According to the Commissioner, the proposal to create the task force was prompted by "intense public debate and congressional scrutiny, which has

resulted in increasing pressure being applied to regulatory and law enforcement agencies to develop consistent, fair policies" to address illegal pharmaceuticals entering the United States. The Commissioner proposed that the task force achieve five specific goals, and according to a CBP official, five working groups were established to achieve these goals. Figure 1 shows the task force goals, the five working groups, and the goals of each working group.

Figure 1: Interagency Pharmaceutical Task Force and Working Group Goals



Source: GAO analysis of CBP documents.

CBP officials and other members of the task force provided examples of activities being carried out or planned by task force working groups. For example, the working group on mail and express consignment operator facilities procedures has carried out special operations at five international mail and three express carrier facilities to examine parcels suspected of containing prohibited prescription drugs over specific periods of time, such as 2 or 3 days. While similar operations have occurred since 2000, a CBP official told us that those conducted under the

task force are multiagency efforts; they are expected to continue during the remainder of 2005 at all of the remaining mail facilities and some of the carrier facilities. Our report describes activities of the other working groups.

In addition, we report that the task force members are working with ONDCP to address the importation of controlled substances through international mail and carrier facilities. In October 2004, ONDCP issued a plan for addressing demand and trafficking issues associated with certain man-made controlled substances—such as pain relievers, tranquilizers, and sedatives.[27] Among other things, ONDCP recommended that DEA, CBP, ICE, State Department, National Drug Intelligence Center, and FDA work with USPS and private express mail delivery services to target illegal mail order sales of chemical precursors, synthetic drugs, and pharmaceuticals, both domestically and internationally. ONDCP officials said that a multiagency working group is meeting to discuss what can be done to confiscate these controlled substances before they enter the country.

[27]ONDCP, *National Synthetic Drugs Action Plan: The Federal Government Response to the Production, Trafficking, and Abuse of Synthetic Drugs and Diverted Pharmaceutical Products* (Washington D.C.; October 2004). According to ONDCP, the *Action Plan* is to provide a blueprint for action under the President's National Drug Control Strategy and "focuses primarily on illicitly manufactured synthetic drugs which are not of primarily organic origin" and "selected pharmaceutical products which are sometimes diverted from legitimate commerce."

Finally, we report that USPS is exploring what additional steps it can take to further help the task force. USPS officials said that they proposed, during a July 2004 hearing, the possibility of cross-designating U.S. Postal Inspectors with Customs' authority so that Postal Inspectors can conduct warrant-less searches, at the border, of incoming parcels or letters suspected of containing illegal drugs. According to USPS officials, such authority would facilitate interagency investigations. They said that their proposal has yet to be finalized with CBP. In addition, internationally, USPS has drafted proposed changes to the U.S. listing in the Universal Postal Union List of Prohibited Articles.[28] This action is still pending.

A Strategic Framework Would Further Enhance Task Force Efforts

In our report, we state that although the task force has taken positive steps toward addressing issues associated with enforcing the laws on personal imports, it has not fully developed a strategic framework that would allow the task force to address many of the challenges we identify in this report. Our review showed that the task force has already begun to establish some elements of a strategic framework, but not others. For example, the Commissioner's January 2004 memo laid out the purpose of the task force and why it was created. However, it has not defined the scope of the

[28]The Universal Postal Union List of Prohibited Articles is a listing of articles prohibited for importation into the United States, as well as other member countries of the UPU. The listing is shared with foreign postal administrations to enable them to educate their customers on country prohibitions for international mail.

problem it is trying to address because, as discussed earlier, CBP and FDA have yet to develop a way to estimate the volume of imported prescription drugs entering specific international mail and carrier facilities. In addition, while the task force and individual working groups have goals that state what they are trying to achieve, the task force has not established milestones and performance measures to gauge results. Furthermore, the task force has not addressed the issue of what its efforts will cost so that it can target resources and investments, balancing risk reduction with costs and considering task force members' other law enforcement priorities. Instead, according to a CBP official, working group projects are done on an ad hoc basis wherein resources are designated for specific operations.

Carrying out enforcement efforts that involve multiple agencies with varying jurisdictions is not an easy task, especially since agencies have limited resources and often conflicting priorities. According to our report, the challenges we identify could be more effectively addressed by using a strategic framework that more clearly defines the scope of the problem by estimating the volume of drugs entering international mail and carrier facilities, establishes milestones and performance measures, determines resources and investments needed to address the flow of imported drugs entering the facilities and where those resources and investments should be targeted, and evaluates progress. Advancing such a strategic framework could establish a mechanism for accountability and oversight. Our report

acknowledges that such a strategic framework needs to be flexible to allow for changing conditions and could help agencies adjust to potential changes in the law governing the importation of prescription drugs for personal use.

GAO Conclusions, Recommendations, and Agency Responses

While acknowledging the complexities of enforcing the laws governing prescription drug imports for personal use, including the involvement of multiple agencies with various jurisdictions and differing priorities, our report concludes that current inspection and interdiction efforts at the international mail branches and express carrier facilities have not prevented the reported substantial and growing volume of prescription drugs from being illegally imported from foreign Internet pharmacies into the United States. CBP and other agencies have taken a step in the right direction by establishing a task force designed to address many of the challenges discussed in this report. However, a strategic framework that facilitates comprehensive enforcement of prescription drug importation laws and measures results would provide the task force with an opportunity to better focus agency efforts to stem the flow of prohibited prescription drugs entering the United States. In addition to the issues addressed by the task force, FDA has also expressed continuing concern to Congress that it encounters serious resource constraints enforcing the law at mail facilities because packages containing personal drug imports must be handled in accordance with FDA's time-consuming and resource-

intensive notification process. FDA has stated that it cannot effectively enforce the law unless the requirement to notify recipients is changed.

Accordingly, to help ensure that the government maximizes its ability to enforce laws governing the personal importation of prescription drugs, our report recommends that the CBP Commissioner, in concert with ICE, FDA, DEA, ONDCP, and USPS, develop and implement a strategic framework for the task force that would promote accountability and guide resource and policy decisions. At a minimum, this strategic framework should include

- establishment of an approach for estimating the scope of the problem, such as the volume of drugs entering the country through mail and carrier facilities;
- establishment of objectives, milestones, and performance measures and a methodology to gauge results;
- determination of the resources and investments needed to address the flow of prescription drugs illegally imported for personal use and where resources and investments should be targeted; and
- an evaluation component to assess progress, identify barriers to achieving goals, and suggest modifications.

In view of FDA's continuing concern about the statutory notification requirement and its impact on enforcement, our report also recommends that the Secretary of HHS assess the ramifications of removing or modifying the requirement, report on the results of this assessment, and, if appropriate, recommend changes to Congress.

In commenting on our report, DEA and ONDCP generally agreed with our recommendation that the CBP task force develop a strategic framework. DEA agreed that such a framework needs to be flexible to allow for changing conditions and said DEA will, in concert with other task force agencies, support the CBP Commissioner's strategic framework for the interagency task force. DHS generally agreed with the contents of our report and said that CBP is convening a task force meeting to discuss our recommendation. While generally concurring with our recommendation for a strategic framework, HHS questioned the need to include an approach for estimating the volume of unapproved drugs entering the country, because it believed its current estimates are valid. HHS also said our statement that the task force agencies could develop statistically valid volume estimates and realistic risk-based estimates of the number of staff needed to interdict parcels at mail facilities did not recognize FDA's current level of effort at these facilities relative to its competing priorities. We believe that developing more systematic and reliable volume estimates might position agencies to better define the scope of the problem so that

decision makers can make informed choices about resources, especially in light of competing priorities. Regarding our recommendation to assess the ramifications of removing or modifying FDA's statutorily required notification process, HHS generally agreed and stated that it intended to pursue an updated assessment. USPS did not state whether it concurred with our recommendations, but it noted that discussions of options to expedite the processing and disposition of prescription drugs must consider international postal obligations.

Mr. Chairman, this concludes my prepared testimony. I would be happy to respond to any questions you or other members of the committee may have at this time.

GAO Contacts and Staff Acknowledgments

For further information about this testimony, please contact me at (202) 512-8816. John F. Mortin, Leo M. Barbour, Frances A. Cook, Katherine M. Davis, Michele C. Fejfar, and Barbara A. Stolz made key contributions to this statement.

Related GAO Products

Prescription Drugs: Strategic Framework Would Promote Accountability and Enhance Efforts to Enforce the Prohibitions on Personal Importation. GAO-05-372. Washington, D.C.: September 8, 2005.

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MR. WHITFIELD. At this time, I'll recognize Mr. Rannazzisi for his opening statement.

MR. RANNAZZISI. Thank you and good afternoon.

Chairman Whitfield, Ranking Member Stupak and distinguished members of the subcommittee, on behalf of Administrator Karen P. Tandy and the men and women of the Drug Enforcement Administration, thank you for the opportunity to discuss our efforts to combat the illegal distribution of controlled substance pharmaceuticals via the Internet.

The illegal use of pharmaceuticals, particularly those containing controlled substances, remains a significant problem. Users obtain these illegal prescriptions from a variety of sources, including doctor shopping, falsified prescriptions and theft.

In recent years, the DEA has seen a significant increase in the availability of controlled substance prescriptions via the Internet. DEA's

efforts are focused on the drug traffickers behind these Internet sites. Often these Internet-based drug traffickers most commonly selling pharmaceutical substitutes or those marketed as pharmaceutical substances often mask their activity as those of legitimate online pharmacies. Their illicit products have no guarantee of safety or effectiveness and offer no assurance of meeting appropriate handling, storage, or shipping standards. These sites provide pharmaceutical products with no face-to-face medical evaluation, no tests, no drug interaction screening, and no follow-up care, all elements present when substances are legitimately prescribed.

Pursuing the organizations that facilitate the illegal sale of controlled substances via the Internet is a priority for DEA. A concerted organizational attack is the most effective way to stop and not just relocate Internet drug traffickers.

Two recent OCDETF operations, Operation Cyber Chase and Operation CYBERx, illustrate such a concerted organizational attack on Internet traffickers on both an international and national scale. As successful as these operations were, no significant investigation could take place without a well-coordinated effort at all levels of law enforcement.

Traditional geographic lines of jurisdiction do not exist on the Internet. Yet law enforcement must abide by such limits. This means that collaboration between the public, interagency, and private sector levels is a key component to successful investigations.

Among other activities, an Internet agency task force with participation from CBP, ONDCP, DOJ, FDA, ICE, and DEA meets regularly to address Internet diversion threats.

Collaboration with the private sector is equally important. Internet drug traffickers must rely extensively on the commercial Internet services, express package and delivery carriers, and financial service companies. The DEA has reached out to each of these sectors and is working to educate and facilitate their assistance in shutting down Internet drug trafficking operations.

In addition, we are working with state authorities and the medical community to disseminate information regarding illegal controlled substance activities via the Internet.

Despite the collaborative efforts, there remains significant challenges in tackling this Internet threat; and a legitimate transaction involving controlled substances over the Internet must be in compliance with the Controlled Substances Act.

Additional clarification of the roles and responsibilities of professionals that use the Internet to meet the needs of clients would not only allow us to more readily identify legitimate online pharmacies and

persons operating or promoting them but assist in gathering information pointing to patterns of abuse. Such clarification would also help us investigate the illegal traffickers hiding behind the facade of an otherwise legitimate practice.

In addition, a statutory definition outlining what constitutes a valid doctor-patient relationship should be established. Also, the penalties associated with the illegal sale of Schedule III to V substances, which are the most common illegally sold controlled substances on the Internet, are not as significant as may be warranted.

The DEA will continue to promote collaborative actions in order to investigate and arrest the individuals illegally selling controlled substances. We're appreciative of the support from key sectors of the Internet-related business community. The DEA is committed to developing this relationship even farther.

The Internet presents a new and significant challenge for law enforcement. Each investigation helps DEA and sister agencies learn how to conduct better investigations. From the experiences that we have had, DEA has refined the methods by which we identify, pursue and ultimately dismantle these trafficking groups; and we will continue to make this a priority.

Chairman Whitfield, Ranking Member Stupak, members of the subcommittee, I thank you again for this opportunity to testify and look forward to addressing any questions you may have. Thank you.

MR. WHITFIELD. Thank you very much.

[The prepared statement of Joseph Rannazzisi follows:]

PREPARED STATEMENT OF JOSEPH RANNAZZISI, DEPUTY ASSISTANT ADMINISTRATOR, OFFICE OF DIVERSION CONTROL, DEPUTY CHIEF, OFFICE OF ENFORCEMENT OPERATIONS, DRUG ENFORCEMENT OPERATIONS

Introduction

Chairman Whitfield, Ranking Member Stupak, and distinguished Members of the Subcommittee, on behalf of Administrator Karen P. Tandy, and the men and women of the Drug Enforcement Administration, thank you for the opportunity to discuss our efforts to combat the illegal distribution of controlled substance pharmaceuticals via the Internet.

The illegal sale of pharmaceuticals over the Internet, the most dangerous of which are also controlled substances, continues to be a significant challenge facing the DEA. Internet-based drug traffickers, most commonly selling pharmaceutical substances or those marketed as pharmaceutical substances, often mask their activities as those of legitimate online pharmacies. Their illicit products have no guarantee of safety or effectiveness and offer no assurance of meeting appropriate handling, storage, or shipping standards. Perhaps most disturbing is that many of these Internet pharmaceutical sites—calling them "pharmacies" gives them more credit than they deserve-- are hiding behind a façade of legitimacy by pretending to ask customers health questions. After customers fill out a superficial questionnaire, which is given an

even more cursory review (if any) by a doctor employed by the internet pharmacy, these sites provide pharmaceutical products with no face-to-face medical examination, no tests, no drug interaction screening, and no follow-up care.

Trends in Abuse

A quick search on the Internet reveals thousands of sites offering pharmaceutical controlled substances for sale. The sale of these substances over the Internet is only one way that users illegally acquire pharmaceuticals. The DEA has also investigated cases where prescriptions have been forged; pharmacies have been robbed: unscrupulous doctors have operated "pill mills" that essentially sell prescriptions or drugs after perfunctory or non-existent medical examinations; or pharmaceuticals have been smuggled into the United States. However they are acquired, the illegal use of pharmaceuticals is one of the fastest growing forms of drug abuse.

- According to SAMSHA's (Substance Abuse and Mental Health Services Administration) 2004 National Survey on Drug Use and Health, 6.0 million Americans that year reported non-medical use of psychotherapeutic drugs[1].

- The 2003 Monitoring the Future study found that the annual prevalence of Vicodin (Hydrocodone) abuse, a narcotic pain-reliever, by 12th graders was second only to marijuana.

- A 2005 study by the National Center on Addiction and Substance Abuse (CASA) at Columbia University indicated the abuse of pharmaceutical controlled substances grew at a rate of twice that of marijuana, five times that of cocaine, and 60 times that of heroin between 1992 and 2003.

- The Partnership for a Drug-Free America's 2004 Partnership Attitude Tracking Study found teen abuse of prescription and over-the-counter medications is higher or on par with teen abuse of a variety of illicit drugs—i.e., cocaine/crack (9 percent), Ecstasy (9 percent), methamphetamine (8 percent), LSD (6 percent), ketamine (5 percent), heroin (4 percent), and GHB (4 percent).

Problem of Internet Drug Trafficking

Internet drug traffickers offer drugs for sale without a prescription, without benefit of a legitimate doctor-patient relationship, and at highly inflated prices. Recent DEA investigations involving pharmaceutical drug traffickers using the façade of legitimate online pharmacies reveal pharmaceutical controlled substances being sold at four to ten times the price offered by legitimate "brick and mortar" pharmacies. In all cases, the online scheme is perpetrated by collaborators seeking to profit by trafficking either diverted or counterfeit drugs.

Purchasing pharmaceuticals over the Internet exposes consumers to risks such as purchasing a product that is counterfeit, is improperly handled or stored, is contaminated, or is lacking any warnings or instructions for use. With few exceptions, the consumer has no idea of the content of the substances they are receiving.

Internet traffickers who illegally offer pharmaceutical controlled substances through their websites frequently share characteristics, such as:

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[1] Non-medicinal use of prescription-type pain relievers, tranquilizers, stimulants, or sedatives; does not include over-the-counter drugs.

- Advertise that no prescription is necessary
- Fail to participate in any insurance plan and require payment by credit card or cash C.O.D.
- Offer a limited selection of medications for sale, mostly controlled substances and "lifestyle drugs"
- Fail to request the name, address, and phone number of a current physician
- Are willing to deliver drugs to a post office box or other location to avoid detection by authorities
- Deceptively and inaccurately advise about the law and why it is permissible to obtain pharmaceutical controlled substances from foreign countries via the Internet

As part of the scheme, online "consultations" consisting of medical questionnaires filled out by an individual purport, yet fail, to create a legitimate doctor-patient relationship. A legitimate doctor-patient relationship includes a face-to face consultation, where a licensed physician can examine the physical symptoms reported by a patient before making a diagnosis and authorizing the purchase of a prescription medicine. Filling out a questionnaire, no matter how detailed, is no substitute for this relationship.

DEA's contention that no legitimate doctor-patient relationship exists during these transactions is shared by the medical profession. The Federation of State Medical Boards' (FSMB) policy on Internet prescribing affirms that the prescribing of medications by physicians based on an online medical questionnaire clearly fails to establish an acceptable standard of medical care.[2] The American Medical Association (AMA) has stated that a face-to-face evaluation is necessary to diagnose and confirm a medical need for prescribing.[3] Further, the AMA declares it unethical for a physician to authorize a prescription for someone identified only through electronic means.

Pharmaceuticals can be purchased legitimately over the Internet, but only if the proper protocols are followed. Currently, there are only 12 DEA-registered pharmacies that have been included on a list of Verified Internet Pharmacy Practice Sites (VIPPS) compiled by the National Association of Boards of Pharmacy (NABP), an independent, non-profit organization of licensing boards. The NABP list identifies to the public those online pharmacy practice sites that are appropriately licensed, are legitimately operating via the Internet, and that have successfully completed a rigorous criteria review and inspection. Most other Internet pharmaceutical sales in the United States are legally suspect and potentially very dangerous.

DEA Enforcement Activity

The DEA focuses a significant amount of its resources on attacking Priority Target Organizations (PTOs), which are major drug supply and money laundering organizations operating at the international, national, regional, and local levels that have a significant impact on drug availability. DEA's core competency, the disruption and dismantlement of drug trafficking organizations impacting the United States, is an integral component to both the Department of Justice's Strategic Plan for Fiscal Years 2003 – 2008 and The President's National Drug Control Strategy, February 2005. A concerted organizational attack is the focus of our effort to counter drug traffickers utilizing the Internet to facilitate their illicit trade.

As of October 2005, DEA has initiated 236 investigations of online sales of controlled substances without a prescription. In FY 2004, as a result of online

[2] 2002 – Model Guidelines for the Appropriate Use of the Internet in Medical Practice
[3] H120.949 Guidance for Physicians on Internet Prescribing

pharmacy investigations, DEA seized over $14.5 million in cash, bank accounts, property and computers—a 480 percent increase over 2003 ($2.5 million). Two operations in particular warrant specific mention:

Operation Cyber Chase

- On April 19th and 20th, 2005, the DEA dismantled an international pharmaceutical controlled substance trafficking organization that supplied an estimated 100,000 "customers." As a result of this Organized Crime Drug Enforcement Task Forces (OCDETF) investigation, the leader of the organization (Akhil Bansal) and 25 co-conspirators were arrested in 4 countries. Their web of operations, however, touched many, many more.

  We know that, since at least July 2003, the Bansal organization was responsible for the illegal distribution of 2.5 million dosage units of controlled substances per month to more than 100,000 "customers" without a medical evaluation by a physician. Bansal, an Indian national, supplied eight separate drug organizations that together operated over 200 websites with pharmaceutical controlled substances he arranged to be smuggled from India.

  The success of this operation required the cooperation of numerous international, federal, state, and local law enforcement agencies. Participants included the Federal Bureau of Investigation; Immigration and Customs Enforcement; Food and Drug Administration; Postal Inspection Service; and the Internal Revenue Service, as well as several overseas police agencies including the Australian Federal Police; the Narcotics Control Bureau of India; the Costa Rican Judicial Police and two additional Costa Rican federal agencies, The Drug Control Police, and Drug Institute.

  State and local law enforcement agencies were integral as well. Officers from Pennsylvania, New York, and Florida, contributed to the success of this operation that resulted in the seizure of over 10 million dosage units of pharmaceutical controlled substances, as well as 231 pounds of Ketamine, and $8.5 million.

Operation CYBERx

- On September 21, 2005, a 15-month OCDETF multi-agency Internet investigation concluded with the dismantlement of the Johar Saran drug trafficking organization based in Ft. Worth, Texas. The investigation resulted in 19 arrests including the leader of the organization, Johar Saran. This operation is the domestic bookend to Operation Cyber Chase.

  Saran and his co-conspirators were arrested for supplying pharmaceutical controlled substances directly to U.S. Internet customers without a medical examination by a physician. We believe that since August 2004, the Saran organization was responsible for the illegal distribution of 3.5 million dosage units of Schedule III-V controlled substances per month.

  To date, this investigation has resulted in the seizure of $16.8 million in assets—$1 million in U.S. currency, $5.5 million in bank accounts, $8.6 million in real property, and $1.7 million in jewelry. Immediate suspension orders against the DEA registrations of 21 pharmacies and 20 physicians were served in Texas, New York, Florida, Utah, Washington State, and Puerto Rico.

Again, the success of this operation depended upon the cooperation of several other law enforcement agencies. The Federal Bureau of Investigation, the Internal Revenue Service, the Food and Drug Administration, the Texas Department of Health Services, the Texas Board of Pharmacy, and the Florida Department of Law Enforcement were all key to shutting this organization down.

Interagency Collaboration

I highlighted the cooperation between the DEA and our international, federal, state, and local law enforcement partners because, particularly when we are discussing Internet investigations, no significant investigation could take place without a well coordinated effort. Traditional geographic lines of jurisdiction do not exist on the Internet, yet law enforcement must abide by such limits. This means that collaboration is a key component to successfully investigating and arresting those who are nothing more than drug dealers utilizing the anonymity of the Internet to ply their trade.

To better facilitate this interagency cooperation, a federal interagency task force was established in early 2004 with the purpose addressing Internet diversion of drugs and conducting public outreach on pharmaceutical issues in general. Among other groups, DEA, ONDCP, ICE, CBP, and FDA have been represented at task force meetings past and present. A major focus of this evolving task force has been to reach out to business leaders in key industry sectors that provide services used by Internet pharmaceutical trafficking groups. The purpose of this outreach has been twofold: to raise awareness of the problem; and to elicit voluntary efforts to restrict their services from being used by illicit Internet pharmaceutical traffickers. The task force has also provided support to DEA through ICE and CBP special authorities. ICE and CBP have primary jurisdiction in the enforcement of trans-border smuggling laws and periodically conduct interdiction operations at international mail facilities to identify packages containing illicit pharmaceuticals. The task force meets quarterly and is currently evaluating options for establishing a single reporting point for businesses to report suspicious Internet pharmaceutical sites.

In January and July 2005, DEA in conjunction with the Department of Justice Narcotics and Dangerous Drugs Section hosted a training seminar for Assistant United States Attorneys and DEA personnel to share information on prosecution and investigative strategies for targeting pharmaceutical diversion of controlled substances.

DEA/Private Industry Initiatives

To successfully ply their trade, Internet drug traffickers must rely extensively on the commercial services of three principal business sectors: (1) providers of various internet services – including web hosting, domain name registration, and search; (2) express package delivery companies; and (3) financial services companies, including major credit card companies and third party payment service providers. The DEA has reached out to each of these sectors and is working to educate and facilitate their assistance in shutting down Internet drug trafficking operations.

Several interagency meetings have been held with senior managers and legal counsel from leading Internet, express parcel carriers, and financial services companies. These meetings provided an opportunity for government and the private sector to reach a better understanding of relevant federal laws and explore areas of potential cooperation and voluntary industry actions to curb the expanding illicit sale of pharmaceuticals over the Internet.

In addition to our investigative efforts aimed to shut down Illegal drug sales over the Internet, we are working with the state authorities and representatives of the

pharmacy and medical communities to disseminate information regarding activities that can legally be conducted via the Internet

DEA Field Offices have also taken action to help with this threat. Diversion Investigators conduct on-site licensing inspections to ensure that the pharmacy is aware of its responsibilities under the law. New pharmacy applicants or those seeking a renewal through on-line procedures are now linked to the April 2001 Federal Registrant Guidance Document regarding "Dispensing and Purchasing Controlled Substances over the Internet." Titled "Retail Pharmacy Advisory," this pop up link takes the applicant to the aforementioned Federal Register notice outlining important information for prescribers, pharmacists, and law enforcement alike.

During the CYBERx investigation, the DEA discovered that the main suppliers were legitimate DEA registrants. While we didn't find any criminal negligence in this case, we did implement the Internet Distributor Initiative to increase the awareness of DEA registrants regarding their obligations and possible role in the illegal distribution of pharmaceuticals via the Internet. Based on these meetings, the distributors voluntarily reviewed their customer base and apprised DEA of the termination of business with over 100 known or suspected illegitimate Internet drug trafficking organizations. An analysis of these pharmacies' buying patterns from January – September 2005 revealed over 60,000,000 dosage units of controlled substances had been purchased.

We believe that because of this initiative, many illegal Internet pharmaceutical sites are now unable to purchase large quantities of controlled substances for illegal sale domestically. While this is an effective approach to go after some of the domestic sources of illegal pharmaceuticals supplying the Internet, this will not affect foreign sources of pharmaceuticals. The global nature of the Internet adds to this challenge, as many substances which are controlled in the United States are not controlled elsewhere, and therefore offering to sell these substances on line is not illegal per se.

As a consequence of these and other initiatives, DEA is able to effectively monitor both the supply and dispensing sides of the domestic Internet trafficking problem. The communication between the DEA and the distributors continues to increase. An example of increased cooperation is the fact that distributors are notifying DEA of potential targets, unusual purchasing patterns, and queries from the potential illegitimate Internet pharmacies who have been effectively cut off from supplies by this initiative.

Continuing Challenges

Although no special DEA registration is currently required to market controlled substances online, the tangible aspects of manufacturing, distributing, prescribing, and dispensing pharmaceutical controlled substances remain squarely under the jurisdiction of the Controlled Substances Act. Any legitimate transaction over the Internet must be in compliance with these existing laws. Additional clarification of the roles and responsibilities for professionals seeking to use the Internet to meet the needs of clients would not only allow us to more readily identify legitimate online pharmacies and persons operating and promoting them, but it would also assist in gathering information pointing to patterns of abuse. Such clarification would also help us investigate the illegal traffickers hiding behind the façade of an otherwise legitimate practice.

In addition, there exists no statutory definition specifically outlining what constitutes a valid "doctor/patient" relationship. Further, the penalties associated with the illegal sale of Schedule III-V substances are not as significant as may be warranted.

This does not mean however that Internet drug traffickers can operate freely, as demonstrated by Operations CYBERx and Cyber Chase. The DEA will continue to promote public/private sector and international collaborative actions and use our

existing authority to investigate and arrest the individuals illegally selling controlled substances. The increasing support that we receive from key sectors of the Internet-related business community is essential to turning the tide in this critical area of drug trafficking and abuse. The DEA is committed to developing this relationship even further.

Conclusion

The Internet is a universe that by its very nature is impossible to fully monitor, regulate, and control. While drug traffickers who exploit the Internet to target America's most vulnerable continue to pose a significant threat to citizens' lives and health across the country, the DEA has learned from experience and refined its methods by which we identify, pursue, and ultimately dismantle these groups.

I appreciate the opportunity to testify here today and look forward to answering any questions the subcommittee may have.

MR. WHITFIELD. Mr. Ahern, you are recognized for five minutes.

MR. AHERN. Mr. Chairman, Ranking Member Stupak, let me begin.

Chairman Whitfield, Congressman Norwood, Ranking Member Stupak, I appreciate the opportunity to testify today at today's hearing; and my testimony today will focus on Customs and Border Protection's efforts to prohibit the illegal importation of controlled substances into the United States.

CBP, as the guardians of the Nation's borders, is America's frontline of defense. CBP safeguards the homeland foremost by preventing the entry of terrorists and instruments of terror, while insuring the speedy, orderly, and efficient flow of travel and commerce. At the same time, we must continue to perform our time-honored duties, including the duty to enforce laws related to the admissibility of controlled substances.

Mr. Chairman, I would like to thank this committee for bringing this issue to the forefront of the public's attention. An enormous volume of controlled substances are either purchased over the Internet and shipped through international mail and express courier facilities.

The volume of illegal importation is so great that Customs and Border Protection was forced to streamline its operational processes of controlled substances interdictions at the mail facilities and courier facilities throughout the country. On September 1st of 2004, we implemented a policy in which these locations interdicted Schedules III, IV and V controlled substances but no longer formally seized these items due to the fact it takes approximately one hour to process each one of these seizures. As an alternative, since the majority of these substances are imported in noncommercial quantities, the controlled substances are held as unclaimed personal property. The intended recipients are subsequently then notified of the interdictions and provided with the option of requesting CBP formally seize the controlled substance or abandoning the controlled substances to the government. If the

controlled substances are abandoned or if the intended recipient does not respond to our notification within 30 days, destruction immediately occurs.

Customs and Border Protection is undertaking significant measures to protect U.S. residents from controlled substances manufactured abroad. Specifically, we are instituting a strategy that includes identifying national importation trends by centralizing the functions out of one of our field analytical units, utilizing these trends along with shipper information identified from interdictions at our mail facilities so we can electronically target illegal shipments and conduct both national and localized enforcement operations.

CBP is also an active participant on the interagency task force that works cooperatively with the DEA, the FDA, U.S. Immigration and Customs Enforcement, the Office of National Drug Control Policy, and the Department of Justice. The task force law enforcement principals conducted three-day special operations named Operation Safeguard in 19 instances at international mail branches and two express consignment facilities over the last two years. These enforcement efforts are designed to identify the type, volume, and quality of such shipments. Results from Operation Safeguard indicate in some instances importations are of questionable origin.

The task force has accomplished other significant efforts as well. During my testimony last year before the Senate Permanent Subcommittee on Investigations, I stated that a public service announcement communicating the potential dangers of foreign-made controlled substances was being made jointly by the Food and Drug Administration and with the Customs and Border Protection. I'm pleased to report that the public service announcement has been completed and can be found on CBP and FDA websites.

The task force has also worked with Google Incorporated to provide consumers searching for online pharmacies the ability to obtain information on importation restrictions concerning controlled substances. Specifically, individuals who query Google for items such as steroids are provided a linked page on CBP's website which informs them of importation restrictions. I believe this is an excellent example of private and public sectors partnering together to protect the American public from the illegal acquisition of controlled substances.

In addition, the task force is currently discussing with leading Internet companies, parcel carriers, and payment providers efforts that these industries can undertake to assist Federal authorities in curtailing the supply of illicit Internet sales.

I would also like to recognize efforts by U.S. Immigration and Customs Enforcement. ICE has conducted Operation Apothecary to

address, measure and attack potential vulnerabilities in the entry process that might allow for smuggling of commercial quantities of these illegal products. These special operations include investigative work by the Cyber Crimes Center and enforcement blitzes jointly with Customs and Border Protection at our mail facilities and express consignment facilities.

In conclusion, Customs and Border Protection officers are vigilant in detecting products that violate the Controlled Substances Act. We utilize our agency's valuable resources on a priority basis in protecting U.S. residents against the threat of terrorism, and our experience shows us our officers are unable to identify all the parcels that are coming into our mail and courier facilities.

Even though we have made strides in addressing this problem, the growing problem presents a formidable challenge. We are aggressively utilizing tools to combat the proliferation of controlled substance importations purchased on the Internet, and we'll continue to evaluate approaches that might enhance these efforts.

I thank you for the opportunity to testify today, and I'll look forward to your questions.

MR. WHITFIELD. Thank you, Mr. Ahern.

[The prepared statement of Jayson Ahern follows:]

PREPARED STATEMENT OF JAYSON AHERN, ASSISTANT COMMISSIONER, OFFICE OF FIELD OPERATIONS, BUREAU OF CUSTOMS AND BORDER PROTECTION

INTRODUCTION:

Mr. Chairman, Ranking Member Stupak and other Members of the Committee, I am Jayson P. Ahern, Assistant Commissioner, Office of Field Operations at the Bureau of Customs and Border Protection (CBP). I appreciate the opportunity to testify at today's hearing. My testimony will focus on CBP's efforts to prohibit the illegal importation of controlled substances into the United States.

CBP, as the guardian of the Nation's borders, is America's frontline of defense. CBP safeguards the homeland—foremost, by preventing the entry of terrorists and instruments of terror into the United States, while ensuring the speedy, orderly, and efficient flow of lawful trade and commerce. At the same time, we must continue to perform our time-honored duties, including the duty to enforce laws related to the admissibility of controlled substances falling under the jurisdiction of the Drug Enforcement Administration (DEA).

Mr. Chairman, I would like to thank this Committee for bringing this issue to the forefront of the public's attention. An enormous volume of controlled substances are either purchased over the Internet and shipped through our international mail and express courier facilities, or they may transit our borders through other ports of entry.

The volume of illegal importations is so great that CBP was forced to streamline its operational processing of controlled substance interdictions at the 13 international mail and 29 express courier facilities. On September 1, 2004, we implemented a policy in which these locations interdict Schedules III, IV and V controlled substances but no longer formally seize these substances due to the fact that it takes approximately one hour

to process each seizure. Rather, since the majority of these shipments are imported in non-commercial quantities, the controlled substances are held as unclaimed personal property. The intended recipients are subsequently notified of the interdictions and provided with the option of either requesting that CBP formally seize the controlled substances or of abandoning the controlled substances to the Government. If the controlled substances are abandoned or if the intended recipient does not respond to our notification within 30 days, destruction will occur.

Customs and Border Protection is undertaking significant measures to protect U.S. residents from controlled substances manufactured abroad. Specifically, we are instituting a strategy that includes identifying national importation trends by centralizing this function under one of our field analytical units, using these trends along with shipper information identified from interdictions at our mail facilities to electronically target illegal shipments, and conducting both national and localized enforcement operations.

CBP is also an active participant on an inter-agency task force that works cooperatively with the DEA, the FDA, U.S. Immigration and Customs Enforcement (ICE), the Office of National Drug Control Policy (ONDCP), and the Department of Justice (DOJ).

The task force's law enforcement participants conducted three-day enforcement blitzes named "Operation Safeguard" at all international mail branches (IMBs) and two express courier facilities. These enforcement efforts are designed to identify the type, volume, and quality of such shipments. Results from Operation Safeguard indicate that many importations are of questionable origin. Specific results from recent phases of these blitzes are:

JFK Airport, New York, June 29 through July 1, 2004

- 300 packages contained illicit products.
- 137 of the 300 packages contained a controlled substance.

Seattle, Washington, July 27 through July 29, 2004

- 300 packages contained illicit products.
- 64 percent of the illicit products were manufactured in Canada, 27 percent did not list a country of manufacture, and 9 percent were manufactured in the United States, Japan and Western Europe.
- 2 of the 300 packages contained controlled substances.

Chicago, Illinois, August 17 through August 19, 2004

- 300 packages contained illicit products.
- 30 percent of the illicit products were manufactured in Mexico, 15.8 percent were manufactured in Canada, 22.8 percent did not list a country of manufacture, 7.4 percent were manufactured in the United Kingdom, and 4.9 percent were produced in the United States.
- 7 of the 300 packages contained controlled substances.

Newark, New Jersey, September 21 through September 22, 2004

- 24 packages contained illicit products.
- Most of the packages were person to person shipments from China and Norway.
- Many of the packages from China contained either herbal products or could not be identified.

FedEx Hub, Memphis, Tennessee, October 25 through October 27, 2004

- 153 packages contained illicit products.

- 88 of the parcels were exported from Germany.
- 90 of the 153 packages contained controlled substances.

United Parcel Service Hub, Louisville, Kentucky, November 16, through November 18, 2004

- 35 packages contained illicit products.
- The majority of the parcels were exported from Canada and China.

Honolulu, Hawaii, March 15 through March 17, 2005

- 183 packages contained illicit products.
- Canada was the country of manufacture for 18 percent of the products, Germany was the country of manufacture for 11 percent of the products, 6.5 percent were manufactured in Thailand, and the country of manufacture could not be determined for 37 percent of the products.
- 4 of the 183 packages contained controlled substances.

San Francisco, California, August 9 through August 11, 2005

- 301 packages contained illicit products.
- Canada was the country of manufacture for 23 percent of the products, 9 percent were manufactured in Thailand, and for 37 percent the country of manufacture could not be determined.
- 4 of the 301 packages contained controlled substances.

Dallas-Fort Worth, Texas, December 6 through December 8, 2005

- 300 packages contained illicit products.
- Canada was the country of manufacture for 56.7 percent of the products, 5.6 percent were manufactured in Mexico, and for 30.3 percent the country of manufacture could not be determined.
- 19 of the 300 packages contained controlled substances.

The task force has accomplished other significant efforts. During my testimony last year before the Senate Permanent Subcommittee on Investigations, I stated that a public service announcement communicating the potential dangers of foreign-made controlled substances was being jointly developed by CBP and the FDA. I am pleased to report that the public service announcement has been completed and can be found on both CBP's and FDA's web sites.

The task force also worked with Google, Inc. to provide consumers searching for on-line pharmacies the ability to obtain information on importation restrictions concerning controlled substances. Specifically, individuals who query Google for items such as steroids are provided with a link to a page on CBP's web site which informs them of importation restrictions. This is an excellent example of the private and public sectors partnering to protect the public from the illegal acquisition of controlled substances.

In addition, the task force is currently discussing with leading Internet companies, parcel carriers, and payment providers efforts that these industries can undertake to assist federal authorities in curtailing the supply of illicit Internet sales.

I would also like to recognize efforts undertaken by U.S. Immigration and Customs Enforcement (ICE). ICE has conducted Operation Apothecary to address, measure and attack potential vulnerabilities in the entry process that might allow for the smuggling of commercial quantities of illegal products. This special operation includes investigative work by the Cyber Crimes Center and enforcement blitzes at international mail branches, express courier facilities, and land border ports of entry.

CONCLUSION

Customs and Border Protection officers are vigilant in detecting imported products that violate the Controlled Substances Act. However, given our agency's available resources and priority of protecting U.S. residents against the threat of terrorism, experience shows that our officers are unable to identify all of the parcels containing controlled substances arriving via mail and express courier each day. Even though we have made strides in addressing this problem, the growing volume presents a formidable challenge.

We are aggressively using our existing enforcement tools to combat the proliferation of controlled substance importations purchased on the Internet, and we will continue to evaluate approaches that might enhance these efforts.

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

MR. WHITFIELD. Dr. Meyer, you're recognized for five minutes.

DR. MEYER. Thank you.

Mr. Chairman, Ranking Member Stupak, Congressman Norwood, I'm Doctor Robert Meyer. I'm the Director of FDA's Office of Drug Evaluation II in the Center for Drug Evaluation and Research, or CDER. I oversee the Division of Anesthetic, Analgesic, and Rheumatologic products, a division where many of the scheduled drugs are regulated, including the opiate analgesics. This division works closely with the Center's controlled substances staff which coordinates CDER's activities related to controlled substances and the DEA, and I thank you for the opportunity to talk to you today about our role in regulating controlled substances.

Before any drug is approved for marketing in the U.S., FDA must decide whether the studies submitted by the drug's sponsors have adequately demonstrated the drug is safe and effective under the conditions of use proposed in the drug's labeling. It's important to realize "safe" does not mean free of risk, as there is always some risk of potential adverse drug reactions when therapeutic drugs are used. Rather, safe in this context means that, for the indications or indication approved, FDA has determined that when it's used according to the product labeling the benefits outweigh the risk.

So during the approval process, FDA assesses a drug product's potential for use and misuse; and the agency utilizes animal, clinical and epidemiological data to determine whether a drug under review requires abuse liability studies, scheduling under the CSA, or warrants a risk minimization action plan designed to reduce abuse, overdose or diversion.

Abuse liability assessments are based on a constellation of the drug's properties, including its chemistry, its pharmacology, its clinical effects, its similarity to other drugs with known abuse potential, and its potential for public health risk following introduction of the drug to the general

population. If potential for abuse exists, the drug's sponsor is required to provide FDA with all the data pertinent to the abuse of the drug, a proposal for scheduling under the CSA and data on overdoses. FDA's job is not done, however, after a drug is approved and/or scheduled. The goal of FDA's post marketing surveillance is to continue to monitor marketed drugs for safety. Safety and risk assessment, combined with efforts to minimize known risks, comprise what FDA calls risk management. Risk management is the overall and ongoing process of assessing that product's benefits and risks, taking action, where necessary, to decrease known risks, and tracking safety and making sure adjustments are made to assure that benefits continue to outweigh risks as new safety information emerges.

As part of risk management, FDA may ask companies to collect specific information to improve the speed and sensitivity of detecting suspected safety problems.

When this enhanced data collection is requested by FDA, it is called a pharmacovigilance plan. Actions to minimize risks that go beyond providing an informative package insert are themselves called risk minimization action plans or Risk MAPS. These are strategic safety programs designed to decrease identified product risk by using one or more interventions such as specialized education or targeting prescribing, dispensing, or use.

All of these risk management mechanisms are in place to ensure safe and effective products are available and used in a responsible manner.

FDA is continuing to meet with DEA, other Federal agencies, and industry to share information and insights needed to address the problem of prescription drug abuse and misuse. We participate in a number of task forces and other working groups. DEA is the lead Federal agency responsible for regulating controlled substances and enforcing the CSA.

However, the complexity of the cases and the solutions to the problems of misuse, overdose, and diversion of prescription drug products requires the collaboration of DEA and FDA as well as other governmental agencies and other State and nongovernmental entities.

For instance, FDA's office of criminal investigations works closely with DEA on criminal investigations where there is a nexus between sales of noncontrolled and controlled substances.

Both FDA and DEA have utilized the full range of regulatory, administrative and criminal investigative tools available, as well as engaged in extensive cooperative efforts with local law enforcement groups to pursue cases involving controlled substances.

FDA will continue to work with other agencies to address the myriad issues related to synthetic drugs and prescription drugs abuse. These problems are broad in reach and implications. And we are committed to

a collaboration with our partners, Federal, state, and local, as well as professional societies and industry to prevent abuse and help ensure these important drugs remain available to appropriate patients through appropriate channels.

I would like to thank the subcommittee, again, for the opportunity to testify today on this important issue, and I would be pleased to answer any questions.

MR. WHITFIELD. Dr. Meyer, thank you.

[The prepared statement of Robert Meyer follows:]

PREPARED STATEMENT OF ROBERT MEYER, M.D., DIRECTOR, OFFICE OF DRUG EVALUATION II, OFFICE OF NEW DRUGS, CENTER FOR DRUG EVALUATION AND RESEARCH, FOOD AND DRUG ADMINISTRATION

INTRODUCTION

Mr. Chairman and Members of the Subcommittee, I am Robert J. Meyer, M.D., Director of the Office of New Drug Evaluation II, Center for Drug Evaluation and Research (CDER), U.S. Food and Drug Administration (FDA or the Agency). I oversee CDER's Division of Anesthetic, Analgesic and Rheumatologic Products, a division where many of the scheduled drugs are regulated, including opiate analgesic products. This division works closely with CDER's Controlled Substances Staff, which coordinates CDER's activities related to controlled substances and the Drug Enforcement Administration (DEA). I appreciate the opportunity to talk to you today about FDA's role in regard to controlled substances.

FDA is aware and concerned that some consumers are able to obtain controlled substances without a prescription, using the Internet. We recognize the seriousness of this issue and sympathize with the families and friends of individuals who have lost their lives as a result of prescription drug abuse and misuse. The Agency has taken many steps to prevent abuse and misuse of prescription drugs, while making sure they are available for patients who need them. FDA is committed strongly to promoting and protecting the public health by assuring that safe and effective products reach the market in a timely manner and monitoring products for continued safety after they are in use.

THE FDA DRUG APPROVAL PROCESS

Under the Federal Food, Drug, and Cosmetic (FD&C) Act, FDA is responsible for helping ensure that all new drugs are safe and effective. Before any drug is approved for marketing in the U.S., FDA must decide whether the studies submitted by the drug's sponsor (usually the manufacturer) have adequately demonstrated that the drug is safe and effective under the conditions of use proposed in the drug's labeling. It is important to realize, that "safe" does not mean free of risk, and that there always is some risk of potential adverse reactions when using prescription drugs. FDA's approval decisions, therefore, always involve an assessment of the benefits and the risks for a particular product. When the benefits of a drug are determined to outweigh the risks, and the labeling instructions allow for safe and effective use, FDA considers a drug safe for approval and marketing.

During the approval process, FDA assesses a drug product's potential for abuse and misuse. Abuse liability assessments are based on a composite profile of the drug's chemistry, pharmacology, clinical manifestations, similarity to other drugs in a class, and

the potential for public health risks following introduction of the drug to the general population. If a potential for abuse exists, the product's sponsor is required to provide FDA with all data pertinent to abuse of the drug, a proposal for scheduling under the Controlled Substances Act (CSA), Title 21, United States Code (U.S.C.) §801 et seq., and data on overdoses.

The CSA requires the Secretary of Health and Human Services (HHS) to notify the Attorney General through DEA, if a "new drug application is submitted for any drug having a stimulant, depressant, or hallucinogenic effect on the central nervous system, …" because it would then appear that the drug had abuse potential (21 U.S.C. §811(f)). HHS has delegated this function to FDA.

The Agency assesses preclinical, clinical, and epidemiological data to determine whether a drug under review requires abuse liability studies, scheduling under the CSA, or a risk minimization action plan, (RiskMAP) designed to reduce abuse, overdose, or diversion. FDA's job is not over after a drug scheduled as a controlled substance is approved. The goal of FDA's post-marketing surveillance is to continue to monitor marketed drugs for safety. This is accomplished by reassessing drug risks based on new data obtained after the drug is marketed and recommending ways of trying to manage that risk most appropriately.

THE IMPORTANCE OF RISK MANAGEMENT

Safety or risk assessment combined with efforts to minimize known risks comprise what FDA calls risk management. Risk management is the overall and ongoing process of assessing a product's benefits and risks, taking action as necessary to decrease known risks, and then tracking safety and making adjustments as necessary to assure that risks are kept in line with benefits.

As part of risk management, FDA may ask companies to collect specific information to improve the speed and sensitivity of detecting suspected safety problems. When this enhanced data collection is requested by FDA, it is called a pharmacovigilance plan. These exist for many long-acting and potent opioid products and contribute to safe use of the product by detecting, as rapidly as possible, adverse outcomes, including misuse, overdose, abuse and diversion. Once problems are detected there need to be actions to address them.

Actions to minimize risks that go beyond providing an informative package insert are called risk minimization action plans or RiskMAPs. These are strategic safety programs designed to decrease known product risks by using one or more interventions, such as specialized education or restrictions on typical prescribing, dispensing, or use. The small number of RiskMAPs that exist are largely customized programs, although consistent approaches are being sought, for example, in the control of drugs that cause birth defects, such as thalidomide and isotretinoin.

FDA COLLABORATES WITH OTHER GOVERNMENT AGENCIES, PROFESSIONAL GROUPS, AND INDUSTRY

Under the FD&C Act, FDA is responsible for the approval and marketing of drugs for medical use and for monitoring products for continued safety after they are in use, including controlled substances. DEA is the lead Federal agency responsible for regulating controlled substances and enforcing the CSA. The CSA separates controlled substances into five schedules, depending upon their abuse potential and medical use. Schedule I controlled substances have the highest potential for abuse and have no medical use while Schedule V substances have the lowest abuse potential. Schedule II substances also have a very high potential for abuse but are approved for medical use. Schedules III, IV, and V substances and drugs have lower abuse potential and fewer

controls under the CSA. The U.S. Immigration and Customs Enforcement (ICE) is the lead agency for enforcing transborder smuggling laws. ICE focuses its efforts on individuals and organizations involved in the smuggling of counterfeit pharmaceuticals both controlled and non-controlled, scheduled narcotics, medical devices and medical test kits via the Internet.

The President's 2005 National Drug Control Strategy has recognized the effectiveness of state prescription drug monitoring programs, and called on the pharmaceutical industry, medical community and state governments to become partners in an effort to prevent the illegal sale, diversion, and use of prescription drugs in a way that does not impede legitimate medical needs.

FDA is continuing to meet with DEA, ICE, the Substance Abuse and Mental Health Services Administration (SAMHSA), the National Institute on Drug Abuse (NIDA), the Office of National Drug Control Policy (ONDCP), the Centers for Disease Control and Prevention, the American Medical Association (AMA), and industry to share information and insights needed to address the problem of prescription drug abuse as described below.

FDA and DEA meet regularly to discuss new ways to prevent prescription drug abuse and misuse. In addition to assisting one another with criminal investigations, as described below, FDA (or other components of HHS) is working on the following initiatives:

Task Force Participation – FDA participates in a number of task forces and other groups. Agents of FDA's Office of Criminal Investigations (OCI) frequently participate in and/or assist many DEA-led Federal-state task forces throughout the country focusing on the illegal sale of controlled prescription drugs. FDA and DEA are members of the following working groups: Cross Border Pharmacy Working Group, Interagency Pharmaceutical Task Force, Permanent Forum on International Pharmaceutical Crime, Interagency Committee on Drug Control, Federal Trade Commission/FDA Health Fraud Working Group, and a working group composed of representatives from HHS (including FDA, SAMHSA, the National Institutes of Health, and NIDA), DEA, ONDCP, and other agencies to address issues of drug abuse and control under the CSA. ICE and CBP participate in many of these working groups in an effort to collaborate with FDA in reducing the quantity of illegal dangerous drugs imported into the U.S. as well as to improve information sharing, increase public awareness and work cooperatively with industry.

In March of 2004, a cooperative effort was announced which included various efforts aimed at addressing prescription abuse, including careful consideration of labeling and commercial promotion of opiate drug products and additional efforts to investigate and prosecute "pill mills" - Internet pharmacies that provide controlled substances illegally.

In addition, FDA is a member, along with other HHS agencies (SAMHSA and NIDA), DOJ, DEA, DHS, ONDCP, and other Federal agencies, of the Synthetic Drugs Interagency Working Group (SDIWG), which was established to implement the recommendations of the National Synthetic Drugs Action Plan. Prescription drug abuse is one of the many topics that the Plan's recommendations address. Some other topics directly involving FDA include the use of over-the-counter pseudoephedrine to manufacture methamphetamine, Internet sales of drug products, and working with drug manufacturers to reformulate abused drug products .

Assessment of New Products With Abuse Potential – FDA provides DEA with a scientific assessment of a certain drug product's potential for abuse and misuse. In addition, DEA often participates in FDA public meetings to provide advice and recommendations to the Agency on scheduled drugs.

FDA/DEA JOINT ENFORCEMENT EFFORTS

DEA is the lead Federal agency responsible for regulating controlled substances and enforcing the CSA. However, the complexity of the cases and the solutions to the problems of misuse, overdose, and diversion of prescription drugs requires the collaboration of DEA and FDA, as well as state and non-governmental entities.

FDA's OCI works closely with DEA, as well as ICE, on criminal investigations when there is a nexus between sales of non-controlled and controlled substances. Both FDA and DEA have utilized the full range of regulatory, administrative, and criminal investigative tools available, as well as been engaged in extensive cooperative efforts with local law enforcement groups, to pursue cases involving controlled substances. FDA regularly consults with ICE on their web monitoring procedures for Internet pharmacies. Headquarters representatives from both FDA and ICE meet on a regular basis to share information, and to coordinate investigations.

CONCLUSION

FDA will continue to carefully review the new drug applications for controlled substances, create effective RiskMAPs, and work with DEA to appropriately schedule controlled substances and enforce the FD&C Act and CSA to take down bad actors trying to illegally sell these products over the Internet. We continue to work with other agencies to address the myriad of issues related to synthetic drugs and prescription drug abuse. These problems are broad in reach and implications and we are committed to collaborating with our partners – Federal, state and local officials, professional societies, and industry - to prevent abuse and help ensure that these important drugs remain available to appropriate patients through appropriate channels.

I would like to thank the Subcommittee for this opportunity to testify today on this important issue. I would be pleased to respond to any questions.

MR. WHITFIELD. And I thank all of you for your testimony. On this first panel, we have individuals with a lot of experience in this area, FDA, Customs, DEA, GAO, and many of you heard Bart Stupak in his opening statement say, well, there has been a lot of hearings, repeated hearings on this issue, and not a lot seems to be accomplished in really dealing with the problem. Each of you, as I said, has experience and expertise in the area, and we have interagency task forces working on this issue. We have working groups working on this issue.

So I would like to ask each of you individually, what do you see as the major obstacle to effectively dealing with this problem of controlled substances being sold on the Internet? Just from your individual responsibilities, from your experience, what would you say are some of the major obstacles in really effectively dealing with this issue? Mr. Stana.

MR. STANA. Well, I think there are a number of obstacles. First, just the nature of how these websites and Internet sites work make it very difficult for law enforcement to trace and do anything about the sales of the drugs. They are up for a while, they are down for a while. They

change Web names. They change locations. It is just tough to get a handle on it.

The second thing, though, and I think it is something we can work at, is to forge a more committed union among task force members, to be sure that we get better data on the exact nature and scope of the problem so we can better justify the need for more resources, if the data shows the need for it. We can then better target what resources we do get, and we get the information needed to assign accountability, not just an ad hoc task force operation, but assign accountability for doing something and follow up on it, to make sure that this has teeth.

Now, in the past, there have been task forces that have tried to do the right thing. And I think they do have some success stories as the other members of the panel have mentioned. But at the same time, unless you have a mechanism that commits resources, assigns accountability, establishes performance measures, and measures against predetermined goals and objectives, we are just doing more task forces. Finally, I would say if you're looking for one dagger to thrust into the heart of this dragon, it probably isn't there. If you're going to kill this dragon, it is going to be death by a thousand cuts. Every means at every agency's disposal needs to be brought to bear to address this problem.

MR. WHITFIELD. Mr. Rannazzisi.

MR. RANNAZZISI. Thank you, sir. If we were dealing with pharmacies that were located domestically only, this wouldn't be a problem, because with our indices and our tools to track pharmaceuticals that are created in the United States and moved throughout the normal chain of commerce to our registrants, we would be able to basically handle the problem.

The unfortunate thing is that we are dealing with a lot of so-called pharmacies that are operating overseas that are not really pharmacies. For instance, a couple years back, we worked with FDA on an investigation where the pharmacy was not really a pharmacy. It was a, for lack of better word, store front in Central America that was not only manufacturing, but distributing from a website that was allegedly located in Canada.

What we are seeing more and more is, websites that are operated independently in the United States, but the drugs are coming from one overseas site, the financial transaction and the money are going to another overseas site. They are not consolidated. It is not like our drug traffickers domestically, where if we find the money, we will find the drugs; if we find the drugs, we will find the money.

There is no regulatory control of these sites. Absolutely none. We have regulatory control over all of our registrants here. We can take administrative action or criminal action. I don't have a method of

reaching out and taking regulatory action against a foreign site. We don't have control over them.

The same token, it is very difficult to reach out and take criminal action against a lot of these sites. Now we have talked about steroids already. A couple of people mentioned steroids. Steroids are not universally controlled. In fact, they are uncontrolled in several countries. For us to go after a violator in that country and ask our counterparts to take criminal action against them could be difficult because the counterparts are going to say, well, it's legal here.

That's the biggest obstacle we are facing right now. Thank you.

MR. WHITFIELD. Mr. Ahern.

MR. AHERN. Thank you very much. Certainly one of the things we need to be doing at our borders is feeding off of information. When we're dealing with the millions of parcels that come into our international mail facilities and carrier systems, we need to be able to have information to do electronic targeting in advance so we can use the concepts of risk management successfully upon arrival. Some of the things that have been stated by the other panel members about the overseas aspect of this and changing identity on a frequent basis adds to these challenges. But one of the things we do, as with other drug problems, we need to be able to attack it on two fronts, one on the demand side and one on supply side.

And I think we need to continue to attack through the demand by doing the outreach and dealing with those issues that we have been doing successfully with the examples that I spoke of in my opening statement. And also we need to be able to continue with the supply aspects through good strong enforcement operations. We have done some of that through Operation Safeguard. And we are going to continue to do that.

But I think one of the successful things we will be undertaking in January of this year is a very focused special operation that we will be using some of the information we have taken historically from the seizures and using that for proactive targeting so we can focus on what we believe are some of the foreign locations of risk or shippers of risk so we can focus our interdiction efforts, our resources, at the border in a much more focused and more successful fashion.

And then lastly, I would state that in the last year when we have had the opportunity to streamline the seizure process which was taking close to an hour per seized item, whether it is 10 pills or a pound of cocaine, we still had to use the same seizure process, but be able to take this more efficient streamline processing and actually do the summary forfeiture where we are cutting it down to a minute to two minutes for the administrative aspect of it, those types of operational impediments are realities that really do constrain our abilities.

MR. WHITFIELD. Dr. Meyer.

DR. MEYER. Well, as is clear from my testimony, I work on the new drug approvals side. And we spend quite a bit of time assuring that the drugs that we do approve meet acceptable standards of safety and efficacy and quality, and that they are scheduled, if they need to be scheduled, such that there is informed prescribing and prescribing by doctors who are registered under the Controlled Substances Act or under the DEA.

So speaking from a personal standpoint, I guess it is quite disturbing as a physician to see that these mechanisms that we have in place are being undermined. And I suppose, again, just speaking from the personal standpoint that these ever-changing Internet sites with differing sites for the money versus the source of the drugs seems to just undermine what is a very well well-tuned system in other ways.

So I suppose if I had to name one thing that seems frustrating to me on a personal level, it is the lack of being able to really get at some of these sources and to identify what they are and how they act.

MR. WHITFIELD. Has anyone on the panel had any meetings with the IntegriChain representatives? Are any of you aware of IntegriChain?

MR. RANNAZZISI. There is at least two, maybe three offices from DEA who did meet with IntegriChain. I was not present.

MR. WHITFIELD. Okay. The task force that, Mr. Rannazzisi, that your agency is a part of, and I guess the Customs is a part of it, what other agencies are involved in the task force dealing with this issue?

MR. RANNAZZISI. FDA, CBP leads the task force, ICE, DOJ, ONDCP. Is there another component of HHS? That's basically it.

MR. WHITFIELD. And how often does the task force meet?

MR. RANNAZZISI. I believe on a quarterly basis.

MR. WHITFIELD. Have you all developed a legislative package or anything that you feel would be helpful in dealing with this issue? Have you -- I know in reading the testimony, there are few legislative suggestions that had been mentioned, but has any -- has the task force coming up with any comprehensive legislative method of dealing with this?

MR. RANNAZZISI. I don't know of any. But I would like to defer to my colleague. He might be more familiar with the legislative package that comes out of the task force.

MR. AHERN. There has not been any legislative framework that has actually come out. At this point, the strategic framework has been one of the recent undertakings of the group in developing our strategies further for the Federal agencies to collaborate with one another on various special operations.

We have also added, as far as the performance measures, taking a look at what we can do for improving performance measures, but there has not been a legislative undertaking at this point.

MR. WHITFIELD. Do you feel there needs to be?

MR. STANA. Well, that is really the crux of the recommendation we made about having an improved, stronger strategic framework. I think experience has shown, since 1999, that these task forces are useful, but they have been limited because no one has been placed in charge. Discrete milestones have not been established in many areas, and accountability hasn't been fixed for certain actions being taken. And I think if we strengthened what we already have in place, and assigned those tasks and responsibilities, we would go a long way.

We would get the kinds of proposals and the kind of legislation, perhaps, once we bring to bear all we have in Government and in the private sector.

MR. RANNAZZISI. May I add something? ONDCP, HHS, and the Department of Justice share the National Synthetic Drug Action Plan Working Group that investigates -- it looks at all synthetic drugs, including pharmaceuticals, methamphetamine. There is a specific sub group that is looking at the pharmaceutical problem, and I think that is where your recommendations will come from.

I think the CBP-led working group is more of a investigative tool. It is our ability to not only meet with the public and private sector, but also meet with each other and share ideas and network. The National Synthetic Drug Action Plan Working Group is where you will see recommendations coming from.

MR. WHITFIELD. My time is expired. So I will recognize Mr. Stupak.

MR. STUPAK. Well, thank you, Mr. Chairman. Mr. Rannazzisi, am I saying that right?

MR. RANNAZZISI. Yes, sir, Rannazzisi.

MR. STUPAK. You said you didn't think there was a lot we could do because a lot of these are foreign sites, but yet the chairman you asked about IntegriChain. And in their investigation, they find that 65 percent of these websites are partly or wholly within the United States. So why can't we do something here in the United States, if 65 percent of these sites are partly or wholly here in the United States?

MR. RANNAZZISI. Just because the websites are in the U.S. does not mean that is where the trafficking is occurring.

MR. STUPAK. Why can't you shut them down if they are in the U.S.?

MR. RANNAZZISI. To shut them down, we initiate a criminal investigation, which we do.

MR. STUPAK. And by the time you get that done -- it takes quite a while, doesn't it?

MR. RANNAZZISI. Yes.

MR. STUPAK. There are many more that have taken its place by then, right?

MR. RANNAZZISI. Yes.

MR. STUPAK. Who is in charge of this task force? Is anyone in charge? Or are these agencies at this task force level equal partners? Mr. Ahern?

MR. AHERN. I believe we have a lead responsibility within Customs Border Protection because it does focus on the border entry aspect of this. But I would say it is a full partnership. And it is a collaborative effort and all the different agencies are there. We are bringing together both the health aspects of it as well as the regulatory aspects as well as the investigative aspects of it.

MR. STUPAK. So you would be in charge? Because we talk about holding people accountable. So your agency then should be held accountable for the lack of nothing being done?

MR. AHERN. We would certainly accept responsibility for our role at the borders, yes.

MR. STUPAK. My frustration, my concern is here is the hearing from July 30, 1999, when I asked questions about the interagency task force. They had met once or twice. And they were going to do things. And as it shows throughout page 231, 232, nothing really got done. And here we are six years later still talking about interagency task force, and then how that is going to somehow magically solve the issue. But if we listen to GAO and in their study, they basically said that look, while the task force may be a step in the right direction, as I said in my opening, and we have heard here today, you have to really define the scope of the problem at the mail and carrier facilities, determine the resources, establish performance measures and evaluate progress. And there just doesn't seem to be any work around that. Have you looked at the GAO report, Mr. Ahern?

MR. AHERN. Yes, I have.

MR. STUPAK. Well, are you guys working to establish this strategic framework?

MR. AHERN. Yes, the strategic framework has been completed.

MR. STUPAK. What have you done then to address the problem at the mail and at the carrier facilities then?

MR. AHERN. Within the resource levels we are currently working in, as I stated earlier, we are working on targeted and focused enforcement operations. We conducted 19 of those operations. We are also looking in January of this year to run special operations at our carrier facilities

because I am not satisfied that the results we have had at our express consignment facilities thus far, when you compare the interdiction efforts we have had at the mail facilities.

MR. STUPAK. What recommendations have you made for mail and carrier sites? Have you asked them to do anything differently?

MR. AHERN. Specifically what we did going back in September 1st of 2004, we implemented the abandoned property aspect of it, we were capacity challenged with just doing the seizure forms for the -- we showed the pictures earlier for mail facilities. Those were at JFK. That is when we had actually over a five- or six-month period, 40,000 seizures that had accrued over that period of time.

Again, as I stated, the one hour for processing actually took our officers off of doing front line interdiction efforts just doing the seizure paperwork involved. We actually did implement this process to streamline it so that we could go ahead and get that down to a minute to two minutes for processing so we can get our front line officers back out there doing the interdiction effort. I think that is a substantial step forward.

MR. STUPAK. I am disturbed when you look at the mail places here, you take at Miami, from September 1st, to August 31st, 2005, September 1st, 2004 to August 31st, 2005, one year, Miami, U.S. mail seizes 33,000, and yet the FedEx Memphis seizes only six packages.

Memphis is the largest facility in the United States and only seizes six packages, where Miami seizes 33,000 packages. It doesn't sound like it is working very well.

MR. AHERN. That is exactly why we are focusing the efforts beginning in January with having our resources to focus on special operations at consignment hubs.

MR. STUPAK. January, have you worked with FedEx or UPS to try to get at their facilities? Because there has to be more than six of them coming through the largest UPS place -- excuse me, FedEx place in the country at Memphis.

MR. AHERN. We have a very strong relationship with FedEx --

MR. STUPAK. You have a strong relationship. But what have you done to try to knock down on all these things coming through here?

MR. AHERN. We have a targeting system that we jointly use with their information that provides electronic data for us --

MR. STUPAK. Is this the targeting system that should only take two or three minutes to identify a package?

MR. AHERN. This will help us with that process, and one of the things we are doing additional is having one our field --

MR. STUPAK. But has FedEx and UPS accepted that process that takes two, three minutes, your surveillance here to get your packages, target these packages?

MR. AHERN. I think we are talking about two different things as far as being able to get the electronic information in advance from FedEx so we can actually use that for targeting. We think that is something that will prove very fruitful to us, because we are now going to be utilizing, through one of our field analysis units, based in Cleveland, specifically focused on historical seizure data we have seen in mail facilities, we are going to take that to see if there is trends we can identify, to use targeting rules for the express consignment facilities. And we begin the operation in January.

MR. STUPAK. All right. GAO, and Mr. Stana, if I may, you have indicated in your report that Customs and DEA and FDA need to come up with a strategic framework by which to go after these rogue Internet sites, yet, as we have examined our former hearing records and correspondence to this committee, I submitted quite a bit here to the chairman for entry into the record. They have all promised to do this before and they are all working together and they have great cooperation and they formed these interagency task forces, but what exactly have they been doing wrong up to this point in time?

MR. STANA. Well, first, let me say that maybe three months has passed since we completed our work, but at the point in time that we completed the work, we had not seen a strategic framework in place. Now, if that came to be in the last three months, that is really good. But we haven't seen it nor have we examined it.

MR. STUPAK. Mr. Ahern, will you provide them the strategic framework so we can have GAO look at it?

MR. AHERN. We would be happy to do that.

MR. STANA. Some of the shortcomings of the task forces in the past have really circled around nobody being in charge, and no one being assigned accountability in a real sense. The commissioner of Customs, to his credit, formed the latest task force and they have working groups which have done some things, like these special operations and public service announcements and other things along those lines. But as far as a true partnership with the private sector, as far as sitting with the other agencies and the private sector and getting a better handle on the dimensions of the problem, how many resources need to be devoted to certain areas, which locations, to understand better what type of drugs are coming in and which agency is in the best position to address that problem, those are things that really haven't been done to any degree. And we would be looking for that kind of analysis in a strategic framework.

MR. STUPAK. So in this task force where we are all studying as equal partners, you should really have someone in charge to that is going to accept responsibility.

MR. STANA. Certainly that would be helpful, because someone has to assign responsibility, and monitor results.

MR. STUPAK. Mr. Rannazzisi, I mentioned in my opening the report by the National Center on Addiction and Substance Abuse at Columbia University, and it noted that Americans are now abusing prescription drugs more than cocaine, hallucinogens, inhalants, and heroin combined. The report also found that the abuse rates of prescription drugs by teen-agers has increased substantially in just the past decade. One reason cited for the recent increase in abuse is easy access of prescription drugs through the Internet. Your current approach to these problems seems to be failing the American people.

What do you believe you can do differently to stop this click with your mouse and buy drugs over the Internet?

MR. RANNAZZISI. Well, first, I don't think we are failing the American people. We are doing what we are charged to do. DEA investigates organizations. We go after the largest organizations, the so-called baddest of the bad. For us to go after -- we triage our Internet investigations. We make sure that the Internet investigations we are going after, like Cyber RX and Cyber Chase, have multiple sites. Cyber RX has 200 sites operating domestically. Cyber RX, hundreds of sites operating domestically and worldwide and drugs coming in from, you know, places like India, we had no idea what those drugs, what the drugs coming in, if they are pure drugs, if they are adulterated. We didn't even know if those drugs were what they purported to be.

The fact is, that is what we are supposed to be doing --

MR. STUPAK. What are you doing differently? That is my question.

MR. RANNAZZISI. We are doing what we do, what we are charged to do, go after organizations, going after the largest organizations behind those websites. The public is getting more bang for their buck if we go after an organization that is running 200 websites --

MR. STUPAK. I mentioned rapid increase of use of teenagers in the last decade. Are you going after teenagers?

MR. RANNAZZISI. I am sorry, that --

MR. STUPAK. I mentioned Internet, the increase in use of prescription drug abuse by teenagers has increased substantially. You said you are going after the baddest of the bad. If this is the biggest increase, are you going after those people using, teen-agers using the Internet?

MR. RANNAZZISI. I don't think teenagers are running these organizations. If you're talking about teenager users, we don't target users.

MR. STUPAK. We are miscommunicating. We are seeing, as Dr. Norwood and all of us had indicated, sort of like the click of the mouse, while you're out there chasing the bad guy, we are worried about the click of the mouse and how to keep that out of here. Maybe we ought to look at the Web servers, mail houses, U.S. postal services, to try to stop the flow of these drugs instead of worrying about who is behind a website. Sixty-five percent of them, as the report shows, are right here in the United States.

MR. WHITFIELD. The gentleman's time has expired.

At this time, I recognize the gentleman from Texas, Dr. Burgess.

MR. BURGESS. Thank you, Mr. Chairman. I apologize that I had to be out of the room and missed a portion of the testimony.

But Dr. Meyer, if I could ask you, there was a, seems like it was almost two years ago now when one of the New Orleans television stations produced a local news show about drugs that they had bought over the Internet. And they had, oh, a fellow there with a mass spectrometer to test the drugs to see what was in the drugs. And this was not so much done to test whether the active ingredients were present in the drugs, but their findings were rather startling to me, the levels of cadmium, the levels of chromium, the levels of nickel that presumably were in the inert components of these drugs that they bought over the Internet.

We go into a tailspin up here about Thimerisol, but these were levels of cadmium that were clearly in the toxic range. They did some more investigation in this report and traced it back to a street corner pharmacy in Mexico who bought their drugs from India.

I guess my question is, does the FDA have any role in monitoring these compounds once they get into our country? Do you all concern yourselves at all with these counterfeiters or knock-off medications? These were not even generics. These were copies of, I believe, it was Lipitor was the drug that they had been mimicking.

Since that is a drug that is already approved by the FDA, do you do any type of surveillance to see if this -- if we have breached our supply chain with these products?

DR. MEYER. We are certainly concerned by those kinds of considerations. The FDA is, at least as far as the new drugs go, spends its time, as I am sure you're well aware, assuring the quality of the domestic supply.

To the degree that these products are imported, I guess FDA certainly has a role in trying to interdict them at entry if they appear to pose a risk.

Of course, there is a resource issue there in terms of identifying them and then successfully stopping their distribution, if we know them to be adulterated or misbranded.

I am not sure that I have directly answered your question.

MR. BURGESS. Is there any type of ongoing surveillance that the FDA undertakes so that when we, as consumers, go and buy Lipitor, or any other product, that it, not only is it safe and effective and approved by the FDA, but any ongoing surveillance to make sure that our supply chain has not been compromised, that pharmacies are not stocking drugs that they bought off the Internet? It would be pretty tempting if you could buy for pennies on the dollar.

DR. MEYER. I am not aware of any such efforts but I would be happy to take that question back and get you an answer.

MR. BURGESS. Very good. I would be very interested in knowing that. In general, what is the FDA doing to educate physicians about these problems with controlled substances over the Internet?

DR. MEYER. Again, I am unaware of any specific educational efforts about controlled substances over the Internet. But I will be happy to get back to you with that as well. I am not personally aware of it.

MR. BURGESS. Well, the chairman referenced a couple of very unfortunate cases that occurred in the recent past, and just thinking as a clinician in the exam room as you are taking a history of something that the doctors really ought to have, ought to have some awareness of, they ought to have at their, as part of their perhaps part of their differential, could this individual, this young person be taking a controlled substances that they have gotten illegally off the Internet? How do you and the DEA work together on criminal investigations?

DR. MEYER. I know that our Office of Criminal Investigation, particularly in cases where controlled substances and noncontrolled substances are involved together, do work in collaboration and share resources to prosecute such cases. So there is certainly that level.

The DEA and the FDA also work together in other ways, as well as participating in this task force, and also other discussions about, for instance, the education of doctors and patients about the correct prescribing use of prescription opiates and other drugs that are highly valuable, but also clearly have potential for abuse and danger when used in an inappropriate manner.

MR. BURGESS. Just overall, what is your impression of the -- how big a problem is this, from the FDA's perspective?

DR. MEYER. I can't say in terms of the magnitude, you know, the volume of the problem. But clearly, the opiates, in particular, are a narrow, therapeutic indexed drugs. You need to be well educated. You need to know what kind of drug you're dealing with. You need to be well educated in how to use them, how to prescribe them. That is part of the spirit behind having a registration of physicians.

So to the degree that the Internet pharmacies may be circumventing all those safeguards that the FDA and DEA carefully try to effect, I would be very concerned by it. So I can't, again, personally speak about the magnitude of it. Clearly from a clinician standpoint, it is very concerning indeed to think that there may be circumvention of our system that otherwise, I think, is very reasonable and very well thought out and executed.

MR. BURGESS. To me, it seems like the damage may extend far beyond just the, as you point out, the narrow opportunity for someone with drugs seeking behavior to find another avenue. Of course, through my professional career, people with drug seeking behavior, we will occasionally identify those individuals, and it also was a challenge on what to do. But if it is just a mouse click away, that sort of takes it out of the clinician's office and into a different realm.

Just last week, we had a hearing in this committee, or perhaps was a health subcommittee about our doctors prescribing enough pain medicine to their patient who are in chronic pain. So here we see the other side of that dilemma where Mr. Stupak correctly points out that the diversion of prescription drugs may be one of the greatest opportunities for misuse or for drug abuse in this country, particularly among teenagers. And at the same time, we have people on the other side of the equation who legitimately need these compounds, and if their doctor has been challenged in the past by someone with drug seeking behavior and burned, they may be less likely to prescribe the medication that is now needed by the verifiable chronic pain patient.

So it is a tough problem, one that we need to continue to keep our eye on and continue to work on. I want you to please feel free to communicate with my office if there are things we can do to be helpful. We want to.

Mr. Chairman, with that, I have no further questions. I will yield my time to any other member who would like to follow up.

MR. WHITFIELD. Thank you, Dr. Burgess. At this time, I recognize Mr. Ferguson for his questioning.

MR. FERGUSON. Thank you, Mr. Chairman. You and Mr. Stupak and Dr. Burgess have been asking some really good questions about enforcement, largely about enforcement, very important questions, serious questions that need to be addressed.

I want to pick up on one of Dr. Burgess's themes, which is a little bit more toward the drug safety side. And I want to follow up with Dr. Meyer if I might.

I was reading this -- this is an FDA news release from January of 2004. It is almost two years ago. And it is on import blitz exams by FDA investigators. This news release, which you are likely familiar

with, in that news release, the FDA said that in these blitzes at the mail processing facilities all across the country, they found numerous examples of improperly labeled drugs, potentially recalled drugs, so-called foreign versions of FDA approved drugs, and, what we are talking about a lot today, controlled substances in general.

Of the close to 2,000 packages that were searched of the 1,982 packages that were searched, we are told in this news release, 1,728 of them, so, 1,700 and change of the 1,900 and change of those packages that were searched had unapproved drug products found in them. That is a staggering number. It blows the mind.

Dr. Meyer, at the mail facilities, Customs screens packages and then refers packages to FDA for review where Customs suspects packages contain prescription drugs. Customs suspects them. They are passed to FDA. How does FDA determine whether the package contains a prescription drug at all, as opposed to an over-the-counter drug or vitamins or something, how does FDA determine what the drug is and then whether it is a controlled substance?

DR. MEYER. I can't give you specifics, but I can say that since the time of that report, there were standard operating procedures put in place by the FDA at the international mail facilities to best expend our limited resources, and clearly, this is a huge issue that outstrips our resources -- but to better spend those in a risk-based manner to try to identify which packages, perhaps, had the most egregious examples of unsafe drugs, and then those are opened and, actually if they contain controlled substance, another thing that has more recently happened is those are then given or sent to the DEA for DEA action on those.

MR. FERGUSON. If you determine that it is a controlled substance, because Customs doesn't make that determination. Is that correct?

DR. MEYER. Right. That is my understanding. Yes.

MR. FERGUSON. So if you determine -- you go through the process that you go through and you determine if it is a prescription drug or a controlled substance -- and it sounds like what you're describing is a, if I can use a different term, an overwhelming problem, you're talking about a problem that outstrips the resources that you currently have.

DR. MEYER. Well, clearly we saw depictions of the volume that we are talking about. To determine what is in the box, you essentially have to open it. It is a resource-intensive thing to open it and then to determine what is in there, whether they are just prescription drugs, whether they are other over-the-counter drugs, whether they are controlled drugs, how to handle those particular packages.

MR. STUPAK. Would the gentleman yield on that point?

MR. FERGUSON. I would be happy to yield.

MR. STUPAK. Thanks, because I'm a little confused here. Dr. Meyer, it seems to me from what staff had told us, it takes you one to two hours, close to two hours of paperwork to identify the drug, where Customs and Border Patrol does it in three minutes. Why the difference?

DR. MEYER. I cannot speak to that personally, Congressman. I would be happy to get you an answer, but I can't speak to that personally.

MR. AHERN. The three minutes that was talked about was actually the administrative processing, not a laboratory analysis or determination.

MR. STUPAK. But you don't do laboratory analysis in these two hours, that is just to process your paperwork. So I am trying to get at why the difference, because what Mr. Ferguson points out is a classic example of the pictures we showed, when you go down to Dulles, no matter where it is, you guys are doing it in three minutes to see if it should or not and you guys are taking two hours.

Can you get back with an answer then?

DR. MEYER. I will do so, sir.

MR. FERGUSON. Reclaiming my time. Getting back to figuring out what these substances are, when they are determined that they might not be exactly what they say they are, from your knowledge, from FDA's knowledge, and your expertise in approving legitimate therapeutic uses of controlled substances, that is one of the things that FDA does, you figure out what are legitimate uses for these various products, and then properly test them and label them and whatnot.

How would, and given the scope of this what sounds like a deluge, and overwhelming, at times, problem, or situation, that is faced, how would you characterize the public health threat that is posed by controlled substances that are sold by these rogue Internet pharmacies?

DR. MEYER. I'm not sure I can speak to the magnitude of that, but clearly FDA has, if you will, a closed system for drug approval where we are involved with the domestic distribution of the drugs and the prescribing and so on. To the extent that these are outside of that, and outside of the normal regulatory and legal framework, I think it is clearly a concerning situation that is a very serious situation from the public standpoint.

MR. FERGUSON. We can boil it down and say is it serious or is it not serious. We would probably agree it is serious. You use the term “very serious.”

DR. MEYER. And I think that is fair. Because clearly, this is -- the opiates, in particular, are a very important class of drugs that have very legitimate use and perhaps they are underused for legitimate purposes. But at the same time, to have a source of these that is outside any kind of standard legal and regulatory framework is very serious, yes.

MR. FERGUSON. What about counterfeit drugs? How would you characterize the public health threat posed by counterfeit drugs sold by rogue Internet pharmacies?

DR. MEYER. I don't know enough about that issue to really opine. Clearly, there is probably a very wide spectrum of what a counterfeit may be. Some of them may contain the active that they are purported to. They may have various impurities.

MR. FERGUSON. Just assuming that a counterfeit drug is, by a very simple definition, not what it is supposed to be.

DR. MEYER. Obviously, that is of great therapeutic concern.

MR. FERGUSON. If you were a patient and you needed a particular product or drug to address a specific ailment that you had, and you took something, whether that made you sick or not, if it wasn't what you thought you were taking --

DR. MEYER. It is obviously very concerning. Just to get back to the FDA, to the degree that these, any product that is bought over the Internet and shipped, is not necessarily assured to be what it purports to be, I think that is of significant concern.

MR. FERGUSON. The FDA report that I was citing before talked about improperly labeled drugs, potentially recalled drugs, so-called foreign versions of drugs and controlled substances. So that is why I am asking these -- I am using FDA categories to ask these questions. Counterfeit drugs, we have talked about controlled substances, I think you said you characterized it as a very serious public health threat, could we say the same for counterfeit drugs sold on rogue Internet pharmacies?

DR. MEYER. I think it potentially could be. It certainly poses a serious concern. Whether I would say it is a serious threat or not, I think that is integrating other considerations. But it is certainly a serious concern.

MR. FERGUSON. What about recalled drugs?

DR. MEYER. Recalled drugs, they are recalled for a purpose, which is they do not meet their regulatory standards to assure their safety and efficacy.

MR. FERGUSON. For someone getting a recalled drug through a rogue Internet pharmacy, would you say that posed a serious public health threat?

DR. MEYER. I think the very fact that we recalled the drug product in the first place implies that, yes.

MR. FERGUSON. What about an improperly labeled drug, someone is taking a drug that is actually something else but the label says it is, as FDA found in these examined packages, an improperly labeled drug. Would that, in your estimation, pose a serious public health risk?

DR. MEYER. That is probably more of a spectrum, because an improper label may be a dated label, all the way up to saying it is drug X, when, in fact, it is drug Y. So that is clearly a spectrum. But again, that would be at least a potential concern.

MR. FERGUSON. So essentially, the point I am raising, and I appreciate your answering these various questions, we are talking about controlled substances today, but you know FDA has cited, and I think it is a very legitimate public health concern, if not a very legitimate public health threat, that when we are talking about Internet pharmacies, particularly these rogue Internet pharmacies, which are multiplying, it seems, as Mr. Stupak and others have pointed out, it seems to be multiplying, whether it is counterfeit drugs or recalled drugs, or improperly labeled drugs or controlled substances, it just seems to me there is a very serious public health threat, at least a very potentially serious public health threat and certainly, in many cases, a very serious legitimate public health threat that are posed by these Internet pharmacies.

I know that I am out of time, Mr. Chairman. So I appreciate your generosity. And I yield back.

MR. WHITFIELD. Mr. Norwood is recognized for his questions.

MR. NORWOOD. Thank you very much Mr. Chairman. Gentlemen, I want you to understand my questions are not intended to criticize you or your agency. It is pretty clear that we can hear the frustration in your voice that we are having a hard time getting this job done, and that isn't necessarily something that should be laid at your door.

But let me start by establishing a baseline. Perhaps all of you are fathers or grandfathers. Would you agree with this statement: that your children can go on the Internet and order today a controlled substance? Does anybody disagree with that?

MR. STANA. No, I wouldn't disagree with that.

MR. NORWOOD. Let the record show, Mr. Chairman, all the panel agrees with that.

Could anyone tell me then if your grandchild ordered a controlled substance, what is the probability today that they would get it? What is the percent? What is the possibility that will actually get it in their hand?

MR. STANA. Well, in our sample, we ordered 22, we received 14. So if you use that as any indication, it would be over 50 percent.

MR. NORWOOD. Gentlemen, any other comment? I am impressed if we are stopping 50 percent now. Any thoughts?

MR. AHERN. I wouldn't offer a sample at this point as far as what we would actually intercept.

MR. NORWOOD. Well, we do know we are not intercepting a lot, and a lot is getting through. Too many. If one gets through, if it is your

grandchild, that is one too many, I guess. Though we are putting a great deal of effort into trying to stop this. But I hear in your voices, that you are not sure we can stop this, that we have the ability to stop this, or that we know how to stop this.

Would any of you care to tell me, if there are any Internet pharmacies in this country -- in this country, now, not from overseas -- selling illegal controlled substances? Do we have them in this country?

MR. RANNAZZISI. Absolutely.

MR. NORWOOD. Are we closing them down?

MR. RANNAZZISI. Yes, we are.

MR. NORWOOD. How many are left?

MR. RANNAZZISI. That I couldn't tell you, sir, because, again, the Internet pharmacies, as we go through our investigations we find more. So if I gave you a number today, that number would probably change tomorrow.

MR. NORWOOD. I am not trying to get too specific. I guess the point I am saying is the harder we work, the further behind we get it seems to me. So maybe we need to start thinking about another solution to this problem. And I don't know what it is. That is part of what I am here to try to look and see if any of you have a solution.

Most of you have been talking about intercepting drugs once they have been ordered, how do we catch them once the grandchildren ordered them, OxyContin.

Now are any of the agencies having any thoughts or making any efforts on how to address this problem, say, at the point of sale? Is there another way we could go about this other than checking the mail as it comes into the airports and so forth? Have you any thoughts about that?

MR. STANA. Most of the existing statutes focus on importation rather than purchase. In many of these countries where the Internet sites operate, it is not illegal to purchase the drugs in those countries. That is why we try to intercept them at the border where importation becomes an issue. But I think that there are opportunities to think more creatively about a partnership with the private sector, to see what the credit card companies, the banks, the consignment carriers, and others can do, to see what the Internet operators can do to help us identify the sources of these drugs and help take action.

It is not enough just to suspect someone is doing something wrong with respect to selling controlled substances. You have to prove it. And the private sector has been reluctant to engage in these kind of investigations and “stop actions” unless they have a lot of evidence to help them do so.

MR. NORWOOD. Well, would it not be illegal today for any citizen actually to try to order a controlled substance over the Internet without a doctor's prescription? Is that legal?

MR. RANNAZZISI. No, sir. It is not legal.

MR. NORWOOD. It is not legal. So actually there is something maybe can be done. It may be legal for Canada to sell us a drug or India to sell us a drug, but it is illegal for us to order it.

Are we doing anything in thinking in those terms?

Well, you have got a hard job gentlemen and we are not -- the problem is, we are not solving the problem. It is not, I think, any fault of your own.

Mr. Chairman, with your permission, I would like to ask each of you to go back to your agencies and submit to this committee some thoughts about what else can be done. We are struggling trying to come up with an answer. You're struggling to try to solve a problem. But you are very involved in it, and you maybe could have some suggestions that legislatively or otherwise, that this Congress can do. Because this thing has got to get stopped one way or the other. And the way we are doing it apparently is not going to stop it. So we have got to find another solution to this problem.

I thank you for your work gentlemen. I know you're trying. Mr. Chairman I yield back.

MR. WHITFIELD. Dr. Norwood, thank you. And to follow up on Dr. Norwood's comments, when the GAO issued their report in September, you recommended a strategic framework, and then Mr. Ahern, I think in your testimony a few minutes ago, you said you now have a strategic framework. I don't guess the GAO has seen it. And this committee is not aware of it either.

But what I want to do is, I want to have our staff contact you, Mr. Ahern, because I am assuming you're sort of the focal point in this task force in developing this framework. And we are going to have another panel of witnesses, and IntegriChain is going to be one of the companies represented in that testimony, in that second panel. But we would like to get with you, our staffs would get together and like for you to brief this subcommittee more in detail about this strategic framework, and specifically about some issues that we can help address this problem, as Dr. Norwood talked about trying to get to the bottom of it and develop some sort of solution.

So, we will be in touch with your staff and look forward to meeting you to go into more detail on that.

At this time, I would recognize Mr. Stupak. He had a few additional questions he wanted to pursue.

MR. STUPAK. Thank you, Mr. Chairman.

Now, Mr. Norwood, before you leave, there if you take a look at the GAO report on page 32 and 33, you will see that back in May, this subcommittee asked, May 2001, we asked the FDA commissioner and HHS to change some of their procedures so we could deny the personal use drugs coming into this country as of July 2005. And we still have never received any changes. And you said the changes will have to be made legislatively. We just never get a proposal from FDA or HHS to make those changes. So I think that is one of the frustrations we see up here.

Mr. Stana, let me ask you this: In a July 26, 2004 letter Mr. Dingell received from the Drug Enforcement Agency, DEA, we had asked specifically whether DEA had a coordinated comprehensive written plan to address this growing threat to our public health. And DEA indicated they had a national drug control strategy of this current administration.

Have you had a chance to review that strategy, the GAO?

MR. STANA. We have seen the response to Mr. Dingell's letter, yes. We haven't reviewed all the actions and all the implementation steps that have been taken in response to the plan but we have seen the broad strokes it outlines.

MR. STUPAK. Was it similar to the recommendations you made here that we need to get a strategic plan going?

MR. STANA. Well, there is a difference between a strategic plan and a strategic framework. And not to get too wonkish on you, but with a strategic plan you outline broad themes and goals and objectives. But with a strategic framework, we are talking about assigning responsibility, placing someone in charge, establishing milestones and holding people accountable. It has worked with other governmental organizations with other issues. And we think it can work here. But it is not simply a strategic plan.

MR. STUPAK. Does everyone on the panel, Mr. Rannazzisi and Mr. Ahern and Dr. Meyer, do you all agree that Customs are basically the lead agency on this? Can we establish that today? Mr. Rannazzisi.

MR. RANNAZZISI. I think the problem is that each agency has a different component of the overall problem.

MR. STUPAK. Yes or no?

MR. RANNAZZISI. It depends on what component you're talking about. Are you talking about the distribution of controlled substances domestically from Internet sites?

MR. STUPAK. Maybe that is the problem we have. Maybe you are too busy fighting over turf and not taking the lead. We have to establish someone is in charge here. This has obviously been going on -- this is my sixth year in this hearing. I will be here next year doing number

seven and eight too, if we leave it to this kind of rigmarole. Someone has to be in charge, right?

MR. RANNAZZISI. Again, since there is so many different components of this problem, you have CBP is in charge of the task force. And we are working well together. We are working well with FDA and the rest of the components.

MR. STUPAK. If you're working so well, why is there a dramatic increase every year? It is not working. That is the reason why we are having this hearing. Right?

MR. RANNAZZISI. No. I don't believe that is the case.

MR. STUPAK. Okay. Let me ask this.

Dr. Meyer, do you believe to require Internet pharmacies on their Web page, since 65 percent are, in part or wholly, served here in the United States, that if they had their name address and telephone number and a place of business do you think that would help?

DR. MEYER. I am not sure I have the expertise to say that. But I think it certainly makes sense that any Internet pharmacy --

MR. STUPAK. How about a list of each state where the pharmacy is licensed or dispenses prescription drugs. Would that help?

DR. MEYER. To the degree that the practice of pharmacy is under state control, it seems that would make sense.

MR. STUPAK. How about the name of each individual who serves as a pharmacist for the purpose of the site in each site where the individual is authorized by law to dispense prescription drugs. Would that help?

DR. MEYER. Again, to the degree that these would match what is required of pharmacies that are bringing brick and mortar, I think they certainly make sense.

MR. STUPAK. How about that if the site provides medical consultations and the name of those providing the consultation type of license is held and the states in which the licenses are held, would that be helpful?

DR. MEYER. I think if there is going to be medical consultation it would be helpful to know who is providing the consultation. I would certainly expect that if I were in a doctor's office.

MR. STUPAK. Do me a favor, go back to whoever is in charge at the FDA ask them to comment on that, that legislation that has been sent since 2000, we have been waiting for the FDA to comment on.

DR. MEYER. I will do so, sir.

MR. STUPAK. Let me ask this question. I think I went through that one already.

Let me go back to Mr. Ahern. We talked a little bit about Memphis having six packages, and yet Miami is getting 33,000. Customs have people at Memphis, do they not, at this facility?

MR. AHERN. Yes, we do.

MR. STUPAK. Why the difference then, if one is 33,000 packages, the other one is only six. Why the big discrepancy?

MR. AHERN. I can't explain the discrepancy. And that is one of the things I share your same concern, and that is why we are going to have the undertaking for a special enforcement operation beginning in January.

MR. STUPAK. Is it the use of x-rays? Does FedEx there use x-rays?

MR. AHERN. There is x-ray technology.

MR. STUPAK. Does everything go through those x-ray equipments like they do at Miami?

MR. AHERN. No.

MR. STUPAK. Do you know what percentage goes through?

MR. AHERN. No, I don't. But I would be happy to report back on that.

MR. STUPAK. Hasn't that ever puzzled you, why if you only get six packages in Memphis, which is the largest facility, and you get 33,000 out of Miami?

MR. AHERN. Absolutely. And that is exactly why we are taking a look through two different initiatives, beginning with a special operation in January, taking a look at all the historical seizures we have made in our mail facilities throughout the country, using that shipper and commodity information to develop targeting rule so we can use a more efficient risk-based approach with the career facilities.

MR. STUPAK. When you were made aware of this great discrepancy between Miami and FedEx in Memphis?

MR. AHERN. I reviewed the year end numbers back at the end of this fiscal year.

MR. STUPAK. So November, just a year, October 1st.

MR. AHERN. Within the last couple of months, yes.

MR. STUPAK. Other than working together cooperatively, do any of you others have any other comments we could possibly do that would help establish a good framework so we can try to crack down on this drug Internet pharmacy problem? I mentioned a couple. Any of you have any like websites, like, medical consultants?

MR. AHERN. Some of the things we talked about earlier, acting as far as the demand, making sure people are aware as far as the concerns that they purchase from online pharmacies, also looking through the task force, to go ahead and have the Department of Justice attorneys take a look at, if there can be a government and public sector partnership to provide information about online pharmacies so we can, again, have some information about the reliability of what people may be purchasing

online. So that is another undertaking that we are in the final stages of review at this point through the task force.

MR. STUPAK. Have you taken a look, Mr. Ahern, at this GAO report, Strategic Framework Would Promote Accountability and Enhance Efforts, have you taken a look at it at all?

MR. AHERN. Yes, I have.

MR. STUPAK. Do you agree with the notification process which you seem to use, your agency, on your summary forfeiture, do you think we could really dry up a lot of these drugs coming in if we use a summary forfeiture which basically says this, if I have it right, that when you get a drug in you don't think it looks proper, you send a letter to the addressee that basically says, we have received a shipment here that doesn't look proper, we don't know if this is obtained properly in this country, therefore, if you want to come claim it, otherwise we are going to discard it. Is that basically summary forfeiture?

MR. AHERN. I would say absolutely, and that would increase our capacity to do effective interdiction at the borders much more so.

MR. STUPAK. That takes about three minutes when you do it, right?

MR. AHERN. Three minutes versus one hour and beyond, as far as the 72,000 pieces we seized last year when we went through this forfeiture process, we only had 120 people that came back looking to go through the full --

MR. STUPAK. Is there any reason why FDA can't do the same thing so we crack down on these big supplies we see at Dulles and Miami, can't they do a summary forfeiture?

MR. AHERN. I don't know what their capabilities would be for summary forfeiture. But that is certainly something that works as an opportunity for us and I would defer to FDA and HHS on that.

MR. STUPAK. I would refer FDA and you to page 32 and 33 outlines. That is what I talked about earlier when I talked about May 2001, when we finally impressed upon FDA to do this and here we are five years later waiting for legislative proposals.

Mr. Stana, any reason why, though, you couldn't do a summary forfeiture.

MR. STANA. Obviously they need legislation to do that. If CBP or FDA summarily destroys drugs, they may be losing an evidence trail, which could attempt to connect dots among purchasers. Number two, watch for due process. Again, they would need a legislative change.

MR. STUPAK. But the process, due processing does not take effect until you take control of it. So if you reject the package when it comes in, then there is probably requirements.

MR. STANA. That's a possibility.

MR. STUPAK. Dr. Meyer, care to comment on that?

DR. MEYER. As far as the actual seizure of the package, I think clearly as is stated there are legal problems.

MR. STUPAK. Such as?

DR. MEYER. Well, I'm not sure I understand all the ramifications of that, but I think they were cited properly by the GAO, the gentleman from GAO.

MR. STUPAK. We're talking about summary -- my time is up -- summary forfeiture. That doesn't kick in unless you take control of it. If it comes in and not properly marked, physical location and address, you can reject so it can never get that.

MR. WHITFIELD. I might ask DEA one other question, Mr. Rannazzisi. I understand there is some difficulty with doctor-patient relationship as relates to prosecutions. Would you elaborate on that briefly?

MR. RANNAZZISI. There's no statutory definition of what a doctor-patient relationship is. DEA has taken the view there should be in-person examination and medical history before any prescription is given. That view is shared by the American Medical Association and the Federation of Medical Boards, national association.

MR. WHITFIELD. I want to thank the first panel, and I look forward to working with Mr. Stupak when Mr. Ahern, and you and whoever you want to come with you, comes up and does the briefing on the strategic framework. As I said, our staff will be in touch with you about that.

It's going to take about five minutes for them to set up for this second panel, so we're going to recess for about five minutes, then we're going to come back and start the second panel. Thank you very much.

I want to thank you on the second panel. It has been quite exciting to sit and listen to these questions and comments, but we do appreciate your being here on this important subject, and we look forward to your testimony.

On the second panel today we have Mr. Joshua Halpern with IntegriChain. We have Mr. James Dahl, who is formerly with the FDA Office of Criminal Investigations. We have Mr. Mark MacCarthy, who is senior vice president, public policy, at VISA U.S.A.; Mr. Michael McEneney, who is an attorney with Sidley, Austin, Brown, & Wood, representing, I suppose, MasterCard International. We have Mr. Bruce Townsend, who is vice president of corporate security for FedEx. We have Mr. Dan Silva, corporate security manager for UPS; Mr. Andrew McLaughlin, senior policy counsel for Google; and Mr. John Scheibel, vice president of Yahoo!. So once again, thank you for being with us.

As you understand, whenever we do an investigation and oversight, we ask that everyone testify under oath, and before doing so, do any of

you have any attorneys that will be advising you today? Okay. Do you object to testifying under oath?

If you would stand, and I will swear you in.

[Witnesses sworn].

MR. WHITFIELD. Okay. All of you are sworn in now and we look forward to your testimony.

And, Mr. Halpern, you are recognized for your opening statement.

TESTIMONY OF JOSHUA HALPERN, VICE PRESIDENT, INTEGRICHAIN, INC.; JAMES DAHL, FORMERLY WITH FOOD AND DRUG ADMINISTRATION, OFFICE OF CRIMINAL INVESTIGATIONS; MARK MacCARTHY, SENIOR VICE PRESIDENT, PUBLIC POLICY, VISA, U.S.A., INC.; MICHAEL McENENEY, ATTORNEY, SIDLEY AUSTIN BROWN & WOOD, LLP, MASTERCARD INTERNATIONAL; BRUCE TOWNSEND, VICE PRESIDENT, CORPORATE SECURITY, FEDEX CORPORATION; DAN SILVA, CORPORATE SECURITY MANAGER, UPS; ANDREW McLAUGHLIN, SENIOR POLICY COUNSEL, GOOGLE, INC.; AND JOHN SCHEIBEL, VICE PRESIDENT YAHOO! INC.

MR. HALPERN. Thank you, Mr. Chairman and members of the committee. My name is Josh Halpern, and I represent IntegriChain, a Princeton, New Jersey, company that helps pharmaceutical manufacturers to combat illicit activities that threaten their products and supply chains.

In November of this year, IntegriChain examined 180 websites that claimed to sell Schedule II, III or IV prescription medicines. We reviewed each website for the purported availability of 9 scheduled substances and 13 branded medicines containing those substances. No purchases were made as part of this survey; however, we examined in each case whether our researchers could add one of the nine substances to an electronic shopping cart and whether we were then invited to provide payment and other information to complete the transaction.

We also examined whether certain websites in our sample appeared to be operated by a common entity or whether they engaged in a, quote/unquote, bait and switch, ultimately selling the consumer not a product, but an informational or pharmacy listing service. Please also note that no VIPPS-approved Internet pharmacies were included in our sample of 180 websites.

At this time we can share the following findings from our survey. First, excluding paid information and listing services, and filtering for

related websites that are part of a website ring where you have multiple portals and an anchor website, we believe our sample of 180 websites represents a maximum, and I emphasize maximum, of 103 distinct operations that sell scheduled prescription medicines.

Two, only 18 percent of this filtered list of websites claim to sell Schedule II medicines in our product lists. Only 44 percent claimed to sell Schedule III medicines in our product list. By comparison, 83 percent claim to sell Schedule IV medicines in our product list.

Three, 58 percent of surveyed websites, according to the free Internet information service, the Wayback Machine at archive.org, appear to have been active Internet pharmacies or related services for over one year.

And, finally, 65 percent, as has been mentioned earlier today, of the surveyed websites are hosted on servers located within the United States.

Because fraud and misrepresentation are commonplace in what might be called the deep Web, the actual on-line availability of Schedule II and III medicines may be even lower than our findings suggest. Purdue Pharma has given us permission to share the summary findings of an analysis of an on-line OxyContin distribution we prepared on their behalf in August and September of this year. In that project we conducted in-depth reviews at 122 websites that solicited consumer business for products containing oxycodone. We researched businesses related to those websites, and we also used chat rooms and forums related to on-line drug buying to examine consumer comments about their experience with these websites.

Through this process we found only 6 websites out of 122 that credibly offered to sell OxyContin. Even then, no purchases having been made, we could not exclude the possibility that the six websites do not actually ship OxyContin to the consumer, but rather a counterfeit or other product that does not contain oxycodone.

Ultimately we believe that our survey offers good news for law enforcement and private sector companies responsible for the integrity of U.S. prescription medicine distribution. While our survey found Schedule IV prescription medicines to be broadly advertised in Internet pharmacies, our findings seriously questioned whether Schedule II and III prescription medicines are as available on line as might be indicated by a casual search of the Internet through a search engine like Google or even a scan of Internet pharmacies that claim to sell those products.

Admittedly, our product list and website sample are not comprehensive. However, we believe our survey's constraints and the potential for fraud we have cited above make our estimate of Schedule II and III availability if anything conservatively high. Our sample of websites is limited to those that at least offered a Schedule IV medicine. Thus, our survey does not reflect the many transient websites that market

erectile dysfunction products together with a handful of other unscheduled prescription medicines.

Industry estimates of the total number of Internet pharmacies vary greatly. In our work with the pharmaceutical industry, we often work from the assumption that no more than 5,000 distinct website rings distribute prescription medicine on the Internet at a given time. If one accepts this assumption, fewer than 1,000 distinct website rings distribute Schedule II prescription medicines. Meanwhile, other data points in our survey suggest a concerted effort to take down those websites that illegally distribute scheduled prescription medicines could have a significant impact on illicit product availability.

Given that a majority of the websites in our sample appear to have been on line for over one year, it is likely that many consumers have become accustomed to purchasing from specific websites at specific domains; meanwhile nearly two-thirds of those websites appear to be hosted in the United States. If the number of websites selling Schedule II and III prescription medicines is limited, and if many, perhaps most, have multiyear histories, we believe that a comprehensive assessment of such websites is feasible. We also believe that programmatic action against those websites proven to illegally distribute would disrupt what appears to have been historically a stable community of websites.

We do not suggest that increased action can altogether eliminate illicit on-line distribution. At the end of the day, some consumers will go to great lengths and take shocking risks to buy scheduled medicines from on-line sources. Rather, we suggest that for some suppliers the apparent stability of the status quo may hold a commercial appeal that would be absent in the presence of increased risk and instability.

We hope that by sharing our findings at this time, we have conveyed the potential for programmatic ongoing action to materially reduce illicit on-line availability of scheduled prescription medicines. Thank you for the opportunity to testify today, and I welcome your questions.

MR. WHITFIELD. Thank you.

[The prepared statement of Joshua Halpern follows:]

PREPARED STATEMENT OF JOSHUA HALPERN, VICE PRESIDENT, INTEGRICHAIN, INC.

A Survey of Scheduled Prescription Medicine Distribution on the Internet

December, 2005

Executive Summary

The following IntegriChain whitepaper examines the distribution of scheduled prescription medicines on the Internet. The whitepaper is based on a sample of 180 websites that, as of November, 2005, claimed to sell Schedule Two, Three, and Four prescription medicines. IntegriChain surveyed each website for the purported availability of a basket of thirteen Schedule Two, Three, and Four prescription medicines, and collected information about the websites' hosting, shipping and payment options, age, and relationships to other websites within our sample. At this time we can report the following findings from our survey.

Significant Findings:

- Analysis of site content, contact information, payment systems, and other open source information suggests that a maximum of 129 unique entities operate the 180 sites reviewed in this survey.
- After filtering for related sites and "paid portals", only 18% of surveyed sites claimed to sell Schedule Two medicines in our product list, and only 44% to sell Schedule Three medicines in our product list.
- By comparison, 83% of the websites in our filtered sample claimed to sell the Schedule Four medicines in our product list.
- Over one dozen websites in our sample claimed to supply anabolic steroids; eight of these websites offered no other scheduled substances from our product list, and were thematically focused on anabolic steroids.
- A majority of surveyed websites appear to have been active Internet pharmacies (or related services) for over a year.
- 65% of surveyed websites are hosted – in part or in whole – on servers located in the U.S.

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Introduction

The following IntegriChain whitepaper examines the distribution of Schedule Two, Three, and Four prescription medicines on the Internet. The whitepaper is based on a survey of 180 websites that, as of November, 2005, claimed to sell one or more of thirteen Schedule Two, Three, and Four prescription medicines.

First, the whitepaper probes the number of unique "Internet pharmacy" operations behind the 180 websites in our survey. We also examine the role that "portal" sites and "drug clubs" played in our sample, and how we controlled for such sites in our survey of purported availability. Ultimately, we show how rings of related websites greatly inflate the perceived number of Internet pharmacies distributing scheduled prescription medicines.

The whitepaper next surveys the purported availability of a list of scheduled prescription medicines at the 180 websites. In particular, we examine the relative frequency with which Schedule Two, Three, and Four medicines were offered at the sample websites.

Next, the whitepaper surveys characteristics of the websites in our sample, including the location of website servers, the age of the websites and their related domains, and shipping and payment options the websites claim to accept.

Finally, the whitepaper reviews four examples of the websites contained in our sample, exploring the availability of open source intelligence about their operators, their relationship to other websites, and their representations regarding the products and services they offer to consumers.

Important Notes Regarding this Survey

The sample used to date is not comprehensive. Rather, the sample is intended to reflect a broad range of websites tied to the online sale of scheduled prescription medicine, with a slight emphasis on sites more readily visible to consumers via Internet search engines. A more detailed explanation of how IntegriChain compiled its site sample follows below.

No purchases were made as part of this survey. As such, readers should understand that IntegriChain cannot be certain that the websites in our sample in fact distribute scheduled prescription medicines to U.S. consumers, or that they distribute the *specific* products that consumers believe they are purchasing.

Moreover, without purchases we have no way to verify whether website representations regarding prescription requirements (or the lack thereof) are accurate. It is possible that some websites reflected in this study are not violating U.S. laws.

Methodology for Compiling the Site Sample

Between November and December, 2005, IntegriChain compiled a sample of 180 websites that represent themselves as a source for Schedule Two, Three, or Four prescription medicines.

Our sample consists of websites drawn from IntegriChain's proprietary databases of Internet pharmacies, and websites that are returned in the first several pages of search engine results for a scheduled prescription medicine in our product search list (see Product Offer Survey below). We included sites returned near the top of search engine results in order to ensure that our findings reflected, in part, the sites most visible to consumers searching for a scheduled prescription medicine.

IntegriChain analysts first used the search engines Google, Lycos, and Teoma to enumerate websites related to the brand and generic names of the scheduled prescription medicines in our product list. The search strings used included the word "buy" followed by the brand name of the product, and also "buy" followed by the generic name of the product. Next, IntegriChain analysts reviewed the first 50 websites returned by each search engine. We included in our list those websites that either:

a. Listed a price at which consumers could purchase a scheduled prescription medicine in our product list;
b. Invited consumers to request a quote for purchase of a scheduled prescription medicine in our product list; or,
c. Invited consumers to pay to access a private section of the site where they would have access to resources (presumably other websites) that would sell them a scheduled prescription medicine in our product list.

This process returned a total of 82 unique websites (meaning unique website domain) for the Schedule Two, Three, and Four products in our list. IntegriChain supplemented this list with 98 websites from our databases.

IntegriChain maintains a database of 2.5 million domains (and related domain registration records) that we have identified in the course of working with manufacturers, ISPs, and others impacted by illicit Internet activities. Over 3,000 of these domains are Internet pharmacy websites or "portal sites" that IntegriChain has monitored or investigated in the course of its work with the pharmaceutical industry. IntegriChain analysts randomly reviewed sites from this

list to identify websites that met one of the three product listing criteria noted above for at least one Schedule Two, Three, or Four prescription medicine in our product list.

Half of the websites in our sample were included based on their listing a Schedule Two or Three product in our list, and half were included based on their listing a Schedule Four product in our list (the list is 50% Schedule Four substances and 50% Schedule Two and Three substances).

See Appendix F for a complete list of the websites contained in our sample.

Notes Regarding Our Site Sample

First, the sample is not a comprehensive list of Internet pharmacies that claim to sell Schedule 2, 3, and 4 prescription medicines. While our experience (and our findings below) suggest that the total number of websites that claim to sell Schedule 2 and 3 prescription medicines is limited by comparison to the number of websites selling other prescription medicines, our site sample methodology in this report does not support a conclusion regarding the actual number.

Second, the sample is not restricted to sites that actually process a consumer transaction for a specific scheduled prescription medicine. We chose to include in our sample sites that could be called "portals" and "paid portals".

While the word "portal" has many usages in Internet parlance, for our purposes a portal in this report is a site that gives the appearance of being the site that a consumer is searching for – say, an Internet pharmacy – but that ultimately routes the consumer to different site to complete their transaction. The portal site would include a price list, and might include a rudimentary eCommerce system such as a "shopping cart". However, when the consumer goes to checkout, they are automatically directed to the checkout page of a different site. Alternatively, checkout at the portal site might direct the consumer to the front page of a different website – an Internet pharmacy where the consumer must restart their purchase process.

We use "paid portal" to refer to those sites that charge a fee for consumers to access a private section of the site where they are told they will have "access" to doctors that will perform paid consultations, and pharmacies that will in turn dispense their medicines. Paid portals might, in some cases, give the appearance of running an eCommerce system, leading consumers on to believe they are purchasing a product, and then informing them that they can buy the product eventually but must join the paid service first.

Lastly, please note that IntegriChain did not consider whether a site required prescriptions or not in compiling our sample. Because we did not make purchases as part of our survey, it is impossible to account for Internet pharmacies that misrepresent their requirements. We *do not* represent that every site in our sample is violating U.S. law, just as we *do not* represent that every site in this sample in fact sells the products that it claims to sell.

Analysis of Site Relationships

IntegriChain estimates that the 180 websites in our sample represent, at most, 129 distinct operations or Internet pharmacy "rings". We arrived at this estimate via the following process:

- If the sites domain registration records shared two items of information in the Registrant field of the WHOIS record – for example, name and address, name and phone, phone and email, or name and email – then IntegriChain listed the sites as related.

- If sites in the sample had identical front pages and product lists, IntegriChain considered them related sites even if the WHOIS information and checkout process appeared independent.

- If the sites acted as a portal forwarding consumers to another Internet pharmacy at time of checkout, then we counted the site as related to that other Internet pharmacy.

- If multiple sites' checkout processes noted the name of a particular pharmacy that would appear on billing statements, we listed them as related sites.

- If the sites proved to be portals that, at time of checkout, routed users to a site not contained in our sample (but that claimed to sell the product in question), we treated the portal as a unique site for the purposes of the study. (We did not insert the new site into the sample.)

Based on our experience investigating Internet pharmacies, this process would not capture all websites in our sample that share a common "backend" pharmacy. First, our WHOIS linking process was highly conservative – requiring two pieces of information specifically in the registrant fields to match. Second, open source information such as that referenced in our case studies often identifies additional links between sites. A comprehensive review of open source information on the 180 sites is not within the scope of this whitepaper. Third, as noted repeatedly in this whitepaper, we have made no purchases in the course of our research – the best way to detect relationships between even those businesses that appear entirely distinct in open source intelligence and business records. Therefore, we feel our estimate of unique site operations is a safe maximum, but the actual number of unique site operations is likely lower.

Filtered Website Sample

For our product offer survey, we have produced a filtered website sample that reflects our effort to screen for a) related websites, b) portal websites, and c) paid services.

The original sample of 180 websites contained 33 paid portals. Our analysis of site relationships identified a total of 44 (non-paid service) websites that we classified as either portals or related websites. Please note that we also classified seven of the paid portal websites as related websites. Excluding related sites (accepting only one site per ring), portals, and paid services, results in a filtered survey sample of 103 websites. For most of our survey, we have used the filtered website list. However, for analysis of website hosting information, age, and domain information, we have used the full sample of 180.

Product Offer Survey

IntegriChain reviewed each site in our sample of 180 to determine if it claimed to sell or to provide consumers access to a basket of thirteen scheduled prescription medicines. The thirteen scheduled medicines contain nine different scheduled substances – three of which are Schedule Two, two of which are Schedule Three, and four of which are Schedule Four. (See product list in Figure 1 below).

As noted above, IntegriChain made no purchases in the course of our research to verify the availability of the products that the websites in our sample claim to sell. Therefore, we cannot be certain that the following figures accurately reflect the availability of Schedule Two, Three, and Four prescription medicines from our website sample. Moreover – and perhaps just as importantly – the websites in our study may not actually ship the product that consumers believe they are purchasing. Without making purchases and forensically examining the purchased product, it is not possible to reliably predict whether product advertised as a branded drug is not, ultimately, a generic, nor is it possible to predict that product advertised as a brand or generic is not ultimately a non-bio-equivalent counterfeit. We further examine this uncertainty in Appendices A and E – respectively, our review of the website ABCOnlinePharmacy.com and summary findings from a report on websites claiming to sell OxyContin® that IntegriChain prepared in August, 2005, on behalf of Purdue Pharmaceuticals.

This said the findings of our product offer survey still offer a useful basis for considering the relative number of websites that solicit consumer business for Schedule Two, Three, or Four prescription medicines, or combinations thereof.

Generic Name	Related Brand Names	Schedule
Oxycodone	OxyContin®, Percodan®, Percocet®	Two
Methylphenidate	Ritalin®, Concerta®	Two
Fentanyl	Duragesic®	Two
Hydrocodone	Vicodin®	Three
Stanozolol	Winstrol®	Three
Sibutramine	Meridia®	Four
Propoxyphene	Darvocet®, Darvon®	Four
Diazepam	Valium®	Four
Zolpidem	Ambien®	Four

Figure 1: Scheduled prescription medicines included in the IntegriChain product offer survey

For comparison purposes, we also reviewed each site to determine if it claimed to sell or to provide consumers access to the non-scheduled prescription medicines Lipitor® (Atorvastatin) and Viagra® (Sildenafil). We selected Lipitor® because it is the best selling non-Schedule Two, Three, or Four prescription medicine. We selected Viagra® because it is the best selling prescription treatment for erectile dysfunction, and because in our experience erectile dysfunction products are among those offered most frequently by websites selling prescription medicines.

Please note that where findings are broken out by product from our list, we report our findings under the generic name of the scheduled substance. We do this in part because some scheduled substances appear in multiple prescription medicines (for example, three in our list contain oxycodone and two contain methylphenidate). However, we have also reported results under the generic product names because of our uncertainty, absent purchase, that the websites in question are not abusing the brand names to increase consumer traffic (and then selling a generic or counterfeit product).

Figure 2 lists the number of websites within the filtered sample (affiliated sites, portals, and paid portals excluded) that claimed to sell each prescription medicine (listed by generic name).

Generic Name	# of Websites	Schedule
Oxycodone	7	Two
Methylphenidate	13	Two
Fentanyl	5	Two
Hydrocodone	31	Three
Stanozolol	21	Three
Sibutramine	70	Four
Propoxyphene	13	Four
Diazepam	39	Four
Zolpidem	52	Four

Figure 2: # of websites in filtered sample claiming to sell each prescription medicine (listed by generic name) in our product list

Of the 103 websites in the filtered sample, 19 claimed to sell Schedule Two medicines from our list, 46 to sell Schedule Three medicines from our list, and 86 to sell Schedule Four medicines our list.

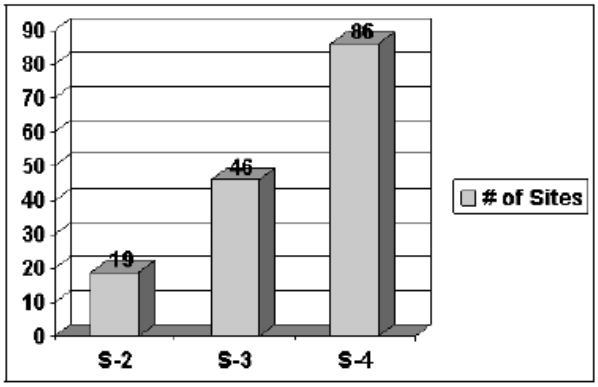


Figure 3: Number of websites in the filtered sample claiming to sell Schedule Two (S-2), Schedule Three (S-3), and Schedule Four (S-4) medicines from our product list.

Nearly half (50) of the websites in the filtered sample exclusively offered Schedule Four products from our list (see Figure 5 below). Given that half of our sample was formed from sites positively identified as claiming to supply a Schedule Four medicine from our list, it would seem that very few of the websites we originally found by initially scanning for Schedule Four medicines ultimately proved to carry the Schedule Two and Three medicines from our list. Conversely, most of the websites we initially included because they claimed to sell one of the Schedule Two or Three products in our list ultimately claimed to sell Schedule Four products as well. This clearly suggests that at least some of the Schedule Four prescription medicines in our list are more frequently listed on Internet Pharmacies than the Schedule Two and Three (and some of the Schedule Four) prescription medicines in our list. Admittedly, the size of our site sample and product list in this survey is limited. However, this finding is consistent with IntegriChain's experience in the field – not all Scheduled prescription medicines are equal when it comes to Internet distribution.

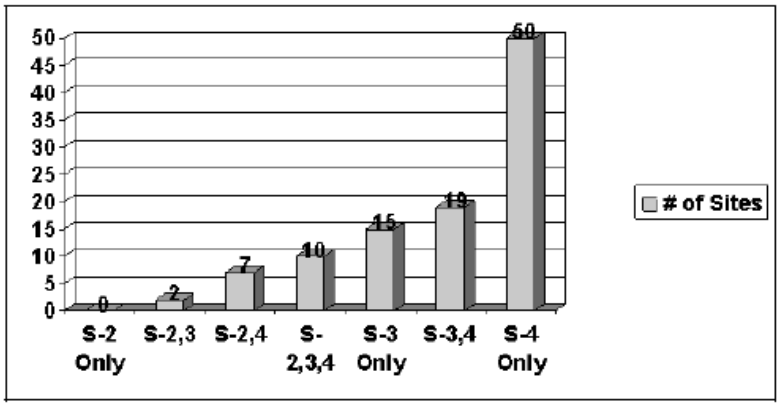


Figure 4: Diversity of scheduled medicines (from our product list) offered by websites in the filtered sample.

Further examining Figure 4, it is interesting to note that 15 websites claimed to supply only the Schedule *Three* medicines in our list, out of a total of 46 that claimed to supply Schedule Three and other scheduled medicines in our list. IntegriChain surveyed the sample websites for two Schedule Three medicines – stanozolol and hydrocodone. 11 of the 15 websites claimed to sell stanozolol – an anabolic steroid. Images taken from one of these sites – norxshop.com – are

displayed in Appendix D, showing the site's thematic focus on body building and their solicitations to consumers seeking steroids without a prescription.

82 of the websites on the filtered site sample offered to sell one of the two non-scheduled medicines in our product list. Of the remaining 21 websites that did not list one of the two non-scheduled medicines, 8 were websites that offered stanozolol but none of the other scheduled medicines in our product list. Excluding those, only 13 websites offered one of the scheduled medicines in our product list but not one of the two non-scheduled prescription medicines. It would therefore appear that some websites focus on scheduled substances – whether anabolic steroids or other products – but that such websites are a minority.

Sample Website Characteristics

IntegriChain tracked the server IP addresses, domain registrations, and DNS information of each website in our sample of 180, along with the shipping and payment options that the websites offered for their products and services. We have used IP address, domain, and DNS information – together with information available from the free Internet service archive.org – to examine the approximate age and locations of the websites in our sample. Using our filtered sample, we have also examined whether the websites claimed to support particular payment or shipping methods more often than others.

Domain Registration Information

For those experienced in Internet investigations, domain registration or "WHOIS" records are notorious for their unreliable information. That said there are a number of data points worth noting. IntegriChain captured the countries listed in the Administrative contact fields for each domain, and the registrar responsible for each registration record.

By far the most common country provided for websites in our sample was the United States, with 91 of the 180 domains. Only six other countries had more than two domain registrations in our sample.

Country	# of Domains
United States	91
Canada	17
India	7
United Kingdom	4
Mexico	4
Hong Kong	4
Bahamas	3
No other country had more than two domain registrations (administrative contact) based on our sample.	

Figure 5: Top six countries listed in the administrative contact section of the domain registration records

According to domain registration records, the domains of the 180 websites in our sample were registered at a total of 29 registrars (3 were returned unknown in this search). Five companies – GoDaddy.com, OpenSRS.net, Joker.com, NetworkSolutions.com, and Enom.com – were the registrar for over 100 of the 180 domains.

Registrar	# of Domains
Godaddy.com	41
Opensrs.net	19
Joker.com	15
Networksolutions.com	14
Enom.com	13
Dotster.com	8
Publicdomainregistry.com	8
Register.com	6
Wildwestdomains.com	5
Names4ever.com	5

Figure 6: Top ten registrars responsible for domain registration records in our website sample

Sample Website Hosting

IntegriChain traced each of the 180 websites in our sample to determine the IP address of its web server. For each IP address, we referenced an IP address to location database to determine its approximate geographic location, and looked up network WHOIS information to determine the ISP responsible for service on the address.

The websites from our survey proved to be highly concentrated in a very limited number of countries, with over 65% hosted in the United States, 8% hosted in the United Kingdom, and 7% hosted in Canada. The remaining 20% were distributed over 12 countries.

Country of IP Address	# of Websites
United States	118
United Kingdom	15
Canada	14
Slovenia	5
Bahamas	4
Israel	4
Russia	3
Hong Kong	2
Panama	2
Singapore	2

Figure 7: Top ten country locations for the web servers of website in our survey

Although the web servers appear to be heavily concentrated in the United States, the same cannot be said of the ISPs on whose networks the servers are operated. The top ten ISPs by number of websites from our survey account for only 64 websites – roughly 36% of the sample. The remaining 116 websites are hosted on a total of 80 ISPs – a remarkably broad distribution, given that we estimate there are only 129 unique entities in our survey.

Country of IP Address	# of Websites
Netcetera	13
Ethr.Net LLC	11
Everyones Internet, Inc	6
iPowerWeb, Inc	6
Go Daddy Software, Inc	5
InfoQuest Technologies, Inc	5
Interland	5
ThePlanet.com Internet Services, Inc.	5
Abacus America Inc.	4
Maxil Communications Ltd.	4

Figure 8: Top ten networks (ISPs) on which the web servers of websites in our survey are operated

Sample Website Age

IntegriChain searched a free service called the "Way Back Machine", located at www.archive.org, which maintains archived copies of the content that was located at websites in the past. We examined whether the websites in our sample, as of one year ago, contained content related to the online distribution of prescription medicines. We did not examine whether the specific products in our list, or other scheduled medicines, were available at that time. This process determined that 105 of the 180 websites (58%) in our sample were active and related to the online distribution of prescription medicines. Tellingly, of those sites on the filtered list of 103 – excluding paid portals, portals, and related sites – the percentage of active, prescription medicine related websites increases to 67%.

In short, a majority of websites in our sample, and a significant majority of websites in our filtered sample, appear to have been active for over one year. These do not appear to be "transient" operations.

Shipping Options

IntegriChain reviewed a filtered list 103 websites that excluded related sites, portals, and paid portals. At each website, IntegriChain noted the options advertised on the product pages of the websites, and then noted the shipping options listed at the product checkout page. However, we were only able to observe a shipping option at the product checkout page for a total of 31 websites. Given that the websites could easily be misusing well known brands such as FedEx and UPS to build consumer confidence in their operations – particularly when displaying such brands' logos on their front pages – we would assume that the actual number of websites that ship FedEx or UPS is lower than what is represented in Figure 9.

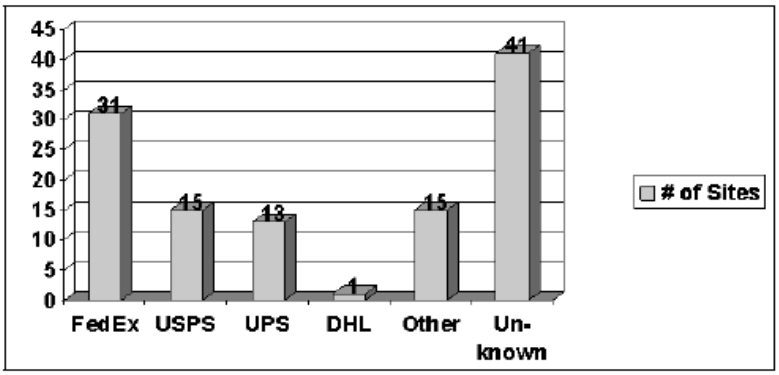


Figure 9: Shipping options that websites in the filtered sample of 103 claim to support.

Payment Options

For payment options, IntegriChain reviewed a filtered list of 129 websites that excluded related sites and portals, but included paid portals that charge for access to their services.

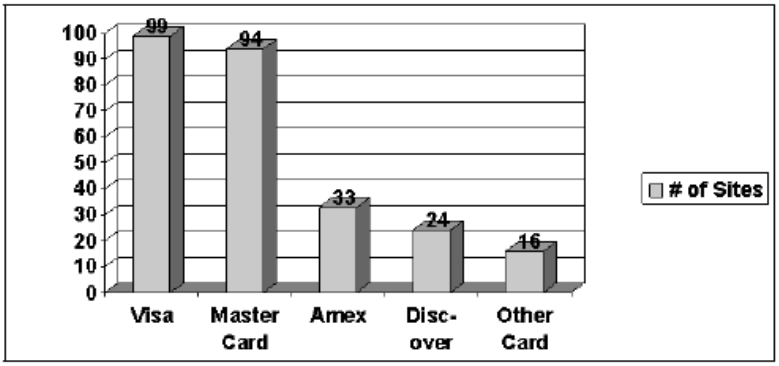


Figure 10: Credit cards accepted at websites from filtered sample of 129 (does not exclude sites reliant on payment services)

Not surprisingly, the sites most often claimed to accept Visa and Master Card. However, please note that as with all other findings in this survey, IntegriChain did not attempt purchases of the products on the surveyed websites. Therefore, our same concerns regarding brand abuse from our shipping findings apply here as well. The number of actual websites that accept Visa and Master Card may – and based on our experience we would expect is – smaller than the numbers noted in Figure 10.

IntegriChain also noted websites that offered to accept Western Union, personal checks, PayPal, or some other form of non-credit cards payment. Figure 11 displays our results.

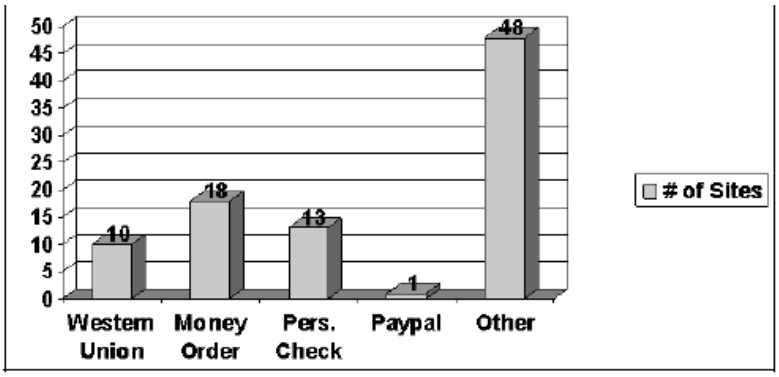


Figure 11: Other payment methods accepted at websites from filtered sample of 129 (does not exclude sites reliant on payment services)

Finally, IntegriChain noted those sites that relied on a payment service – a third party website (or seemingly third party, as the site could be operated by the same brick and mortar entity) that handles eCommerce functions for the vendor website. Some of these services appeared to be payment clearinghouses that would service multiple types of activities, while others appeared focused specifically on Internet pharmaceuticals sales. We tracked the payment service by its root domain name – i.e., for Ticket Club we noted ticketclub.com. Obviously, the actual name of the business behind the payment service may well be different than the names in the domains. Figure 12 summarizes the payment services used by filtered list of 129 websites.

Payment Service	# of Websites	Payment Service	# of Websites
Biggiweb.com	1	Safewaypurchase.net	2
Cartserver.com	1	Securecheckout2.com	2
CCBasket.com	2	Securemservce.com	1
iBill.com	2	Securerxcart.com	1
iPay.com	2	Securerxshopping.com	1
MoneyBookers.com	1	Securewebexchange.com	1
MPLLC.net	1	Storesonline.com	1
NETBilling.com	3	Stormpay.com	2
Paytrustnet.com	1	TicketsClub.com	6
Prescriptionbilling.com	1	Veripayment.com	1
Rx-cart.com	1	Verisign.com	1
Rxsecurecart.com	1	Verotel.com	2
Safetrustprocessing.com	2	WRCWorldWide.com	1

Figure 12: Payment services for filtered list of 129 websites

Conclusions

While our survey clearly finds that a large number of websites claim to sell scheduled prescription medicines to consumers via the Internet, we believe that our survey also offers good news for law enforcement and private sector companies responsible for the integrity of U.S. prescription medicine distribution.

While our survey found Schedule Four prescription medicines to be broadly advertised at Internet pharmacies, our findings seriously question whether Schedule Two prescription medicines are as available online as might be indicated by a casual search of the Internet or even Internet pharmacies.

As for Schedule Three medicines, anabolic steroids appear to be a particular area of concern. Many – perhaps most – of the websites offering anabolics may prove to be focused on that specific line of business. At a minimum, it is safe to say that we found very few instances in which websites offering anabolic steroids would also claim to sell narcotic pain relievers.

Leaving aside Schedule Three and Four prescription medicines, our study would suggest that the number of websites selling Schedule Two medicines is limited. First of all, our sample of websites is limited to those that at least offered a Schedule Four medicine. Thus, we do not capture websites selling "erectile dysfunction" and a handful of other prescription medicines. We found only 18% of websites in our sample claimed to sell the Schedule Two medicines in our product list. Since this percentage is representative of a sample that is already scheduled substance-related, we are confident that the overall percentage of Internet pharmacies offering the Schedule Two medicines in our product list is actually much lower.

If one accepts that there are no more than 5000 unique Internet pharmacy operations on the Internet (accounting for portals and site networks), then the total number of websites even *claiming* to sell the Schedule Two medicines in our basket would be in the hundreds.

Meanwhile, several other data points in our survey suggest that a concerted, programmatic effort to take down those websites that illicitly distribute Schedule Two, Three, *or* Four substances could have a significant impact on illicit product availability. Nearly two thirds of the websites in our filtered sample (no portals, paid portals, or affiliates) appear to have been online for over one year. Meanwhile, nearly two thirds of the websites in our sample also appear to be hosted in the United States. Given the ease with which these websites currently stay online, operating under the same domain for a year or more, action to restrict access to illicit domains

and to take down illicit web servers would have an immediate impact on the status quo. Given the extent to which these websites are presently tied to the United States, an action campaign focused on the websites digital infrastructure would seem to hold real promise.

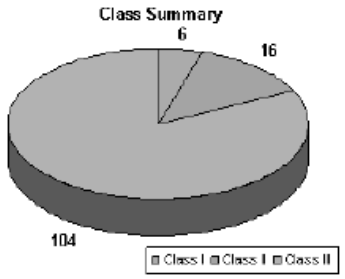
At a high level, our survey suggests that our sample websites are heavily utilizing express carrier services and major credit cards – perhaps suggesting additional avenues through which to bring pressure on those websites that illegally distribute. However, we cannot emphasize enough that our findings are not based on product purchases. Absent purchases, it is very difficult to know, at this time, whether the websites in our survey are not simply abusing the brands of the express carriers and credit card companies.

We call our conclusions preliminary because we acknowledge that our survey covers a limited sample of websites, and is based on a limited basket of products. Moreover, our analysis of relationships between sites has not been exhaustive, even in terms of what is possible with only open source intelligence.

As noted above, IntegriChain's databases contain thousands of websites that purport to sell prescription medicines to consumers. In 2006, IntegriChain will issue a follow-up to this whitepaper that reflects an expanded sample of websites and products, and additional analysis of open source intelligence. Though the most conclusive findings will only come with the collection of intelligence via purchases, we believe that an expanded survey of open source intelligence will be able to capture that maximum (if not the minimum) scale of online scheduled medicine distribution.

Appendix E – IntegriChain Survey of OxyContin® Online Offers

In August and September of 2005, at the request Purdue Pharma, manufacturer of OxyContin®, IntegriChain carried out comprehensive searches of its proprietary databases, Internet pharmacy related forums, paid portals, and other Internet mediums to identify websites claiming to sell OxyContin®. This information is provided herein with Purdue's permission as a point of reference for readers considering our whitepaper's findings. No purchases were made as part of this study. However, based on a more thorough examination of open source information than the constraints of the present white paper permitted, IntegriChain and Purdue established a three-tiered system to rate the likelihood that the 126 websites identified in our research would supply Oxycontin®:



Class I Site: Based on website analysis, including source of its identification, comments of consumers in forums related to drug purchasing, affiliation with other entities, and ownership, the product (or a substitute scheduled substance) is likely to be available.

Class II Site: Website identified through searches for sale of Oxycontin®, and reference to the drug is made on the site – but without the supporting information available for Class I Sites. Or, if no reference is made, availability of product(s) is implied or suggested through offering of other controlled substance. As such websites belonging to this category are potential but not likely sources of the drug(s).

Class III Site: Website identified through searches for sale of Oxycontin®, however, when the ultimate "selling" site was reviewed, no reference to the drug was identified. Availability of Oxycontin® is highly unlikely.

Ultimately, our research found only 6 websites that we could classify as "Class I" sites. Even if all Class II sites turned out to actually sell the product, that would result in a total of 22 websites selling OxyContin® out of 126 that solicited consumers for the product.

MR. WHITFIELD. Mr. Dahl, former Assistant Director, Office of Criminal Investigations, FDA.

MR. DAHL. Mr. Chairman, Mr. Stupak, members of the committee, thank you for the opportunity to testify today before you on this important issue. I'm here today because I share some of Mr. Stupak's frustrations on these matters. I do not purport to represent the official position of the Government on any topic, but I do hope to share the interests and opinions and probably frustrations of the 185 Special Agents of FDA's Office of Criminal Investigations.

The dangerous drug products being discussed today are sold using a number of schemes with an endless number of variations. The most common is the direct Internet sell of finished dosage form drugs. The websites of most concern are those that offer controlled substances along with many noncontrolled lifestyle drugs.

The interdiction of the small parcels containing the drugs is a difficult situation given the enormous volume of packages, the lack of sufficient government resources, and the cumbersome bureaucracy surrounding the seizure and ultimate destruction of the products. The purveyors of these products operate in a largely anonymous fashion through the use of complex networks, sometimes involving hundreds of foreign and domestic domain registrations, dozens of Internet service providers and host computers at sites all over the globe, multiple packaging and shipping centers, and numerous domestic and international credit card processing and banking relationships.

Another problem is the use of the Internet to distribute dangerous pharmaceutical chemicals intended for use by young people as hallucinogenic, weight loss, rave, or party drugs. Some of these chemicals are new designer drugs which may not be covered by the Controlled Substance Act. Others are used in over-the-counter drugs often sold in bulk quantities and frequently consumed by teenagers in superpotent capsules.

A common method of distribution of these chemicals is the use of Internet chat rooms or message boards at which the products are discussed anonymously. The chat rooms provide methods for use, including the required dosage and identities of websites offering the dangerous products.

The websites themselves are usually full of disclaimers such as not intended for human use or for research purposes only. These products are extremely dangerous because of the experimental method of dosage and the word-of-mouth tendency to call them legal and, by inference, safe products.

A couple of examples. Earlier this year five young people died over a three-month period after overdosing on DXM, a common ingredient in OTF cough medications. The bulk material was purchased from an Asian chemical supplier, shipped to the U.S., placed in the capsules in Indiana, and sold nationwide over a domestic Internet site. Although the FDA public health notice and follow-up on this particular case was weak, OCI was very successful in quickly arresting the seller of this deadly product, thereby shutting down his operation.

In a 2003 case, an OCI investigation led to a mail fraud conviction for an individual selling DNP under the name Dr. Evil. He was promoting DNP for weight loss and body-building uses, and his sales were linked to

the death of at least one individual and several other serious overdoses. DNP used for weight loss resulted in numerous deaths in the 1920s and 1930s and has been cited as one of the primary reasons of the passage of the Food and Drug Act in 1938. Here we are again.

Other illegal drug schemes involve products intended for athletic enhancement. The well-publicized BALCO case being investigated by the IRS and FDA/OCI involves the illegal distribution of THG to professional and world-class athletes. Because THG was not yet listed as a controlled substance analog, the primary criminal drug violation is a Food, Drug and Cosmetic Act offense. You can be sure that other steroid analogs are constantly being developed for use in international athletic circles.

Along the same line, huge quantities of human growth hormone are being illegally imported from Asia and sold to aspiring young athletes along with illegal steroid products.

OCI has been involved in many joint criminal investigations with DEA and other agencies. OCI actively seeks these joint investigations in order to leverage its meager resources and weak laws.

In August 2005, I and other OCI colleagues received a briefing at the DEA Special Operations Division on their relatively new program for including Internet controlled substance offenses as part of DEA's multiagency SOD effort. This is clearly a step in the right direction and seeks to integrate and analyze all available U.S. Government information in one location. DEA extended an invitation to OCI to participate in this effort, but to date resource limitations have precluded OCI from assigning anyone to DEA/SOD.

In my opinion FDA will not act on its own to emphasize and enhance OCI's potential contributions to a more robust law enforcement effort. Congress will have to prod the agency through direct appropriations for these efforts and/or through more aggressive congressional oversight.

I believe new legislation should be introduced, and OCI has suggested to FDA that new legislation be introduced for years, to enhance the law enforcement part of the agency. Let me suggest today that this legislation in the least should call for more FTEs and operational funding so OCI can enhance its field and headquarters investigative and analytical efforts, begin to establish a more formal program to pursue criminal targets in foreign countries, and fully participate in multiagency efforts such as DEA/SOD initiatives.

The legislative effort should also call for better laws to address pharmaceutical crime, including stronger maximum penalties, improved sentencing guidelines, administrative subpoena authority, direct forfeiture authority, and a simplified and efficient method for interdicting

and disposing of illegal imports. I'll be pleased to continue to assist the committee staff in any way and to answer any questions.

MR. WHITFIELD. Thank you very much.

[The prepared statement of James Dahl follows:]

PREPARED STATEMENT OF JAMES DAHL, FORMERLY WITH OFFICE OF CRIMINAL INVESTIGATIONS, FOOD AND DRUG ADMINISTRATION

Mr. Chairman and members of the committee, thank you for the opportunity to testify today on this important issue. I appear before you as the recently retired Assistant Director of the FDA's Office of Criminal Investigations (OCI). I do not purport to represent the official position of the government on any topic, but I do hope to share the interests and opinions of the hard working special agents of FDA/OCI who have had considerable experience with many of the issues you are addressing today.

As you know the problem of foreign and domestic internet sales of controlled substances and other dangerous pharmaceutical products is a large and complex issue that appears to be growing exponentially. The problem is complicated by a myriad of political, commercial, public health, education, legal, and enforcement issues. I would like to direct my comments today to matters most closely related to the criminal enforcement component of the issue.

These dangerous drug products are sold using a number of schemes with an endless number of variations. The most common is the direct internet sale of finished dosage form drugs which too many Americans have come to view as a quasi- legal source for obtaining what they choose to believe, but are unable to verify, are legitimate drugs. The websites of most concern are those that offer controlled substances along with many non-controlled "lifestyle" drugs. These websites often tout on-line physician consultations that almost always result in the sought after prescription. Although DEA regulations do not recognize this as a valid doctor patient relationship the various state laws regulating non-controlled prescription drugs vary widely on what constitutes that relationship. The propensity of these websites to accept any type of consumer supplied prescription ensures their continued growth in sales. Many other websites offer these dangerous products without any prescription whatsoever. The only real concern of the owners of these internet operations is not the health and well being of the consumer, but their ability to collect payment through the credit card used for the purchase.

Any kind of meaningful interdiction of the small, and not so small parcels, containing these drug products is almost impossible given the enormous volume of packages, the lack of sufficient government resources, and the cumbersome bureaucracy surrounding the seizure and ultimate destruction of the products. The purveyors of these products operate in a largely anonymous fashion through the use of complex networks sometimes involving hundreds of foreign and domestic website domain registrations, dozens of internet service providers and host computers at sites all over the globe, multiple packaging and shipping centers, and numerous domestic and international credit card processing and banking relationships.

Another problem is the use of the internet to distribute dangerous pharmaceutical chemicals usually intended for use by young people as hallucinogenic, weight loss, rave or party drugs. Some of these chemicals may themselves be controlled by the DEA, but others are new designer drugs that may or may not be legally defined as controlled substance analogs. Even some over the counter (OTC) drugs are being sold in bulk quantities, put into capsules or other forms, and sold to teenagers as "legal" products. A common method of distribution of these chemicals is the use of internet "chat rooms" or message boards in which the products are "discussed" anonymously by interested parties. Methods of use including dosage and preparation are "discussed," and websites selling

the dangerous products are identified in the "chat rooms." The websites themselves are usually full of disclaimers saying "not intended for human use" or "for research purposes only." But our experience is their customers intend to use and/or further distribute the drugs, and the sellers clearly understand and cater to the (human) uses to which their products will be put.

The above described products are extremely dangerous not only because of the chemicals themselves, but especially because of the experimental method of self-dosage and the word of mouth tendency to call them "legal" or "natural" and by inference "safe" products. A few examples:

- Earlier this year five young people died over a three month period after overdosing on DXM (dextromethorphan), a common ingredient in OTC cough medications. The bulk material was purchased from an Asian chemical supplier, shipped to the United States, placed into capsules in Indiana, and sold nationwide over a domestic internet site. Although the FDA public health notice and follow up on this particular case was extremely weak, OCI was very successful in quickly identifying and arresting the seller of this deadly product thereby putting him out of business.
- In another OCI case worked jointly with the DEA, search warrants executed at a location selling DXM, ecstasy analogs, and other controlled substance analog products disclosed a drug production and distribution operation that was filled with trash, lacked any attempt at GMPs, and had hazardous materials and other chemicals stored without any regard to safety. At least one death has been directly linked to this operation.
- A 2003 OCI investigation led to a mail fraud conviction for an individual selling DNP (2,4 Dinitrophenol) over the internet using the name "Dr. Evil." He was promoting DNP for weight loss and body building uses, and his sales were linked to the death of one individual and several other very serious overdoses. DNP use for weight loss resulted in numerous deaths in the 1920s and 1930s and has been cited as one of the reasons for the passage of the Food and Drug Act in 1938.

Other illegal drug schemes involve products intended for athletic enhancement. The well publicized BALCO case being investigated by the IRS and FDA/OCI involves the illegal distribution of THG (tetrahydrogestrinone), to professional and world class athletes. Because THG was not yet listed as a controlled substance analog the primary criminal drug violation charged in the indictments is a Federal Food Drug and Cosmetic Act offense. You can be sure that other steroid analogs are constantly being developed for use in international athletic competition circles.

Along the same line huge quantities of human growth hormone (HGH) are being distributed illegally in the U.S. for athletic enhancement, fat loss, and age-slowing purposes. Because of its propensity for abuse and the dangers associated with unapproved use, HGH is addressed by a specific FD&C Act section making all off-label distribution and possession with the intent to distribute illegal. 21 USC 333(f). The growing abuse of human growth hormone can be linked to FDA's inaction with respect to enormous quantities of Asian HGH being allowed to cross our borders. Many American firms now openly import bulk amounts of HGH, and the problem is worsening daily. Too often these growth hormone products end up being distributed to aspiring young athletes along with illegal steroid products.

OCI has been involved in many joint criminal investigations with the Drug Enforcement Administration, the Bureau of Immigration and Customs Enforcement, the Federal Bureau of Investigation, the Postal Inspection Service, and various state and local law enforcement agencies. OCI actively seeks these joint investigations in order to leverage its very meager FTE resources of only 185 special agents. Joint cases also assist OCI investigations through the application of modern law enforcement powers, which

otherwise are not always available to the FDA. These include criminal laws that adequately address the offensive conduct, maximum sentences and sentencing guidelines that effectively deter and punish that conduct, direct forfeiture authority that allows for effective dismantling of criminal organizations and the seizure of illegal proceeds, and administrative subpoena authority to promote timely, efficient and effective investigations.

In August 2005 I and an OCI colleague received a briefing at the DEA Special Operations Division (SOD) on their relatively new program for including internet controlled substance intelligence as part of the multi-agency SOD effort to analyze and track this type of criminal activity. This is clearly a step in the right direction and seeks to integrate and analyze all available U.S. Government information in one location. DEA extended an invitation for OCI to participate in this effort and it was clearly understood that there were mutual benefits to be obtained through the sharing of information on a real time basis and leveraging our combined skills and interests. To date, resource limitations have precluded OCI from assigning anyone to DEA/SOD.

The most current information I have is that FDA/OCI has two headquarters FTEs whose primary duties are to address internet crime (although drugs are their primary focus other illegal products sold over the internet are also their responsibility). There are no field agents fully devoted to this or any other specific issue within OCI's jurisdiction. In addition OCI has no presence in overseas locations where much of this problem originates.

Although most of the drugs discussed here today fall within the primary jurisdiction of the DEA and the Controlled Substances Act, FDA/OCI must be part of the overall enforcement strategy if the problem is to be fully addressed. There are just too many emerging, and as yet non-controlled, designer drugs, lifestyle drugs, and other related prescription drug investigations to leave OCI and FDA out of the enforcement part of the solution. But in my opinion FDA will not act on its own to emphasize and enhance OCI's potential contributions to a more robust enforcement effort. Congress will have to prod the agency through direct appropriations for these efforts or through more aggressive Congressional oversight.

Recent Congressional efforts to pass new legislation to regulate internet drug sales have become bogged down in the complex political, legal, and commercial issues we read so much about. These problems must be overcome. In my personal (FDA/OCI influenced) opinion, any new legislation should also enhance the FDA portion of the enforcement solution to this problem. I suggest that the legislation include provisions for:

- More FTEs and operational funding so OCI can enhance its field and headquarters investigative and analytical efforts, begin to establish a formal strategy to effectively pursue criminal targets in foreign countries, and fully participate in multi-agency efforts such as the DEA/SOD initiative;
- Better laws to address pharmaceutical crime including: more severe maximum penalties linked to the actual or potential harm to individuals; improved sentencing guidelines; administrative subpoena authority; direct forfeiture authority; and a simplified and efficient method for interdicting and disposing of illegal imports.
- Extra-territorial jurisdiction allowing all U.S. law-enforcement agencies to prosecute foreign based individuals and organizations selling illegal dangerous drugs in the U.S. marketplace.

I would be pleased to continue to assist Committee staff in addressing any of the issues discussed here today. Thank you for the opportunity to contribute to this important discussion.

SUMMARY

- Description of the problems associated with internet drug distribution

  Direct finished dosage form drugs through complex international systems

  Pharmaceutical chemical and CS analog sales advertised through internet "chat rooms" and message boards

  Dangerous drugs for athletic enhancement, weight loss and other uses

  Not all of our most dangerous products are covered by the CSA

- Effective enforcement methods

  Joint investigations (FDA/OCI – DEA – FBI – ICE, etc.)

  Sharing/Analysis of intelligence (DEA/SOD offer to FDA/OCI)

- Needs / Solutions

  Realization by FDA that criminal enforcement cannot remain status quo

  Increased in FTE resources and operational funding for FDA/OCI

  New legislation to provide FDA with necessary enforcement tools including stricter penalties, better sentencing guidelines, administrative subpoena authority, direct forfeiture authority, and authorization the efficiently interdict violative products at ports of entry

MR. WHITFIELD. Mr. MacCarthy, with VISA.

MR. MACCARTHY. Thank you, Chairman Whitfield, Ranking Member Stupak and members of the committee. My name is Mark MacCarthy, senior vice president for public policy for VISA U.S.A. Thank you for the invitation to participate in this hearing. VISA appreciates this opportunity to testify as part of the committee's investigation into the safety of imported prescription drugs.

The VISA payment system consists of VISA itself, which performs various communications and settlement services for its member financial institutions, and VISA member financial institutions themselves. Some of these financial institutions issue VISA payment cards, and some of them authorize merchants to accept VISA cards. But VISA itself does not have direct relationships with merchants. VISA member financial institutions do have those direct relationships with merchants.

We do require our members to submit only legal transactions into our system, and in particular they must ensure that Internet merchants do not violate laws governing prescription medications.

VISA has a long history of working with law enforcement, with Secret Service, with the FBI, with the FTC, and with state and local law enforcement. VISA has met with representatives of the DEA and the FDA to discuss enforcement measures and other areas of interest in the area of Internet pharmacies. The latest such meeting was in August of 2005, this year.

In March of 2004, in May of 2005, and again in September of 2005, VISA reminded its member financial institutions of their responsibilities regarding Internet pharmacies. We directed their attention to the list of controlled substances and problematic drugs that are maintained at the FDA and the DEA websites. We noted that a safe website should be licensed by the state board of pharmacy where the website is operating, and must require a prescription from a U.S.-licensed doctor. VISA also advised its members to allow a reputable seal program such as the VIPPS program as a means of identifying reputable Internet pharmacies.

VISA has retained the services of an outside firm to search the Internet for websites selling controlled substances and accepting VISA payment cards. We have hired additional in-house staff to direct this program, which builds on our global initiative for monitoring the Internet for child pornography.

Our vendor looks for websites that display the VISA logo; that sells Schedule II controlled substances or other prescription drugs that the FDA and the DEA have indicated are most abused; and, three, that do not require a prescription or medical exam. These sweeps are ongoing, they're conducted daily, and search hundreds of millions of Web pages every month. As a result of this monitoring effort, we have had discussions with some of our member financial institutions regarding their merchants who appear to be involved in selling controlled substances. These member financial institutions have conducted their own investigations and have terminated or restricted the activity of merchants that have been found to be dealing in controlled substances.

In May of 2004, VISA updated its consumer website to provide safety messages to consumers regarding the dangers of purchasing pharmaceuticals over the Internet. As part of their due diligence responsibilities, VISA U.S.A. members must examine the websites of Internet merchants before signing them and must periodically reexamine them. In addition, all of these merchant websites must contain the address of the merchant's permanent establishment.

We have also taken steps to ensure illegal Internet pharmacies cannot enter our system indirectly as merchants that are sponsored by aggregators. As of March 2005, Internet pharmacies cannot accept VISA cards as sponsored merchants. This added control will help ensure that

acquirers conduct meaningful due diligence reviews before merchants in this category are signed.

Mr. Chairman, I would be happy to answer any questions that you or other members of the committee might have in this area.

MR. WHITFIELD. Thank you very much.

[The prepared statement of Mark MacCarthy follows:]

PREPARED STATEMENT OF MARK MACCARTHY, SENIOR VICE PRESIDENT, PUBLIC POLICY, VISA, U.S.A., INC.

Chairman Whitfield, Ranking Member Stupak and the Members of the Subcommittee, my name is Mark MacCarthy. I am the Senior Vice President for Public Policy for Visa U.S.A. Inc. Thank you for the invitation to participate in this hearing. Visa appreciates this opportunity to testify as part of the Committee's investigation into the safety of imported prescription drugs.

The Visa Payment System, of which Visa U.S.A.[1] is a part, is one of the leading consumer payment systems in the world. The Visa Payment System consists of Visa, which performs communication and settlement services for its member financial institutions, and Visa's member financial institutions that issue Visa payment cards or that authorize merchants to accept Visa payment cards in payment for transactions. Accordingly, Visa, and Visa member financial institutions that only issue credit cards, do not have direct relationships with Internet pharmacies or other merchants that accept Visa payment cards. On the other hand, Visa member financial institutions that acquire transactions from merchants do have a direct relationship with the merchants that accept Visa payment cards. Visa rules require these acquiring financial institutions to assume responsibility for certain aspects of their relationships with merchants. A fundamental Visa rule is that acquiring financial institutions submit only legal transactions into the Visa payment system. In particular, acquirers must ensure that Internet merchants do not violate laws governing prescription medications.

Visa plays a pivotal role in advancing new payment products and technologies, including technology initiatives for protecting personal information and preventing identity theft and other fraud, for the benefit of its member financial institutions and their hundreds of millions of cardholders. Visa recognizes that payment cards are an important part of electronic commerce.

Visa believes that the Visa Payment System has responded, and continues to respond, effectively to the challenges posed by Internet transactions. In this regard, Visa has a keen interest in curbing illicit pharmaceutical sales, as well as other illegal activity, in which Visa cards are used. Visa rules prohibit the use of the Visa Payment System for illegal transactions. Visa has a long history of working with law enforcement (including the Secret Service, the Federal Bureau of Investigation, the Federal Trade Commission, and state and local law enforcement) where the Visa Payment System may have been used in connection with illegal transactions.

In the specific area of illicit sales of prescription pharmaceuticals over the Internet, Visa has met with representatives of the Drug Enforcement Administration ("DEA") and the Food and Drug Administration ("FDA") to discuss approaches to the problem of illicit transactions with Internet pharmacies, and has alerted its member financial institutions to the problem of illicit activities by Internet pharmacies.

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[1] Visa U.S.A. is a membership organization comprised of U.S. financial institutions licensed to use the Visa service marks in connection with payment systems.

In March of 2004, in May of 2005, and again in September of 2005, Visa reminded its member financial institutions of their responsibilities to ensure that only legal transactions enter the Visa Payment System and directed their attention to the lists of controlled substances and problematic drugs maintained at the FDA and DEA websites. Visa also directed its members to the FDA public safety bulletins on the FDA website on buying medicines online and noted that a safe website should be licensed by the state board of pharmacy where the website is operating, have a licensed pharmacist available to answer questions, require a prescription from a U.S. licensed doctor or other healthcare professional licensed in the U.S. to write prescriptions and provide a way to speak to a person about problems. Visa also advised its members to consider relying on a reputable seal program, such as the Verified Internet Pharmacy Practices Site Program ("VIPPS") operated by the National Association of Boards of Pharmacy, as a means of identifying reputable Internet pharmacies. When alerted that specific Internet pharmacies may be accepting Visa cards for illicit transactions, Visa has worked with its member financial institutions to investigate these pharmacies and to terminate the acceptance of Visa cards for illicit activity.

Visa has retained the services of an outside firm to search the Internet for websites selling controlled substances and accepting Visa payment cards. Using this firm, Visa has initiated a program of monitoring the Internet on a regular basis to ensure that our payment services are not used for the sale of Schedule II controlled substances. We have hired additional staff in-house to direct this program. This program builds on our global initiative for monitoring the Internet for child pornography, uses the same web crawling and filtering technology, and the same outside search firm to conduct the Internet sweeps. Our vendor looks for websites that display the Visa logo, that sell Schedule II controlled substances or other prescription drugs that the FDA or DEA have indicated are especially dangerous, and that do not require a prescription or an exam. The sweeps are ongoing; they are conducted daily and search hundreds of millions of web pages each month. As a result of this monitoring effort, we have had discussions with some of our member financial institutions regarding their merchants who appear to be involved in selling controlled substances. These member financial institutions have conducted their own investigations and have terminated or restricted the activity of merchants found to be selling controlled substances.

In May of 2004, Visa updated its consumer website to provide safety messages regarding the dangers of purchasing pharmaceuticals over the Internet, to provide links to the websites of the DEA and the National Association of Boards of Pharmacy and to remind consumers that they should only use their Visa payment cards for legal purposes.

More broadly, Visa requires its U.S. members to periodically examine the websites of merchants that they service and requires all Visa merchant websites to contain the address of the merchant's permanent establishment to help consumers determine the identity and assess the nature of an entity with which he or she seeks to do business over the Internet.

We have also taken steps to make sure that illegal Internet pharmacies cannot enter our system indirectly. In 2004, we learned that some Internet pharmacies have been signed up to accept Visa cards as "sponsored merchants" by aggregators or other payment providers. As result, some of our acquiring financial institutions have been unaware that potentially illegal merchants have been operating in their portfolios. To help ensure that our financial institutions remain compliant with Visa regulations that prohibit illegal transactions, in March 2005, Visa modified its rules to make certain that Internet pharmacies or Internet pharmacy referral sites cannot accept Visa cards as sponsored merchants. Acquirers could still sign Internet pharmacies, but they must have direct relationships with them. This added control will help ensure that acquirers conduct meaningful due diligence reviews before merchants are signed and will help increase the level of risk management scrutiny provided to this category of merchant.

Although Visa aggressively tries to prevent the Visa Payment System from being used to support illegal transactions, Visa believes that, in many cases, the only parties that can accurately and effectively determine the legality of transactions, including Internet transactions, are the parties to the transactions themselves. Legality may depend on a variety of factors, such as the geographic location of the parties to the transaction, possession of a required license, intent, or age, among other factors, that cannot be known to third parties that are merely intermediaries in the transmission of payment information.

Accordingly, telephone companies, payment systems and delivery services typically are not required to know whether transactions that are effected using their facilities or services are legal. Historically, it has been only in those circumstances where the use is so unusual as to suggest illegality in its own right (such as transactions that trigger Suspicious Activity Report or Currency Transaction Report requirements) or where the illegality is so overt and egregious (such as child pornography and Schedule II controlled substances) that Congress and law enforcement have enlisted the aid of the third-party intermediaries to monitor the use of their facilities or services for policing illegal transactions.

Visa appreciates the opportunity to appear before you today. I would be happy to answer any questions that you may have.

MR. WHITFIELD. Mr. McEneney, representing MasterCard, is recognized for five minutes.

MR. MCENENEY. Thank you.

Good afternoon, Chairman Whitfield, Ranking Member Stupak. My name is Michael McEneney, and I'm a partner in the law firm of Sidley, Austin, Brown, & Wood here in Washington, D.C. I am pleased to appear before you today on behalf of MasterCard International, Incorporated, to discuss the important issue of the sale of pharmaceuticals over the Internet.

MasterCard deplores the use of its system for any illegal purchase, including the illegal sale of pharmaceuticals. In addition to a standing prohibition against the use of its system for illegal activities, MasterCard has recently taken a number of steps to help stop Internet pharmacies from accepting MasterCard cards for illegal pharmaceutical sales. To date these efforts have resulted in more than 500 websites being shut off from accepting MasterCard payment cards.

By way of background, MasterCard is a global organization comprised of more than 23,000 financial institutions that are licensed to use the MasterCard service marks in connection with a variety of payment systems. MasterCard itself does not issue payment cards, nor does it contract with merchants to accept those cards. Instead, those functions are performed by its customer financial institutions.

The financial institutions that issue payment cards bearing the MasterCard brands are referred to as card issuers, and the financial institutions that enter into contracts with merchants to accept MasterCard-branded cards are referred to as acquirers. MasterCard provides the networks through which customer financial institutions

interact to complete payment transactions, and MasterCard sets the rules regarding those interactions.

MasterCard first became involved in efforts to address this issue after an inquiry from the House Energy and Commerce Committee on December 9 of 2003. Less than a week later, MasterCard met with Majority staff of the House Energy and Commerce Committee to discuss the issue, and shortly thereafter MasterCard met with staff of the Senate Permanent Subcommittee on Investigations and Democratic staff of the House Energy and Commerce Committee to discuss how MasterCard handles these issues and to discuss what role MasterCard could play in the future.

These meetings with congressional staff were particularly helpful in highlighting the magnitude of the problem and in clarifying some of the legal issues surrounding the Internet sale of pharmaceuticals, particularly the issues as they relate to controlled substances.

Based on the information received during these meetings, MasterCard embarked on a three-pronged proactive approach to address this issue. First, MasterCard established a working relationship with appropriate officials at the DEA and FDA. As a result, MasterCard had a number of productive meetings and conversations to identify ways in which MasterCard could be helpful to the agencies in connection with their efforts.

Second, MasterCard sent a number of bulletins to its customer financial institutions worldwide reminding them of their obligation to ensure that the MasterCard system is not used for illegal activity. The bulletin specifically highlighted Internet transactions as involving a heightened risk of potential illegal activity. The bulletin also reminded customer financial institutions of their obligation to perform due diligence to determine the legitimacy of each Internet pharmacy before allowing the pharmacy to accept MasterCard cards.

Acquirers that failed to comply with the rules may be required to absorb the cost of any illegal transactions, may be assessed fines, may be suspended or even terminated in MasterCard's sole discretion.

Third, MasterCard directed its merchant security team to search the Internet for pharmacies that purport to accept MasterCard-branded cards for illegal sales of controlled substances. Their initial effort identified approximately 400 websites that appeared to be engaged in the illegal sale of pharmaceuticals. For each of these sites, MasterCard attempted to identify the acquirer that contracted with the Internet pharmacy to accept MasterCard-branded cards. MasterCard then directed each of the identified acquirers to immediately stop the Internet pharmacy from accepting MasterCard cards as payment for the illegal sale of pharmaceuticals.

MasterCard also directed each of the acquirers to respond in writing either to confirm that it had stopped the merchant's acceptance of MasterCard cards, or to confirm that the merchant was not engaged in illegal activities, and to provide all documentation regarding the steps the acquirer took to confirm the legality of those activities. MasterCard is pleased to report that to date these efforts have been largely successful in shutting off the acceptance of MasterCard cards at more than 500 websites.

Chairman Whitfield and Ranking Member Stupak, thank you again for the opportunity to discuss these important issues with you today. MasterCard is fully committed to doing its part to prevent the illegal sale of pharmaceuticals over the Internet, and it looks forward to continuing its work with you. It has also been our pleasure to work with subcommittee staff and the DEA, FDA, and others, and I'd be happy to answer any questions you may have.

MR. WHITFIELD. Thank you very much.

[The prepared statement of Michael McEneney follows:]

PREPARED STATEMENT OF MICHAEL MCENENEY, PARTNER, SIDLEY, AUSTIN, BROWN, & WOOD, LLP, ON BEHALF OF MASTERCARD INTERNATIONAL INCORPORATED

Good morning, Chairman Whitfield, Ranking Member Stupak and Members of the Subcommittee. My name is Michael McEneney and I am a partner in the Washington, DC office of the law firm Sidley Austin Brown & Wood. I am pleased to appear before you today on behalf of MasterCard International Incorporated to discuss the important issue of the sale of pharmaceuticals over the Internet.

MasterCard deplores the use of its system for any illegal purposes, including for the illegal purchase of pharmaceuticals. In addition to its standing prohibition against the use of its system for illegal activities, MasterCard has recently taken a number of steps to help prevent Internet pharmacies from accepting MasterCard cards for illegal pharmaceutical sales. MasterCard takes its obligations very seriously and is committed to doing its part to address this important issue. These steps, which are discussed in greater detail below, include: (i) working with MasterCard's customer financial institutions to shut off more than 500 web sites from accepting MasterCard-branded payment cards in connection with the illegal sale of pharmaceuticals over the Internet; (ii) publishing a bulletin to all of its customer financial institutions worldwide reminding them of their obligations to ensure that the MasterCard system is not used for illegal pharmaceutical sales or other illegal transactions; and (iii) working with the Drug Enforcement Administration ("DEA") and the Food and Drug Administration ("FDA") in a collaborative fashion. The efforts MasterCard has taken to date represent important steps in fulfilling MasterCard's commitment to play an appropriate role in addressing this issue.

Background

MasterCard is a global organization comprised of more than 23,000 financial institutions that are licensed to use the MasterCard service marks in connection with a variety of payments systems. It is important to note that MasterCard itself does not issue payment cards nor does it contract with merchants to accept those cards. Instead, those functions are performed by its customer financial institutions. The financial institutions

that issue payment cards bearing the MasterCard brands are referred to as "Card Issuers." The financial institutions that enter into contracts with merchants, including Internet pharmacies, to accept MasterCard-branded cards are referred to as "Acquirers." MasterCard provides the networks through which the customer financial institutions interact to complete payment transactions and sets the rules regarding those interactions.

A fundamental rule of the MasterCard system is that each customer financial institution must conduct its MasterCard programs and activities in accordance with all applicable laws. This includes, for example, ensuring that any transaction a customer submits into the MasterCard system pertains to only legal activity. MasterCard also has a series of rules that require Acquirers to ensure that the merchants they contract with to accept MasterCard-branded cards are legitimate and engage in solely legal activities. These rules mandate, among other things, that Acquirers perform due diligence on a merchant before authorizing the merchant to accept MasterCard cards and that Acquirers monitor merchants for compliance with the rules. Customer financial institutions that fail to comply with the rules may be required to absorb the cost of any illegal transactions, and may be assessed fines, suspended or terminated, in MasterCard's sole discretion. MasterCard also works extensively with law enforcement officials to address situations where the legality of activities related to MasterCard payment card transactions is in question. For example, in the U.S., MasterCard works with a variety of federal and state law enforcement agencies on these issues generally, including state Attorneys General, the DEA, the FDA, the U.S. Secret Service, the Federal Bureau of Investigation, and other branches of the Department of Justice. A major objective of these efforts is to ensure that MasterCard provides appropriate support to law enforcement in their efforts to address illegal activity. MasterCard is sensitive to the fact that its efforts to enforce the MasterCard rules have the potential to hinder ongoing law enforcement investigations and the like. For example, when a merchant is shut off from accepting MasterCard-branded cards because the merchant violated MasterCard's rules, law enforcement's ability to gather evidence through MasterCard's system can be impeded and shutting off a merchant might be a tip-off to that merchant of an ongoing investigation.

Efforts to Address Illegal Pharmaceutical Sales

MasterCard first became involved in efforts to address the important issue of illegal pharmaceutical sales over the Internet after an inquiry from the House Energy and Commerce Committee on December 9, 2003. Less than a week later, on December 15, 2003, MasterCard met with majority staff of the House Energy and Commerce Committee who explained the efforts that were underway in Congress to find solutions to this issue, including solutions that may involve payments systems. Shortly thereafter, MasterCard met with staff of the Senate Permanent Subcommittee on Investigations and Democratic staff of the House Energy and Commerce Committee to discuss how MasterCard handles these issues, and what role MasterCard could play in the future. The meetings MasterCard has had with congressional staff, including the staff of this Subcommittee, were particularly helpful in highlighting the magnitude of the problem and in clarifying some of the legal issues surrounding the Internet sale of pharmaceuticals, particularly the issues as they relate to controlled substances. MasterCard has also met with staff of the DEA and FDA to exchange information and to explore ways in which MasterCard could be helpful to them in their efforts against illicit Internet pharmacies. Prior to this series of meetings, MasterCard did not have sufficient knowledge of the legal issues involved in the Internet pharmacy debate to take action.

Based on the information it received during these meetings, MasterCard embarked on a three-pronged proactive approach to address this issue. First, MasterCard established a working relationship with appropriate officials at the DEA and FDA. As a result, MasterCard has had a number of meetings and conversations to identify ways in which MasterCard could be helpful to the agencies in connection with their enforcement efforts,

and it successfully established lines of communication that remain open in order to exchange information and do its part to assist in apprehending those violating the law. MasterCard has also provided information to the DEA on several occasions to help it with ongoing investigations.

Second, MasterCard sent a bulletin entitled "MasterCard Rules Prohibit MasterCard Transactions for Illegal Activities" to all of its customer financial institutions worldwide. This bulletin reminded MasterCard's customer financial institutions of their obligation to ensure that the MasterCard system is not used for illegal activity. The bulletin specifically highlighted Internet pharmacy transactions as involving a heightened risk of potential illegal activity. The bulletin also reminded customer financial institutions of their obligation to perform due diligence of merchants, including Internet pharmacies, before allowing them to accept MasterCard cards, to properly identify MasterCard transactions that are submitted into the system, and to ensure that merchants accepting the MasterCard cards comply with applicable law. The bulletin went on to note that if there was a lack of clarity regarding the legality of particular transactions, the customer financial institution should not submit those transactions.

Third, MasterCard directed its merchant security team to search the Internet for Internet pharmacies that purport to accept MasterCard-branded cards for illegal sales of controlled substances. These initial efforts identified approximately 400 web sites that appeared to be engaged in the illegal sale of pharmaceuticals—both controlled substances and other prescription drugs. For each of these sites, MasterCard attempted to identify the Acquirer that contracted with the Internet pharmacy to accept MasterCard-branded cards. In some cases, MasterCard could readily identify the Acquirer through "dummy" transactions. However, because MasterCard and its employees are prohibited by law from knowingly making illegal buys, MasterCard security personnel could not legally complete any transactions, making it difficult to identify the Acquirer in some circumstances. MasterCard then directed each of the identified Acquirers to immediately stop the Internet pharmacy from accepting MasterCard cards as payment for the illegal sale of pharmaceuticals. MasterCard also directed the Acquirer to respond in writing either to confirm that it had stopped the merchant's acceptance of MasterCard-branded cards or to confirm that the merchant was not engaged in illegal activities and to provide all documentation regarding the steps the Acquirer had taken to confirm the legality of those activities. MasterCard also reminded the Acquirer that any failure to comply with MasterCard's instructions might subject the Acquirer to fines, penalties, suspension, or termination by MasterCard. MasterCard is pleased to report that, to date, these efforts have been largely successful in shutting off the acceptance of MasterCard cards at more than 500 web sites. It is important to note, however, that MasterCard has seen already some web sites that have been terminated through one Acquirer popping up elsewhere in its system. Unfortunately, this reflects one of the limitations of private enforcement efforts by industry. Although MasterCard can be successful in shutting off web sites engaged in illegal activity, it does not have the ability to uproot the bad actors the way state and federal law enforcement could.

Although MasterCard has had success to date in addressing this situation, the task has been made more difficult by a lack of clarity on what sales of prescription drugs by Internet pharmacies are actually illegal. In this regard, it appears that there are unlikely scenarios that the sale could be legal if it met a variety of standards, which generally can only be confirmed through actually completing a purchase from the web site which, as mentioned above, MasterCard cannot legally do at this time. It is MasterCard's understanding from staff of the DEA and FDA that these standards are almost never achieved. However, the lack of a clear prohibition has made it more difficult to educate MasterCard's Acquirers about the illegality of the sale of pharmaceuticals over the Internet to U.S. cardholders. In addition, this lack of clarity increased the risk of

litigation. In fact, MasterCard is being sued in Israel by a merchant who was blocked from accepting MasterCard-branded cards in connection with the sale of pharmaceuticals.

Chairman Whitfield and Ranking Member Stupak, thank you again for the opportunity to discuss these important issues with you today. MasterCard intends to do its part to prevent the illegal sale of pharmaceuticals over the Internet, and it looks forward to continuing its work with each of you. It has also been our pleasure to work with Subcommittee staff and the DEA, FDA, and others, and we look forward to continuing these efforts. I would be glad to answer any questions you may have.

MR. WHITFIELD. Mr. Townsend of FedEx is recognized.

MR. TOWNSEND. Good afternoon, Mr. Chairman. On behalf of FedEx Corporation, I would like to thank you as well as the distinguished Ranking Member and the other members of the subcommittee for the opportunity to testify today to add our voice of concern regarding the safety of imported prescription drugs.

FedEx strongly supports efforts to address the sale of controlled substances over the Internet, particularly international sales. FedEx has a long history of working cooperatively with law enforcement and other government agencies to prevent the transportation of illegal drugs, especially controlled substances. Over the years FedEx has worked diligently with DEA, FDA, U.S. Customs, U.S. Postal Service, and others on this issue, and will continue to do so.

We have met and talked with staff of both this committee and the Senate Permanent Subcommittee on Investigations on numerous occasions since this issue was brought to our attention. Our conclusion from these meetings and our own research is that this is a complicated and difficult law enforcement issue which presents no easy solutions. It requires a new way of thinking about the problem on the part of both the government and the private sector. Traditional government efforts to arrest and criminally prosecute offenders must be supplemented with new government-led initiatives that engage the private sector to help disrupt the offenders' illicit operations.

From our perspective enforcement is complicated by two primary factors. First, one must consider the nature of the Internet. These so-called Internet pharmacies are virtual entities and cannot be linked by us to a shipping site unless law enforcement makes that association for us. We have retained a digital asset protection company to analyze the public information available on several thousand Internet pharmacies that are using the FedEx brand on their website without our permission.

A second fundamental problem is even if the identities of foreign Internet shippers were readily available, our experience indicates that law enforcement agencies have numerous obstacles to overcome in order to institute a criminal prosecution. In many instances the United States Attorney may not authorize prosecution on small amounts of pharmaceutical drugs. Additionally, prosecution may not be successful,

in any event, without testimony or evidence from the originating foreign country. Also, present reporting requirements for the FDA and Customs and Border Protection may be severely limiting their abilities to process their seizures; and finally, they may lack sufficient manpower to handle the suspected volume of illegal shipments now arriving in our ports.

These obstacles suggest the need for a parallel enforcement strategy aimed at disrupting illicit operations, in addition to pursuing complex and lengthy criminal investigations leading to judicial action. We applaud the work of the men and women of law enforcement who are on the front lines every day carrying out a difficult and dangerous mission. The criminal prosecution of drug traffickers is critical to the security of our country and cannot be replaced. However, we would welcome the opportunity to work with these government agencies to find a way to supplement traditional efforts with an approach aimed at disrupting the distribution networks and processes of known offenders.

FedEx Corporation does not tolerate any attempted use of our global network or the FedEx brand for illegal purposes, and we take immediate steps to stop it when it comes to our attention. If we receive information from law enforcement agencies that a particular customer is violating the law, we will assist in the gathering of evidence for the government pursuant to legal requirements and other restrictions, and we will cease accepting packages from that company.

No Internet pharmacies are authorized to use the FedEx logo to promote their service. Unfortunately, there are numerous cases where our brand is used without our consent. To the extent possible, we are taking appropriate legal action to stop such activity.

In closing, I want to emphasize that we believe we have a role to play, and that we want to be part of what must be a joint effort to shape a new approach to this problem. We have package tracking technology that can be of significant assistance to law enforcement agencies, and we can specifically target suspect packages identified by authorities for inspection.

FedEx welcomes the opportunity to continue to work with the Congress, law enforcement and our private sector colleagues to find ways to disrupt these networks that negatively impact the health and safety of our citizens; however, we do not have law enforcement authority and do not have available the tools that would allow us to solve this problem on our own.

Mr. Chairman, thank you for the opportunity to address this subcommittee. I'd be happy to respond to Members' questions.

MR. WHITFIELD. Thank you, Mr. Townsend.

[The prepared statement of Bruce Townsend follows:]

PREPARED STATEMENT OF BRUCE TOWNSEND, VICE PRESIDENT, CORPORATE SECURITY, FEDEX CORPORATION

Good afternoon, Mr. Chairman. On behalf of FedEx Corporation, I would like to thank you as well as the distinguished Ranking Member and the other members of the Subcommittee, for the opportunity to testify today to add our voice of concern regarding the safety of imported prescription drugs. FedEx strongly supports efforts to address the sale of controlled substances over the Internet, particularly international sales.

The FedEx family of companies specializes in fast, reliable transportation services for documents, packages and freight and employs more than 215,000 American workers. FedEx has a large global delivery network reaching more than 220 countries and territories including every address in the U.S. Additionally, FedEx moves more than 5 million packages each day, providing jobs for more than 246,000 employees and contractors worldwide. FedEx Express operates 674 aircraft and FedEx Corporation has revenues of approximately $30 billion annually.

FedEx has a long and successful history of working cooperatively with law enforcement and other governmental agencies to prevent the transportation of illegal drugs, especially controlled substances. Over the years FedEx has worked diligently with the Drug Enforcement Administration (DEA), Food and Drug Administration (FDA), U.S. Customs, the U.S. Postal Service and others on this issue and will continue to do so.

The recent GAO report on Prescription Drugs (issued September 8, 2005) makes it clear that the proliferation of illegal Internet pharmacies offering controlled substances is a serious and growing problem. FedEx representatives have worked with a variety of federal, state, and local governmental agencies to address the Internet pharmacy issue over the last two years. Our first meeting on the subject was held on May 13, 2002 with representatives from the DEA, FDA Office of Criminal Investigations, U.S. Customs & Border Patrol and the U.S Postal Inspection Service. At that meeting we offered our assistance to do whatever was required to assist the agencies in their investigations and we described what our capabilities were in that regard. We learned that the agencies were well aware of the problem, working on ways to attack it and appreciative of our offer of assistance.

Since then we have had several additional face-to-face meetings, telephone calls, and exchanged e-mail messages with various members of agencies represented at that original meeting. We have furnished information to law enforcement agencies as appropriate, and have discontinued business with specific customers when requested by those agencies.

We have met and talked with staff of both this committee and of the Senate Permanent Subcommittee on Investigations on numerous occasions since this issue was brought to our attention. Our conclusion from these meetings and our own research is that this is a complicated and difficult law enforcement issue which presents no easy solutions. It will require a new way of thinking about the problem on the part of both the government and the private sector. Traditional government efforts to arrest and criminally prosecute offenders must be supplemented with new government-led initiatives that engage the private sector to help disrupt the offenders' illicit operations.

From our perspective, enforcement is complicated by two primary factors. First, one must consider the nature of the Internet. These so called Internet pharmacies are "virtual entities" and cannot be linked by us to a shipping site unless law enforcement makes that association for us. We have retained a digital asset protection company to analyze the public information available on several thousand Internet pharmacies that are using the FedEx brand on their website without our permission.

Last year we commissioned, NameProtect, Inc., a private company, to help us with this problem. They analyzed approximately 400 million web pages and found 650,310

instances where the FedEx brand was used on the same page as a specified list of the top 22 drug names including some controlled substances.1 These initial search results contained multiple pages from the same root domain name; however, NameProtect was able to distill these hundreds of thousands of pages down to 12,200 unique domain names. These reported results were as of March 9, 2004.

Because in virtually all instances the actual brick and mortar address of the Internet pharmacy is not listed on the website, we asked NameProtect to obtain whatever public information is available about the owners of these 12,200 unique domain names. They compiled so-called "WhoIs" information on each website registrant, including names, street addresses, telephone numbers and e-mail addresses. Due to the hundreds of different registrars that control their own WhoIs data, however, a complete Reverse WhoIs analysis was not available for this project. Furthermore, because the legal requirements for registering a website are so lax, this registrant information is deemed highly unreliable. Clearly, individuals who sell illegal drugs go to great lengths to maintain their anonymity and seldom list their real names or their real addresses. In fact, our experience is that Federal law enforcement agencies have difficulty in tracing the real address through internet address protocols. An electronic copy of all of this information, which runs some 18,000 pages, has been provided to the appropriate government agencies and is available to this committee upon request.

To further complicate this situation, many of these websites are just "fronts" for an Internet pharmacy. Even if we could identify the registrant of one of these websites as a FedEx customer the entity is not likely to be the real owner of the Internet pharmacy. It is more likely the website host is several layers removed from the actual shipper utilizing FedEx services. NameProtect identified many Internet pharmacies that use multiple servers linked to each other, sometimes in different countries and found that the actual drug shipments come from a location that is not linked to the Internet site.

Additionally, we suspect that even if we were able to identify the real owners of the Internet pharmacies they may not be a Fedex customer because (1) our logo may appear on the website but they do not actually use FedEx services, (2) they may ship using a different account name, (3) they may use a third party distributor to maintain inventory at a different brick-and-mortar address, or (4) they may use a drop shipper to arrange for shipping the product via FedEx or some other delivery service. Many of these drop shippers are legitimate businesses serving a variety of online stores and would have no knowledge or reason to know that the underlying transaction is illegal. Therefore, we would need law enforcement to make the determination of which persons are acting illegally and share those findings with us. We could then use that verified information to take appropriate action up to and including closing an illicit shipper's FedEx account.

A second fundamental problem is even if the identities of foreign Internet pharmacy shippers were readily available our experience indicates that government law enforcement agencies have numerous obstacles to overcome in order to institute a criminal prosecution. In many instances 1) the United States Attorney may not authorize prosecution on small amounts of pharmaceutical drugs; 2) successful prosecution may not be successful in any event without testimony or evidence from the originating foreign country; 3) present reporting requirements for the FDA and Customs and Border Protection may be severely limiting their abilities to process their seizures; and 4) they

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[1] 400 million web pages is less than one-tenth of the actual Internet; therefore, it is estimated these results represent approximately 9.93 percent of the internet pharmacy web pages using the FedEx brand available in a typical Google search. In fact, on March 9, 2004 the same queries were run in Google and generated 6,546,700 hits. However, the number of unique domain names represented in this number cannot be determined using the standard Google search engine. That is why we relied on the smaller NameProtect database.

may lack sufficient manpower to handle the suspected volume of illegal shipments now arriving at our ports.

These obstacles suggest the need for a parallel enforcement strategy aimed at disrupting illicit operations, in addition to pursuing complex and lengthy criminal investigations leading to judicial action. We applaud the work of the men and women of law enforcement who are on the frontlines every day, carrying out a difficult and dangerous mission. The criminal prosecution of drug traffickers is critical to the security of our country and cannot be replaced. However, we would welcome the opportunity to work with these government agencies to find a way to supplement traditional efforts with an approach aimed at disrupting the distribution networks and processes of known offenders.

FedEx Corporation does not tolerate any attempted use of our global network or the FedEx brand for illegal purposes and we take immediate steps to stop it when it comes to our attention. If we receive information from law enforcement agencies that a particular customer is violating the law, we will assist in the gathering of evidence for the government, pursuant to legal requirements and other regulations, and we will cease accepting packages from that company. No Internet pharmacies are authorized to use the FedEx logo to promote their service. Let me repeat that, NO INTERNET PHARMACIES ARE AUTHORIZED TO USE THE FEDEX LOGO TO PROMOTE THEIR SERVICE. Unfortunately, there are numerous cases where our brand is used without our consent. To the extent possible, we are taking appropriate legal action to stop such activity.

In closing, I want to emphasize that we believe we have a role to play and that we want to be part of what must be a joint effort to shape a new approach to this problem. We have package tracking technology that can be of significant assistance to law enforcement agencies and we can specifically target suspect packages identified by authorities for inspection. FedEx welcomes the opportunity to continue to work with the Congress, law enforcement, and our private sector colleagues to find ways to disrupt these networks that negatively impact the health and safety of our citizens. However, we do not have law enforcement authority and do not have available the tools that would allow us to solve this problem on our own.

Mr. Chairman, thank you for the opportunity to address the subcommittee. I would be happy to respond to Member's questions.

MR. WHITFIELD. Mr. Silva with UPS is now recognized.

MR. SILVA. Thank you, Chairman Whitfield. Mr. Stupak and members of the subcommittee, my name is Dan Silva, and I'm the corporate security manager for UPS. I have responsibility for security matters worldwide for the company. I'd like to thank you for the opportunity to appear this afternoon to discuss the issue of the sale of controlled substances over the Internet and the efforts of UPS to work with law enforcement to ensure that our system is not used to transport these substances.

It's the clear policy of UPS, as stated in our tariff, that illegal products of any type are prohibited from being transported through our system. We have a long history of working with law enforcement agencies at all levels to enforce legal requirements.

While our company privacy policy prohibits us from disclosing customer information in general, we regularly provide law enforcement agencies with information required by a lawful subpoena. Since 2001,

we have conducted an on-line pharmacy monitoring program. Through our outside counsel we conduct weekly searches of the Internet to identify on-line pharmacies that use the term "UPS." We send cease and desist letters and are prepared to follow up with appropriate legal remedies to on-line pharmacies that offer UPS services and offer to sell pharmaceuticals without a prescription and the display of UPS trademark or logo to avoid any appearance of sponsorship or endorsement. We've shared information about Internet pharmacy sites that we have gathered through our monitoring program with the U.S. Food and Drug Administration and the U.S. Drug Enforcement Administration.

Since much of the concern in this area arises from the imported pharmaceuticals, I'd like to mention efforts we've undertaken with the U.S. Bureau of Customs and Border Protection and the FDA. First of all, UPS identifies to Customs and FDA all packages it delivers into the United States that are declared to be pharmaceuticals. Customs and FDA have the ability to pull any of these packages for further examination and enforcement action.

Additionally, in conjunction with our automated air hub in Louisville, Kentucky, we developed a computer program called Target Search for the use of Customs. This is a sophisticated and flexible tool that enables Customs to search manifest information for all imported packages passing through that facility.

Customs can use this system to help identify illicit shipments by screening for a wide variety of data. On an ongoing basis we respond to subpoenas with information requested in support of ongoing investigations by the DEA and FDA. We've had periodic meetings with the DEA and FDA on the issue of the sale of controlled substances over the Internet. Additionally, we have met periodically with officials of FDA and DEA here in Washington to discuss ways in which we might further our cooperation concerning illegal pharmaceutical shipments. These meetings have been productive, and we'll continue to meet as needed in the future.

As I have already indicated, we have shared information about Internet pharmacies we've identified through our monitoring program with both agencies. I'd like to specifically mention some of the activity we've undertaken in the State of Kentucky. After an increase in Internet pharmaceutical activity was reported in southeastern Kentucky about a year ago, we became more involved with state, Federal and local enforcement in dealing with the problem.

I have traveled to Hazard, Kentucky, in April of this year and met with Operation Unite, the local drug task force, and we agreed on certain actions we could take together. Subsequently the State of Kentucky passed a law to tighten up requirements relating to Internet pharmacies,

including requiring registration of Internet pharmacies. We have met twice with the attorney general's office and the Kentucky Bureau of Investigation to discuss ways in which we can work together to implement the new law.

While the Kentucky law appears to be having a positive effect, we believe this is a problem that calls for a national response. A number of bills have been introduced in both the House and Senate. We support legislation that would establish clear standards for Internet pharmacies. In particular, we support requiring Internet pharmacies to be licensed and to meet a number of common-sense requirements, such as providing the address of the principal place of business, the names of persons serving as pharmacists, and State license information.

In addition, we support provisions that would prohibit Internet sales of pharmaceuticals to individuals without a prescription obtained from a practitioner with a qualifying medical relationship which requires at least one in-person medical evaluation. Such legislation would help ensure that requirements for the safety and efficacy of drugs are met when U.S. consumers make purchases in this new marketplace. From the standpoint of a package delivery company, we would welcome more certainty that the products we are carrying meet the requirements of law and, therefore, meet our own tariff requirements. As a carrier we can take actions such as those I have described in conjunction with law enforcement agencies, but we do not have the independent ability to judge the validity of prescriptions or the legitimacy of a particular drug.

Thank you for the opportunity to share the views of UPS, and I look forward to any questions you hey have.

MR. WHITFIELD. Thank you very much, Mr. Silva.

[The prepared statement of Dan Silva follows:]

PREPARED STATEMENT OF DAN SILVA, CORPORATE SECURITY MANAGER, UPS

Chairman Whitfield, Mr. Stupak and members of the subcommittee, my name is Dan Silva and I am the Corporate Security Manager for UPS. I have responsibility for security matters worldwide for the company. Thank you for the opportunity to appear this afternoon to discuss the issue of the sale of controlled substances over the internet and the efforts of UPS to work with law enforcement to ensure that our system is not used to transport these substances.

It is the clear policy of UPS, as stated in our tariff, that illegal products of any type are prohibited from being transported through our system. We have a long history of working with law enforcement agencies at all levels to enforce legal requirements. While our company privacy policy prohibits us from disclosing customer information in general, we regularly provide law enforcement agencies with information required by a lawful subpoena.

Since 2001 we have conducted an Online Pharmacy Monitoring program. Through our outside counsel, we conduct weekly searches of the internet to identify online pharmacies that use the term “UPS.” We send cease and desist letters and are prepared to

follow-up with appropriate legal remedies to online pharmacies (1) that offer UPS services and offer to sell pharmaceuticals without a prescription, and (2), that display a UPS trademark or logo (to avoid any appearance of sponsorship or endorsement). We have shared information about internet pharmacy sites that we have gathered through our monitoring program with the U.S. Food and Drug Administration ("FDA") and the U.S. Drug Enforcement Administration ("DEA").

Since much of the concern in this area arises from imported pharmaceuticals, I would like to mention efforts we have undertaken with the U.S. Bureau of Customs and Border Protection ("Customs") and FDA. First of all, UPS identifies to Customs and FDA all packages it delivers into the Untied States that are declared to be pharmaceuticals. Customs and FDA have the ability to pull any of these packages for further examination and enforcement action. Additionally, in conjunction with our automated international air hub in Louisville, Kentucky, we developed a computer program called Target Search for the use of Customs. This is a sophisticated and flexible tool that enables Customs to search manifest information for all imported packages passing through that facility. Customs can use this system to help identify illicit shipments by screening for a wide variety of data.

On an ongoing basis, we respond to subpoenas with information requested in support of ongoing investigations by the DEA and FDA. We have had periodic meetings with the DEA and FDA on the issue of the sale of controlled substances over the internet. Additionally, we have met periodically with officials of FDA and DEA here in Washington to discuss ways in which we might further our cooperation concerning illegal pharmaceutical shipments. These meetings have been productive, and we will continue to meet as needed in the future. As I have already indicated, we have shared information about internet pharmacies that we identified through our online pharmacy monitoring program with FDA and DEA.

I would like to specifically mention some of the activities we have undertaken in the state of Kentucky. After an increase in internet pharmaceutical activity was reported in southeastern Kentucky about a year ago, we became more involved with state, federal and local law enforcement in dealing with the problem. I traveled to Hazard, Kentucky in April of this year and met with Operation Unite, the local drug task force, and we agreed on certain actions that we could take together. Subsequently, the state of Kentucky passed a law to tighten up requirements relating to internet pharmacies, including requiring registration of internet pharmacies. We have met twice with the Attorney General's Office and the Kentucky Bureau of Investigations to discuss ways in which we can work together to implement the new law.

While the Kentucky law appears to be having a positive effect, we believe this is a problem that calls for a national response. A number of bills have been introduced in both the House and Senate. We support legislation that would establish clear standards for internet pharmacies. In particular, we support requiring internet pharmacies to be licensed and to meet a number of common sense requirements, such as providing the address of the principal place of business, the names of persons serving as pharmacists, and state license information. In addition, we support provisions that would prohibit internet sales of pharmaceuticals to individuals without a prescription obtained from a practitioner with a qualifying medical relationship, which requires at least one in-person medical evaluation.

Such legislation would help ensure that requirements for the safety and efficacy of drugs are met when U.S. consumers make purchases in this new marketplace. From the standpoint of a package delivery company, we would welcome more certainty that the products we are carrying meet the requirements of law and therefore meet our own tariff requirements. As a carrier, we can take actions such as those I have described in conjunction with law enforcement agencies, but we do not have the independent ability to judge the validity of a prescription or the legitimacy of a particular drug.

Thank you for the opportunity to share the views of UPS and I look forward to any questions that you may have.

MR. WHITFIELD. At this time I recognize Mr. McLaughlin with Google.

MR. MCLAUGHLIN. Thank you very much, Mr. Chairman and Mr. Stupak.

Let me make one big point, then I'll make three small points. The big point is this: We get what a serious problem this is. Google is an Internet company. We see what is going on. It is evident to us as much as anybody that there is a serious problem with illegal sales of on-line drugs over the Internet.

We have been trying to think through for a couple of years, in dialog with the staff of this subcommittee and with Senate PSI and so forth, what's the right approach for a company that deals in information. We have been trying to think through what's the right balance here. Information can be used for good; it can be used for ill. We don't want to be too restrictive, we don't want to be too permissive, so we're trying to strike a balance that puts restrictions on our advertising system and focuses on getting good information in front of consumers and users through our search engine and through the free ads that we provide.

So let me refer specifically to the three things that we're doing, and I'll say as I go through these we're looking for better ideas, too. We're looking for things that we can do that would be smarter, but consistent with that balance.

So the first thing I want to mention is that on our advertising system, where Google makes most of its money, we've implemented a third-party verification system which focuses on licensing. If some entity wants to advertise on Google using pharmaceutical terms, scheduled substances, the brand names that go along with them, or any of the numerous creative misspellings or terms that look like drug names, they have to be a licensed pharmacy. And so we have partnered with a company called SquareTrade, which is a verification company, and their job is to go and verify that the company that wants to advertise on Google has a license in the jurisdiction where it's located.

To date, since we've launched this program, we've rejected more than 30,000 ads. We have somewhere in the neighborhood of about 250 advertisers that have qualified by demonstrating their licensing status today, and from what we can tell, the system seems to be working pretty well. Again, we are interested in feedback, trying to figure out ways to make it work better, but for our advertising system our focus is squarely on making sure an advertiser that wants to show ads in the U.S. is licensed in the state in the U.S. where it's operating.

Point two, as I said, we try to also provide good information, and so in that spirit we have been providing free advertising to any Government agency that wants to run a public service campaign on these issues. We are pleased the CBP and the DEA have taken up that offer and running ads targeted at various substances. In my testimony I have given an example. It's an open offer. We hope more agencies will take advantage of it in the future, and we've also offered up the assistance of our teams of advertising experts to help them figure out how to target the ads, how to write them better, how to get more users to see them in a way that's relevant and direct given those searches.

The third thing, we have been actively cooperating and collaborating with the Interagency Federal Task Force that you have heard about. There's an effort organized through Harvard University that includes academics, some government officials, prosecutors, companies like Google trying to create a meaningful partnership.

As I said, our goal here is to help an American with a legitimate prescription to find a licensed pharmacy. That's a useful service that Google can provide.

In some ways the easy road would be just to block all pharmaceutical-related advertising, and that's something we thought about, but then you have removed a source of legitimate connections between people with prescriptions and the pharmacies that are properly licensed to fill them. So we'd like to continue doing that. It seems like the more responsible thing to do for our users.

At the same time, we don't want to block information from detox centers, from treatment facilities, from medical authorities that can provide legitimate information, so we're not a big fan of doing across-the-board blocking of specific terms. Some of those terms can be used, as I said, for bad; they can be used for good. We're trying to strike the right balance.

Finally, we have been thinking about legislation. I don't have any brilliant ideas to recommend to you about what legislatively can fix this problem in our area. It does seem like it's a huge enforcement problem. In that spirit I think there are some promising avenues where we can contribute to enforcement efforts that are going on.

One of the earlier witnesses from IntegriCheck, if I have said that right, mentioned a couple of these promising avenues. There are ways that you can use the Internet to identify these websites and go after them more quickly. I know they are trying hard, but it could be done in a more speedy and effective way with more sophistication about how the Internet works and how you track people down in a forensic way.

Google is an index to the Web. It can help law enforcement. We would like to do more of that. As I said, we're looking for better ideas all

the time, and with your help and the help of the members of this subcommittee and staff, I hope we'll able to do that. Thank you very much, Mr. Chairman.

MR. WHITFIELD. Thank you very much for that testimony.

[The prepared statement of Andrew McLaughlin follows:]

PREPARED STATEMENT OF ANDREW MCLAUGHLIN, SENIOR POLICY COUNSEL, GOOGLE INC.

The Internet enables consumers to make better health care decisions, giving consumers on-demand access to a vast realm of useful information about medical and pharmaceutical products and services. At the same time, the Internet is a means by which would-be customers can find, purchase and obtain controlled substances from rogue, unlicensed, online drug-merchants. Today's hearing highlights the need for strong, sustained, and coordinated action to disrupt illegal online sales of controlled substances. Google stands ready to do its part.

In the following testimony, I detail two of the voluntary steps that Google has taken to ensure that our online advertising services protect our users by providing access to safe and reliable information.

First, Google has implemented a rigorous third-party review and verification process that allows only licensed pharmacies and pharmacists to display advertisements in the United States.

Second, Google is actively assisting those agencies of the federal government that are leading the fight against illegal drug sales. The Google Grants program provides free advertising to U.S. government agencies, allowing them to run public information campaigns that utilize Google's sophisticated targeting techniques to reach Internet users right as they perform relevant online searches. In addition, Google has been actively contributing to several interdisciplinary efforts, including the federal inter-agency working group, to improve coordination and develop effective strategies against dangerous, rogue online drug-merchants.

We appreciate the hard work of the Subcommittee to explore and understand the entire system surrounding illegal online drug sales, and to pinpoint the potential points of interdiction. We look forward to working with you and your staff as you continue to explore these important issues.

Google's Advertising Products

Google's mission is to organize the world's information and make it universally accessible and useful. In 2000, Google added advertising to complement our growing search services business and to provide another method for users to find pertinent and useful information easily on the Internet. In doing so, Google put to the test our belief that highly relevant advertising can be as useful as our search results. Our advertising has the same aim as our search results: give users information they will find useful.

Google first built an advertising system to accompany our search engine. When a user searches on a keyword, advertisers may bid to be placed next to the search results for that keyword. For example, when typing the word 'flowers' into the search box, relevant search results will appear accompanied by relevant advertisements about flowers displayed along the right-hand side. Google then extended the search advertising platform to provide highly-relevant ads for any website with content. Here's how it works: Google's system analyzes the content of a partner's web page to determine which advertisements would likely be relevant to the content; based on that analysis, the Google system selects relevant ads to appear on the page. The result is that advertisers can match

their advertising to broader content concepts, allowing their ads to reach a wider audience through many different channels beyond the various Google websites.

We offer our advertising technologies to advertisers through our AdWords™ service, and to publishers of websites through our AdSense™ service.

Google AdWords™

Launched in autumn 2000, Google AdWords allows any potential advertiser — from a neighborhood drycleaner in Louisville to a Big Three automaker in Detroit — to easily create text- or image-based ads and to display them online in a targeted manner. AdWords is principally a self-managed program, meaning that most advertisers create and control their advertisements through an online interface.

Google's advertising ranking algorithm aims to target ads according to relevance, so that we show only ads that our users will find useful. The AdWords system monitors in real time how well each ad is performing in order to calculate the relevance of a given ad or keyword to the user. An ad's performance is measured largely in terms of its clickthrough rate, a measure of how often the people who view the ad click on it. The most relevant, and therefore the most useful, ads are displayed more prominently and more frequently; conversely, ads and keywords with consistently low clickthrough rates may not be shown. Our focus on relevance means that an advertiser cannot secure top ad placement in the AdWords program simply by paying more—rather, advertisers have every incentive to make their ads as relevant to users as possible.

Google AdSense™

In 2003, we expanded the reach of AdWords through a new service called Google AdSense. AdSense is a program that permits website publishers to deliver relevant ads generated by Google on their own sites, and thereby to earn money every time a user clicks on one of those ads. AdSense gives web publishers of any size —from an individual weblogger or hobbyist to a global news site—a powerful new means to generate revenue and to enhance the user experience on their sites. AdSense essentially allows anyone who publishes through a website to become part of the Google Network, to include relevant, targeted, unobtrusive Google ads on their webpages, and to earn shared revenues when readers click on them. Like AdWords, AdSense is largely a self-managed program, allowing even the smallest of web publishers to participate.

Google Standards and Policies for AdWords and AdSense

The AdSense and AdWords services employ numerous automated and manual checks, program policies, and enforcement mechanisms to provide our users, publisher partners, and advertisers with advertising services that are high-quality and relevant.

Google recognizes that the success of any of our products ultimately depends on quality. We have therefore implemented rigorous quality standards for all our ads, and have developed a range of tools to help our users and publishing partners identify the advertising content that's right for them. For example, most Google ads on AdSense partner websites display an "Ads by Google" label, which links to a feedback form. Through this form or by an email to customer support, users are invited to report poorly targeted ads or ads they may find objectionable.

From the launch of our advertising services, in keeping with our company values and mission, Google has had policies restricting the types and content of advertising we accept. The policies and Terms and Conditions for AdWords and AdSense are posted online, addressing editorial, content, and usability issues.[1] Advertisers, their

[1] AdWords Terms and Conditions are available at <https://adwords.google.com/select/tsandcsfinder> . AdWords Editorial Guidelines are available at <https://adwords.google.com/select/guidelines.html>. AdSense Terms and

advertisements and the websites to which they point must adhere to these standards as a condition of joining and continuing to participate in either program.

Some of these policies prohibit specific forms of online advertising. For example, we have never supplied pop-up advertising, nor do we permit pop-up windows to be launched from clicking on the link in the ads. Other policies relate to the nature of what is being advertised. For example, we do not allow the advertising of tobacco or tobacco products, regardless of its legality in the different jurisdictions in which we serve advertising.

Enforcement of Google's Standards and Policies

The AdWords system begins performing automated policy checks as soon as an advertiser submits an ad. Ads entered through our online system are subject to real-time automatic screening for potentially sensitive or objectionable terms, as defined in our policies. If the ad and its list of associated keywords pass this automated screening process, it will be displayed initially on the Google website. If not, the ad is flagged for further review by the Google AdWords team, and will not appear anywhere until it has been reviewed and approved.

All ads and keywords must eventually pass review to ensure that they meet Google's advertising standards. Only ads that have passed review are permitted to run in the Google Network, which includes not only Google's own website, but also the sites and products of our AdSense partners.

Google's Online Pharmacy and Pharmacist Policy

Internet users want information about pharmaceuticals. At Google, we recognize that providing relevant information from trusted sources can be critically important. Over the past few years, we have received numerous emails from individuals who have found life-saving information through Google's search and advertising results. We handle many queries every day from users looking for information about pharmaceuticals — how they work, what they do, where to fill prescriptions for them, and so on. Google's role is to make relevant information available, whether for a homebound patient searching for access to prescribed medication or for a doctor looking for diagnosis and treatment indications beyond what can be found on her shelves. In addition to our search results, relevant and trustworthy advertising has a role to play helping all of these users.

Google believes that our users benefit from advertising by licensed pharmacies and pharmacists, addiction treatment and detoxification centers, pharmaceutical manufacturers, and other organizations with involvement or interest in pharmaceuticals. Advertising by licensed pharmacies and pharmacists helps consumers locate services, compare among options, and make cost-effective choices when tending to their health. For all these reasons, Google is committed to providing its users with information about pharmaceuticals, pharmacies, and pharmacists.

Of course, pharmaceutical advertising carries risks along with its benefits. We recognize that there are bad actors on the Internet, including unlicensed online pharmacies that peddle unsafe and counterfeit products. Consequently, we have implemented policies that will protect our users from encountering potentially dangerous rogue drug-merchants through our advertising services.

Google's Approach: Third-Party Verification

As the online pharmaceuticals market has become more complex, Google has taken proactive steps to ensure that information going from our advertisers to our users and

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Conditions are available at <https://www.google.com/adsense/localized-terms>. AdSense Program Policies are available at <https://www.google.com/adsense/policies>.

partners is as relevant, useful, and trustworthy as possible. In the context of pharmacies and pharmacists, Google has voluntarily implemented a third-party verification process.

In order for an online pharmacy to advertise with Google, it must establish, to the satisfaction of our trusted third-party verification service, that both the pharmacy and its pharmacist are properly licensed; that the Internet website associated with the ad is owned by the licensed pharmacy; that it will not dispense prescription drugs without receiving and verifying a lawful and valid prescription from a personal practitioner; and that it will perform age verification for all prescriptions, among other requirements.

In practical terms, this means that online pharmacy advertisers must be members in good standing of the SquareTrade Licensed Pharmacy Program and must meet all other conditions of the Google AdWords Online Pharmacy Qualification Process.

One practical consequence of these requirements is that Google policy does not permit pharmaceutical-related advertising from outside the United States and Canada.

SquareTrade Licensed Pharmacy Program

SquareTrade is a leading online trust infrastructure company. Its Licensed Pharmacy Program has been reviewed and approved by the National Community Pharmacists Association (NCPA).[2]

SquareTrade verifies that the online pharmacy and its pharmacist are licensed by an appropriate governmental entity, and requires that members commit to industry- and NCPA-approved practices, which include compliance with all laws and regulations in the jurisdiction where the pharmacy is located as well as the jurisdiction where the buyer is located. SquareTrade regularly monitors the licensure status of member pharmacies and their pharmacists and will investigate disputes or complaints against a member pharmacy. If a change in SquareTrade member status occurs, SquareTrade notifies Google so that we may take appropriate action.

SquareTrade has a multi-step verification process to confirm that the online pharmacy is appropriately licensed. To begin with, the licensing information of both the pharmacy and the pharmacist is verified with the state or federal licensing body, a process which is repeated every three months. After this has been completed, the pharmacy is called at its number on record to confirm employment of the pharmacist, who must then go through an identity verification process, either by providing his/her Social Security Number and going through a credit header check or by providing copies of two government issued pieces of identification. As a final check, the ownership of the website by the pharmacy is confirmed, and, if the online pharmacy meets all required criteria, two physical letters are sent to the pharmacy, one addressed to the pharmacist and one addressed to the Head of Finance of the pharmacy, confirming the application and their obligations.

The SquareTrade Licensed Pharmacy Program requires its pharmacies to adhere to a stringent set of conditions that are designed to protect consumers against dangerous online practices. SquareTrade-certified pharmacies must agree to full compliance with all applicable laws, rules, regulations, and accepted industry standards of ethical business conduct. The SquareTrade program is only open to online pharmacies based in the U.S. or Canada.[3] A SquareTrade-certified pharmacy must also, at all times, employ a licensed

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[2] More information about SquareTrade is available at <http://www.squaretrade.com>.

[3] While licensed Canadian pharmacies are permitted to obtain SquareTrade certification, they are also required to agree that they will not target US consumers, whether by providing shipping rates and information, by comparing the efficacy of Canadian drugs to FDA-approved drugs, or by any other means that would lead a US consumer to believe that s/he can purchase pharmaceutical drugs from Company's website. Canadian pharmacies must also put a disclaimer on the home page of their website that states: "The FDA, due to the current state of their regulations, has taken the position that virtually all shipments of

pharmacist in charge of its pharmacy and only permit licensed pharmacists to dispense prescription drugs. A certified pharmacy is required to notify SquareTrade immediately if one of its pharmacists becomes the subject of adverse government or other regulatory action relating to its licensure or the dispensing of prescription or controlled substances.

SquareTrade-certified pharmacies must agree to a series of requirements relating to the dispensing of prescription drugs. For example, they cannot provide prescription drugs without receiving and verifying a lawful and valid prescription from the customer's personal healthcare practitioner, and further, must ensure that the prescription was not obtained via an online or telephone consultation only. SquareTrade-certified pharmacies are required not to dispense any controlled substance in violation of state or federal law or without verifying the prescriber's current DEA number and conducting age verification. Finally, to qualify for SquareTrade certification, a pharmacy must agree that deliveries of prescription drugs will be made only through U.S. mail or a delivery service that requires the signature of an adult for package delivery.

SquareTrade issues a patented electronic seal to licensed pharmacies. This electronic seal has the licensure information of the pharmacy embedded into it, ensuring that consumers have transparency and visibility into why the pharmacy is legitimate. If a user clicks on the online pharmacy's SquareTrade seal, the user is able to review the SquareTrade Seal Member Profile, allowing them to confirm the pharmacy's participation in and commitment to the program.

Together, these requirements mean that U.S. consumers will not be confronted with unlicensed, rogue pharmacies or pharmacists through Google advertising services.

The Benefits of the Google / SquareTrade Partnership

Google makes every effort to provide an advertising service that is effective for advertisers and useful to our users. Our emphasis on technological innovation and ad relevance helps us reach the goal of effectiveness. Reaching our second goal, usefulness, depends in part on our ability to verify that our pharmaceutical advertisers are licensed and trustworthy and remain so throughout the course of their relationship with Google. This is SquareTrade's area of expertise.

SquareTrade provides the resources and experience needed to implement Google's pharmacy-related advertising policies on a consistent and sustainable basis without compromising our ability to focus on our search technology and advertising programs. Our partnership with SquareTrade allows each company to focus on what each does best. As a result, we permit only licensed pharmacies to advertise through Google, allowing us to say with confidence that we are providing a means by which individuals in need of education, rehabilitation, or medical care can find the information they seek and can trust that it comes from a reputable source.

The Google Online Pharmacy Qualification Process

It may be helpful to explain in some detail how Google has integrated the SquareTrade Licensed Pharmacy Program into our advertising systems.

Most importantly, to have its ads appear in the United States or its territories an online pharmacy must provide Google with a valid SquareTrade I.D., certifying its licensing status and agreement to operate in a legal and responsible manner. In addition to the requirements of the SquareTrade Licensed Pharmacy Program, Google's own advertising policies impose further requirements on online pharmacy advertisers. For example, websites advertising prescription drugs or using prescription drug names as keywords must clearly state the prescription requirement. And Google prohibits the advertisement of certain non-FDA-approved drugs.

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prescription drugs imported from a Canadian pharmacy by a U.S. consumer will violate the law."

We monitor all AdWords ads and keyword lists including drug-related terms. Ads that contain certain restricted drug-related terms will not appear to users until they have been reviewed by a Google client service representative. After reviewing the ad, the client service representative will either approve or reject the ad, according to Google's policies for online pharmacy advertisers.

Moreover, Google's policy is to reject ads or sites promoting controlled substances or any items that are primarily intended or designed for use in manufacturing, concealing, or using a controlled substance. References to certain Schedule I and II substances are closely monitored. Drug-related keywords may be approved if they are for ads and websites marketing addiction treatment and rehabilitation services, provided that illegal drugs aren't being marketed as a means of treatment.

The list of drugs and drug-related terms is updated regularly based on publicly available information found in a number of sources, including the news and drug names and schedules detailed within the Diversion Control Program web pages of the Drug Enforcement Administration website.[4]

The Evolution of Google's Online Pharmacy Advertising Policy

Google has monitored and enforced policies on all drug-related ads and keyword lists since the AdWords service was first launched. In mid-2003, Google began requiring online pharmacies to clearly state on their websites that a prescription from a licensed physician was required to obtain prescription pharmaceuticals. A team of Google representatives has since been dedicated to enforcing all aspects of Google's online pharmacy policies. Toward the end of 2003, in response to user feedback and our commitment to improving advertising quality, we began developing a new policy requiring pharmacy-related AdWords advertising to pass even more rigorous quality checks. As part of that process, we evaluated several companies that could provide third-party verification services to help us ensure policy compliance. During this time Google also talked with staff at the Federal Drug Administration about our intended policy changes and received strongly positive feedback, especially on our plan to implement third-party verification. Based on a number of factors, including specific experience and ability to scale, Google selected, in January 2004, SquareTrade L.L.C. as the trusted third-party vendor for verifying online pharmaceutical advertisers.

Google also built an automated system that identifies pharmaceutical-related advertisers before they even create their first ad. When the system identifies a prospective advertiser as an online pharmacy attempting to run ads in the United States or its territories, the AdWords interface immediately presents the advertiser with several options, including the option to submit a valid SquareTrade I.D. Without a valid SquareTrade I.D., the advertiser is able to set up an account, but will not be able to run an ad until the advertiser submits a valid SquareTrade I.D., or a client service representative reviews the account and determines that a SquareTrade I.D. is not needed. For example, informational medical sites, addiction treatment and detoxification facilities, and drug rehabilitation support groups may advertise and are not required to obtain a SquareTrade I.D.

The Impact of Google's Online Pharmacy Advertising Policy

Today, Google has approximately 250 SquareTrade-certified advertisers, ranging from large to small enterprises. Since launching our third-party verification program for online pharmaceutical advertisers, Google has rejected more than 30,000 pharmaceutical-related advertisements.

We believe that the SquareTrade program has been very successful in many ways. Rather than simply rejecting all drug-related advertising, our partnership with Square

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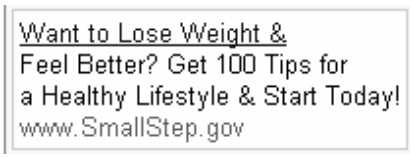
[4] Available at <http://www.deadiversion.usdoj.gov>.

Trade has enabled Google to connect users with licensed pharmacies and trustworthy information. The number of advertisements being rejected because of failure to comply with SquareTrade requirements shows that the program has teeth. We have rejected on average over 1500 advertisements per month since the start of the program – driving legitimate advertisers to get certified by proving their licensure if they want to advertise through Google. Of course, we are continually evaluating our efforts, and intend to improve our use of SquareTrade over time.

Google Grants: Free Advertising for Public Information Campaigns

To help educate users about the dangers of rogue, unlicensed drug-merchants, Google is utilizing its Google Grants program to provide free advertising to government agencies that wish to run public education campaigns. Google Grants is a unique in-kind advertising program that supports organizations that share our philosophy of community service in areas such as science and technology, education, global public health, the environment, youth advocacy, and the arts. Google Grants has awarded AdWords advertising to hundreds of non-profit groups whose missions range from animal welfare to literacy, from supporting homeless children to promoting HIV education.

Though designed for 501(c)(3) non-profit organizations, Google has made Google Grants available to selected government agencies that are seeking to inform and engage their constituents online. For example, the federal Department of Health and Human Services is currently running, in cooperation with the Advertising Council, the following public service education ad:



This ad is triggered by search queries such as “diet help”, “fast weight loss tips”, and “foods that help you lose weight”. It is a good example of the kind of public education campaign that Google Grants supports.

In the area of controlled substances, the Drug Enforcement Agency is currently running several targeted “Online Drug Alert” ads, such as:

This ad, and others like it, is triggered by a long list of keywords such as “buy online prescriptions”, “internet drugs”, “no prescription needed”, “cheap oxycontin”, and “buy vicodin”. As a result, Google users conducting searches on those kinds of keywords will be presented with the ad above. Though Google Grants advertising is free, the DEA maintains full control over its online advertising campaign (subject to Google’s usual guidelines and policies), giving it the ability to change the ad text and adjust the list of keywords. The ability to constantly update the ad campaign allows the DEA to experiment with various ad and keyword combinations, measure the results, learn from experience, and make changes, thereby maximizing the overall impact. Google has likewise offered the expertise of its creative ad experts to help the DEA calibrate and target its campaigns to greatest effect.

Assistance to Federal and Private-Sector Initiatives to Coordinate Policy, Strategy and Enforcement

In addition to Google Grants, Google has been contributing actively to various initiatives to coordinate policy, strategy, and enforcement. For example, we have participated in meetings of the federal inter-agency task force on this issue, which includes a presence from the Drug Enforcement Agency, Department of Justice, Federal Bureau of Investigation, Food and Drug Administration, Federal Trade Commission, U.S. Postal Service, and U.S. Customs and Border Protection, along with various other private-sector entities in the Internet community. We have worked cooperatively to help those agencies understand the Internet environment and more effectively address the problem of illegal online drug sales.

We also actively participate in a task force coordinated through Harvard University that has been examining the issues around illegal online pharmaceutical sales. This task force is attended by prominent criminal and Internet law professors, government prosecutors, medical doctors, federal agency representatives, federal law enforcement officials, non-profit drug education executives, and a variety of business and legal representatives from the Internet and payment processing industries. This task force is aimed at the creation of a public/private/academic partnership to think through and craft possible solutions to the problem of illegally available drugs on the Internet.

Other Approaches: Thoughts on Filtering Search Results

Google believes that promoting trustworthy advertising, providing a voice for government agencies, and offering expertise and assistance to law enforcement are the most effective and appropriate tools we have to contribute to this problem. Some have asked why search engines do not simply prohibit searches based on certain drug-related search terms, or block suspect sites from our search index. Such an approach may at first glance have some appeal, but we think it would be a serious mistake. We are deeply committed to providing objective search results and we only interfere with the neutrality of our search index in very rare instances. More importantly, Google does not believe that tampering with searches or search results would be an effective approach:

- Screening search results is impractical and inappropriate – Google indexes a tremendously large number of web pages and other online content, and we serve up responses to a vast number of search queries in the U.S. every day. It is simply not practical for our employees manually to review all the web pages in our index for all drug-related terms, and then to filter out potentially unlawful from apparently lawful sites – nor should Google be making those judgments, as we are not a law enforcement agency. Likewise, automatically banning certain search queries – like all searches for "oxycontin" - would be overbroad and prevent users from getting valuable information about addiction, treatment, and lawful prescription.

- Filtering search results is not effective - Search engines are a mere reflection of the Internet. In a sense, search engines are to the World Wide Web what the table of contents and index are to a book. Removing search results from the Google search index does nothing to remove the offensive sites from the web itself. Even worse, it would eliminate an important tool for law enforcement and other investigators in identifying potential illegal activity. Law enforcement officials have told us that they use Google daily to find and identify the websites of unlicensed, rogue drug-merchants. Moreover, blocking specific URLs tends to be ineffective against sophisticated sites that simply change domain names frequently to evade blocking. Experience has shown

that users seeking to find illegal activity online are quite able to do so despite filtering at the search level, if the illegal sites are allowed to remain active.

For these reasons, we will continue to focus our energies on the efforts that we believe are likely to be most helpful to users and most effective in combating illegal drug sales online.

Conclusion

Google believes that the Internet is a valuable resource that can provide individuals with crucial information needed to make informed health care decisions. At the same time, we recognize that it can facilitate the sale and delivery of dangerous substances from rogue, unlicensed drug-merchants. We are proud to have taken a leadership role in improving the quality and safety of online prescription drug advertising. In particular:

1. Though the SquareTrade license-verification program, Google works to protect our users. We make sure that the only pharmaceutical-related ads we display in the United States are from properly licensed pharmacies that are legally authorized to fill prescriptions in the United States.

2. Through the Google Grants program, Google offers free advertising to government agencies that wish to run public education campaigns And we have dedicated significant employee time and energy to assisting the federal inter-agency task force and other policy coordination and strategy initiatives, and will continue to do so for as long as they exist.

Thank you for the opportunity to share our views on the important issues addressed by this hearing. We appreciate the Subcommittee's attention to these issues and hope that this testimony has been helpful.

MR. WHITFIELD. Mr. Scheibel, you're recognized for five minutes. Mr. Scheibel is with Yahoo!.

MR. SCHEIBEL. Chairman Whitfield, Ranking Member Stupak and members of the subcommittee, thank you for the opportunity to testify on the actions Yahoo! has taken to address the serious issues presented by prescription drug sales over the Internet. We share Congress's interest in protecting consumers from the potential dangers of illegal prescription drug sales. For that reason Yahoo! has taken a leadership position in the industry. In November of 2003, we took groundbreaking action to better ensure our sponsored search listings of on-line pharmacies meets high standards of integrity and accountability.

MR. WHITFIELD. Mr. Scheibel, excuse me, do you have your microphone on?

MR. SCHEIBEL. I'm sorry, Mr. Chairman. I was saying how we took groundbreaking action in 2003 to better deal with the issue of sponsored search and the availability of prescription drugs over sponsored search. And sponsored search is a program under which advertisers bid on search terms relative to their businesses, and those with the highest bid gets the best placement in our sponsored search results.

In November 2003, we took the unprecedented action of removing all sponsored search pharmacy listings for prescription drugs as an interim step to develop a more comprehensive program that would maintain our commitment to providing consumers, advertisers, and partners with the best on-line experience possible. Our message was clear: until we could create a safer environment for such on-line advertising, there would be no sponsored search listings for prescription drugs on Yahoo!.

Beginning in February of 2004, we launched our more comprehensive program, which was the first of its kind. Our goal is to enable a more trusted marketplace for legitimate on-line pharmacies to competitively offer consumers access to prescription drugs.

Yahoo!'s on-line pharmacy qualification program employs a five-facet approach to enhance consumer trust of participating on-line pharmacies. First, we determine whether an advertiser is participating in the sale of prescription drugs. If it is, Yahoo! requires the advertiser to participate in the qualification program in order to advertise in sponsored search.

Second, the advertiser is directed to SquareTrade, a leading on-line trust infrastructure company which verifies whether the appropriate governmental body where the company is located has licensed both the pharmacy itself and its associated pharmacist. Unless SquareTrade determines that the advertiser and its associated pharmacist are currently licensed, Yahoo! will not allow the pharmacy to advertise.

Third, the advertiser is required to certify that it engages in a set of industry best practices that have been approved by the National Community Pharmacists Association, including certification that it is acting lawfully in the jurisdiction where it is located as well as each jurisdiction in which it sells, that it is operating consistent with the terms of its license, and it will not provide prescription drugs without verifying the existence of a valid prescription from the person's personal health care practitioner, and such prescription was not obtained solely by means of an on-line or telephone prescription.

Fourth, SquareTrade, in a program administered in conjunction with NCPA, regularly monitors the licensure status of participating pharmacies and additionally responds to any complaints it receives regarding these pharmacies. Any negative action taken by the licensing entity or any complaints substantiated by SquareTrade are reported to Yahoo!, and the advertiser will be removed as appropriate. Complaints will be forwarded by SquareTrade to the appropriate government licensing authority.

Finally, Yahoo! prohibits on-line pharmacies from advertising the most dangerous and abused prescription drugs, Schedule II controlled substances, in the Yahoo! marketplace. To do this, we prohibit

pharmacies from bidding on keyword terms associated with Schedule II drugs. We only allow rehabilitation clinics to advertise in connection with such terms. We are currently enabling the DEA to run public service announcements free of charge in connection with search terms related to Schedule II controlled substances.

Prior to finalizing the terms of our program, we briefed officials of the Food and Drug Administration. They warmly received our program and were very encouraged by the fact that we were taking a leadership role in this area. Based on our experience, we believe it has made a positive change in the quality of advertisers. We knew going in only a small percentage of on-line advertisers of prescription drugs would go through the process we have imposed. We estimate that in October of 2003, prior to implementation of the program, we had several thousand advertisers of prescription drugs on sponsored search. Of these, only approximately five percent are participating in the program and therefore eligible to advertise through sponsored search. Each is a licensed pharmacy.

Approximately 10 percent of the approved pharmacies have been disqualified as part of the ongoing review process. Of those, nearly one in three has been later reinstated.

Mr. Chairman and members of the subcommittee, we at Yahoo! are proud of the steps we have taken to create a safer environment for on-line advertising of prescription drugs. We are constantly looking for ways to improve our services to Internet users, and this area is no exception. This program is only 18 months old, and we are interested in your feedback in how we may improve the program.

We recognize, however, that even the most robust program will not preclude consumers from finding on-line sites that illegally sell prescription drugs. The program I have just described applies to sponsored search in which advertisers bid on search terms. As a search engine, however, Yahoo! acts as a card catalog of what is on the Internet. Yahoo! now has approximately 20 billion different objects in its search index, including Internet Web pages, images, and audio files. In Web search we facilitate user access to the vast array of information that is available across the Internet. Web search produces rules that reflect the most relevant results in response to a request typed in by a user.

A single search term can produce a broad spectrum of results. Typing in the name of a prescription drug can produce results that vary from where to buy such a drug, to information about the harmful effects of such a drug, to antidote, to treatment centers of the drug. It may provide for more choices for consumers that may enable them to produce prescription drugs in a legal manner at a lower manner.

We have taken additional steps to curb illegal sales of prescription drugs on line. We have participated in the joint industry-government dialog on this issue. We have also had one-on-one meetings with FDA and DEA. To support law enforcement efforts we held a training event with DEA in October of 2005. At this training event DEA shared information regarding law enforcement concerns with on-line pharmaceutical sales and Yahoo! provided training to the DEA on what information is available from on-line providers to assist in law enforcement investigations.

Finally, Yahoo! has provided funding to allow DEA to place public service announcements. Recently a search for Vicodin brought up a sponsored search result for DEA stating ordering prescription drugs on line may be illegal. Yahoo! has also included links to FDA safety materials regarding on-line drugs and Yahoo! health.

Yahoo! is committed so supporting the work of the government, the law enforcement community in their efforts to enforce the laws that regulate the distribution of these substances. We look forward to continuing to improve our programs to better address this important issue. Thank you so much for this opportunity to appear before you.

MR. WHITFIELD. Thank you, Mr. Scheibel, very much.

[The prepared statement of John Scheibel follows:]

PREPARED STATEMENT OF JOHN SCHEIBEL, VICE PRESIDENT, PUBLIC POLICY, YAHOO! INC.

Chairman Whitfield, Ranking Member Stupak, and Members of the Subcommittee, thank you for the opportunity to testify on the actions Yahoo! has taken to address the serious issues presented by prescription drug sales over the Internet. I am John Scheibel, Vice President of Public Policy for Yahoo!

Yahoo! is a leading provider of comprehensive online products and services to consumers and businesses worldwide. Yahoo! is the Number 1 Internet brand globally and the most trafficked Internet destination worldwide. Yahoo! offers a broad and deep array of communications, commerce and content services.

We share Congress' interest in protecting consumers from the potential dangers of illegal prescription drug sales. For that reason, Yahoo! has taken a leadership position in the industry. First in 2002, Overture, which later became a wholly-owned subsidiary of Yahoo!, instituted a policy prohibiting online pharmacies from advertising that prescription drugs could be purchased without a prescription. Then, in November of 2003, we took ground breaking action to better ensure that our sponsored search listings of online pharmacies meet high standards of integrity and accountability. Sponsored search is a program under which advertisers bid on search terms relevant to their businesses and those with the highest bids get the best placement in our sponsored search results.

In November of 2003, Yahoo! took the unprecedented action of removing all sponsored search pharmacy listings for prescription drugs as an interim step to develop a more comprehensive program that would maintain our commitment to providing consumers, advertisers and partners with the best online experience possible. Our message was clear: until we could create a safer environment for such online advertising, there would be no sponsored search listings for prescription drugs on Yahoo!

Beginning in February of 2004, we launched our more comprehensive program, which was the first of its kind. Our goal is to enable a more trusted marketplace for legitimate online pharmacies to competitively offer consumers access to prescription drugs. Yahoo!'s Online Pharmacy Qualification Program employs a five-facet approach to enhance consumer trust in participating online pharmacies.

First, we determine whether an advertiser is participating in the sale of prescription drugs. If it is, Yahoo! requires the advertiser to participate in the Qualification program in order to participate in sponsored search.

Second, the advertiser is directed to SquareTrade, a leading online trust infrastructure company, which verifies whether the appropriate governmental body where the company is located has licensed both the pharmacy itself and its associated pharmacist. Unless SquareTrade determines that the advertiser and its associated pharmacist are currently licensed, Yahoo! will not allow the pharmacy to advertise.

Third, the advertiser is required to certify that it engages in a set of industry best practices that have been approved by the National Community Pharmacists Association (NCPA), including certification that the pharmacy is acting lawfully in the jurisdiction where it is located as well as each jurisdiction in which it sells, that it is operating consistent with the terms of its license, and that it will not provide prescription drugs without verifying the existence of a valid prescription from the person's personal health care practitioner and such prescription was not obtained solely by means of an online or telephone consultation.

Fourth, SquareTrade, in a program administered in conjunction with the NCPA, regularly monitors the licensure status of participating pharmacies and additionally responds to any complaints it receives regarding these pharmacies. Any negative action taken by the licensing entity or any complaints that are substantiated by SquareTrade are reported to Yahoo! and the advertiser will be removed as appropriate. Complaints will also be forwarded by SquareTrade to the appropriate government licensing authority.

Finally, Yahoo! prohibits online pharmacies from advertising the most dangerous and abused prescription drugs--- Schedule II controlled substances—in the Yahoo! marketplace. To do this, we prohibit pharmacies from bidding on keyword terms associated with Schedule II drugs. We only allow rehabilitation clinics or other similar sites to advertise in connection with such search terms. We are currently enabling the DEA to run public service announcements free of charge in connection with search terms related to Schedule II controlled substances.

Yahoo! believes that this five-pronged Online Pharmacy Qualification Program complements our mission of bringing consistency to the interests of consumers, advertisers, and Internet destination sites. Other Yahoo! programs such as banner ads and Yahoo! store are in alignment and at the very least, Yahoo! will not accept advertising dollars unless an online pharmacy is participating in Yahoo!'s Online Pharmacy Qualification Program.

Prior to finalizing the terms of our program, we briefed officials at the Food and Drug Administration on its terms. They warmly received our program and were very encouraged by the fact that we were taking a leadership role in this area.

Based on our experience with our Program, we believe it has made a positive change in the quality of advertisers in the Sponsored Search area. We knew going in that only a small percentage of online advertisers of prescription drugs would go through the process we have imposed. We estimate that in October 2003, prior to implementation of the program, we had several thousand advertisers of prescription drugs on sponsored search. Of these, only approximately 5% are participating in the program and are therefore eligible to advertise through sponsored search. Each one of these advertisers is a licensed pharmacy. Approximately 10% of the approved pharmacies have been disqualified as part of the ongoing review process. Of those, nearly one in three were later reinstated.

Mr. Chairman, and Members of the Subcommittee, we at Yahoo! are proud of the steps that we have taken to create a safer environment for the online advertising of prescription drugs. We are constantly looking for ways to improve our service to Internet users, and this area is no exception. This program is only 18 months old and we are interested in your feedback on how we may improve the program. We always reserve the right to get better.

We recognize, however, that even the most robust program will not preclude consumers from finding online sites that illegally sell prescription drugs. The program I have just described applies to sponsored search, the program in which advertisers bid on search terms and those with the highest bids, get the best placement in our sponsored search results.

As a search engine, however, Yahoo! acts as a card catalogue of what is on the Internet. Yahoo! now has approximately 20 billion different objects in its search index, including internet web pages, images, and audio files. In web search, we facilitate user access to the vast array of information that is available across the Internet. Web search produces results that reflect the most relevant results in response to a request typed in by a user.

A single search term can produce a broad spectrum of results. Typing in the name of a prescription drug, even a Schedule II drug, can produce results that vary from where to buy such a drug, to information about the harmful effects of such a drug, to antidotes to the drug, to treatment centers for abuse of the drug. It may also provide more choices for consumers that may enable them to purchase prescription drugs in a legal manner at lower cost.

Yahoo! has taken additional steps to curb illegal sales of prescription drugs online. We have participated in the joint industry-government dialogue on this issue. We have also had one-on-one meetings with FDA and DEA. To support law enforcement efforts, we held a training event with the DEA at our Sunnyvale campus in October 2005. At this training event, DEA shared information regarding law enforcement concerns with online pharmaceutical sales and Yahoo! provided training to the DEA on what information is available from online providers to assist in law enforcement investigations. Yahoo! frequently cooperates with law enforcement agencies that are conducting investigations that involve the Internet.

Finally, Yahoo! has provided funding to allow the DEA to place public service announcements regarding the dangers of online drug sales in Sponsored Search. For example, recently a search for "vicodin" on Yahoo! brought up a sponsored search result for DEA stating: "ordering prescription drugs online may be illegal." Yahoo! has also included links to FDA safety materials regarding online drug sales in Yahoo! Health.

Members of the Subcommittee, what you see before you today are two Internet companies who are fierce competitors. We have taken the initiative to create a safer environment for the online advertising of prescription drugs. We also agree on the need to protect the value of web search. That said, we are also committed to supporting the work of the government, law enforcement community, and state licensing authorities in their efforts to enforce the important laws that regulate the distribution of these substances. We look forward to continuing to improve our programs to better address this important issue.

Thank you so much for this opportunity to appear before you.

MR. WHITFIELD. Mr. Halpern, in your white paper on page 23, you mention an action campaign focused on the drug website's digital infrastructure would seem to hold real promise. What type of ideas should be pursued as part of this action campaign, and tell me why you believe that would be an effective way to go.

MR. HALPERN. Thank you, Mr. Chairman. I would say two avenues of action: First of all, a concerted effort to work with the domain registrars to eliminate access to the websites via the domain name would be helpful in the sense that consumers become accustomed to accessing a website via its domain name. They are not going to use the underlying technical information to get to the site, at least not the average consumer. So if we can force websites to change their domain names with increased frequency, and given that our study found that a majority had the same domain name for at least a year, that would seem to be quite possible, that would make it more difficult for consumers to get to the websites.

Second, we would encourage law enforcement to focus on trying to seize those web servers that are, at least at present, located within the United States. The web servers themselves, let me be clear, may only have a limited role in the operation of the overall Internet pharmacy. We acknowledge this. However, those web servers may have either -- some form of digital relationship or financial relationship that ties back to physical brick-and-mortar parties responsible for the website's operation. For example, there may be back-end systems that are difficult to identify from the surface of the website. However, if the web server itself were seized and forensic examinations were performed, it may be possible to learn some of this additional, very valuable intelligence in that process. Then a principle of learn it once and use it many times would apply. If you know a given website is related to rings of websites that are overseas and not in the U.S., and you get the information from the U.S. web server, you have an opportunity to leverage that in taking action against websites that are more difficult to get to.

MR. WHITFIELD. I also want to thank IntegriChain for working with our subcommittee on this issue. You all have provided a lot of useful and helpful information, and we really do appreciate that as well.

Mr. McEneney, in your testimony you made a reference that the lack of clarity on what prescription drugs are actually illegal. Would you explain that issue in a little more detail for us?

MR. MCENENEY. Absolutely. I think on the Schedule II and III drugs that MasterCard has been focusing on, MasterCard has gotten a lot of clarity, including from staff of the subcommittee and others, that those sales over the Internet are clearly illegal.

What is happening around the world is there is more confusion on the part of the banks as to where the lines are in terms of which transactions are legal and which are not. One of the things MasterCard has asked for in that context that would be very helpful would be some database or list of pharmacies that are authorized to sell prescription drugs in the United States via the Internet. If MasterCard had a list like that, it would greatly simply MasterCard's efforts to police its own system. For example,

MasterCard could then go to the acquiring banks that sign up merchants and say, look, if you want to sign up an Internet pharmacy to sell prescription drugs in the United States, this is the universe of pharmacies that are eligible to do so.

Anyone else you either cannot sign up to accept MasterCard cards, or you at least can't sign them up to sell into the United States. It is that sort of clarity that I think would be very helpful in making the private sector policing of a system like MasterCard's be more efficient.

MR. WHITFIELD. Can any of you think of any negative reasons why the Federal Government should not require a Federal legislation of registering any entity that sold controlled substances on the Internet?

MR. MACCARTHY. On behalf of Visa, we think such a list could be very helpful. It could be based on whatever registration criteria that you deem to be appropriate. But that kind of list, as my friend from MasterCard indicated, would greatly simplify and help our job of keeping our systems clear of people who are engaged in illegal transactions.

MR. WHITFIELD. DEA does require registration of some pharmacists. Does that help in any way?

MR. MCENENEY. At this point, I am not aware that DEA has a database that you can identify as the universe of pharmacies that are authorized to sell prescription drugs over the Internet.

And as I was listening to the earlier panel, one of the things that I could see that the folks on that panel had in common with I believe all of the private sector folks who are out here trying to address this problem, is everybody is independently going through this process of searching on the Internet, trying to identify the Internet pharmacies, trying to figure out what their real business is, trying to figure out what they are selling. And that whole process could be greatly truncated and be made far more efficient if we really understood who is authorized to sell these drugs and who is not.

MR. WHITFIELD. I thought DEA did require registration for any pharmaceutical company selling a controlled substance.

He tells me there is 12. There are 12 that have been authorized in DEA's testimony. So what would prevent you from looking at that list?

MR. MCENENEY. I don't think there is anything that would prevent us from looking at that list. I would imagine that that list is a universe of domestic companies. Obviously there are a lot of companies that are involved internationally, and the idea would be that regardless of where the entity is located, if the Federal Government had a centralized database that companies like these could consult with to decide who is authorized and who is not, that would make the process far more --

MR. WHITFIELD. Mr. McLaughlin, do you have any thoughts on that? You had mentioned something about that registration in your testimony.

MR. MCLAUGHLIN. Yes. I totally agree. Actually, you know, we are now using an independent third-party company to go out and verify licensing status. And if there was a centralized registry of the entities, not just pharmacists with their DEA numbers, but actual entities that were qualified to sell, pharmacies consistent with whatever set of practices you might want to attach to that registry, we would be gleeful, frankly, to rely on it instead of having to have that work done by an independent entity.

MR. WHITFIELD. Okay. Mr. Townsend, you had mentioned in your testimony that we needed a new government initiative that would encourage the private sector to help disrupt the offender's illicit operations, and I was just curious. Does FedEx have any specific recommendations on ways that they could work with the government in addressing this issue?

MR. TOWNSEND. Mr. Chairman, you heard on the last panel, and you're familiar from your work in this area, about the lengthy time it takes to conclude criminal investigations, the legal requirements which are required to go through all the way up into a judicial action. The nature of the Internet, requiring sometimes our own U.S. agencies to operate outside the United States, complicates that process and lengthens it even further.

I think that one thing we would be interested in participating in is a strategy that identifies in some way -- and we just talked about a list -- but identifies in some ways those sites -- and for us it wouldn't need to be linked to a brick and mortar pharmacy -- which could be identified that DEA does not intend to undertake prosecution; that it falls in one of those categories -- either the amounts are small, the U.S. Attorney won't take it, or for some other reason merits our attention -- but is not going to be one of those few cases out of the many that actually gets prosecuted, but nonetheless is a problem.

And this strategy -- the gentleman on the panel talked about part of an action campaign. If an action campaign could be formed to address the digital environment, make it much more difficult by those who have expertise -- and they are here on the panel -- to make it much more difficult for the digital world, for the pharmacies to be hosted there. While at the same time, we could be identified -- pharmacies could be identified that we would not accept packages from, could have an impact even though they may not -- the criminal prosecution may not be undertaken all the way. It could have a disrupting effect and to keep the drugs off the streets.

MR. WHITFIELD. Mr. McEneney, how many accounts has MasterCard closed because of their relationship to illegal Internet pharmacy? Do you have any idea how many, you all?

MR. MCENENEY. MasterCard, working with their acquiring banks, the acquiring banks have shut down, I believe, somewhere in the neighborhood of 500 different sites.

MR. WHITFIELD. And what about Visa?

MR. MACCARTHY. Mr. Chairman, our program is recently started. We have 49 sites that we have worked with our acquiring financial institutions, and they have committed to us that they will be shut down.

Going forward, we are going to continue our web search program. And we think that going forward into the future, that kind of program will result in us, you know, doing a more comprehensive job than we have up to now.

MR. WHITFIELD. Okay. Mr. Stupak, you are recognized for 10 minutes.

MR. STUPAK. Thank you, Mr. Chairman.

Mr. Halpern, DEA told our staff that they had about the same computer forensics capability that you have. Do you believe this to be the case? Why or why not?

MR. HALPERN. I am not aware of DEA's forensic capabilities.

MR. STUPAK. How long did it take you to put together this report that you did here?

MR. HALPERN. Approximately one week.

MR. STUPAK. Okay. Sixty-five percent of the websites hosted, in whole or in part, are here in the United States. Do you see this website issue as a manageable problem or unmanageable?

MR. HALPERN. I think that depends on the perspective you're asking the question from. We feel it is manageable to comprehensively identify, at least from a snapshot perspective, the websites that offer to sell scheduled prescription medicines. What you do with that data then becomes the crux of the issue.

MR. STUPAK. You did this report for who? I mean, who financed this study?

MR. HALPERN. No one. We do reference a paid project that we did on behalf of Purdue as a data point to add as a qualification. That was a much more in-depth examination of one specific scheduled substance, oxycodone; however, this survey as a whole is provided as a public service.

MR. STUPAK. Since this hearing here is about controlled substances and -- do you think it would be helpful if we had the manufacturers here? How would the websites get the controlled substance if not shipped from a manufacturer?

MR. HALPERN. Well, there are many ways a website can get a controlled substance and it doesn't need to come from a manufacturer within the United States or authorized by the FDA.

MR. STUPAK. But that is pretty easy to track, isn't it, if I am a manufacturer and my drugs are being sold on a illegal site?

MR. HALPERN. Not necessarily. With respect to controlled substances, it is easier to track where a controlled substance goes than a noncontrolled. However, we are frequently helping manufacturers with that very problem of they know who they sell to. They do not always know who the person they sell then goes and sells to.

MR. STUPAK. Exactly. But they could put pressure on the person they sell it to.

MR. HALPERN. It is our understanding that many manufacturers are working aggressively to get exactly that knowledge.

MR. STUPAK. Thank you. That was a pretty interesting report. Let me ask you this. And on your -- in the payment options, since we have Visa and MasterCard here, of the 129 websites you looked at in that area, 99 offered Visa, 94 offered MasterCard, I understand you didn't actually make the purchases. So whether they actually did or did not, but -- and that is what they were advertising, right?

MR. HALPERN. That is what they were advertising. But that is just a claim on their part.

MR. STUPAK. Sure. Let me ask you this other one while I am asking you questions here. On the shipments, again, of the 103 you looked for on shipping options, 31 used FedEx, 15 used the U.S. Postal Service, and 13 used UPS.

MR. HALPERN. That is based on the options that they list. For most sites, when we go to that checkout process --

MR. STUPAK. Do they have multiple ones?

MR. HALPERN. Many would have multiple ones, yes. But, again, keep in mind it is just a representation. And that is all it is.

MR. STUPAK. As you come to buy them, they send you somewhere else.

MR. HALPERN. I could select Federal Express, and they could ship it some other way. There is a great deal of misrepresentation on the Internet as a whole, of course.

MR. STUPAK. That is why you believe everything you read on the Internet, right?

MR. HALPERN. Of course.

MR. STUPAK. Let me ask this question, MR. TOWNSEND. In the earlier panel, I was asking about why does Memphis only find six documents, where the U.S. mail at the same time used 33,000, if it is

being represented by these websites that you're sort of like the preferred shipper of this stuff? FedEx more so than the others.

Why the big disparity in numbers here?

MR. TOWNSEND. Well, I listened with interest in the last panel about that number, Mr. Stupak, and I am not entirely clear about that data. Could you clarify that?

MR. STUPAK. What customs gave us where they seized documents; Miami U.S. mail, 31,051; JFK, 24,000; FedEx Memphis, 6.

MR. TOWNSEND. And is that six in what period of time sir?

MR. STUPAK. A year; from September 1, 2004 to August 31, 2005.

MR. TOWNSEND. Without having the full document in front of me, I am hesitant to challenge that; but it certainly does not sound right from my experience and from what I am told about that.

As you know, we have the ability to take a look at those packages through x-ray technology which Customs and Border Protection operates in the Memphis hub. If they identify packages to us, we provide them to them, and they can take a look through the available technology.

MR. STUPAK. So you don't x-ray them first, they just come in and if Customs Border Patrol -- if they say, well, look at that package, that is when you grab it?

MR. TOWNSEND. They are set up in a permanent fashion in our Memphis hub to operate on a daily basis.

MR. STUPAK. Right. But you don't x-ray them first. See, the mail x-rays then come in before it goes any further. You don't do that at FedEx, I take it?

MR. TOWNSEND. With regard to pharmaceutical drugs, we do not.

MR. STUPAK. So we have no way of knowing what is in those packages unless there is something else on the outside of the container that catches someone's eye.

MR. TOWNSEND. Well, as you may know, we provide advanced data to CBP regarding our manifests.

MR. STUPAK. But advanced data, is there some characteristic of a package that you would look for for illegal Internet sales?

MR. TOWNSEND. It is my understanding that CBP does have criteria -- and I don't want to speak for them -- that they do have criteria that they may use to in fact profile cargo.

MR. STUPAK. Why won't you just x-ray it when it comes in? I mean, really, the numbers are staggering, 33,000 to 6.

MR. TOWNSEND. If one accepts those numbers sir.

MR. STUPAK. Do you have any reason to dispute the numbers?

MR. TOWNSEND. I haven't seen the data you're referring to.

MR. STUPAK. You have seen the folders we put up. Why wouldn't you just x-ray it? Because that's when you find it.

MR. TOWNSEND. My experience has been when you're referring to the Memphis hub, that at no time there would be six packages in there but, rather, it might look something like that.

MR. STUPAK. Sure. But answer my question. When a package comes in, why wouldn't you just -- why won't you just x-ray it to see if there is any illegal drugs in it? Just run it through? Is there a time concern?

MR. TOWNSEND. Certainly it is.

MR. STUPAK. Okay.

Would you check with your -- whoever you have to check with, and get an answer back on that?

MR. TOWNSEND. Yes, sir.

MR. STUPAK. One way to clamp down is just x-ray the packages, and we could get into these summary forfeitures, which take three minutes, as was testified earlier, and we can really crack down on a lot of what is coming through in UPS or whatever it is.

MR. TOWNSEND. We will be happy to take a look at those numbers and get back to you, sir.

MR. STUPAK. Let me ask Mr. MacCarthy or Mr. McEneney.

You both indicate that whether it is Visa or MasterCard, you certainly don't allow people to use your card for illegal transactions.

How do you monitor this? How do you know it is an illegal transaction? How do you know if the person bought the drugs from pharmacy.com -- whatever it is -- is legal or illegal?

MR. MACCARTHY. Mr. Stupak, the way we approach it is first we find out that it is a problematic site through a number of mechanisms. One could be referral from law enforcement. It could be from committee staff who have concerns about a particular site. Or it could be from our own search of the Internet which we think, going forward, is going to be the predominant way we will get the leads for problematic Internet pharmacies. And we search for websites where we think the activity involved is illegal, we think they are dealing in controlled substances, Schedule II --

MR. STUPAK. So let's say you find a website you think is illegal. How do you prevent your customers then from using that website?

MR. MACCARTHY. Since we are an association of financial institutions that work directly with the merchants, we find out which financial institution has been working directly with that merchant. We pass that information on to that bank or credit union, whoever it is that is working with the merchant, and we say to that entity, here is what we found, whether it comes from law enforcement or from our own searches. This is what it looks like to us. It looks as though this website is engaged in the illegal sale of pharmaceuticals. We would like you to

either shut those people down or explain to us why they are acting illegally.

MR. STUPAK. How does that prevent me from going on there, clicking a mouse and using my Visa to purchase this drug, whether you know if it is legal or illegal?

MR. MACCARTHY. The attempt here is not to focus on the buyer. The attempt is to focus on the illegal website itself. And our approach is to say, if we can find those illegal websites, work with our acquiring banks and sever our relationship with them, then, no cardholder would be able to use his card to deal with that website, because that website would not longer be authorized to accept Visa cards.

MR. STUPAK. How long does this process take?

MR. MACCARTHY. It depends. It can be very, very quick.

MR. STUPAK. Or very, very long?

MR. MACCARTHY. It depends on the investigation that the member financial institution is involved in.

MR. STUPAK. Why wouldn't you just key your computers at this illegal website, when someone tried to use it, it rejects that purchase?

MR. MACCARTHY. Again, we don't have the contractual relationship with the merchant. It is our member financial institution who has that relationship.

MR. STUPAK. But you have it with your customer.

MR. MACCARTHY. We give the financial institution a period of time to investigate the situation and come back to us and tell us what they have done. We have found when we do --

MR. STUPAK. But they are using your card and company to purchase these drugs.

MR. MACCARTHY. We have found that when we bring this to the attention, to the acquiring banks, they uniformly --

MR. STUPAK. I'm trying to get something instantaneous, because it all takes time and, as we know, these sites come up and down.

MR. MACCARTHY. We have to make sure that the website itself is indeed acting illegally and we have done our initial investigation. But the entity that is closest to the merchant is the one that has the contractual relationship with them. We give them a chance to look at it more carefully, and then we find that they have reacted properly, they have reacted effectively, and they have closed down the merchants that they have found to be engaged in the illegal sale of pharmaceuticals.

MR. STUPAK. Would you get back to us and tell us how long that takes?

MR. MACCARTHY. Sure.

MR. WHITFIELD. The gentleman's time has expired. The Chair recognizes Dr. Burgess for 10 minutes.

MR. BURGESS. Thank you, Mr. Chairman. Again I apologize for being out of the room while some of the testimony was going on.

Mr. Dahl, in your experience, do the Internet service providers cooperate with law enforcement to the degree that they should?

MR. DAHL. Generally they all cooperate if we can explain to them that there is an illegal site going on. But the problem becomes, and FDA's experience is that we don't have the tools to gather the information necessary to fully investigate the offense.

For instance, other agencies have administrative subpoenas and you can get the information on who that customer is of the Internet service provider. FDA does not have that authority and, therefore, that information is not available; therefore, you can't go back to them and explain the illegality of their transactions.

MR. BURGESS. Do you think -- there was some rule I was reading about this morning. It says computing power doubles every 18 months, or something along these lines. Do you think this is a problem that's gotten worse as more computing power is delivered to the desktop in the average user's hands?

MR. DAHL. It has gotten worse as we are sitting here this afternoon. It's getting worse all the time. I just take you about back 10 years ago or something, when some executives at FDA were saying why is OCI doing drug diversion cases? Show me why you're doing it. We said, to stop counterfeit drugs. We really haven't even dented the diversion of pharmaceutical drugs. And now we have counterfeits. The same thing is happening at the Internet; the problem is mushrooming every day.

MR. BURGESS. I think Congressman Norwood probably summed it up best as a serious problem. We don't know how to deal with it. And I guess my suspicion, or just observation, is that the generation or two behind us is so much more facile with dealing with things on the Internet. It is almost second nature to them. It is like an extension of their upper extremities.

This problem is going to continue to grow. And honestly, I don't know that a regulatory body that moves with the speed that Mr. Stupak has described today, I don't know if there is a foreseeable way to keep up with it. Do you think that is even within our power to do that?

MR. DAHL. I think it is within your power to make it better than it is. I don't know that we can solve the problem completely. I know that you heard FDA's testimony today was mostly about regulating good guys. And this committee is trying to address this activity conducted by bad guys.

You have got to focus on the problem. And the problem here is not approving new drugs that are controlled substances; the problem is

attacking the criminals that would illegally distribute these products to Americans.

MR. BURGESS. Yes. I guess our only hope is they will go to counterfeiting Britney Spears' CDs and leave drugs alone.

Let me read this statement to you: On July 2005, the National Center on Addiction and Substance Abuse reports specifically recommended that Congress should clarify Federal law to prohibit sale or purchase of controlled prescription drugs on the Internet without an original copy of a prescription issued by a licensed DEA-certified physician licensed in the state of purchase, based on physical examination and evaluation, and to impose higher penalties for illegal sales to minors.

What is your opinion on what impacts such legislative clarification in the investigation and prosecution of cases involving controlled substances over the Internet?

MR. DAHL. Very helpful. I think that -- as a matter of fact, a law like that might put the distribution of controlled substances even more underground. They wouldn't be selling them openly as the branded drugs that we see today.

MR. BURGESS. I agree with you. I think it would be helpful. I have to tell you as I read that, though, as a physician in my former life, we know that the practice of telemedicine in the future is going to hold great promise for delivering care to areas that are perhaps affected by a disaster, or areas where care is just inherently difficult to render. And I do wonder if such restrictive regulation would pose a problem for the practice of telemedicine in the future. Hopefully, we will be clever enough to think about ways around that.

And I do thank you for your testimony today. I think you have really provided a lot of insight into this committee.

Mr. McLaughlin, does Google offer the DEA any assistance in its efforts to track down the hosts of websites that advertise or sell pharmaceuticals illegally?

MR. MCLAUGHLIN. We will be happy to do that. We have been talking to the DEA about what kinds of information would be useful to them. And I am not sure they have a very hard fix on what it is they could learn from us. And I am not sure we have a hard fix on what we can tell them. We have been talking with them about it, though.

We are certainly eager to fork over, in an appropriate way of course, information that we have that would help them catch the people that are peddling these drugs on line.

MR. BURGESS. Not just peddling them, but I think the spam that comes across the wires is just nothing short of mind-boggling.

In its efforts at minimizing the problem of rogue online pharmacies, does Google coordinate with any other private sector companies or entities?

MR. MCLAUGHLIN. We have been participating in two efforts recently. One is the interagency task force we have been discussing here. We have sat in on a couple of those meetings when we have been invited. And Yahoo!, AOL, Microsoft, and those companies have also been part of those meetings.

There's also been a task force that has been meeting up at Harvard University that Professor Hyman at the law school has been convening that includes prosecutors, some agency officials, academics, and some people from private sector companies like Google that have been talking through these issues and working toward what we hope will be concrete recommendations about pressure points in the ecosystem that allows people to order the drugs, get them shipped, and get the money transferred.

And we have talked about some of those pressure points here today. I think hopefully there will be others that can be identified in that report.

MR. BURGESS. Can you tell the committee what actions Google takes when it discovers that an ad refers to a controlled substance?

MR. MCLAUGHLIN. Well, it will either be from a SquareTrade certified advertiser, which means that it's gone to a third-party company and proven that it's a licensed pharmacy in the state in which it is located or not. And if the answer is it is not SquareTrade certified, then the ad gets shut down and I think our response times are well nigh immediate.

MR. BURGESS. Mr. MacCarthy, let me just ask you -- thank you for your responses.

Mr. MacCarthy. Let me just ask you in the time we have left, just as a prelude to this committee hearing I went online yesterday and looked at some of the online pharmacies that were available to me. It really seemed in the forms that we were asked if they were answering Mr. Stupak's questions on getting data, and the forms that I was asked to fill out online really seemed more geared toward assuring that I had a valid credit card rather than I had a valid prescription. Do you have any observation about that?

MR. MACCARTHY. Other than that, they want to make sure they will be paid, and that they are more careful about that than they are about screening what kind of drugs they are dealing with, it strikes me as being an important thing that you found it was more difficult, you know, to ascertain their interests in the prescription than the payment service.

If you have a name of one of those sites and you would like to provide it to us, we would be happy to look into it to see if it was one of the problematic sites that we would like to take some action on.

MR. BURGESS. I will tell you, I wasn't that careful about my search. I just went to the first one that popped up on Google, and went to it, and filled out the form. So if you have an internal group that does that sort of checking for you, I don't think they will find it that hard to encounter. But just, again, just my observation.

Mr. Chairman, it has been a long day. I yield back the balance of my time.

MR. WHITFIELD. Thank you, Dr. Burgess.

I would just like to ask a couple more questions. And I think Mr. Stupak may have a few.

But Mr. Dahl, you were involved in criminal investigations at FDA. And in my opening statement I made reference to a case of Todd Roady, who had purchased some controlled substances I believe from a foreign Internet pharmaceutical company.

Are you familiar with the Todd Roady case at all?

MR. DAHL. I am familiar with it. I was out of government at the time when it was initiated, but I certainly am familiar with it now.

MR. WHITFIELD. Do you know what the consequences were? Did they find -- did they shut that site down? Were there any prosecutions, or do you know?

MR. DAHL. OCI had made test buys from that South African website that had resulted in the tragic death of Mr. Roady.

And I know that in May of 2001, South African police authorities were here in Washington at an OCI-sponsored event called the Permanent Forum on International Pharmaceutical Crime. At that point, OCI agents provided all the evidence they had to South African police, who said they would go back and prosecute the responsible party to the fullest extent of their law. As we continued to press for what results they had gotten, it just was dragging on forever. Ultimately, they admitted that they didn't think they had the laws to address the problem, and they had referred that matter to their medical board, who was going to address the licensing of one of the physicians involved.

I believe that as we continued to press the medical board for information, we found that they did not do anything. We then went to the Department of Justice here in the United States, and got letters rogatory that involved the international tools available to further investigate that matter.

Ultimately, we did get some response to the letters rogatory, but they were not sufficient to bring criminal charges here in the United States. And I am told, or I have learned, that the Department of Justice closed their criminal file in January of 05.

MR. WHITFIELD. Thank you. Mr. Stupak.

MR. STUPAK. Mr. Chairman, if I may, I would like to submit for the record, since we have talked a lot about it today, this e-mail to Chris Nauer and also this e-mail copied to Mr. Slobodin of your staff on the stats we have been using on controlled substance -- whether it is UPS or FedEx or Miami or JFK through the postal service -- if you need it, so everyone will have access to it.

MR. WHITFIELD. Without objection.

[The information follows:]

Knauer, Chris

From: Mackaly, Darren W [darren.mackaly@dhs.gov]
Sent: Tuesday, December 13, 2005 11:12 AM
To: Knauer, Chris; Slobodin, Alan
Cc: Reilly, Dorothy W
Subject: CBP stats

Inf comp page 2.xls

Good Morning,

Please find stats attached.

Thanks,
Darren Mackaly
CBP Congressional Liaison
202.344.2151

(See attached file: Inf comp page 2.xls)

Schedules III, IV, and V Controlled Substance Informed Compliance Interdictions - Summary

33,051	MIAMI, IMB
24,237	JFK IMB
4,165	LOS ANGELES IMB
3,889	SAN FRANCISCO IMB
1,971	DALLAS
1,838	CHICAGO IMB
890	SEATTLE IMB
731	DHL, CINCINNATI
410	UPS, LOUISVILLE
288	NEWARK IMB
225	HONOLULU
82	BUFFALO IMB
67	SAN JUAN IMB
53	DHL, MIAMI
38	DETROIT
27	CFS (COURIER FACILIITY), MIAMI
18	DHL, SAN FRANCISCO
13	UPS, SEATTLE
11	INT'L COURIER ASSN., MIAMI
10	FEDEX, MIAMI
6	UPS, MIAMI
6	FEDEX, MEMPHIS
4	IBC COURIER HUB, MIAMI
1	AIRBORNE, WILMINGTON, OH
72,031	**TOTAL**
	September 1, 2004 - August 31, 2005

September 1, 2004 - August 31, 2005

MR. STUPAK. Thanks. Mr. Halpern, in your report here, I am looking at page 16. We are talking about the different registrars for these websites like GoDaddy and Open, SRS, Joker, Network Solutions. These are folks that don't use the process like Yahoo! or Google have, right?

MR. HALPERN. Which process, the SquareTrade process?

MR. STUPAK. Yes.

MR. HALPERN. I am not aware of what process they use for screening, for instance.

MR. STUPAK. Is there anything else you can think of, like if we use SquareTrade or something like that, that would help focus this down?

MR. HALPERN. Let me make a caution about SquareTrade. SquareTrade verifies that a pharmacy is licensed in the U.S, right. But we have seen instances, to offer an example, where a licensed pharmacy in the United States may be operating one website where it discloses all its information, its mailing address, its brick and mortar operations, its license number, and appears, at least on that website, to have stringent prescription requirements for any product it will sell via that website. Then we will have intelligence linking that website to multiple other websites where there are not those prescription requirements. So at the end of the day, there is only so much that SquareTrade can do to screen.

MR. STUPAK. So it is a solution, then, other than the -- I know there was some discussion on the first round of questioning here with this panel that the 12 sites -- or government certifies the sites?

MR. HALPERN. I'm sorry, can you repeat that question?

MR. STUPAK. What is the solution -- those 12 sites that DEA allegedly indicated, that would be the way to do it, is that the government certified the sites for pharmaceuticals?

MR. HALPERN. Well, I think the first step is intelligence management. There needs to be better communication of the information that is available to the private sector, to law enforcement bodies that are going to take those steps, whatever the regulatory steps may ultimately be.

If we are aware, for instance, through some investigation we have performed on behalf of a client in the manufacturing industry that a licensed pharmacy is engaged in highly suspicious activity, there needs to be a way to effectively communicate that to the parties that are going to make decisions about who should be on the list of good guys and who should not be.

MR. STUPAK. So what you're saying is the strategic framework is -- that we talked about on the first panel -- is really what we need here and some accountability?

MR. HALPERN. Absolutely.

MR. STUPAK. A question, more of a statement. We have been talking about registering sites, and the Chairman and I were just talking a little bit here; one of the arguments we get is if we, the government, went ahead and said all right, we will certify these sites and buy your drugs from there, then -- I don't mean to be partisan in this -- but then you're

really endorsing the idea of reimportation of drugs from other countries that are safe and effective for use in this country, which has been contrary to what the administration wants to see and contrary, actually, to the new Medicare prescription drug law, because if you look at that, you can't go and reimport drugs.

So I think, well, we may be sitting here asking what can we do there? I think politically, this body has to get its act together on reimportation, whether or not you're going to have it or not. Especially with the Internet being a big part of everyone's life, we better take a look at reimportation of drugs as to safety and efficacy of the drugs.

MR. HALPERN. I would merely make the observation that when it comes to controlled substances, at least today, we see a mix of activities that are domestic in origin and international. And it is not, at least yet, purely a matter of importation. That may change in time.

MR. STUPAK. Did you do anything to -- you probably don't have this information. What is the age group of these people hitting the Internet for these pharmaceutical sites?

MR. HALPERN. The age group of the users, the consumers? We do not have that information.

MR. STUPAK. Does anyone have that information? Just a little bit to my reimportation question, I guess. Also you said a big increase in teenage people using controlled substances. That is why I asked the question.

MR. HALPERN. One way to probe that would be to leverage the chat rooms and forums that have developed as independent meeting places for individuals attempting to purchase and procure products, and that may contain information that could be used to profile age.

MR. STUPAK. Nothing further, Mr. Chairman. Thanks to everyone on the panel.

MR. WHITFIELD. Thank you all very much. We appreciate your patience and you were quite helpful in your testimony. And we look forward to working with all of you as we continue to explore ways to deal with this significant issue.

With that, we'll keep the record open for seven days for anyone that wants to file additional information. And with that, the hearing is adjourned.

[Whereupon, at 4:35 p.m., the subcommittee was adjourned.]

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