S. Hrg. 108–684

BUYER BEWARE: THE DANGER OF PURCHASING PHARMACEUTICALS OVER THE INTERNET

HEARINGS

BEFORE THE

PERMANENT SUBCOMMITTEE ON INVESTIGATIONS

OF THE

COMMITTEE ON
GOVERNMENTAL AFFAIRS
UNITED STATES SENATE

ONE HUNDRED EIGHTH CONGRESS

SECOND SESSION

JUNE 17 AND JULY 22, 2004

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BUYER BEWARE: THE DANGER OF PURCHASING PHARMACEUTICALS OVER THE INTERNET

THURSDAY, JUNE 17, 2004

U.S. SENATE,
PERMANENT SUBCOMMITTEE ON INVESTIGATIONS,
OF THE COMMITTEE ON GOVERNMENTAL AFFAIRS,
Washington, DC.

The Subcommittee met, pursuant to notice, at 9:02 a.m., in room SD–342, Dirksen Senate Office Building, Hon. Norm Coleman, Chairman of the Subcommittee, presiding.

Present: Senators Coleman, Levin, Lautenberg, Collins, Pryor, and Carper.

Staff Present: Raymond V. Shepherd, III, Staff Director; Katherine English, Counsel; Mark Greenblatt, Counsel; Jay Jennings, Investigator; Mary D. Robertson, Chief Clerk; Katherine Russell, Detailee, FBI; Claire Diegel, Intern; Elise J. Bean, Staff Director/Chief Counsel to Minority; Jason Hill (Senator Levin); Priscilla Hanley (Senator Collins); Marianne Upton (Senator Durbin); Tate Heuer and Gita Uppal (Senator Pryor); and Demian Moore (Senator Dayton).

OPENING STATEMENT OF SENATOR COLEMAN

Senator COLEMAN. This hearing of the Permanent Subcommittee on Investigations is called to order.

Americans are increasingly turning to the Internet for access to affordable drugs. In 2003, consumer spending on drugs purchased over the Internet exceeded $3.2 billion. Unfortunately, rogue Internet sites have proliferated and rake in millions of dollars by selling unproven, counterfeit, defective or otherwise inappropriate medications to unsuspecting consumers. Even more dangerously, these sites are profiting by selling addictive and potentially deadly controlled substances to consumers without a prescription or any physician oversight.

In today's technological environment, it is essential that we understand the forces at work here. Internet pharmacies have the potential for bringing important and, in many cases, lifesaving drugs to our homes in a way that we have never before imagined. But, unless we understand the safety issues surrounding the use of the Internet and the delivery of prescription drugs, what should be about improving our lives may very well end up costing lives. I believe we have an obligation to develop coherent public policy that addresses these safety concerns.

As Chairman of the Permanent Subcommittee on Investigations, I endeavored to provide an objective snapshot of what drugs are available to consumers on the Internet—the good, the bad, and the ugly.

Our first inspection was at the JFK International Airport, in New York, home to the largest International Mail Branch (IMB) in the United States. Senior Customs officials at JFK estimate that 40,000 parcels containing drugs are imported through that airport on a daily basis. During last summer's FDA/Customs blitz, 28 percent of the drugs tested were controlled substances. This means that as many as 11,200 drug parcels containing controlled substances, like the painkillers Vicodin and OxyContin, are imported daily through JFK; 78,400 weekly; 313,600 monthly, and 3,763,200 annually.

Top countries of origin include Brazil, India, Pakistan, the Netherlands, Spain, Portugal, Canada, Mexico, and Romania.

On March 15 and 17, 2004, PSI discovered at least 2,000 boxes from a single vendor in the Netherlands that contained hydrocodone and generic Valium or Diazepam.[1] In addition, Customs regularly seizes shipments of OxyCodone, a codeine-laced product, GHB (the date rape drug), and morphine.

With PSI present, FDA uncovered a number of boxes of fake Lipitor—the real Lipitor is the last bottle on the right in this slide.[2]

FDA and Customs regularly seize and inspect packages containing: Counterfeit Viagra from India,[3] injectable steroids from China,[4] and boxes of unidentified drug product.[5]

FDA and Customs often discover packages of drugs without any of the required inserts that lack labeling and have directions for usage in foreign languages. An example of this is Lupron, an injectable hormone used to treat prostate cancer.[6] I will note that I was with former Mayor Giuliani when we looked at the Lupron, and he looked at it and said, "I know that drug"—he has suffered from prostate cancer and was well aware of it. He turned to me and said, "You know, this is something that needs close physician supervision," and there it is, without any instructions, something that is clearly very dangerous when individuals use it without physician supervision. Unfortunately, all the labeling and directions for usage of this product are in Spanish.

Unfortunately, we found similar problems at Chicago O'Hare International Airport, which is home to the Nation's fifth-largest International Mail Branch. Approximately 16,600 parcels are imported through the Chicago IMB each day. Of those parcels, 4,300 are estimated to contain drug products imported for personal use by consumers. Customs estimates that 75 percent of the parcels that contain drug products are imported from Canada. Other top countries of origin include Great Britain, the Netherlands, and Mexico.

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[1] See Exhibits 1, 2, and 3 which appear in the Appendix on pages 286, 287, and 288.
[2] See Exhibit 4 which appears in the Appendix on page 289.
[3] See Exhibit 5 which appears in the Appendix on page 290.
[4] See Exhibit 6 which appears in the Appendix on page 291.
[5] See Exhibit 7 which appears in the Appendix on page 292.
[6] See Exhibit 8 which appears in the Appendix on page 293.

While inspecting the Chicago IMB, PSI discovered packages of: Injectable steroids,[1] counterfeit Viagra from Mexico,[2] growth hormone from Mexico,[3] codeine-laced products injectable insulin from Canada, which was not properly refrigerated,[4] and a large box of unidentified and unlabeled white pills from Mexico.[5]

The same dangerous conditions are present at the Miami IMB. Senior Customs inspectors at Miami IMB estimate that as many as 30,000 parcels that contain drug products are imported through Miami each day. This means that as many as 6 million parcels containing drugs are imported annually through this one IMB. Of the 30,000 daily imports, a couple thousand are dangerous controlled substances, including Valium, Ritalin, Bromazepam, Zolpidem, and steroids. Other types of drugs that FDA and Customs inspectors routinely see include fake Viagra from Belize, antibiotics including Ciprofloxin, and unknown drug products identified as vitamins or dietary supplements. Top countries of origin include Great Britain, Honduras, Mexico, Canada, Costa Rica, and the Bahamas.

During the same period, at my request, the General Accounting Office made purchases of pharmaceuticals from both domestic and foreign Internet Websites. Their results confirmed what we discovered at JFK, Chicago and Miami—when consumers log onto the Internet to purchase their pharmaceuticals, it is truly "buyer beware."

GAO demonstrated just how easy it is to purchase these drugs over the Internet. GAO used the Internet to purchase numerous prescription drugs— including highly-addictive narcotics and other controlled substances. Notably, GAO purchased 66 percent of these pharmaceuticals, including narcotics, without a prescription and without visiting a doctor.

GAO also used the Internet to purchase from foreign pharmacies counterfeit versions of American drugs, pharmaceuticals that have not been approved by the FDA, counterfeit drugs that lacked the active ingredient, damaged products, and drugs without proper packaging, no warning information, or instructions for use.

The GAO investigation does reveal some encouraging news for those of us who use bona fide established domestic Internet pharmacies and those of us who support the safe importation of Canadian drugs to ease the cost of prescription medications. The preponderance of problems uncovered by GAO investigators with virtual pharmacies was associated with drugs that came from foreign countries other than Canada. All of the drug samples that GAO received from U.S. and Canadian Internet pharmacies included dispensing pharmacy labels that generally provided patient instructions for use. None displayed evidence of mishandling, and most included warning information.

However, most disturbingly, GAO's Office of Special Investigation found that: Anyone, including children, can easily purchase the highly addictive painkiller hydrocodone from the Internet without providing a prescription or being examined by a physician; the

[1] See Exhibit 15 which appears in the Appendix on page 300.
[2] See Exhibit 16 which appears in the Appendix on page 301.
[3] See Exhibit 17 which appears in the Appendix on page 302.
[4] See Exhibit 18 which appears in the Appendix on page 303.
[5] See Exhibit 19 which appears in the Appendix on page 304.

Internet pharmacies from which GAO purchased hydrocodone charge significantly higher prices than walk-in pharmacies, regardless of whether a patient has health insurance; and some Internet pharmacies focus exclusively on selling hydrocodone. GAO has concluded that these sites are in the business of profiting from illegal drug use rather than providing a safe, inexpensive alternative source for consumers lacking health insurance.

In order to put a human face on this dangerous and potentially lethal situation, we will hear testimony from two individuals who lost family members because of overdoses of drugs procured through rogue Internet sites.

Francine Haight will tell us about her son, Ryan, who died from a mix of hydrocodone, morphine, and Valium. Ryan obtained these highly potent narcotics from Internet pharmacies. For some of these drugs, Ryan did not have a prescription; for others, Ryan had a prescription from a doctor that he had never met.

Elizabeth Carr's husband, James Lewis, a tri-athlete, died of an overdose of Darvon on April 10, 2003. He purchased the Darvon, as well as other drugs from Internet pharmacies doing business in South Africa, Thailand, and Spain. Some of the websites that James used required him to fill out a short questionnaire before he could order the medication, while others required nothing.

I cannot tell these witnesses how appreciative I am of their brave decision to come here and tell your story to Congress. I promise that I will do whatever is in my power to prevent the same tragedy from befalling other families.

I also look forward to hearing testimony concerning his assessment of the U.S. pharmaceutical system from my friend, former New York Mayor, Rudy Giuliani. Lastly, I am eager to hear the results of the study performed by Dr. Marv Shepherd of the College of Pharmacy at the University of Texas at Austin that details the Canadian drug market.

Now that PSI has identified some serious problems in the Internet pharmacy industry, we must start fashioning solutions. That is why I introduced S. 2464, the Ryan Haight Act, and S. 2465, the Todd Rode Act. Taken together, these bills: Empower Customs to immediately seize and destroy any package containing a controlled substance that is illegally imported into the United States; provide new disclosure standards for Internet pharmacies; bar Internet sites from selling or dispensing prescription drugs to consumers who are provided a prescription solely on the basis of an on-line questionnaire; and allow State Attorneys General to go to Federal court to shut down rogue Internet pharmacies.

Surely, we do not want to play what some correctly call "Rx roulette" with the health of American consumers by blindly ignoring real safety concerns of the drugs we allow to be imported from the vast unregulated Internet pharmacy. Ignoring those concerns can have tragic consequences, like the tragic stories of Ryan Haight and James Lewis.

With that, I will turn to the Ranking Minority Member, Senator Levin.

OPENING STATEMENT OF SENATOR LEVIN

Senator LEVIN. Thank you very much, Mr. Chairman, and thank you for your focus on this very critical issue and for your commitment to trying to see if we cannot get at the real fundamental problem here that you have just identified.

As prescription drug prices in the United States continue to skyrocket, American consumers have become increasingly desperate to find the cheapest drugs available. In recent years, consumers are turning to the Internet to comparison shop and buy the lowest cost drugs online. The problem is that many Internet pharmacies are dispensing medicine illegally and, in some cases, selling counterfeit or unsafe drugs.

Because U.S. enforcement efforts are currently inadequate to stop the illegal operators, the high cost of U.S. prescription drugs is driving increasing numbers of Americans to play Russian roulette with Internet pharmacies, gambling their safety on the lure of more affordable prices.

Over the past 4 years, U.S. prescription drugs have increased an average of nearly 20 percent annually. Today, on average, Americans pay 60 percent more than the British or the Swiss for the same prescription drugs, two-thirds more than Canadians, 80 percent more than Germans, and twice as much as Italians. For poor and middle class individuals suffering chronic illnesses, high drug costs are forcing some to choose between taking their medicine on any given day, paying their bills, and even buying food.

The GAO report before us today leads me to two conclusions. First, Internet purchases of illegal pharmaceuticals are out of control, and we need to increase enforcement. Second, medicines purchased from Canada are as safe or safer than those purchased in the United States.

Now, I say that because 100 percent of the medicines purchased by the GAO on the Internet from Canadian pharmacies required patient prescriptions compared to only 5 out of 29, or 17 percent of U.S. pharmacies.

In addition, none of the Canadian medicines was counterfeit. That was also true of the U.S. medicines.

Internet pharmacies are a relatively new response to the problem of high-cost medicines. Some Internet pharmacies are completely legal operations, set up to offer clients convenience and cost savings. They required patient prescriptions and deliver medications from U.S.-approved facilities.

Other Internet pharmacies operate illegally, selling medications without prescriptions and using unapproved manufacturers either in the United States or offshore. Some shadowy operations send unsolicited offers to millions of Internet users, hawking medications like junk food bargains. These illegal operators have begun to capture attention as a health and safety threat requiring criminal and civil enforcement action. And again, I commend our Chairman, Senator Coleman, for focusing on this problem and holding this inquiry today.

Pharmacies and pharmaceutical sales involve a complex web of State and Federal regulation to protect the public from unsafe or improperly prescribed drugs. In the United States, the practice of pharmacy is regulated by State boards which license both phar-

macists and pharmacies. To legally dispense a prescription drug, a licensed pharmacist working in a licensed pharmacy must be presented with a valid prescription from a licensed health care professional before delivering the drug to the purchaser. On the Federal level, the Food and Drug Administration (FDA) is charged with ensuring the safety, effectiveness, and quality of domestic and imported drugs; the Bureau of Customs and Border Protection (Customs) is supposed to screen and stop unauthorized controlled substances at the border; and the Drug Enforcement Agency (DEA) is responsible for combating illegal narcotics and the abuse of controlled substances.

To get a better sense of the enforcement problems associated with Internet pharmacies, at the request of this Subcommittee, the General Accounting Office (GAO) spent several months earlier this year buying prescription drugs online, tracking the Internet pharmacies and drugs delivered in response to their on-line orders, and then testing the delivered drugs to ascertain if they were actually the medications ordered. GAO efforts focused on buying popular medications such as Celebrex, an anti-inflammatory pain reliever; Lipitor, a cholesterol lowering drug; Viagra, a medication for sexual dysfunction; and Zoloft, an antidepressant.

GAO found that buying medications from Internet pharmacies was not difficult. GAO placed 90 on-line orders for prescription drugs and received 68 samples, a success rate of 75 percent. Of those 68 medications, 45 were shipped illegally because there had been no patient-provided prescription. Many were also shipped without FDA-required precautions such as patient instructions and temperature-controlled packaging. Of the 68 samples, 48 were from the U.S. or Canadian-based Internet pharmacies, 18 were from foreign or Canadian sites, and two could not be determined. Of the 18 foreign samples, three were found to be counterfeit, including two that contained incorrect but not necessarily dangerous chemical compositions, and one that had no active ingredients at all. Again, GAO determined that none of the U.S. or Canadian samples was counterfeit, evidence indicating that medications delivered from other foreign countries were less safe than those originating in the U.S. or Canada.

The Subcommittee also examined operations at three U.S. ports of entry, in New York, Chicago, and Miami, to evaluate how Federal agencies screen parcels containing pharmaceutical products and originating from foreign countries. The investigation determined that tens of thousands of dangerous and addictive controlled substances are streaming into the United States on a daily basis from overseas and that, at ports of entry such as the John F. Kennedy International Airport, Miami International Airport, Customs agents are being overwhelmed as they attempt to prevent potentially hazardous materials from entering our borders.

At JFK Airport, Customs officials estimated that over 40,000 parcels containing pharmaceutical products pass through its facility every day. Miami Intentional Airport saw 30,000 packages a day. Neither facility had sufficient personnel to screen those parcels. For example, JFK had an average of 50 Customs agents and just six FDA inspectors working at its facilities during the course of a day, which meant that every person was responsible for

screening more than 700 pharmaceutical parcels every day—and remember, these agents and inspectors have lots of other responsibilities, too. They are charged, for example, with screening packages for firearms, nuclear material, counterfeit currency, and other contraband items.

Millions of packages containing pharmaceutical products were imported into the United States last year and in 2003, and an estimated $1.1 billion worth of prescription drugs were imported into the United States solely from Canada. Internet pharmacies have contributed to this increase and to the ongoing strain on our enforcement resources. While some of these Internet pharmacies are based in the United States, many others are based in foreign countries which makes them harder to investigate, inspect, and shut down. Recent research indicates, for example, that the top countries of origin for imported medications include Brazil, Canada, India, Mexico, the Netherlands, Pakistan, Portugal, Romania, and Spain. While Federal agencies such as FDA, Customs, DEA, and the Department of Justice have successfully taken enforcement actions against both domestic and foreign Internet pharmacies and associated physicians in the past, these agencies face a host of enforcement issues with scarce resources. In an age of global terrorism where these same agencies are charged with protecting the public from dirty bombs, heroin sales, and chemical and biological weapons, it is tough to believe that stopping Internet pharmacies will become a top priority.

There is also, again, the larger issue of drug reimportation. The importation of prescription drugs happens every day in this country, whether it is through private individuals purchasing drugs through the Internet, or a busload of seniors traveling to Canada to buy cheaper drugs from their drug stores there.

It is the exorbitant price of prescription drugs in the United States that is driving Americans to buy low cost medicines from foreign countries. Folks are doing what they have to do in order to find and buy more affordable medicine.

It is an ironic but comforting fact that the GAO study found no counterfeit drugs among the medications imported from Canada, since so many Americans are now shopping there, including thousands of my constituents from Michigan. And I am one of the Senators who favors legalizing the importation of drugs from countries such as Canada as a way to bring down prices here at home and stop the current practice of forcing American taxpayers alone to bear the burden of subsidizing research and development costs for drug companies.

While I support stronger enforcement action—and I very strongly support enforcement action—to shut down illegal Internet pharmacies and to confiscate unsafe medications at the border, those actions will not cure the larger problem of overpriced drugs here in the United States. It is my hope that Congress will have an opportunity this year to vote on a real proposal, such as the Dorgan-McCain Pharmaceutical Market Access and Drug Safety Act, S. 2428, that will legalize the importation of drugs and begin to address the real issue of high drug prices for Americans.

Again I commend you, Chairman Coleman, for taking on this important and complicated safety issue.

Senator COLEMAN. Thank you, Senator Levin.

It is my great pleasure to have with us the distinguished Chairman of the Committee on Governmental Affairs, Senator Collins.

OPENING STATEMENT OF CHAIRMAN COLLINS

Chairman COLLINS. Thank you, Mr. Chairman.

Let me start by commending you for holding these very important hearings to highlight the safety concerns that can be associated with the purchase of prescription drugs over the Internet.

I also want to echo Senator Levin's comments that one of the greatest challenges facing American consumers is the high cost of prescription drugs. Soaring drug costs have placed a tremendous strain on family budgets. They have also imposed a heavy burden on employers, both public and private, who are struggling to provide affordable health insurance coverage to their employees.

It is therefore no wonder that American consumers throughout our country are looking across the border and into their computer screens in search of more affordable prescription drugs.

It is well-documented that the average price of prescription drugs is much lower in Canada and in Western European countries than in the United States. The price differential we are particularly aware of in my home State of Maine, because consumers often do go across the border to Canadian drug stores to get the prescription drugs that they need.

For example, a drug commonly used to treat Type II diabetes costs $124.65 in the United States and just $26.47 in Canada. It simply does not seem fair that American consumers are footing the bill for the remarkable yet costly advancements in pharmaceutical research and development, while our neighbors just across the border receive exactly the same medications at substantially lower prices. And that is why I have long supported legislation to allow American consumers to benefit from international price competition on prescription drugs by permitting FDA-approved medicines to be reimported into this country.

But I am also concerned that we make certain that reimportation is done safely and responsibly. As Senator Levin mentioned, this is not likely to be a problem when we are dealing with a country like Canada, but as the evidence that Senator Coleman has outlined in his opening statement, it can be a very serious problem in dealing with imports from other countries.

Today's hearing focuses on a closely-related issue, and that is the safety challenges posed by the sale of prescription drugs over the Internet. The Internet offers many advantages for on-line shoppers—convenience, competitive prices, privacy, and easy access to health and medical information. Moreover, through the Internet, individuals with disabilities, the elderly, and patients living in remote areas can more easily obtain the information, medicines, and services that they previously could acquire only with great difficulty.

It is not surprising, therefore, that the number of on-line pharmacies has increased dramatically from the 190 identified by the General Accounting Office in October 2000 to an estimated 1,400 sites in April of this year.

While on-line drug sales by reputable pharmacies can have many advantages for patients, they nevertheless present unique challenges for regulators, law enforcement, and policymakers. Years ago, when I was in State Government, I was responsible for the Board of Pharmacy, so I am well aware of how State regulators inspect pharmacies, something that is very difficult to do if you are dealing with an on-line entity.

Much more problematic, however, are rogue on-line pharmacies that sell unsafe or counterfeit drugs that can be a prescription for disaster for unwary consumers. I have been particularly alarmed by recent surveys which have found that more than 90 percent of on-line sites do not require a prescription or even validate that there is a legitimate patient-physician relationship behind the prescription.

The avenues for drug abuse that are provided by such pharmacies are painfully obvious and have caused much heartache to the family members who will be testifying before us today.

I believe we need legislation to protect consumers from these rogue Internet pharmacies, and that is one of the reasons why I have joined with the Chairman in cosponsoring Senator Gregg's Safe Import Act, which establishes Federal licensing requirements for all Internet pharmacies. It also requires the verification of a legitimate patient-prescriber relationship and establishes verification procedures for all prescriptions. No longer could a teenager go on-line without having a valid prescription and be able to get powerful addictive drugs sent through the mail via the Internet pharmacy.

Mr. Chairman, while I believe that we must do all that we can to make prescription drugs more affordable—and that includes passing a reimportation bill this year—we must also ensure patient safety. These hearings are a very important part of that process and will help ensure that we reach that goal.

Thank you for your leadership.

Senator COLEMAN. Thank you, Senator Collins. Senator Lautenberg.

OPENING STATEMENT OF SENATOR LAUTENBERG

Senator LAUTENBERG. Thanks, Mr. Chairman, and my compliments for the work you have done thus far. It is really critical to focus on what the problems are that would have people who in many cases desperately need these materials, these drugs, these products, and often are forced to make choices between food and medicine. That is a terrible place for anyone to be, and we ought to do what we can. We certainly do a lot to help people afford food in this country, with food stamps and things of that nature; yet the pharmaceutical needs are often unable to be met, and people resort to anything they can do to get their hands on these products. And it is understandable, whether you feel pain or you have other effects of illness that can be relieved, we certainly have a responsibility to deal with it, and I think you are doing it in a forthright fashion, and again, I commend you for it.

I noticed a coincidence here, my three colleagues sitting on this Subcommittee with me all have borders that touch Canada. Accessibility to the marketplace is quite interesting, and people are pushing very hard.

I come from the "medicine chest State" in the country. New Jersey is the place where so much is manufactured. These are responsible companies that invest huge sums in research, and many of these research attempts turn out to be fruitless after years and millions of dollars. But that in no way excuses the fact that you have different pricing structures in one place, radical differences that are avoided in another place. And we have got to do what we can to get these prices down.

Again, I am pleased that we are examining what the problems are with importation, or reimportation as it is called, because when we heard Senator Levin's commentary about the safety of products coming from Canada, it starts to question the rationality of saying, well, the safety issue, because we have lots of problems within our own society with mixes of drugs that produce terrible effects, including death in many cases. So we have to be aware of that and scrutinize it very thoroughly.

Unfortunately, the FDA does not have the funds available to it to provide the kind of monitoring that we need, and when we look at what is out there in front of us, and we see that on-line pharmacies offer advantages—lower prices, easier accessibility, improved privacy—and many of these on-line pharmacies are legitimate businesses that do offer safe and convenient services and products similar to those provided by traditional pharmacies, and other on-line pharmacies engage in practices that are illegal, such as selling unapproved or counterfeit drugs, or dispensing drugs without a prescription. But the question is how can we protect consumers and regulate rogue pharmacies that peddle counterfeit medications, sell drugs without a doctor's prescription. There is a constant search. I use a local pharmacist, and he tells me about the number of times that suspicious prescriptions have come across his counter.

So this is not a problem that is exclusively of on-line companies or reimportation. Since 2000, the number of counterfeit cases that the Food and Drug Administration has investigated has quadrupled, and it is obvious to me that the trend is going to continue. Americans looking for cheaper drugs online, especially from pharmacies abroad, are taking some gambles with their health, but again, if it is a choice that is so desperately motivated, then people do take risks in those conditions.

Last November, the *New York Times* reported that Internet pharmacies have recently sprung up that claim to be based in Canada and do business from another country, using a Canadian domain name. We need to investigate these on-line pharmacies, but we also need to consider, as has been said, the underlying issue—what is driving consumers to risk their health by purchasing drugs from sources that they are not familiar with.

The answer is obvious—the lower price that they can get these products for is very appealing. And we have got to protect consumers from fake drugs and unscrupulous on-line pharmacies. But we also must recognize that consumers, particularly the elderly on fixed incomes or modest-income families, are flocking to the Internet because it is the only way they can afford to buy these essential products. Prescription drugs in this country cost much more than people can generally afford to pay.

Today we are looking at ways to regulate on-line pharmacies, protect consumers more effectively, but we cannot ignore the real problem, which is that prescription drugs in many cases are way too expensive, and ultimately, we have got to find ways to lower prescription drug costs for all Americans.

Here, I will say that I have invited, and I extend the invitation again to those in the pharmaceutical industry to come forward and offer their ideas about how we can modify these prescription drug prices and equalize them, whether they are purchased in Canada or purchased here. Yes, we want to avoid price-fixing as is done in Canada, but the fact of the matter is that when the difference can be as much as 50 percent, you are talking about sums of money that are really very tough for people to pry.

So, Mr. Chairman, once again, my compliments for doing this, and I look forward to hearing from our witnesses.

Senator COLEMAN. Thank you very much, Senator Lautenberg.

I would note that Senator Levin, before he left, and I were also reflecting on the fact that he, Chairman Collins and myself all represent States that border Canada, so this is a very personal issue for the folks that we represent.

I would also note that Senator Levin is managing the Defense Authorization Bill right now on the floor of the Senate and could not stay, but he is deeply committed to this issue of ensuring access to safe, affordable prescription drugs for his constituents and for all Americans, and I applaud him for that.

I would now like to welcome our first panel to today's hearing. I welcome Marcia Crosse, Director of the Health Care Team at GAO, and Robert J. Cramer, Managing Director of GAO's Office of Special Investigations.

As I mentioned in my opening statement, this morning, GAO is here to release the report of its investigation of Internet pharmacy website drug sales. The purpose of this hearing is to examine the extent to which consumers can purchase pharmaceutical and controlled substances over the Internet without a medical prescription or medical diagnosis and whether the pharmaceuticals that are pouring into the United States from foreign countries are counterfeit, unsafe, or legitimate.

I appreciate your attendance at today's important hearing, and I am anxious to hear the results of your investigations.

Before we begin, pursuant to Rule 6, all witnesses who testify before the Subcommittee are required to be sworn in. At this time, I will ask you to rise and please raise your right hand.

Do you swear that the testimony you are about to give before this Subcommittee is the truth, the whole truth, and nothing but the truth, so help you, God?

Ms. CROSSE. I do.

Mr. CRAMER. I do.

Senator COLEMAN. We will be using a timing system today, so when you see the amber light come on, you know it is time to wind up. If you have full written statements, they will be entered into the record at your request.

I understand, Ms. Crosse, that we will have you go first, followed by Mr. Cramer. After we have heard all the testimony, we will turn to questions.

Ms. Crosse, you may proceed.

TESTIMONY OF MARCIA CROSSE,[1] DIRECTOR, HEALTH CARE—PUBLIC HEALTH AND MILITARY HEALTH CARE ISSUES, U.S. GENERAL ACCOUNTING OFFICE

Ms. CROSSE. Thank you, Mr. Chairman. I am pleased to be here today as you discuss the safety of prescription drugs sold by Internet pharmacies. Various types of pharmacies offer prescription drugs over the Internet, including those that require a patient to provide a prescription, and other pharmacies that issue a prescription based on an on-line medical questionnaire or have no prescription requirement. My testimony will summarize the findings of a report that we are releasing today that examines issues surrounding the availability and safety of prescription drugs sold over the Internet as well as the business practices of certain Internet pharmacies.

My colleague Mr. Cramer will provide additional details on our purchases of narcotics.

At your request, Mr. Chairman, we examined the extent to which certain prescription drugs can be purchased over the Internet without a prescription; whether drugs sold by Internet pharmacies are handled properly, are FDA-approved and are authentic; and the extent to which Internet pharmacies are reliable in their business practices.

With respect to the availability of drugs, we were able to obtain the majority of prescription drugs we targeted for purchase from a wide variety of Internet pharmacies without providing a prescription. We obtained a total of 68 drug samples, each from a different pharmacy in the United States, Canada, or other foreign countries, including Argentina, Costa Rica, Fiji, India, Mexico, Pakistan, the Philippines, Spain, Thailand, and Turkey.

The samples included drugs with special safety restrictions that require close physician supervision. We also purchased addictive narcotic painkillers.

Some U.S. and all Canadian pharmacies where we purchased drugs required the patient to provide a prescription, but the majority of U.S. and all other foreign Internet pharmacies where we made purchases either issued prescriptions based on their own medical questionnaires or did not require a prescription.

With respect to the safety of the drugs, we identified several problems with the handling, FDA approval status, and authenticity of the drug samples we received from foreign Internet pharmacies outside the U.S. and Canada, but fewer problems among the samples received from U.S. and Canadian Internet pharmacies. None of the samples from these other foreign pharmacies included dispensing pharmacy labels that provided instructions for use, and only about one-third included warning information.

As you can see in this first figure,[2] some samples arrived with no labeling of any kind. As you can see, there is no information as

[1] The prepared statement of Ms. Crosse with an attachment appears in the Appendix on page 109.

[2] See Figure 1 of prepared statement of Ms. Crosse which appears in the Appendix on page 121.

to even what drug is supposed to be contained in the bottle much less how many pills to take or how frequently.

In our second figure,[1] you can see that we also received products with no warnings in English. All of the information that came in this package was printed in Spanish.

A majority of these samples displayed other problems associated with the handling of the drugs, such as three samples of a temperature-sensitive drug that were sent in envelopes without insulation. The product shown here requires refrigeration but was shipped from abroad in a regular envelope without any temperature control.

We also received five samples containing tablets enclosed in punctured blisterpacks, potentially exposing the tablets to damaging light or moisture. You can see in this figure[2] that this product arrived damaged, and this is a moisture-sensitive product.

Some of the samples we received from these other foreign pharmacies arrived in unconventional packaging, in some instances with the apparent intention of concealing the actual contents of the package.[3]

These are two unique shipping containers we received—one with the product packaged inside a CD case—as you can see, it was wrapped just in brown tape. Another product that we received was placed inside a sealed pop-top can and packaged in a box with a misleading label. This, as you can see, says "Gold Dye and Stain Remover Wax."

Manufacturers who tested the drugs for us reported that almost all of the drug samples from these other foreign pharmacies were unapproved for the U.S. market because, for example, the labeling or the facilities in which they were manufactured had not been approved by FDA. However, they reported that the chemical composition of all but four of the other foreign samples was comparable to the product that we had ordered.

Among the exceptions, two samples were found to be counterfeit versions of the product we had ordered—Viagra—containing a lesser amount of the active ingredient, and two samples had a significantly different chemical composition than that of the product that we had ordered—OxyContin and Accutane.

In contrast, all of the drug samples that we received from U.S. and Canadian Internet pharmacies included dispensing pharmacy labels; almost all including warning information; and none displayed evidence of mishandling.

Like the samples from other foreign pharmacies, most of those from Canada were also unapproved for the U.S. market. However, manufacturers determined that the chemical composition of all of these samples was comparable to the product that we had ordered.

With respect to business practices, some Internet pharmacies, mostly other foreign pharmacies, were not reliable in their business practices. We did not receive six of the orders that we placed and paid for, five of which were placed with other foreign Internet

[1] See Figure 2 of prepared statement of Ms. Crosse which appears in the Appendix on page 122.

[2] See Figure 2 of prepared statement of Ms. Crosse which appears in the Appendix on page 123.

[3] See Figure 1 of prepared statement of Ms. Crosse which appears in the Appendix on page 124.

pharmacies and one of which was placed with a pharmacy whose location we could not determine.

Also, we found that several of the drug samples were sent from locations that raised questions, such as from private residences.

We also observed Internet pharmacies that obscured details about the drugs sold, such as other foreign pharmacies from which we ordered brand name drugs but then received a generic or foreign version of the drug.

Finally, about 21 percent of the Internet pharmacies that sent us samples were found to be under investigation by DEA or FDA. Reasons for the investigations included allegations of selling adulterated, misbranded, or counterfeit drugs and providing prescription drugs where no valid doctor-patient relationship exists. Nine of these pharmacies were from the United States, one from Canada, and four from other foreign countries.

In summary, Mr. Chairman, consumers can readily obtain many prescription drugs over the Internet without providing a prescription, particularly from certain U.S. pharmacies and from foreign Internet pharmacies outside of Canada. Drugs available include those with special safety restrictions, for which a patient should be monitored for side effects, and narcotics, where the potential for abuse is high.

For these types of drugs in particular, a prescription and physician supervision can help ensure patient safety.

In addition to the lack of prescription requirements, some Internet pharmacies can pose other safety risks for consumers. Many foreign Internet pharmacies outside of Canada dispense drugs without instructions for patient use, rarely provide warning information, and in four instances provided drugs that were not the authentic product that we ordered.

Consumers who purchase drugs from foreign Internet pharmacies that are outside of the U.S. regulatory framework may also receive drugs that are unapproved by FDA and manufactured in facilities that the agency has not inspected.

Other risks that consumers may face were highlighted by the other foreign Internet pharmacies that fraudulently billed us, provided drugs we did not order, and provided false or questionable return addresses. It is notable that we identified these numerous problems despite the relatively small number of drugs we purchased, consistent with problems recently identified by regulatory agencies.

Mr. Chairman, this concludes my prepared statement. I would be pleased to respond to any questions that you or other Members of the Subcommittee may have.

Senator COLEMAN. Thank you very much, Ms. Crosse. Mr. Cramer.

TESTIMONY OF ROBERT J. CRAMER,[1] MANAGING DIRECTOR, OFFICE OF SPECIAL INVESTIGATIONS, U.S. GENERAL ACCOUNTING OFFICE

Mr. CRAMER. Thank you, Mr. Chairman and Members of the Subcommittee.

[1] The prepared statement of Mr. Cramer appears in the Appendix on page 130.

I am pleased to be here today to report on some of the results of our investigation of the sources of hydrocodone that we purchased without a prescription from eight U.S. on-line pharmacies. hydrocodone is an addictive narcotic pain medication, and illicite use of this drug has increased significantly in recent years.

We found that one can purchase hydrocodone from Websites on the Internet without providing a prescription or being examined by a physician, and the Internet pharmacies from which we made our purchases charge prices that are 3 to 16 times the prices charged by local retail pharmacies at which we inquired.

We concluded that those who participate in these Internet drug operations appear to be in the business of knowingly servicing and richly profiting from individuals who may purchase narcotics for illicit purposes.

We ordered and obtained hydrocodone from eight domestic Websites. Six purchases, each from different Websites, were dispensed by a single pharmacy. The two remaining purchases were ordered from two separate Websites and were dispensed by two other pharmacies.

We obtained the hydrocodone by completing on-line questionnaires in which a GAO staff member, whom I will refer to here as "the customer," claimed that he had pain.

In an attempt to determine the relationship between the Internet site and the pharmacy that dispensed the drug, we contacted one of the pharmacies that sent us hydrocodone. This purchase was made from a Website that claimed that customers had to undergo a complete physical examination in order to receive the narcotic. However, the customer obtained the hydrocodone without undergoing a physical examination or seeing or even speaking to a physician.

Instead, a physician's representative telephoned the customer and offered two options for satisfying the physical examination requirement. For $199, the customer could visit a physician at one of two clinics in the area where the customer lived, or for $49, the representative said that she would send paperwork that the customer could take to his own physician to fill out and return to them; and if the customer chose and paid for one of those options right then and there with a credit card, the physician would immediately issue a 30-day prescription.

The customer chose the $49 option and gave the representative his credit card information and subsequently paid an additional $190 for the hydrocodone.

After we received it, a GAO investigator posing as a relative of the customer contacted the pharmacy listed on the return address of the package in which it was delivered. The pharmacist confirmed that he had sent the drug and explained that he has a business relationship with a Website and with a physician who had sent him a prescription for it.

The investigator then telephoned the physician, who confirmed that he had prescribed the hydrocodone. The physician claimed that he never writes prescriptions for new medications for patients and that he always confirms that the patient has been on the medication in the past. But when the investigator asked the doctor whether he had actually spoken with his relative, the doctor re-

sponded that one of his associates had in fact spoken to the relative. He said that he has a staff of several people who make such telephone calls. He repeatedly asserted that the staff calls and speaks with the customer's physician who previously prescribed the medication, but he confirmed that the telephone number his staff had called with respect to our purchase was the telephone number of the customer himself, not that of a physician.

The physician indicated to our investigator that his Internet drug business is run from a clinic that he operates, but when asked the name of the clinic, it indicated that it is part of a health care network and gave a name that does not correspond to the name of any existing health care network we could find or to any medical practice with which this physician is in fact connected.

He said to our investigator, "Ninety percent of our business is for hydrocodone." He also said that he currently provides prescriptions for five different Internet drug sites and that he previously wrote prescriptions for two others that have been shut down.

During our visit to the site where the physician purports to operate a clinic, we saw no evidence of a health clinic. The site is a one-room storefront set up with several computers and telephones. The only individuals that we saw going to or leaving the location appeared to be employees, and there was no sign on the premises indicating that the business there was health-related. When one of the employees was asked what kind of business is operated at the location, she responded that they do "computer consultations."

When asked about the possibility of children buying narcotics through him, the physician claimed that the need for a credit card is the "safeguard to prevent that from happening," and "a kid should not have a credit card." However, he admitted that, in his own words, parents call him "all the time, saying that their children have gotten hold of their credit cards."

The physician repeatedly stressed that his on-line pharmacy offers a service for patients who do not have insurance. However, this assertion is patently false. To the contrary—the customer paid a total of $190 and an additional $49 consultation fee for 60 hydrocodone pills that can be purchased for an average price of about $26 at local retail pharmacies at which we inquired. Thus, we paid nearly 10 times the ordinary retail price of this drug because we did not have a prescription.

The street price, or illegal sales price, of hydrocodone that we bought online is about $5 to $6 per pill. Thus, we paid slightly less than the street price for this drug from this source.

Indeed, as I mentioned earlier, the prices that we paid for hydrocodone at all eight of the Websites from which we ordered it were 3 to 16 times the ordinary retail price charged for it at local pharmacies.

In sum, these Websites appear to purposely cater to hydrocodone customers who are willing to pay a substantial markup for the narcotic because they do not have prescriptions. Claims that these Websites provide a safe, inexpensive, alternative source of drugs for customers are bogus. Instead, they appear to be in the business of profiting from illicit drug use.

That completes my prepared statement. I will be happy to answer any questions that you may have.

Senator COLEMAN. Thank you very much, Mr. Cramer.

To both Ms. Crosse and Mr. Cramer, I am very appreciative of the work that the GAO has done. In a very short period of time—and as Ms. Crosse noted, this is a small sample here; we have not fleshed all the concerns or all the challenges facing the importation of drugs from Canada or other countries—but in a short period of time, you have done outstanding work, and this Subcommittee and this Congress is very appreciative. So I want to start by saying thank you.

Let me talk a little bit about the universe which we are dealing with, and there is some good news and some bad news in this. I am the optimist. The good news is that among those Canadian and American pharmacies that were sampled, the business practices were pretty solid?

Ms. CROSSE. Yes, Mr. Chairman. The problems that we had with the fraudulent billing were with other foreign pharmacies or in one case from a pharmacy where we could never determine the actual location of the pharmacy. We did not have that difficulty with pharmacies in the United States or in Canada.

Of course, some of the narcotics purchases are from U.S. pharmacies. All of our hydrocodone purchases are actually from pharmacies that are located in the United States.

Senator COLEMAN. But the concern is that you can get those narcotics by simply filling out a prescription online, at a minimum.

Ms. CROSSE. That is correct. Three of the sites also telephoned back to the customer with some follow-up questions, but at five of those sites, all that was required was to fill out the questionnaire online.

Senator COLEMAN. Let me take you back a step. You described in your testimony a counterfeit sample, and I believe this purports to be OxyContin, which is a very addictive narcotic.

Ms. CROSSE. That is correct.

Senator COLEMAN. One, do we know what country it was sent from?

Ms. CROSSE. We have been requested because of an ongoing investigation not to reveal that publicly. I would be happy to inform your staff.

Senator COLEMAN. Let me step back. From the consumer's perspective, if I am going online, attempting to do a Google search for "OxyContin," and I get a list of Websites, is there anything that—let us say hypothetically that this came from Pakistan or Turkey—is there anything that requires that Website to be identified as coming from Pakistan or Turkey?

Ms. CROSSE. No. For Internet pharmacies located outside the United States, they are totally outside any regulatory framework that we have in place. They can identify themselves or not identify themselves. In some instances, Websites identify themselves. We sought to try to trace to where their servers were located, to trace to where the payments were made; we also used the return address information on the packages when they arrived to help us identify where the pharmacies were actually located—but it is not a requirement, and it was not always there.

Senator COLEMAN. And weren't there some instances in the investigation where, even looking at return address or other informa-

tion, there was an effort to disguise where the pharmacy was actually located where the drugs came from?

Ms. CROSSE. Yes. There were discrepancies between information on the Websites and the shipping addresses for the packages that arrived.

Senator COLEMAN. So for all we know, this Website could be AllAmerica.com or it could be RoyalCanadianMountedPolice.com, and it could come from Bangladesh or Turkey or Pakistan, and the consumer would not know.

Ms. CROSSE. Our information is that it is from abroad.

Senator COLEMAN. But the consumer, sitting there, as he types in——

Ms. CROSSE. The consumer cannot necessarily tell.

Senator COLEMAN. Thank you.

One of the suggestions that Chairman Collins and I have supported would be having the FDA, even for extraterritorial pharmacies, give some kind of seal of approval which would mean they would investigate and check it out. Do you think that would be helpful to the consumer?

Ms. CROSSE. I think it would certainly be an extra layer of protection for consumers that currently does not exist.

Senator COLEMAN. What is contained in here is called Crixivan.[1]

Ms. CROSSE. Crixivan, yes, Senator. It is a drug for HIV and AIDS patients. Interestingly enough, it was packaged—that can had a sealed pop-top on it. When it arrived, we opened it and found inside an actual manufacturer's bottle of Crixivan. The manufacturer reports to us that it is the actual, authentic product, and that product, even though it came from abroad, was manufactured in an FDA inspected facility and is approved for distribution in the United States.

Senator COLEMAN. And in fact, it notes that it comes from New Jersey, where it is manufactured.

Ms. CROSSE. It took a long route to get here.

Senator COLEMAN. But what is fascinating is that the "Gold Dye and Stain Remover Wax free promotion sample" does say it is a product of Bassick Pharma and Chemicals in Istanbul, Turkey.

Ms. CROSSE. Yes, sir.

Senator COLEMAN. Do we know if that is where this came from?

Ms. CROSSE. We believe that this came from Turkey. The Website and the shipping information led us to believe that the pharmacy we ordered from was in Istanbul.

Senator COLEMAN. Again, I want to get back to the consumer's perspective and what they are looking at, because we are working backward. We get the product, and we trace as best we can where it came from, but from the consumer's perspective, can you help us understand how a consumer would somehow make contact with this particular drug seller?

Ms. CROSSE. They could find it by searching on the Internet for a particular brand name drug. We checked for pharmacies that sold Crixivan. We were specifically looking for pharmacies—for each of the drugs we purchased, we looked for pharmacies that sold them in the United States, in Canada, and in other foreign coun-

[1] See Exhibit 30, which appears in the Appendix on page 315.

tries to the extent we could identify that from Website information. This Website, I believe, did identify that it was located in Turkey, so it was one that met our requirements for an "other foreign purchase." But a consumer could not always tell.

Senator COLEMAN. I believe you showed in one of your charts Roaccutan, which is a foreign version of Accutane.[2]

Ms. CROSSE. That is correct. It is a foreign version of Accutane, which is an acne treatment.

Senator COLEMAN. And this is one where the instructions came in Spanish?

Ms. CROSSE. Yes, that is right. All of the information included with this package was in Spanish. This was a product that came from Mexico. It had no pharmacy dispensing label information on it, and anyone who could not read Spanish would not be able to read the warning. It is also a product that the FDA warns against purchasing over the Internet because it has severe side effects and requires close monitoring by a physician.

Senator COLEMAN. And particularly for women who are pregnant, this is a very dangerous drug.

Ms. CROSS. That is right. It is something that causes birth defects. It is a very dangerous drug for women of childbearing age.

Senator COLEMAN. Mr. Cramer, the physician—I was stunned as I listened to you recount the conversation with the physician, who indicated that parents had in fact called him to raise concerns.

Mr. CRAMER. Yes. His words were: "Parents call me all the time, saying that their children have gotten hold of their credit cards."

Senator COLEMAN. I am amazed your investigator restrained himself from asking about conscience.

Mr. CRAMER. He did. We wanted to encourage him to keep talking rather than turn him off, and as a result, he did give us a lot of very good information which we have been able to present to you today.

Senator COLEMAN. And it is clear that there is nothing in place that would stop a child age 16, 17, perhaps 13 or 14, who had dad or mom's credit card from purchasing hydrocodone?

Mr. CRAMER. It seems that the key thing here is having a credit card. Five of the sources of hydrocodone never made any phone calls to the customer, so that all you had to do was get on the Internet, fill out the questionnaire and have a credit card number, and that was it for those five, and the three made phone calls, but as I explained with respect to our transaction, in which it appears that there actually was a physician involved, the phone call is a window dressing rather than any kind of true consultation.

Senator COLEMAN. I think you were being generous in your testimony when you stated that the folks involved in these particular pharmacies that were subject to your investigation—you used the words "appear to be" in the business of profiting from individuals seeking to illegally obtain drugs.

Would you go further than that, not that they "appear to be," but that your investigation demonstrated very clearly that the individuals here were generating great profit from providing drugs to folks

[2] See Exhibit 28, which appears in the Appendix on page 313.

whom they had no idea whether they in fact had a prescription or who they were—they simply had a credit card.

Mr. CRAMER. Certainly based on the prices alone, it is clear that there is big profit in this business.

Senator COLEMAN. I will turn it over now to Senator Lautenberg. Thank you, Mr. Cramer.

Senator LAUTENBERG. Thank you very much, Mr. Chairman, and I apologize for not having been in the room when these very credible witnesses were testifying.

We are looking at situations here that almost extend beyond the fact that there is some risk in obtaining these products outside normal channels, and the price differences are driving much of this discussion, but if there is an addicted person in the house, and that person is obtaining his drugs over the Internet or across the borders, the fact of the matter is that this person, if he is truly an addict, is going to find other means, and it has little to do with whether they are rogue pharmacies on the Internet or, again, cross-border transactions.

So we are not doing a review of addiction and the problems that follow in that kind of situation, but it is part of the overall problem. And when we look at the results of these investigations and we see that in many cases, these products are delivered in the kind of packaging that we see as original packaging right here in our own country, that in many ways, the safety is practically assured, but the price differential is still going to be enormously attractive to people—here is a product where they can see the container, the packaging, often the instructions are in there as they are if we buy the product in an unopened container—so the problem that results is how can we possibly monitor all of these things.

Should the FDA be more involved? They are terribly short of funds. Which agency do you think should be taking the lead apart from your investigatory responsibility? Should the FDA be more involved? Should we be looking to increase their funding in the interest of the consuming public here? What do we do about this enormous problem?

Ms. CROSSE. Well, Senator, in the United States, the FDA is the Federal agency with the lead responsibility for ensuring the safety of the prescription drugs that are sold to consumers, and their jurisdiction currently does not extend to these foreign Internet sites and the drugs sold there.

Some of the products that come in through these Internet sites are in facilities that are inspected by FDA either because the manufacturer has shipped U.S.-made products to Canada for sale there, or in some instances, because the manufacturer has a facility offshore where the manufacturer imports to the United States, so they have a facility offshore that the FDA already inspects.

So there is some cross-border activity that is covered by the FDA. They could speak to you in greater detail about the extent of that coverage. However, they are certainly currently the most qualified to take on this issue if you want to extend Federal oversight to pharmaceuticals coming in from other countries.

Senator LAUTENBERG. The question that arises is if there is a discount of approximately 37 percent on average by buying drugs in other countries, can we convince people that the risks of order-

ing from outside the U.S. boundary or an Internet pharmacy outweigh the financial benefit to these consumers?

Ms. CROSSE. I think it depends on the product that you are buying and where you are buying it from. I think it is very difficult right now for a consumer to make that determination, however.

Senator LAUTENBERG. But that is not necessarily going to curtail their search for a cheaper product.

Ms. CROSSE. No, sir.

Senator LAUTENBERG. Thanks, Mr. Chairman.

Senator COLEMAN. Thanks, Senator Lautenberg. Chairman Collins.

Chairman COLLINS. Thank you, Mr. Chairman.

Ms. Crosse, how did the GAO select the Internet sites from which you purchased these drugs?

Ms. CROSSE. It is not a random sample. There is no list of Internet sites that exists from which one can make a random selection. We had certain criteria in mind that we were looking for. As I mentioned, we were searching to find Internet sites in the United States, in Canada, and abroad, in other foreign countries, for each of the drugs that we were seeking to purchase.

We also searched to find sites that required prescriptions, those that had on-line questionnaires, and those that had no prescription drug requirement.

So we had certain criteria that we were trying to fill. We began with a list of over 1,400 Internet sites that the FDA passed along to us. This was not their list of sites under investigation; it was a list that they had developed, and some of the information had been provided to them from others who have conducted such investigations.

In addition, we conducted our own Internet searches using a variety of search engines such as Google and Yahoo! and Excite to try to identify different Internet sites that would meet the criteria that we set forth.

Chairman COLLINS. Thank you.

Mr. Cramer, it seems to me that we have two serious problems. First, we have consumers who are looking to save money by shopping for their drugs over the Internet who may be at risk of receiving unsafe, contaminated, or even counterfeit drugs; and then we have a second serious problem of consumers with problems with addiction or teenagers who are looking to experiment who are not particularly concerned about price but rather are looking for a way to get drugs, narcotics, for which they are not entitled.

I want to take you through your testimony to illustrate the second problem.

In any of the cases, did you have to submit a prescription in order to get access to the hydrocodone?

Mr. CRAMER. No. We provided no prescription with respect to any of the eight purchases we made.

Chairman COLLINS. And did a physician interview you to make sure that it was an appropriate medication for your investigator?

Mr. CRAMER. In five instances, there was absolutely no telephone contact with anyone. We filled out the questionnaire, gave the credit card information, and got the drug. In three instances, we received a return phone call. We know in the one instance that we

looked into very carefully that it was not a physician who spoke to our customer. In another instance, the individual identified herself as a customer sales representative of a physician. And in the third instance, it is unclear whether that person was a doctor or not. That was left very ambiguous during the course of the conversation.

Chairman COLLINS. In none of the eight cases was there a physical examination by a qualified health care provider?

Mr. CRAMER. That is right. There was never a physical examination.

Chairman COLLINS. And as I understand it, in the six purchases from six different Websites, you were able to trace the prescription back to a single pharmacy?

Mr. CRAMER. That is right.

Chairman COLLINS. So a single pharmacy in a southeastern State was supplying the drugs that were ordered on six different Websites; is that accurate?

Mr. CRAMER. That is correct.

Chairman COLLINS. How did you determine that? Was it obvious when you received the drug, or did you have to do some investigative work to determine that?

Mr. CRAMER. In three instances, it was obvious from the return address identified on the package. In three other instances, although it came from the same pharmacy, there was an intermediate delivery channel so that particular pharmacy was not in fact identified, and we had to do some further investigation to track down through the intermediary who in fact the source was.

Chairman COLLINS. And I assume that southeastern State in which this pharmacy is located has a typical law that would require a prescription to be presented at the pharmacy before the drugs could be dispensed. Is that a correct assumption?

Mr. CRAMER. I believe that is the case here, yes.

Chairman COLLINS. Was there any referral by the GAO, or has there been a referral yet by the GAO, to the State licensing board?

Mr. CRAMER. We have been in touch with both law enforcement authorities as well as State authorities with respect to our findings to date, to advise them of what we found and to refer to them so they could take further action.

Chairman COLLINS. Thank you.

Mr. Chairman, I think this is an excellent example of how one rogue pharmacy can use the Internet to reach so many people and to actually be involved in six different Websites—and there may be many more, since obviously, you did not look at all 1,400. So I think you are really doing a valuable service in examining this problem. Thank you.

Senator COLEMAN. Thank you, Senator Collins. Senator Pryor.

Senator PRYOR. Thank you, Mr. Chairman.

I concur with Chairman Collins' analysis. You are doing a great job here in getting us focused on this issue.

When I was the Attorney General of my State before I came to the Senate, we had responsibility for the consumer protection in Arkansas. We would always recommend to people in Arkansas that when they purchased drugs, they do it through their local pharmacist, because they are dealing with a licensed professional, they

are dealing with someone in their community, and if there is a problem, they know who to go to, they have recourse. And certainly we felt better because local pharmacists always require a prescription, etc., so we just felt like all the consumer safeguards and the integrity in the system was there.

But given the high prices of prescription drugs in this country, certainly there is a lot of incentive for people to get online and go elsewhere, and in that industry, on-line pharmacies are now a reality.

I would like to ask you a few questions, and either of you can answer. First, if you know, what percentage of on-line pharmacies that you have experience with or have dealt with are legitimate, following all the rules, going through all the procedures that we would hope and expect—how many of these are really operating in a way that we would feel satisfied that the integrity of the system is being protected?

Ms. CROSSE. I think we really cannot answer that. There is no known universe of Internet pharmacies. They change constantly. We observed in our searches that some of the Websites that were on the 1,400 that FDA provided to us had already closed when we went to look there to make a purchase.

There is a very small number of pharmacies participating in a program where they seek certification from the National Board of Pharmacies, but I believe that is a handful of pharmacies, fewer than 20, I understand.

However, I do not think that alone is the signal of whether or not they are dealing honestly and meeting requirements. I am sure there are other pharmacies out there who just have not sought certification who could meet those requirements.

Senator PRYOR. All right. Let me ask that, because this is something that Chairman Coleman mentioned a few moments ago. It seems to me that maybe there should be some kind of seal of approval or some process that these companies go through, and when they meet certain criteria, they get a seal of approval or whatever you want to call it that they can display on their Website so the consumer knows that they have met all of these thresholds.

What you are saying is that only a very small percentage of the on-line pharmacies are participating in such a program?

Ms. CROSSE. That is right. This is a voluntary program from their national association. As you may be aware, pharmacies are regulated at the State level, so each State has its own controlling statutes and regulations. There is currently no Federal regulation of pharmacies, and there is no Federal body that would be empowered to provide such certification of a pharmacy. This is something that is regulated by the States.

Senator PRYOR. Personally, I think that the industry or some independent nonprofit group could provide a seal of approval to give the consumers the comfort level and assurances that they need to go online.

Let me ask about some of your findings. As I understand it—and I do not want to put words in your mouth—but as I understand it, you found repeatedly that prescriptions were not required, a visit to a physician was not required. Were some of these drugs out-of-date as well?

Ms. CROSSE. Of the samples that we received from the manufacturer testing, none of those that we had could be determined to be out-of-date by the manufacturer. That certainly is true for some of the products that the FDA has investigated, but in our small number of samples, we did not find any that were out-of-date.

Senator PRYOR. OK. But there were other problems?

Ms. CROSSE. There were a number of other problems.

Senator PRYOR. I am about to run out of time, but I do want to ask you about the testing and the cost of the testing, because I think that is an important factor for us to consider.

First, on the testing, let me ask a two-part question, because I am almost out of time. Who did the testing, who paid for it, and also, could you give us a sense of the cost that is required in testing these products?

Ms. CROSSE. For each of the products that we purchased, we sought initially to buy brand name drugs. We made a decision mid-course to accept generic products for the hydrocodone because of the difficulty of finding enough sites where we could place orders of the brand name narcotics. The generics were much more readily available. However, for the other drugs—Lipitor, Celebrex, Crixivan—all of those drugs, each was tested by its manufacturer. We entered into an agreement with each manufacturer to conduct the testing for us, because they have the specs on their products, they could make the determination of what the chemical composition was, what it was supposed to be. They have the lot number information to know if it was a valid lot number, to know if it was outdated, to know if it was fully potent. So they conducted the testing for us.

I cannot speak to the price. They did it at their own expense for us and in service to us and to the Subcommittee and this investigation.

Senator PRYOR. Did we have anyone present there when they were doing it?

Ms. CROSSE. No, sir, we did not have anyone present in the laboratories. However, as part of this process, one of the reasons we were seeking to make purchases from what we call control pharmacies, these on-line pharmacies that are associated with big-name retail pharmacies such as Walgreen's or CVS, was to have a control sample. These were blinded to the manufacturers. They did not know which sample came from which country, which type of on-line pharmacy, which on-line pharmacy the product came from. So they had no knowledge; they only had a code number for each product when they did the testing.

Senator PRYOR. Thank you.

Senator COLEMAN. Thank you, Senator Pryor.

I have three very brief follow-up questions. One, Senator Collins in her line of questioning spoke about a single pharmacy that supplied multiple Websites. Do we know where this pharmacy got its drugs?

Mr. CRAMER. No. We do not have that information. This particular pharmacy has now been shut down, and we are unable at this point to probe any further with respect to that particular one.

Senator COLEMAN. Is there anything that prevents the principals involved in that pharmacy from getting back in the business?

[Pause.]

Senator COLEMAN. Ms. Crosse.

Ms. CROSSE. Not to my knowledge, unless they were prosecuted and perhaps jailed.

Mr. CRAMER. It is my understanding that there are pending proceedings with respect to that pharmacy and the principals.

Senator COLEMAN. That was my other question. I presume the results of your investigation have been turned over to the appropriate authorities for further criminal or any other type of enforcement actions?

Mr. CRAMER. Yes, and we will see what happens. But it is now being handled by law enforcement authorities who have taken action.

Senator COLEMAN. Thank you very much. Do any of my colleagues have questions?

[No response.]

Senator COLEMAN. If not, I will thank the witnesses again for outstanding work in a short period of time. We are very appreciative. Thank you very much.

Mr. CRAMER. Thank you.

Senator COLEMAN. I would now like to welcome our second panel to today's important hearing.

I welcome the distinguished former Mayor of New York City, the Honorable Rudy Giuliani, currently Chairman and CEO of Giuliani Partners. Mr. Giuliani brings with him his expertise in border security and public safety issues.

We appreciate you lending your expertise in security and international terrorism to assist us in developing recommendations to control the illegal flow of these unregulated rugs.

And finally, I would like to welcome Dr. Marvin D. Shepherd, Director of the Center for Pharmacoeconomic Studies at the University of Texas at Austin. Dr. Shepherd will discuss his study concerning the Canadian drug supply.

As previously mentioned, the purpose of this hearing is to examine the extent to which consumers can purchase pharmaceuticals and controlled substances over the Internet without a medical prescription or medical diagnosis; what role FDA, the Bureau of Customs and Border Protection, the U.S. Postal Service, and DEA play in preventing the illegal importation of scheduled pharmaceuticals or pharmaceuticals that are violative of the Food, Drug, and Cosmetics Act, and whether the pharmaceuticals that are pouring into the United States from foreign sources are counterfeit, unsafe, or legitimate.

I appreciate your attendance at today's hearing and am anxious to hear your observations on the current state of affairs.

Before we begin, pursuant to Rule 6, all witnesses before this Subcommittee are required to be sworn in. I would ask you to please raise your right hand and repeat after me: I swear that the testimony I am about to give is the truth, the whole truth and nothing but the truth, so help me, God.

Mr. GIULIANI. I swear that the testimony that I am about to give will be the truth, the whole truth and nothing but the truth, so help me, God.

Mr. SHEPHERD. I do.

Senator COLEMAN. Thank you.

You understand the timing—when the yellow light goes on, if you can sum up your testimony. Your full testimony will be entered into the record.

Senator LAUTENBERG. Mr. Chairman, just a side comment. The Mayor knows that when you see a red light, it does not mean stop—it means speed up.

Senator COLEMAN. I thought it ought to be a suggestion.

Mr. Giuliani, we will have you go first, followed by Dr. Shepherd, and after we have heard all the testimony, we will turn to questions.

Mr. Giuliani, you may proceed.

TESTIMONY OF HON. RUDOLPH W. GIULIANI,[1] CHAIRMAN AND CHIEF EXECUTIVE OFFICER, GIULIANI PARTNERS, LLC, NEW YORK, NEW YORK

Mr. GIULIANI. Mr. Chairman and Members of the Subcommittee, good morning, and thank you very much for the opportunity to present the results of the report that we are in the process of doing.

The availability of safe, effective, and reasonably priced medications for all Americans is without doubt, as you have all noted, a very important and very crucial issue for us. Individuals and even State and local governments have sought many different alternatives to see if they can find access to medicines for everyone at reasonable cost, and this is something that has to be pursued, and I commend you, the Members of the Senate and the House, who are trying to do that and to accomplish that.

But pricing, which is the principal driver and motivation for this, although extremely important, can overshadow the dangers that are created or could be created and actually exist now for the integrity of our medicine supply in the United States. So whatever solution we find has to be one that does not pollute the supply of drugs in the United States, or further pollute it, because there is already a pretty serious issue.

Under the current system, from what we have seen so far, there are already significant risks given the importation that takes place with regard to the dangers that are created for Americans, and based on what we have learned so far, there are serious concerns about the present quality of the medicines that people are buying and using. The FDA has warned repeatedly that if people continue to order prescriptions over the Internet or from foreign sources, it will create the danger not only for them but for the entire drug supply in this country that it will be polluted and not properly regulated.

In this regard, my firm, Giuliani Partners, has been retained by the Pharmaceutical Research and Manufacturers of America to conduct a study, of which we are about one-third completed, and we presented our preliminary views to you in a report which I hope you all have and have a chance to look at, and also to the Department of Health and Human Services' Task Force on Drug Importation which has been charged with the responsibility of determining

[1] The prepared statement of Mr. Giuliani appears in the Appendix on page 136.

how safe is the present system and what kinds of safeguards would be necessary if there were to be any expansion of the current system.

Let me very briefly state some of the things that we found and some of our preliminary observations—and I emphasize they are preliminary because we are about one-third of the way through the process of investigating this.

It is evident that the existing pharmaceutical system right now, as it presently exists, before you consider any further expansion of it, is open to significant exploitation for counterfeit medication and diluted, adulterated drugs. The limitations on the system that we presently have are significant.

The U.S. Surgeon General and the Health and Human Services Task Force are considering all of these issues, and the task force really has to complete its analysis before we have a basis on which we can figure out what to do about the present system realistically to make it safe, as safe as the American people deserve, which is a lot safer than it is right now, and then, what would be needed to expand that system and the safeguards that would have to be put in place.

It really is important—and I commend the Chairman and the Members of this Subcommittee for conducting this hearing—because part of the process also has to be putting the public on notice so that we deal with people honestly about the risks they are taking if they use the Internet or if they go to the alternative of seeking drugs from a foreign source. If people make that choice, they should at least be armed with the information that it is significantly different than, as Senator Pryor pointed out before, buying medicines at your local pharmacy. You are taking a risk. It may be a calculated one, but it is only a calculated one if you are on notice and you know the risk that you are taking.

The system has many problems. There is a lack of standardization, a lack of oversight of wholesalers; there is no chain of custody, no pedigree. The volume almost cannot be described. The testimony that you just heard from GAO was very instructive, very valuable, very important, but it talked about 68 samples, I believe. That is a minuscule percentage of what is coming into this country. It is something like 10 million packages a year. At the John F. Kennedy International Airport, where Senator Coleman and I had a chance to inspect the mail facility—which I believe is the largest or second-largest in the country for the receipt of any parcels as well as medications—they receive 40,000 packages a day allegedly containing medicines—40,000 a day. Their capacity—and again, this is one of the largest facilities in the country—allows them to inspect at best between 400 and 600 of those packages each day. So 99 percent are moving through totally uninspected, no one looking at them, no one having any idea of what is in them, and then they are able to inspect, in a fairly cursory way because of the lack of resources, only 500 a day. And that inspection has to be a very quick one and a very brief one.

When we visited there, which happened to be on March 17 of this year, they described it as a "fairly slow" period because there had been some delay in the obtaining of medicines, yet the facility was overwhelmed with medicines of all different kinds. We saw Xanax,

Valium, and Vicodin. As Senator Coleman pointed out, we saw Lupron that had been sent in from a foreign country—I have forgotten which country now, but not the United States, not Canada—it had been sent in from a foreign country. Lupron is a hormone that is administered to people with prostate cancer, and it has to be, should be, administered by a doctor, by injection. This packaging was adulterated. It had apparently been tampered with. There was Lupron, and there were the facilities and the devices for people to self-inject it, which would be extremely dangerous.

We also saw medicines that were expired—you could see it right on the label—I believe it was antibiotics—that were expired by 2 and 3 years, and all you had to do was examine it, and in many cases, antibiotics that are expired by a year or 2 years or 3 years are useless.

We saw what appeared to be adulterated medicines—the coloration appeared suspicious and strange; the packaging was unusual—and medicines from 14 or 15 different countries, including Pakistan, Spain, Greece, Italy, and some from Canada.

So the sheer volume that comes in—40,000 a day in one facility, 10 million a year in the United States—makes the ability to inspect under the present system, without any further increase in methods of foreign importation or Internet use—the present system is overwhelmed at this point, and it presents a threat. It presents a significant threat to the individual who is ordering by that method, because the percentage chance that they are going to receive the wrong medication or adulterated medication is significant. But it also presents a broader threat to this country. It presents the threat of polluting our drug supply because these medicines can also find their way into what appear to be more legitimate sources of medications. It offers an opportunity for organized criminals and for drug traffickers to take advantage, and for terrorists to take advantage.

Here we are going through a period of time in which we are trying the best way can to deal with our borders in a more orderly and a more secure way, consistent with being a country that is open to people coming here, people feeling that they can come here, and also open to doing commerce correctly. But we are trying as best we can to secure our borders. The whole idea of the Department of Homeland Security is to do that, have the Customs Service and the Immigration Service work together more effectively. And this is an area in which our borders are right now, I think it would not be unfair to say, wide open. If you have 1 percent or less of what is coming in inspected, the odds are that if you are operating in Pakistan, or you are operating in Spain, or you are operating in Greece, or you are operating in Turkey, you can calculate that there is a much better than 9 out of 10 chance, and maybe greater than that, that what you are sending into this country is not going to be inspected by anyone even if it purports to be a dangerous medication.

So from our analysis, our summary of our findings at this point, there is already a situation that needs further regulation, further technology, a lot more investment of resources so that significantly more inspection can be done at the vital, crucial point. Things are all going to go through mail facilities whether they are ordered by

phone or by mail or over the Internet. They are all going to end up in these mail facilities to be distributed to different parts of the United States in most cases. And at that crucial point, a great deal more has to be invested in inspecting properly, inspecting with modern technology, and creating a lot more safety for people in the United States.

The results of our preliminary study and the work that we are continuing to do are really no different than studies that have been done in the last 2 or 3 years by the FDA, U.S. Customs, and Border Protection. We have reviewed blitzes that they have done back in the fall and early winter of 2003. In the first one they did, 88 percent of the medicines they had a chance to inspect—that the FDA got a chance to inspect—were not approved by the FDA, and the drugs came from countries such as India, Thailand, and the Philippines. In the second examination, it was 87 percent that were coming in that were not approved, 16 percent of those shipments coming from Mexico. And a recent review of the Miami facility, which is very similar to the one at JFK, showed roughly the same percentages—no better than 1 percent being inspected, and the ones that were inspected, the overwhelming majority being unapproved either for technical reasons or for very serious and dangerous reasons.

So, given that, it seems to me that the focus of the Congress should be on how do we take the present system that we have and make it much more effective in terms of affording safety to anyone who is seeking to buy drugs from a foreign source or an Internet source. And then, after we have accomplished that, and we have accomplished that for some appreciable period of time—2 years, 3 years—then to take a look at how we would open things up to further foreign sources of medicines coming into the United States, because the present situation, without being an alarmist, is probably, even if you understate it, very dangerous and an area in which there can be, if there is not already, significant exploitation.

We would be happy to answer any questions about what we have found or any suggestions about how you would accomplish that.

Again we commend the Chairman and the Members of the Subcommittee for looking at this, because this is a very complex issue, and it has very big implications for individual Americans who are seeking medicines and access to them, but for all of us. Thank you.

Senator COLEMAN. Thank you very much, Mr. Giuliani. Dr. Shepherd.

TESTIMONY OF MARVIN D. SHEPHERD, Ph.D.,[1] DIRECTOR, CENTER FOR PHARMACOECONOMIC STUDIES, COLLEGE OF PHARMACY, THE UNIVERSITY OF TEXAS AT AUSTIN, AUSTIN, TEXAS

Mr. SHEPHERD. How are you all doing? Mr. Chairman, Members of the Subcommittee, I want to thank you very much for the invitation to come here today.

I have been studying drug importation mainly out of Mexico since 1994, and recently, in the last 3 years, have been looking at

[1] The prepared statement of Mr. Shepherd with an attachment appears in the Appendix on page 150.

it coming out of Canada. I have been pretty active in the area and nationally, trying to figure out what is a sound way of doing this thing on drug importation or reimportation, and how can we best go about figuring out how to do it.

There have been several congressional bills—and by the way, I have a written statement, and my report is also part of the record, on the Canadian market, but I am going to vary from my written statement because I do not want to be redundant of what has already been said, and I have inserted some new things.

We have had three bills, I believe—maybe four now—that have been introduced to make drug importation a safe practice and to make drug importation, most importantly, a safe and cost-effective alternative for Americans.

In addition, the legislative efforts of the Medication Prescription Drug Improvement and Modernization Act of 2003 has charged HHS to make a thorough examination of drug importation.

And as stated, as we stand right now in this country, I am absolutely opposed to any type of methodology to figure out how the drug importation is unless we change and get safety back into the issue. It is a huge risk for the American public. There are no doublechecks in the system. There are no prescription drug accuracy checks from pharmacists. There are no drug interaction checks from pharmacists. There are no drug-disease checks from physicians or pharmacists. There is virtually no counseling on the drug therapies coming in. You have lost total access to health care professionals.

To Senator Collins, who mentioned the two classes of people who are using the Internet, I will say there are three classes of people. You have the drug abusers; you have the people shopping for price; and you have the people who have the money, but they do not want to see a physician, and they want simple access. They want access because I can get anything I want without a prescription, and they can go out and buy whatever they want. I have seen that in Mexico—because in Mexico, they do not require prescriptions unless it is a controlled substance—so you see thousands of people cross that border every day, bringing controlled substances back, but they also bring back all kinds of other medications. It is straight access. Plus it is price there. It is cheaper in Mexico than it is in Canada, a lot cheaper. But it is both issues. So you have three types of people going down there to get pharmaceuticals.

The potential problems are very serious for those who obtain prescription drugs via the Internet—very serious, as already pointed out—and I am not so sure on the Canadian market, as some people have already purported in this room. Right now, we have one Canadian Internet site forwarding prescriptions to England. They are being filled there, and Americans are getting their prescriptions out of England and not out of Canada.

I am also aware that a Scrip article reported that one Canadian Internet pharmacy provider is shipping pharmaceuticals which are made in Mexico to U.S. residents. The article goes on to say that the products of Mexico coming in through Canada as a drug diverter have not been approved by Health Canada and have not been approved by FDA.

Furthermore, my research—and in this report, I point out to you that in 2003, Canada imported pharmaceuticals from over 80 different countries. Now, Canada has good manufacturing agreements with 18 different countries, mainly Western Europe, and you would expect Canada to import from Ireland, Scotland, France and Germany. You would expect that because they have mutual recognition agreements. But I did not expect to find Canada importing drugs from Ecuador, Chile, Brazil, and all the other countries that make up the 80.

From 2002 to 2003, Canadian imports from India increased by 109 percent, or have doubled; Singapore, they are up 72 percent; Mexico, they are up 50 percent; and Italy, they are up 283 percent.

Even U.S. pharmaceutical exports to Canada have increased. From 1999 to 2003, our exports to Canada have gone up $1 billion. I think that is a significant amount of drugs going into Canada. But what is interesting is that our portion of the total imports that Canada gets is shrinking. In the year 2000, U.S. drugs comprised 55 percent of all Canadian imports for drugs. In the year 2003, it is down to 43 percent of all imports to Canada. So the Canadian market is decreasing for U.S. drugs in the source chain, and other countries are taking hold of that source of pharmaceuticals.

I understand the plight of individuals having a 91-year-old mother-in-law or an 80-year-old father or mother struggling with prescription drug prices. I understand that completely.

However, I am not too sure that the anticipated savings from importation will justify all the procedures that goes along with importation to make it safe. I am not convinced of that. And some one has to do some studies—either GAO or the FDA has got to look at this very seriously and ask what would it take to import drugs and how cost-effective that would be.

There are 250,000 drugs manufacturers worldwide. You have 1,400 just in Bombay. You have 6,500 in China. To bring all those products in and inspect from what country they are coming from and make sure they are safe is a tremendous task. You have got to do some modeling, hire some people to do some kind of statistical modeling, to figure out what would be the cost impact. If we are only talking about a 30 percent savings, I have a feeling that the intermediaries in the process will take it all away, and the consumer will have nothing in the end. That is not what we want. We want to get prescription prices lower. We do not want the wholesalers and the intermediaries to take off the cotton, and we are left with the stem at the end. That is not fair to the American public. But before we embark on that, we need to seriously look at that and go after it in some kind of modeling.

One potential negative consequence of the program that permits pharmacies and wholesalers to import pharmaceuticals is that it may develop a two-tier pricing system in the United States. I am speaking now as a pharmacist—a two-tier system where you have some pharmaceuticals imported in a store, and you have some pharmaceuticals that are U.S.-made. That has me scared, because a lot of third-party pay plans, including Medicaid reimbursements programs or whatever it is, will gradually shift to the imported product because it is going to be less. I do not know how a pharmacist is going to deal with these two-tier programs if you have a

differential in the price of U.S.-made products and imported products in a store. I do not think that has been mentioned. I raised it with the HHS Task Force on Drug Importation that it needs to be looked at seriously.

The last point I want to raise is that it will definitely hurt the generic drug industry. I cannot see the generic drug industry developing new drugs when the imported drug is probably 20 or 30 percent below the brand name drug. I am not so sure they will invest the money for that generic drug industry product when it comes down to that end. I do not know the answer to that, but it just raises that question—how can you foster the generic drug industry and at the same time bring imported drugs that are cheaper than the generics?

I want to close in the last 38 seconds and say I really believe that more data are needed. The likely impact of importation and the cost of drugs needs to be looked at in a really sophisticated manner. I am opposed to proposals that would allow importation of prescription drugs that leave the safety issue out.

I really urge you and others to let the professionals at the FDA do what you charged them to do in the Medicare bill—let them look at the issue thoroughly, run the numbers, answer some questions, and come up with a proposal for everybody to look at.

I thank you very much.

Senator COLEMAN. Thank you, Dr. Shepherd.

Dr. Shepherd, let me start with you. You mentioned Health Canada. Does Health Canada have any regulatory authority or power over Internet drug sites?

Mr. SHEPHERD. Each province has regulatory authority over each Internet site, and you will see differences from Ontario all the way to Manitoba. Ontario is pretty strict with them and basically does not allow them, versus Manitoba, where it is a free-for-all with 60 to 80 Internet sites out there.

What is really important is that the Canadian rules and regulations do not require approval by Health Canada for drugs exported out of Canada. That is the clincher. If we can get Canada to say we will approve those drugs that are exported, that would be all right.

Coming from the Detroit area originally, I had no problem going across to Windsor to buy a drug at a store, but I do have some serious concerns with going to the Internet in Canada to buy a drug.

Senator COLEMAN. And just on that last point, these Canadian providers are not your neighborhood Canadian pharmacy. In fact, would it be fair to say that for many of them, their sole business is exporting to the United States rather than meeting any Canadian needs?

Mr. SHEPHERD. Yes. There are a half a dozen where that is their main business.

Senator COLEMAN. And you did not testify, but it is in your written report, that clearly, the Canadian market does not have the capacity in itself to supply American drug needs, so is the conclusion from that that they will have to turn to other countries and in effect be a flow-through to satisfy U.S. market needs?

Mr. SHEPHERD. Yes. Can I explain that in just 2 minutes?

Senator COLEMAN. How about 30 seconds?

Mr. SHEPHERD. Thirty seconds, OK.

The Canadian market right now as it stands would only take care of U.S. needs for 38 days. That means that if the United States wanted to buy all its drugs out of Canada, it would last 38 days, and that would be the total annual consumption by Canadians. They only have 300 million prescriptions. We dispense 3 billion. They could not handle it.

So now, with a shortage of supply of drugs coming into Canada—and you get conflicting reports on that—they are going to other countries and other sources to buy their product, and the numbers seem to point that out. They have gone to other sources for their product.

Senator COLEMAN. Mr. Giuliani, I want to get right to the issue of terrorism, and you touched upon it. Just an observation—we see one cow infected with BSE, mad cow disease, from Canada, and we literally shut off the importation of any Canadian beef. We have in this hearing seen drugs coming in from other countries, foreign countries, but nothing to prevent a pass-through, yet we are talking about expanding the importation of drugs, and some of us have been very emphatic about the safety issues.

I will say it publicly—is there anything to stop a terrorist from setting up an Internet site, giving it a red, white, and blue label, providing prices that are so low that consumers concerned about price would think they were getting the best buy ever, and somehow adulterating those medicines with some substance that could have a disastrous impact on the lives of citizens in this country—is there anything today to prevent that?

Mr. GIULIANI. Well, I hate to answer that question, because——

Senator COLEMAN. I hate to ask that question.

Mr. GIULIANI [continuing]. You do not want to suggest anything to anyone—but the reality is that I do not think we are suggesting anything that they could not figure out themselves.

It is pretty much right now a wide-open system with, as I said, 10 million packages a year coming in. The ability to inspect—I am not even sure what the overall percentage is; the percentage at Kennedy is about 1 percent, and I suspect the percentage nationwide is even less than that. So for 99 percent or more of what is coming in, you can rely on the fact that it is not going to be inspected.

There is no really good field test. My experience in my early life before I was mayor was as a U.S. Attorney, an assistant U.S. Attorney and Justice Department official, where we often dealt with the problem of heroin, cocaine, and the traditional narcotics. And at least for those, there is a field test so that if you suspect that there is heroin or cocaine, you can open the package, and you have a fairly reliable field test that will tell you whether it is or it is not.

For most of these, as GAO demonstrated, there is no really good field test. It requires extensive and very expensive analysis by the pharmaceutical company to determine whether or not this is in fact the medication that is ordered, whether it is safe, whether it is the right dosage. So this is a system that is open for exploitation.

Global Options, Incorporated did a study that is now at least a year old—it may be 2 years old—in which they looked specifically

at the potential threats to America in its medical supply and concluded that the threats were very significant and demonstrated what they think they are. I really recommend that. They actually looked at three possibilities—the ability of terrorists, of organized criminals, and of drug traffickers to take advantage of this system.

And then there is one general concept that is enormously important. If the borders of this country are porous in any way, that is the area in which people can take advantage. If you are going to secure our borders, you have to secure them. We have to be more secure in determining the people who are coming into this country, but if we are more secure in determining the people who are coming into this country but not the things that are coming in, we have not accomplished anything, because then, people do not have to come in—all they have to do is send things in. And in an era in which we are trying to figure out a better way to regulate our borders, it would be counterproductive—we would be moving in the opposite direction—if we were to say, well, let us open our borders even more to foreign importation of medicines, which is a way, frankly, as you are asking me, Senator, of attacking us.

Senator COLEMAN. Thank you. I am going to turn to Senator Lautenberg, since he has been here since the beginning. Senator Lautenberg.

Senator LAUTENBERG. Thanks very much, Mr. Chairman.

Mayor, welcome. We have had a lot of contact over the years, and I am glad to see you at work on this project. Your concern about the lives and well-being of our citizens is well-known, and that is also something that is considered here as you pursue this research.

I have enormous respect for the pharmaceutical industry. As a matter of fact, at my stage in life, rather than turn to the sports pages, I turn to the Federal pages and see what is coming along and urge them to hurry up. So we want this research to go on, and we want to make sure that the products that our people buy are safe.

But the cost factor is an enormous difficulty for lots and lots of people. There are people, as I said earlier, who would do without food at times so they can continue to have the drugs they need, whether it is to get rid of the tremors or preserve memory or have their hearts continue to function as they should—all of these things. It is a desperate search for relief. And, unless we understand that, we are kind of fooling ourselves. That is an overriding consideration.

So, why do you think, Mayor, given all the risks that you have highlighted, people continue to buy their drugs over the Internet or from unreliable sources as they seem to be?

Mr. GIULIANI. I think, Senator, you have hit on one of the reasons. Obviously, it is the pressure of lack of access and high cost. There is no question that your efforts, those of Senator Coleman, all of you on this Subcommittee and in the Congress, to try to find ways to reduce the cost will also ease some of this pressure. That is a very important component of this.

But you said something in your opening statement that occurred to me. You said that we do a lot in this country to create access to food for people who are hungry and starving; there are all kinds of programs that we have to feed people—I am very aware of them

in New York City, but they are all over the country. But when we do that, we do not look for programs that are going to make the supply of food more dangerous. We do not look for programs that will pollute the food supply in this country. And the pressure of accomplishing this cannot lead to creating even more danger for the American people. That is why taking a realistic look at the way this system operates now and what can be done—some of the approaches—and I think it is for absolutely the right motivation, which is how do we lower the cost of medicines—some of the approaches are very unrealistic about the dangers, because there is such a desire to produce the result of low cost.

Dr. Shepherd raised the issue whether we will actually even produce that result, but that is the motivation. And you just cannot wave a wand and create the safety. It is going to need significantly more resources. It is going to need a period of time in which we can take the system that we presently have and make it work better before you can figure out how to expand it.

And from Canada, the experience we had, which I neglected to mention earlier in my statement—which I would have liked to ask GAO, but I imagine you can ask them this—we found that the Internet pharmacies in Canada required a waiver signed by an American. I find that extraordinary.

Senator LAUTENBERG. I would like to ask Dr. Shepherd, how is your research being funded?

Mr. SHEPHERD. By me.

Senator LAUTENBERG. By you, personally?

Mr. SHEPHERD. Personally, yes with the help of the University of Texas. My group of graduate studies—I have 38 graduate students, and I chose four of them, and we did this study in 3 months.

Senator LAUTENBERG. You indicated that you were concerned about the supply of drugs that would be left in Canada if we just opened up this importation process of ours. We could ship more, we could export more. You talked about the exports growing, and then you talked about the percentage of reimportation shrinking. I do not know what that signifies except that maybe there is arithmetic ratio here that we are not looking at. If the export supply is growing, then perhaps it is faster than the reimportation factor.

So I do not think that is really the key issue here. I would ask you this. If we could bolster—you are concerned about safety, and you have a professional background that indicates that you have been in the field—if we could deal with the safety factor, would you say open the doors to reimportation?

Mr. SHEPHERD. Yes. I would say you could probably do it if you could assure the quality of the product and assure that people understand how to take the product.

There are two safety issues. You have the commodity, the product, and then you have the safety issue—do people understand how to use the product properly. You have to incorporate both of them together.

Senator LAUTENBERG. I will close, Mr. Chairman, with an observation and a question. That is, with the flow of illegal drugs into this country that kills people, that disrupts our society totally, and we have devoted enormous amounts of resources to stopping that flow, but we cannot do it. And here, with this, we are not spending

anywhere near enough time looking at these products to really determine what the efficacy of the product is. I thank you, Mr. Chairman.

Senator COLEMAN. Thank you, Senator Lautenberg. Senator Pryor.

Senator PRYOR. Thank you, Mr. Chairman.

Mr. Giuliani, let me say at the outset that sometimes the industry may perceive that here in Congress, we are just beating up on the industry all the time, but certainly I recognize—and Senator Lautenberg just mentioned as well—the advances that the pharmaceutical industry has made, and some of the things they have done are just absolutely amazing. But I assume you would agree with me that some of the prices for pharmaceutical products in this country are too high?

Mr. GIULIANI. There is no question about that, and that is one of the driving forces in what is going on here.

Senator PRYOR. Yes. And I am glad to know that—I am sorry, I did not quite catch who funded your research——

Mr. GIULIANI. PhRMA.

Senator PRYOR. I am glad to know that PhRMA is doing this, because it indicates to me that they are starting to get serious about this issue. Can you tell the Subcommittee how much PhRMA is investing in your study?

Mr. GIULIANI. I do not know how much they are investing in my study. The cost of it is insignificant in comparison to the amount of money they are investing in trying to figure out a safe way of doing this and the amount they invest in research. Some companies put $4 and $5 billion into that.

Senator PRYOR. One thing I would encourage you to do as a representative of the pharmaceutical industry is to just encourage the industry to get very proactive on this issue. It is something that is of very grave concern to me and I know to the Subcommittee and to the country. We need to try to get a handle on this.

One thing you mentioned in your testimony is you talked about inspections—repeatedly, you talked about inspections. Is it your view that government inspections are essential to protect Americans, or can we follow more of a market model where the industry kind of regulates itself—in other words, can the industry inspect itself—and put market conditions in there that give them the incentive to do that.

Mr. GIULIANI. I think you need both, Senator. I do not think you could ever have a system where there would not be some degree of inspections. Think of it as how do you create safety with regard to the cargo coming into the United States, where we have great concerns about packages or shipments coming in. There has to be a combination of market conditions and some degree of analysis and intelligence, but then you also have to have a certain basic number of inspections so you have a fail-safe point.

And when you are dealing with dangerous medications—one way that we can get to a better stage is to develop better technology and better pedigrees so that you know where it is coming from, who the manufacturer is, and all of that can be done—the problem is that it costs enormous amounts of money, and we are not doing

it effectively—I think we have to be honest about it—we are not doing it effectively right now.

So it seems to me the best approach is how do we improve the current system, how do we get better control over it, and then, once we have done that, how do we open it up even more, rather than just opening it up and creating a totally unrealistic situation.

Senator PRYOR. We talked a few minutes ago about this concept of a seal of approval—Chairman Coleman was the first to mention it—and someone said that the National Pharmacy Association——

Mr. SHEPHERD. The National Association of Boards of Pharmacy.

Senator PRYOR. [continuing] Has something in place right now that is voluntary. Are they the proper group to do this, or should we somehow broaden that and really force more participation somehow?

Mr. SHEPHERD. It is called the VIPP Program, the Verify Internet Pharmacy Provider, and it is a very strict inspection and certification program.

Senator PRYOR. Is that why a lot of firms will not comply and will not go through the process?

Mr. SHEPHERD. I believe that last week, only 14 pharmacies had VIPP certifications. I was talking to Carmen Cattezone—they have offered the VIPP certification to Canadian Internet pharmacy providers, but none of them has taken them up on the offer.

Senator PRYOR. Do you know how long that offer has been outstanding?

Mr. SHEPHERD. It has been out there for at least 3 months.

Senator PRYOR. Let me ask you, Dr. Shepherd, while we are talking about it—a few moments ago, in your testimony, I got the impression that if it were up to you today, just under the current conditions which exist today, you would ban all on-line pharmacies.

Mr. SHEPHERD. Right. As of today, I would. Without any regulation and what is going on right now, I would stop it from coming in.

Senator PRYOR. Because the safety protection is not there?

Mr. SHEPHERD. Safety.

Senator PRYOR. You also talked about importation. But here in the Congress oftentimes we talk about reimportation, and we use the word "reimportation," the way we usually mean it is drugs that are made in this country or made in FDA-approved facilities that may go to Canada or another country and be reimported back in.

Is that one of the safeguards that you would like to see if you were able to set up your own system here that we should only be able to reimport, or import, however you want to look at it, drugs that are made in FDA-approved facilities?

Mr. SHEPHERD. That is one approach that you could use. I have problems with the reimportation unless I have the pedigree paperwork that the mayor talked about, figuring out where that drug has been, how many times it has been sold, and how it has been stored, because it may have passed through six different countries before it comes back in.

Senator PRYOR. In other words, in the prosecutor's terms, you need a chain of custody.

Mr. SHEPHERD. You need a chain of custody.

Senator PRYOR. You need to know where it comes from. One last clarification—you mentioned that you pay for your research out of your pocket?

Mr. SHEPHERD. My group does, yes.

Senator PRYOR. What do you mean, your "group"? Tell us about that.

Mr. SHEPHERD. My group—the Center for Pharmacoeconomic Studies is comprised of 12 faculty members and 32 some-odd graduate students.

Senator PRYOR. So this is part of the University of Texas.

Mr. SHEPHERD. Part of the University of Texas, right.

Senator PRYOR. Do you know where that funding comes from?

Mr. SHEPHERD. The Center's funding comes from the University of Texas primarily, and then it also comes from grants or contracts that we get from pharmaceutical firms, foundations, grants, and contracts from State Government. The State of Texas provides us a lot of money, the Health Department.

Senator PRYOR. Thank you.

Senator COLEMAN. Thank you, Senator Pryor. Senator Carper.

Senator CARPER. Gentlemen, welcome. Mayor, it is good to see you. Dr. Shepherd, thank you for your testimony.

You know how this place works—we have multiple hearings going on at the same time, and I have been off at another one of those, and I apologize for missing your testimony.

Let me ask both of you, if you were in our shoes, how would you approach this issue?

Mr. GIULIANI. I would approach it from the point of view of first addressing the current needs that the FDA and some of the other agencies have for more resources, more of an ability to inspect, create better pedigrees, work on developing technology. I would look at the current situation that exists and say it is a dangerous situation. Ninety nine percent of the medicines that are coming into this country, no one is inspecting, and no one has any idea what is in them. Any time anyone has had a chance to look—FDA, Customs, anyone else—at least FDA, when they do these "blitz" analyses, and our own analyses—shows that somewhere between 70 and 90 percent of those medicines are unapproved, some for serious reasons, like they are expired or they are the wrong medications, some for technical reasons, but for whatever reason, they are unapproved.

So I would say let us see if you can create legislation, give FDA and the other agencies the help that they need to make that a better system, a safer system, and then take a look at it over a year or two or three and see if it has actually accomplished that—have some of those percentages gone down; is it safer.

I think it is unrealistic to think you will ever have a perfectly safe system, but it has to be a lot better than this. And once that is accomplished, then take a look at are there ways that you can expand importation—but now that you have a better system in place. That is the way in which I would do it.

Senator CARPER. Dr. Shepherd.

Mr. SHEPHERD. You could work with qualified pharmacies, Internet providers; inspect them, come up with a list of products, drugs,

that could be reimported or imported, and work with a small pilot project to see how it flies, and make sure that provider provides it.

You could do it a couple of ways. You could do it not only for personal importation, but you could also do it with a U.S. wholesaler. That U.S. wholesaler works with another wholesaler in another country, gets the U.S.-approved products, comes in and distributes to pharmacies. But they would have to be FDA-approved in quality products.

That is one approach. And I think a pilot project on that would probably be worth looking at to be sure the standards are upheld.

Senator CARPER. Thank you.

Do you have any idea how the purchase of drugs from Canada via the Internet compares with, say, Internet purchasing from countries in the EU?

Mr. SHEPHERD. No.

Mr. GIULIANI. We could find out for you, Senator. We could take a look and find out.

The question that I raised before, which I really would suggesting finding out from GAO—because I am sure this is part of their material, but I have not had a chance to look at the report clearly enough—is the pharmacies in Canada that we have had a chance to look at so far all require waivers. So if you want to buy medicines from them, you have to sign a waiver that if they send you the wrong medication, you have no resources. To me, that is extraordinary.

If I went into my pharmacy to buy the medicine that my doctor prescribed for me, and my pharmacist handed me a document that I had to sign in which I waived any recourse if he gave me dangerous medicine, or he gave my children dangerous medicine, I would not deal with that pharmacist.

So I wonder if the pharmacies that they looked at in Canada have those disclaimers or waivers. And part of this process would have to be that you really should only deal with pharmacies that do not require that, pharmacies that are willing to stand behind the product that they are selling you—if you are ordering Lipitor that it is actually Lipitor, whatever it is. This idea of having recourse is part of the way in which we assure that pharmacists are acting legitimately.

Senator CARPER. Why do you suppose people are willing to take that extraordinary step of signing that kind of waiver?

Mr. GIULIANI. For all the reasons that Dr. Shepherd mentioned, some of them just purely because they are desperate, because medicines are too expensive, and they are seeking—even though it may not be less expensive—they are hoping that they will find a source that is less expensive; some of them because they are drug abusers; some of them because they may actually be drug dealers, and this is an easy method of getting significant quantities of medicines that they can then resell on the black market. I think that would be particularly true with some of the medicines that are painkillers.

Senator CARPER. Thanks to both of you.

Senator COLEMAN. There is so much more that we could explore here, but we do have a very important third panel that we do want to hear from. We have not even touched the issue of wholesale and

that system, which you touch on, Mayor, in your report and some of the challenges that we face there and the opportunities for fraud that has been unearthed in some of the reports that have been done.

So I think we have just touched the surface here, but as I said, we do have a third panel that I want to get to, so I want to thank you, Mayor, and thank you, Dr. Shepherd, for your very important testimony.

Mr. GIULIANI. Thank you, Mr. Chairman and Members of the Subcommittee.

Mr. SHEPHERD. Thank you.

Senator COLEMAN. I would now like to welcome our final panel for today's important hearing—Elizabeth Carr, whose husband died from taking illegal prescription drugs he purchased over the Internet, and Francine Haight, whose son died as a result of taking illegal prescription drugs he purchased over the Internet.

Ms. Carr and Ms. Haight, I want to thank you for your courage in coming forward to testify about what I know are very difficult circumstances to talk about in public. I offer my personal condolences for your loss.

As I mentioned in my opening statement this morning, we are here to address problems that are facing American consumers, the individuals who have been most directly, and unfortunately, affected by this growing phenomenon. So again, I appreciate your willingness to tell your personal stories.

Before we begin, pursuant to Rule 6, in this Subcommittee, we do require the witnesses to be sworn.

I would ask you to please stand and raise your right hand. Do you swear that the testimony you are about to give before this Subcommittee is the truth, the whole truth, and nothing but the truth, so help you, God?

Ms. HAIGHT. I do.

Ms. CARR. Yes, sir.

Senator COLEMAN. Thank you.

As you have seen, we are using a timing system, so when the yellow light comes on, it is time to conclude your testimony. If you have written statements, they will be entered into the record in their entirety.

Ms. Carr, we will have you go first and then proceed to Ms. Haight, and after that, we will go to questions. Ms. Carr, you may proceed.

TESTIMONY OF ELIZABETH CARR,[1] SACRAMENTO, CALIFORNIA

Ms. CARR. Thank you. Good morning, Chairman Coleman and Subcommittee members. Thank you for the opportunity to speak today.

My name is Elizabeth Carr, and on April 10, 2003, I lost my husband to an overdose of Darvon, a controlled substance. My husband Jim purchased this drug and others over the Internet from rogue pharmacies located in India, South Africa, Thailand, Spain, and other foreign countries.

[1] The prepared statement of Ms. Carr appears in the Appendix on page 172.

Jim and I were married in 1996. He moved from Los Angeles to accept a job in Sacramento, California. This was a significant climate change for him, as he was used to the mild temperatures of Los Angeles. He was a former tri-athlete and a marathon runner, and he loved to mountain bike. Through these activities, he had dislocated a hip and had to have operations on both knees.

By 2002, it was painful for him to even take a brisk walk, and he said it was always worse during the winter. In January 2003, Jim told me he was going to purchase codeine over the Internet for his pain. I did not think much about it at the time, because when I was growing up, codeine was in cough syrup. He never told me how much he was taking, and because he was working from home, I never saw the packages arriving. However, by the end of March, I grew concerned about a change in his demeanor, and I confronted him about it and asked him to stop, which he agreed to do.

On the day before he died, he was behaving very disoriented when I got home from work. When I quizzed him about it, he explained that he had turned to Darvon to wean himself off the codeine. This was the first time that I knew he had taken the Darvon. He went to sleep that night, and he never woke up.

The autopsy showed that Jim had eight times the recommended dosage of Darvon in his system. After he died, I received five packages in the mail that Jim had purchased in the weeks before he died. By looking at his credit card statements and the dates posted on the packages and when the packages arrived, I could tell that the time from order to receipt from these pharmacies took several weeks. In fact, all packages were from overseas, and none had a pharmacy label. Some had instructions, but most of the instructions were not in English. One of the packages even had a little green tag attached on the outside that looked to me like it said "Sweets."

As I continued to go through his things, I found all kinds of empty pill containers. I also looked at his computer activities and discovered that he had done research into the different drugs and how to get them. Some Websites required him to fill out a short questionnaire before he could get the medication, while others did not require anything. All the overseas pharmacies required payment in credit card form and were shipped via U.S. mail.

After his death, I worked with the California Medical Board to try to hold someone accountable for the delivery of these substances to my husband. However, there was nothing that the California Medical Board could do because the only documents I could provide them did not implicate doctors that were licensed in California. They told me something needed to be done at the Federal level.

So that is why I am here today, Senator Coleman. I am here to tell you what is happening to real people—not just numbers or statistics on a piece of paper. This problem affects everyone in one way or another in our society, and something needs to be done to stop these companies from making money off of people's trust, their need, or their lack of awareness. Thank you.

Senator COLEMAN. Thank you, Ms. Carr. Ms. Haight.

TESTIMONY OF FRANCINE HAHN HAIGHT,[1] SACRAMENTO, CALIFORNIA

Ms. HAIGHT. Good morning. My name is Francine Hahn Haight. My daughter Natalie and my son Jeremy are present and sitting behind me. I am very grateful for this opportunity to speak before this Subcommittee and share what has happened to our family.

I am the mother of three beautiful children. I am extremely sorry to say that one of them died. I am here to tell you about my son, Ryan Thomas Haight.

Ryan was born on December 28, 1982 and died on February 12, 2001. Ryan died of an overdose of narcotics he had easily purchased on the Internet. A medical doctor, Dr. Robert Ogle, that he never saw, prescribed them to him over the Internet. An Internet pharmacy, Clayton Fuchs of Mainstreet Pharmacy, mailed them to our home. He was only 17 when he purchased the narcotics, and he was only 18 when he died.

Ryan was an incredible boy. From the time he was little, I always believed that he would make a difference in our world. He was very intelligent and excelled in school. He loved math and science. He was always at the top of his class, was a Gate student in the elementary years, and then went on to take honors classes. He was an A student, maintaining a 4.0 or above during his years in high school. He was looking forward to going to college. He loved his family, and we did many things together.

Ryan loved to travel. He loved to hike. He loved the National Parks. He always looked forward to the holidays and gatherings of the family.

He was athletic. In elementary school, he played little league baseball, starting with T-ball, and ended up being a top player in the majors and making the all-star team. He also played open junior tennis tournaments, and went on to play varsity tennis for 3 years in high school. Had he not died in his senior year, he would have been a 4-year varsity letterman in tennis.

He loved to snow ski, snowboard, water ski, kneeboard, and attempted all sports with great enthusiasm. He loved to play billiards, go bowling, and play ping pong. He was competitive and competed on a swim team when he was young and loved to play Nintendo and other video games.

Ryan loved to use the computer. He used the computer to play games against his friends, to compete in fantasy baseball, where you pick your teams, and he loved to chat with his friends online. He loved to trade baseball cards on E–Bay.

Ryan was taking a computer graphics class in high school. He was considering a possible career designing software or doing something with computers. But all of his hopes and dreams died when he discovered that he could buy drugs on the Internet.

He was curious about the party scene, went to Rave parties with friends, and started to experiment with drugs. He was encouraged to experiment with drugs from an Internet chat room. Someone in this chat room told him where you could buy drugs and how to buy them on the Internet. He found that you could buy powerful nar-

[1] The prepared statement of Ms. Haight appears in the Appendix on page 174.

cotics on the Internet very easily, right out of his own house. It was like buying candy in a grocery store.

On February 11, 2001, Ryan had worked a full day at a retail store. He came home at around 8 p.m. and said he was hungry. I made him his favorite chicken soup in the crockpot. He told me his back was hurting because he had been moving plants at the nursery.

It was cold and raining outside. He asked if he could use my spa. He used my bath at around 10 p.m. for about 30 minutes, got out, and we chatted. We talked for a few minutes, and then he said he wanted to relax in his sister's room and play video games. His sister Natalie was away at college. He missed her, and he felt comfortable using her room for the television and video games.

About an hour later, just after midnight, I went to say goodnight to him in his room. He was just getting into bed and said he was going to listen to some music. Ryan loved all kinds of music—rap, techno. We share a common interest in our love for classic rock. I loved it that he loved listening to the Eagles and the Beatles with me. I told him I loved him, as I do every night, hugged him, and he said, "I love you, too, Mom."

The next morning was a holiday, President's Day, so it was not unusual for Ryan to sleep in. I had 12 women showing up for dinner that night, so I had to go out and shop. My housekeeper was there, and I told her to call me if there was anything she needed, and that Ryan would be sleeping in.

I got home about 3 o'clock that day and noticed Ryan's car still in the driveway. It had not moved, and I immediately felt something was wrong. I ran into his room and found that Ryan was not breathing.

I could not believe what I saw. I knew he was dead. I called 911 and tried to do CPR. I screamed and I cried, and I screamed and I cried, and I prayed for him to come back to life. I remember a paramedic pulling me off of him and looking into my eyes and saying, "Oh, my God, I am so sorry. There is nothing we can do."

I thought how, how, how, could this happen? What happened?

The next thing I know, a sheriff is showing me a bottle, a bottle of hydrocodone, Vicodin. On the bottle, it says "Mainstreet Pharmacy." He also shows me a bottle of morphine. I thought, no way. These are controlled prescription drugs. He said he found the drugs after searching his room. These are drugs under lock and key in hospitals. How did he get them—how?

We parents often worry about our children. When they are little, we worry they will fall and get hurt. But as they become teenagers, we worry even more. We worry that they will drink alcohol and drive and get into a car accident. We worry that they will smoke cigarettes and marijuana. We worry that they will try illegal street drugs such as cocaine, LSD, heroin, and others. We worry about porn and strangers that might hurt them on the Internet. But never did I worry about buying prescription drugs on the Internet.

After Ryan died, a friend of Ryan's called and told us that he got drugs off the Internet. Never did I think you could easily get prescription drugs on the Internet. I was in shock. Being an RN, I always thought that controlled substances were under lock and key.

Ryan was encouraged to obtain these powerful narcotics that required nothing but filling out a simple questionnaire on the Internet.

That week, Ryan's dad gave Ryan's computer to the DEA, and the investigation started. I have assisted in helping with the prosecution of these Internet drug dealers. They are just as bad if not worse than the drug dealers on the street.

Since then, from the evidence they got from the Internet, Clayton Fuchs and Dr. Robert Ogle were found guilty and pleaded guilty of selling drugs illegally on the Internet. They said they did it just for the money.

An autopsy report showed that Ryan died from a drug overdose of hydrocodone, Vicodin, which was prescribed by Dr. Ogle and sent to him from Mainstreet Pharmacy. Why did they sell these drugs to my son? They both said they did it for the money.

Dr. Ogle had been to prison twice. Once, he served 3 years in a Federal penitentiary for illegally prescribing Quaaludes, a hypnotic sedative. Another time, for theft. But he still got his medical license back. He should have never gotten his medical license back.

I think Ryan, as most kids would, thought that since a doctor was prescribing the drug, it is a legal drug obtained with a prescription, then it must be safe. The drug was delivered to our home with no instructions, no safety precautions, no adverse reactions attached. Ryan received these drugs without ever seeing the doctor, and never had any follow-up.

The pharmacy delivered these controlled substances with no instructions and no questions asked. These money-hungry drug pushers of doctors and pharmacies have got to be stopped. They are making millions of dollars and are only concerned about the money. They do not care about the person ordering them.

There are over 500 rogue pharmacies on the Internet as I speak. Tighter regulations on our Internet need to be enforced with high penalties. I continue to receive emails from these pharmacies on a daily basis.

What our public do not know is that just because it says "United States pharmacy" does not mean it is coming from the United States. In fact, when you click on the site, it goes to other countries. They can buy from Canadian pharmacies and save money. But what they do not know is the risks that they are taking. Drugs are being distributed daily, like candy, and it is very dangerous.

RyansCause is an organization I have started—Reaching Youths Abusing Narcotics. Saying no to drugs is not enough. We are losing this war against drugs. President Bush in his State of the Union Address a few months back mentioned that drug use in our youth is down. He might be right about street drugs, but he did not mention the increased usage of prescription drugs. Prescription drug usage is up.

My hope is that with tighter restrictions on the Internet and more public awareness, we can save lives. I want to get RyansCause brochures into every high school classroom. I want to talk and educate our youth and parents. This tragic death could have happened to anyone. Ryan was the boy nextdoor. We need to fight this war against drugs and save others.

With tighter regulations on the sale of prescription drugs on the Internet, it will make our increasingly technological world more safe.

I want to thank Senator Feinstein and Senator Coleman for introducing legislation to improve the safety of buying prescription drugs on the Internet. Internet pharmacies should be required to identify their business.

Our grief continues and extends beyond the immediate family. Ryan's grandparents, aunts and uncles, cousins and friends feel Ryan's death very deeply. Ryan will never see Jeremy play his clarinet, or take him out for ice cream. Ryan will never be able to sit for long hours and talk to his sister about what happened during his day. I will not see him graduate from college, attend his wedding, or be a grandmother to his children.

But we continue to water our white roses and drink our sprite with no ice in his memory. Ryan will be forever missed and will remain in our hearts forever.

Thank you for honoring my son Ryan by naming the important legislation you introduced after him.

Thank you for allowing me to tell my story in front of the Subcommittee.

Senator COLEMAN. Thank you, Ms. Haight and Ms. Carr. Again, my deepest personal condolences for your loss.

As the dad of an 18-year-old who loves the computer, your pain is more than an abstract story; it is very personal for a lot of people. So I do want to thank you for coming forward.

And Ms. Haight, I think in a very tragic way, but Ryan will make a difference in our world, and certainly I am committed to that, Senator Feinstein is, and many of my colleagues. So I hope that provides a little glow of warmth in what is a difficult situation.

Ms. Carr, I think you have with you some of the drugs that were received after your husband's death. Let me back up—did he have prescriptions for Darvon to be taken through a local pharmacy? Do you know what kind of prescriptions he had for painkillers?

Ms. CARR. At the time, I do not think he had any. He had not, as far as I know, been to a doctor for that. As a tri-athlete and a mountain biker, he had had painkillers all his life, because he was always hurting himself—but not at the time that I know of.

Senator COLEMAN. Can you show us what you received?

Ms. CARR. OK. This is one of the packages that came after he died. I could tell immediately it was not a normal U.S. package. It has a little label on it from New Delhi, and it has all the weird stamps with the different kind of writing on it.

Do you want me to open this?

Senator COLEMAN. You can take it out.

Ms. CARR. And it was kind of strange when I first opened it. It comes in this wrapping, with scarves or something underneath it, and then you pull it out—professionally wrapped, you see—and it has a newspaper that is probably an Indian newspaper, and then more of that professional look, the cardboard, and then there is the pills.

Senator COLEMAN. No description of dosage or what it is?

Ms. CARR. No. This one did not even have—well, it has some label or something on there. But as far as——

Senator COLEMAN. But no instruction booklets or anything like that.

Ms. CARR. No instructions.

Senator COLEMAN. Did you have a chance to look at the Websites? I think you indicate that you saw some of them.

Ms. CARR. I did, because he not only used it on his computer, but he used it on mine, so I was able to go to a couple of the Websites—although by the time I got around to doing it, some of the Websites, you could not get to anymore, and you got the screen that says they are no longer available. But yes, I did look at some of them to see what was required to get something through them.

Senator COLEMAN. And there was another package you received, you said, or a series of some others?

Ms. CARR. Yes. This one was from Bangkok, just a small, little package. I did not even think it was prescription drugs, but it was one of the five packages that came. I opened it up, and it was really scary, because it looks like that was done in a garage somewhere—no labeling on it at all, nothing. I do not know why anyone would even put this stuff into their body. And it has some word on it, and I could not even quite read it, except it looks like it has a "D" and maybe a "V", and I am thinking maybe that was the Darvon; I do not know. But it was very scary.

Senator COLEMAN. Do you know if, on the Websites that you had a chance to look at, there was a discussion about prescription or anything of that nature?

Ms. CARR. No. The ones that I looked at did not mention anything about a prescription, and I am sure that—I mean, he had done a lot of research, and he was probably looking for places where he did not have to fill out a prescription.

Senator COLEMAN. And law enforcement's response in terms of your desire to deal with this, to shut it down, to impact it in some way—what kind of response did you get from law enforcement?

Ms. CARR. The only law enforcement I dealt with—I talked to the California Medical Board, and they had an investigator who was really good with the computer stuff. I gave him my husband's laptop, and he looked into it as much as he could. I gave him what documents I could. He wanted to find something, but he could only deal with doctors who were licensed in California. That was the extent of what he could do.

Senator COLEMAN. They had no other jurisdiction or control over anything.

Ms. CARR. No other jurisdiction. That is why he told me—he said something has to be done at the Federal level.

Senator COLEMAN. Thank you.

Ms. Haight, how was Ryan able to pay for the Vicodin and the morphine from this Internet pharmacy? Did you ever trace that back?

Ms. HAIGHT. I believe he purchased it with a money order.

Senator COLEMAN. Money orders. Do you know if any credit cards were used at all?

Ms. HAIGHT. I was told that there is a possibility that he bought it with a credit card, but I have not seen that. I believe it was a money order.

Senator COLEMAN. Did you ever talk to Dr. Ogle?

Ms. HAIGHT. No.

Senator COLEMAN. Do you know whether he was subject to any criminal proceedings or any actions after your son's death?

Ms. HAIGHT. Yes. He is actually in prison right now as we speak, awaiting sentencing.

Senator COLEMAN. What about the folks who own Mainstreet Pharmacy—did you ever identify them?

Ms. HAIGHT. The pharmacy has been shut down, and Clayton Fuchs is also in prison at this time.

Senator COLEMAN. And Clayton Fuchs is the principal in Mainstreet Pharmacy.

Ms. HAIGHT. Mainstreet Pharmacy, yes.

Senator COLEMAN. Do you know anything about his background?

Ms. HAIGHT. I do not know anything about his background.

Senator COLEMAN. You are reaching out with RyansCause. You are trying to reach youth that way. What do you recommend we do? If you had a list of one, two, or three things that we could do, both in dealing with the plague of predators that allow young people and others to buy quantities of narcotics that have deadly impact, without any conscience, but beyond that, are there other things that we can do to assist in your cause and the cause that you have dedicated yourself to?

Ms. HAIGHT. I think by passing this bill, having tighter regulations, would definitely help, and being able to go in and make sure that these are legitimate pharmacies, legitimate doctors, that they have actually been seen by the doctor. I do not think any controlled substance or any mind-altering drug should ever be sold on the Internet—I do not care if you have seen your doctor or not—I think it should be done within a doctor's office.

Senator COLEMAN. Thank you.

Senator PRYOR. Thank you, Mr. Chairman. I really just had one question for Ms. Haight, and that is a clarification.

Mainstreet Pharmacy was a U.S. company. Was that in California—where was that?

Ms. HAIGHT. Texas.

Senator PRYOR. And it was just a rogue pharmacy that was giving out drugs to whomever could pay for them?

Ms. HAIGHT. They had actually made millions of dollars selling drugs throughout the United States and other countries.

Senator PRYOR. That is all I have, Mr. Chairman. Thank you.

Senator COLEMAN. Thank you.

Again I want to thank both of the witnesses—Ms. Carr?

Ms. CARR. Could I just say that if you go ahead with setting up the safe pharmaceutical sites, I know that the way the Internet is, there will be other sites that are going to pop up out there, and people like my husband would have gone to those—they would have bypassed the safe ones. So on these safe ones, if you have some way of recognizing when the packages are coming in, because they are just coming in through the U.S. mail, so you have some special package that comes in, and all the other packages that

come in, if you can detect drugs in them, they just do not get shipped, they do not get to their destination.

Senator COLEMAN. You raise an issue that we are struggling with here. There will be a second hearing. I will have a hearing on July 22, and we will have representatives of the Postal Services, United Parcel Service, and FedEx there, to try to figure out how to deal with this.

The problem that we face, as you heard from the other witnesses, is the extraordinary volume. We have heard about millions of packages coming through—in single mail production operations in New York, 40,000 a day. And I have been there, and what they do at the post office is actually have a list of identified countries that they know are most problematic, so they are going to prioritize what they try to pull. But I just have a sense that we are trying to find needles in haystacks here. So it is extraordinarily challenging.

But at a minimum, we should do what we are doing in the Ryan Haight Act, which is requiring pharmacies that ship to be FDA-approved, require them to be subject to inspection, require that individuals have a patient-physician relationship and ensure that you cannot get prescriptions by filling out a form online. That is a joke. It is a sad joke. It is a terrible joke. It is a tragedy.

So we can do some of those things, but we are struggling with this, Ms. Carr. This is not something for which there is an easy answer.

You should know that I will be speaking with DEA Administrator Tandy next week, and I am going to follow up on what the DEA can do in dealing with your case, and Ms. Haight, we are certainly committed to the act named in memory of your son.

So I want to thank the witnesses, I want to thank my colleagues.

The record of this hearing will be kept open for 10 days.

Again, I want to thank the witnesses, and this hearing is now adjourned.

[Whereupon, at 11:38 a.m., the Subcommittee was adjourned.]

BUYER BEWARE: THE DANGER OF PURCHASING PHARMACEUTICALS OVER THE INTERNET—FEDERAL AND PRIVATE SECTOR RESPONSES

THURSDAY, JULY 22, 2004

U.S. SENATE,
PERMANENT SUBCOMMITTEE ON INVESTIGATIONS,
OF THE COMMITTEE ON GOVERNMENTAL AFFAIRS,
Washington, DC.

The Subcommittee met, pursuant to notice, at 9:05 a.m., in room SD–342, Dirksen Senate Office Building, Hon. Norm Coleman, Chairman of the Subcommittee, presiding.

Present: Senators Coleman and Levin.

Staff Present: Raymond V. Shepherd, III, Staff Director and Chief Counsel; Katherine English, Counsel; Jay Jennings, Investigator; Mary D. Robertson, Chief Clerk; Elise J. Bean, Staff Director/Chief Counsel to the Minority; and Clare Diegel, Intern.

OPENING STATEMENT OF SENATOR COLEMAN

Senator COLEMAN. This hearing of the Permanent Subcommittee on Investigations is called to order.

Good morning and welcome to the Subcommittee's second day of hearings into the dangers associated with purchasing pharmaceuticals over the Internet.

According to a 2003 University of Michigan study, the painkiller Vicodin was second only to marijuana in illicit use by 12th graders. Federal statistics estimated that 6.2 million Americans misuse prescription drugs in 2002, compared with 2 million who use cocaine and 700,000 who use Ecstasy.

It is all too easy. Go online with your favorite search engine and type in "purchase Vicodin,"[1] click onto a Website and you can purchase your Vicodin or the generic equivalent, hydrocodone, with a variety of credit cards including MasterCard, Visa, or American Express.[1] No prescription is necessary. All you need to do is have an on-line consultation and your medication will be FedExed to you.

The first Internet pharmacies began on-line services in early 1999, and FDA estimated that 104 businesses were selling prescription drugs on the Internet by July of that year. In 1999, Americans spent an estimated $160 million on prescription drugs pur-

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[1] See Exhibit No. 24 which appears in the Appendix on page 309.
[2] See Exhibit No. 26 which appears in the Appendix on page 311.

chased over the Internet. By 2003, spending on Internet prescription drugs had grown to $3.2 billion.

By November 2000, the FDA had identified between 200 and 400 Internet pharmacies, as well as other Websites, where drugs were accessible with the click of a mouse. A new study by the National Center on Addiction and Substance Abuse at Columbia University identified 495 Websites advertising controlled prescription drugs during a one-week analysis. Of these, 157 sites that sold opioid-based drugs such as OxyContin, Percocet, and Darvon. Only 6 percent of the sites selling drugs required a prescription, and none took steps to prevent the sale of drugs to children.

Other evidence suggests the number of Internet pharmacies is much larger. The firm Cyveillance has identified 1,009 Internet pharmacies that purport to be Canadian pharmacies. Earlier this year, the FedEx brand appeared on 12,200 unique websites selling at least one of the 22 top-selling pharmaceuticals in a search by Nameprotect of its 400 million web page database estimated at one-tenth the size of Google's database.

At our first hearing on June 17, we heard the tragic story of two men who died from taking drugs they had purchased over the Internet. Seventeen-year-old Ryan Haight of La Mesa, California was an honor roll student and avid baseball card collector about to enter college. How did a healthy 17-year-old obtain prescriptions for painkillers without a medical exam? He got them from Dr. Robert Ogle, an on-line physician based out of Texas. With the bogus prescriptions from Dr. Ogle, Ryan was able to order hydrocodone, morphine, and Valium and have then shipped via U.S. mail to his front door. In February 2001, Ryan overdosed on a combination of these prescription drugs. His mother found him dead on his bedroom floor.

James Lewis, a tri-athlete, died of an overdose of Darvon on April 10, 2003. He purchased Darvon, as well as other controlled substances, from Internet pharmacies doing business in South Africa, Thailand, and Spain. Some Websites required James to fill out a short questionnaire before he could order the medication. Others required nothing.

Our investigation found that these are not isolated events. At my request, the General Accounting Office made purchases of pharmaceuticals from both domestic and foreign Internet Websites. With disturbing ease, GAO used the Internet to purchase numerous prescription drugs, including highly addictive narcotics and other controlled substances. Notably, GAO purchased 66 percent of these pharmaceuticals, including narcotics, without a prescription and without visiting a doctor.

GAO also used the Internet to purchase from foreign pharmacies counterfeit versions of American drugs, pharmaceuticals that have not been approved by the FDA, counterfeit drugs, damaged products, and drugs without proper packaging, no warning information, or instructions for use.

As Chairman of the Permanent Subcommittee on Investigations, I endeavor to provide an objective snapshot of what drugs are available to consumers on the Internet by inspecting the operations at the JFK International Airport in New York, home to the largest international mail branch, IMB, in the United States.

Senior Customs officials at JFK estimated that 40,000 parcels containing drugs are imported through the airport each day. During last summer's FDA-Customs blitz, 28 percent of the drugs tested were controlled substances.

This means that as many as 11,200 drug parcels containing controlled substances, like the painkillers Vicodin and OxyContin are imported through JFK daily, 78,400 weekly, 313,600 monthly, and 3,763,200 annually. Top countries of origin include Brazil, India, Pakistan, Spain, Portugal, Canada, Mexico, and Romania.

FDA and Customs officials also regularly seize and inspect packages containing controlled substances like hydrocodone and generic Valium or Diazepam;[1] counterfeit Viagra from India;[2] injectable steroids from China;[3] boxes of unidentified drug products;[4] and drug packages without any of the required inserts that lack labeling and have directions for usage in foreign languages.

PSI staff made similar findings at the IMBs in Chicago and Miami.

Simply put, we are drowning in a flood of imported drugs of unknown composition and origin, as well as potentially lethal controlled substances.

Given the overwhelming volume of drug products imported daily, FDA cannot fully process all the packages containing drugs. For example, at JFK, FDA inspectors can only inspect 200 packages daily. As a result, there is a significant backlog of product waiting to be screened by FDA.[5] Because of the sheer volume of drug product, the FDA acknowledges the vast majority of prescription drugs that are illegally imported into the U.S. through JFK are not screened or regulated in any manner.

Unfortunately, the same is true for Customs. Despite yeoman efforts, because of the sheer number of controlled substances being imported, Customs can screen only a de minimis number of the packages that contain controlled substances.

In conjunction with Senator Levin and John Dingell, the dean of the U.S. House of Representatives, who was the author of the Prescription Drug Marketing Act, I asked the GAO to assess the steps taken by the Federal Government to address this problem. This effort is emblematic of the fact that this issue is not only bipartisan, it is bicameral. GAO confirmed what the Subcommittee has documented at five other sites:

There is no uniform approach to screening and processing imported pharmaceuticals, the quality and health risks associated with imported prescription drugs is unknown, there is no reliable estimate of the quantity of drugs being imported, and most disturbingly, more prescription drugs are released without ever being inspected.

The Federal Government has been on notice about this issue for at least 5 years. On July 30, 1999, representatives from FDA, Customs, and the Department of Justice testified at a hearing entitled, "Drugstores on the Net: The Benefits and Risks of Online Phar-

[1] See Exhibit No. 3 which appears in the Appendix on page 288.
[2] See Exhibit No. 5 which appears in the Appendix on page 290.
[3] See Exhibit No. 6 which appears in the Appendix on page 291.
[4] See Exhibit No. 7 which appears in the Appendix on page 292.
[5] See Exhibit No. 10 which appears in the Appendix on page 295.

macies," before the House Oversight and Investigation Subcommittee. At that hearing, FDA announced that along with DEA and Customs they had formed an interagency working group to address the problem of on-line pharmacies. In addition, FDA testified that they had purchased a web crawler so they could have "surveillance over the Internet." We will be able to refer controlled substances illegally offered for sale to the appropriate enforcement people.

Many of the initiatives that we will hear about today sound eerily familiar. I am concerned by the apparent lack of progress in getting our arms around this glaring problem. Those charged with the responsibility to protect the American consumers from the illegal importation of controlled substances and counterfeit or unsafe drugs cannot allow themselves to fall victim to rapidly advancing technology.

Interestingly, in comparison to the Federal Government's response, the response of much of the private sector has been swift and proactive. For example, in response to news reports about the availability of controlled substances on the Internet, in November 2003 Yahoo! blocked all search terms related to prescription drugs for approximately 2 months while it determined what action to initiate. Yahoo! then contracted with a private company to ensure that Internet pharmacies which buy ad space on Yahoo! are legitimate and properly licensed.

Likewise, of its own accord, MasterCard initiated a campaign to identify sellers of OxyContin and Vicodin. MasterCard identified Internet sites that were offering these drugs and made dummy transactions. These transactions allowed MasterCard officials to identify the member bank where the merchant maintains an account. MasterCard then contacted the appropriate member bank and advised the bank of the need to, one, exercise due diligence to identify illegal activity; two, deny the use of MasterCard services if an Internet site was engaged in illegal activity; and three, to require the Internet site/merchant to demonstrate that its sales are legal.

Last, UPS is proactively identifying Websites that offer prescription drugs without a written prescription and that advertise the services of UPS. UPS provided PSI with a list of 105 such Websites. The same information was provided to DEA and FDA on February 20, 2004, with a request that they identify and address the sites that are offering illegal pharmaceuticals. Of these 105 Websites, 89 are still selling pharmaceuticals. I look forward to hearing what measures DEA and FDA undertook with this information.

The potential problems associated with the importation of controlled substances and drugs of unknown origin and composition are far-reaching. Teenagers are getting unfettered access to controlled substances. Patients are self-medicating and receiving medication that could be sub-potent, super-potent, stored in unsafe conditions, or even counterfeit. And unscrupulous drug dealers are getting rich preying on unsuspecting consumers in dire need of affordable medication.

We as a government must do all we can to ensure access to a safe and affordable drug supply. DEA Administrator Tandy will

testify that for consumers buying drugs over the Internet without a legitimate prescription are no safer than taking drugs offered to you by a street corner hustler. We have developed multiple strategies for controlling and shutting down the street corner hustler. We must approach Internet drug sales with the same vigor.

With that, I would look forward to a statement by my Ranking Member and distinguished colleague, Senator Levin.

OPENING STATEMENT OF SENATOR LEVIN

Senator LEVIN. Mr. Chairman, thank you, first and foremost, for not just convening a second day of hearings into a very important subject, but also for your dogged determination to determine the extent of a real problem, which is the purchase of pharmaceuticals and prescription drugs over the Internet, as you have outlined, and to pursue solutions to this real problem. You are taking a leadership role here in the Senate. As you point out, it is both bipartisan and bicameral. There is strong support in the House for action, as well, for the reasons that you have given.

Last year alone, U.S. consumers purchased over $3 billion in prescription drugs from Internet pharmacies. Now, there are many reasons that consumers do this. Some of them are improper reasons, kids trying to get drugs they otherwise aren't going to be able to get and other inappropriate efforts to obtain pharmaceuticals and prescription drugs over the Internet in ways that can accomplish those goals for the people who are seeking those drugs.

But there are also appropriate efforts being made to obtain prescription drugs over the Internet. One of those appropriate reasons is the high cost of prescription drugs that drive Americans to take drastic measures to pursue lower-cost medications, including buying medicines from unfamiliar and sometimes shady Internet pharmacies.

Right now, on average, Americans pay 60 percent more than the British or the Swiss for the same prescription drugs, two-thirds more than Canadians, 80 percent more than the Germans, and twice as much as Italians. For average Americans suffering chronic illness, high drug costs are forcing some to choose between taking their medicine on any given day, paying their bills, or even buying food.

At the last hearing, the Subcommittee released a report by the GAO describing key problems that are created when people buy medicine from Internet pharmacies. The highlights of that report have already been reviewed by our Chairman, and I will leave my statement for the record to give some of the specifics of the GAO study.

But the picture that was painted raises a host of concerns and today's hearing examines what the Federal and the private sector are doing to protect the American public from unsafe and illegal prescription drugs purchased over the Internet. In its testimony, GAO is going to state that it concludes that very scarce resources in our agencies that are supposed to enforce our laws only selectively target packages by country of origin and other means, and they state that FDA officials acknowledge that tens of thousands of packages are allowed to reach U.S. consumers that violate current laws and pose public health risks.

Our agencies have a key role in overseeing pharmaceuticals which are shipped into the United States. Under one law, the FDA is responsible for ensuring the safety, effectiveness, and quality of domestic and imported drugs. Under another law, the Drug Enforcement Agency is responsible for combatting illegal narcotics and the abuse of controlled substances. And under a third law, the Bureau of Customs and Border Protection is supposed to screen and stop unauthorized controlled substances at the border along with a wide range of other contraband. And the Postal Inspection Service is also charged with investigating the distribution of narcotics through the mail.

So we have got a number of Federal agencies that have a responsibility to protect Americans from unsafe and illegal pharmaceuticals, but as a matter of fact, we know that they are overwhelmed. They are flooded. They are unable to do the job which they must do to protect our people.

The Subcommittee staff that did this field work did not see a single FDA inspector during a 6-hour shift, even though the FDA is charged with helping Customs to look for unsafe and illegal pharmaceuticals. Customs agents interviewed by the staff indicated they had never met their FDA counterparts, even though the two agencies are tasked with coordinating their efforts to identify incoming drug shipments that could be seized and inspected more closely.

Mr. Chairman, because of the number of witnesses that we have, I am going to ask that the balance of my statement be inserted in the record, but I want to just reinforce one point that our Chairman made about the risk to our children.

Right now, a 12-year-old juvenile can use a parent's computer to log onto an Internet search engine, as the Chairman has outlined, type in the parent's credit card number, and direct illegal controlled substances to be shipped to an address via commercial carrier the next day.

We have private organizations and businesses that are here today to help us understand what efforts they are making—and many of them are making great efforts to combat Internet sales of unsafe and illegal prescription drugs—and they will inform us as to how together we can more aggressively work to protect the public.

These responsibilities are vast. We are falling down in terms of carrying out these responsibilities. Our Chairman is taking a leadership role in trying to get us back on track, but more importantly to address a new kind of a problem and a challenge which is represented by the Internet. So Congress has some responsibility, and I congratulate you, Mr. Chairman, in helping us to understand where we are falling short and how we can carry out those responsibilities.

Senator COLEMAN. Thank you, Senator Levin, your entire statement will be entered into the record, without objection.

[The prepared statement of Senator Levin follows:]

PREPARED STATEMENT OF SENATOR LEVIN

Unapproved, misbranded, counterfeit, and adulterated prescription drugs are making their way into the United States, and I commend you, Mr. Chairman, for holding a second day of hearings to examine what we can do to reduce the various

threats to the health and welfare of people buying pharmaceuticals over the Internet. Last year alone, U.S. consumers buying prescription drugs from Internet pharmacies spent more than $3 billion.

The high cost of prescription drugs continues to drive Americans to take drastic measures to find lower-cost medications, including buying medicines from unfamiliar and sometimes shady Internet pharmacies. Right now, on average, Americans pay 60 percent more than the British or the Swiss for the same prescription drugs, two-thirds more than Canadians, 80 percent more than Germans and twice as much as Italians. For average Americans suffering chronic illness, high drug costs are forcing some to choose between taking their medicine on any given day, paying the bills, or even buying food.

At the last hearing, the Subcommittee released a report by the Government Accountability Office (GAO) describing key problems created when people buy medicine from Internet pharmacies, and I'd like to recap a few of the highlights. GAO found that buying medications over the Internet was not difficult. GAO placed 90 on-line orders for prescription drugs and received 68 shipments, a success rate of 75 percent. Of those 68 medications, 45 were shipped illegally, because there had been no patient-provided prescription. Of those Internet pharmacies based in the United States, only 5 out of 29, or 17 percent, had required GAO to provide a patient prescription. Many of the shipped medications also arrived without Food and Drug Administration (FDA) required precautions such as patient instructions and temperature-controlled packaging.

Of the 68 shipments received by GAO, 48 were from U.S. or Canadian based Internet pharmacies, 18 were from foreign sites, and 2 could not be determined. Of the 18 foreign shipments, 3 were found to contain counterfeit medications, including 2 with incorrect but not necessarily dangerous chemical compositions, and one with no active ingredients at all.

Today's hearing examines what the federal and private sector are doing to protect the American public from unsafe and illegal prescription drugs purchased over the Internet. In its prepared testimony for today, GAO concludes that scarce resources have forced our enforcement personnel to "selectively target" pharmaceutical packages for inspection, and that most shipments reach the public without any federal oversight at all. GAO also states that federal officials acknowledge that tens of thousands of pharmaceutical packages that are allowed to reach U.S. consumers may violate current laws and pose public health risks.

Three federal agencies have key roles in overseeing pharmaceuticals shipped into the United States. Under the Federal Food, Drug and Cometic Act, the FDA is responsible for ensuring the safety, effectiveness and quality of domestic and imported drugs. Under the Controlled Substances Import and Export Act, the Drug Enforcement Agency (DEA) is responsible for combating illegal narcotics and the abuse of controlled substances. And under the Homeland Security Act, the Bureau of Customs and Border Protection (Customs) is supposed to screen and stop unauthorized controlled substances at the border—along with a wide range of other contraband. In addition to the FDA, DEA and Customs, the U.S. Postal Inspection Service is charged, among other tasks, with investigating the distribution of narcotics through the mail.

Each of these federal agencies has a responsibility to protect Americans from unsafe and illegal pharmaceuticals, but it is clear that they are being overwhelmed by an increasing flood of pharmaceutical imports. Earlier this month, for example, the Subcommittee staff visited the Memphis International Airport in Tennessee to get a first-hand view of incoming shipments of pharmaceuticals. This visit follows earlier ones described at the last hearing to international airports in New York City, Miami, and Chicago. The Memphis airport is the primary commercial hub for Federal Express (Fed Ex), a commercial company that operates a major shipping business, including shipments from over 200 foreign countries. The Subcommittee staff observed the key 6-hour shift for incoming Fed Ex packages, from 9:30 p.m. to 3 a.m.

The Subcommittee learned that, at this commercial hub at the Memphis airport, approximately 740,000 packages arrive during a single night shift. Only 24 Customs agents were present at the hub to view these incoming packages. That meant each Customs agent had 6 hours to review about 30,000 packages. Those numbers made it impossible for the agents to give more than a cursory glance to pharmaceutical shipments, while also searching for such high priority contraband as narcotics, weapons, and terrorism-related materials.

The Subcommittee staff did not see a single FDA inspector during the 6-hour shift, even though the FDA is charged with helping Customs to look for unsafe and illegal pharmaceuticals. Customs agents interviewed by the staff indicated that they had never met their FDA counterparts, even though the two agencies are tasked

with coordinating their efforts to identify incoming drug shipments that should be seized and inspected more closely. One Customs agent stated that he got his seizure directives from the FDA website, instead of communicating directly with an FDA agent. The FDA later told the Subcommittee that develops these directives by reviewing manifests for incoming shipments, and identifying about 25–30 packages per day to be held by Customs at the hub. The FDA indicated that it inspects these packages at a later time and determines how each should be handled. The FDA also indicated that, beginning in the fall, new funding would enable it to assign 2 FDA inspectors to help with incoming shipments at the Fed Ex hub.

It is also unclear whether federal agencies are working as effectively as they could with the private sector such as the Internet search engines that direct Internet users to particular on-line pharmacies, the credit card companies that approve payments to these pharmacies, and the shipping companies that move pharmaceuticals from Internet pharmacies to American consumers.

Right now, a 12-year-old juvenile can use a parent's computer to log onto an Internet search engine, type in the parent's credit card number, and direct an illegal controlled substance to be shipped to an address via commercial carrier next day air. We need to learn from the private entities represented here today what steps they are taking to combat Internet sales of unsafe and illegal prescription drugs and how they can engage in more aggressive efforts with federal agencies to protect the public.

The agencies here today have vast responsibilities to protect Americans from illegal narcotics, weapons, human trafficking and terrorism. They are also charged with protecting the public from unsafe and illegal prescription drugs. That's a tall order, and Congress needs to exercise our oversight responsibility to determine what is being done, what can be improved upon, and how we can enable these agencies to do their jobs more effectively, including leveraging help from the private sector.

Congress also needs to bring down the escalating cost of prescription drugs in the United States. Chairman Coleman and I both represent northern border States, in which thousands of our constituents are already crossing the border to get their prescription medications from Canada—either in person or over the Internet. Folks are going to continue that conduct until prices become reasonable here at home.

Legislation has been introduced by Senator Dorgan and others to tackle this problem, but there is no sign that the Senate Health, Education, Labor and Pensions Committee plans to take up this legislation in the near future. The latest setback came yesterday, when that Committee postponed action on a more modest drug importation bill that had been scheduled for consideration. While weaker than the Dorgan bill, that legislation included some useful provisions, inspired in part by this investigation, authorizing the FDA to regulate the licensing of Internet pharmacies.

I look forward to the testimony today.

Senator COLEMAN. I would now like to welcome our first witness for today's hearing. I welcome Richard M. Stana, Director of the Homeland Security and Justice Team at the Government Accountability Office. Welcome, Mr. Stana.

Mr. STANA. Thank you.

Senator COLEMAN. As I mentioned in my opening statement this morning, in conjunction with the Subcommittee's June 17 hearing on this matter, GAO recently released a report on GAO's investigation of Internet pharmacy drug sales. The purpose of these hearings is to continue our examination of the extent to which consumers can purchase pharmaceuticals and controlled substances over the Internet without a medical prescription, a medical diagnosis, and whether the pharmaceuticals that are pouring into the United States from foreign countries are counterfeit, unsafe, or illegitimate.

My distinguished Ranking Member talked about the issue of children. It is almost as if there is a candy roll out there for kids who want to get this, and not only is no parent not around, but if you have got Mom and Dad's credit card, you have access to it. Can we do something about that? We need to.

The purpose of today's hearing is to examine the Federal response and the private response to the problems highlighted at our

June 17 hearing and to learn what Internet search firms, credit card companies, and package delivery services, whose participation is needed to complete these transactions, are doing to address the problem.

I appreciate everyone's attendance at today's important hearing and am anxious to hear the testimony this morning.

Before we begin, pursuant to Rule 6, all witnesses before this Subcommittee are required to be sworn. At this time, Mr. Stana, I ask you to stand and please raise your right hand.

Do you swear that the testimony you give before this Subcommittee is the truth, the whole truth, and nothing but the truth, so help you, God?

Mr. STANA. I do.

Senator COLEMAN. Thank you, Mr. Stana. We will have a timing system today. When you see the light change from green to yellow, you have about a minute left. We will enter your complete statement for the record. So at that point, please summarize your testimony and then we will go to questioning after that. You have 5 minutes. You may proceed.

TESTIMONY OF RICHARD M. STANA,[1] DIRECTOR, HOMELAND SECURITY AND JUSTICE ISSUES, U.S. GOVERNMENT ACCOUNTABILITY OFFICE

Mr. STANA. Mr. Chairman, Mr. Levin, I am pleased to be here today to participate in this hearing on prescription drug importation.

As you know, American consumers are increasingly drawn to the convenience, privacy, and cost advantages of purchasing drugs over the Internet. But at the same time, there is growing concern that prescription drugs from Internet pharmacies are risky because they may be compromised or not the authentic product that you think you are going to get.

Further, consumers may also be violating the law unknowingly or intentionally by having these drugs shipped to the United States through international mail and private carriers. It is primarily the responsibility of U.S. Customs and Border Protection and the Food and Drug Administration to inspect and interdict prescription drugs and controlled substances that might be illegally imported into the United States via the mail or private carriers.

My prepared statement discusses these issues in detail and I would just like to summarize four main points.

First, as you mentioned in your opening statements, the amount of unapproved drugs illegally entering the country is said to be large and increasing. Owing to the popularity of Internet drug sales, large numbers of parcels arrive each day at the 13 international mail branches and 29 express consignment carrier facilities operated by private carriers like DHL or FedEx. Even though they are purchased from some sites that might be considered safe, the overall safety and quality of imported drugs, particularly those purchased from foreign-based sites, is not assured.

CBP did an analysis which demonstrates this, and Mr. Chairman, you also mentioned our previous work which showed that

[1] The prepared statement of Mr. Stana appears in the Appendix on page 178.

about 45 of 68 purchases we received were made without a prescription and 29 had labeling, packaging, and handling or other chemical composition problems. Some who feel they are getting reliable drugs at bargain prices might unknowingly be putting themselves at risk.

My second point is that many packages known to contain prescription drugs are released to the addressees with or without inspection. CBP officials told us that certain packages were targeted for inspection, but packages not targeted typically bypass inspection and are released to addressees. Many packages that were targeted by FDA and subsequently inspected were also later released to addressees. FDA officials acknowledge that they release tens of thousands of packages that contain drug products that may violate current laws and pose health and safety risks to consumers. This is because available staff are not able to process the volume of packages turned over to them for inspection.

For example, at one IMB, CBP targeted its efforts on packages arriving from 78 countries and forwarded to the FDA packages arriving from the eight countries it targeted for inspection. Packages coming from countries not targeted by CBP or FDA were not routinely inspected, and most continued in the mail. Further, FDA released to addressees some packages containing drugs that were not considered a priority and packages with drug amounts deemed for personal use.

At another IMB, if CBP's x-ray inspection revealed prescription drugs, FDA's instructions to CBP were to fill eight bins of packages twice each week, which would total about 3,000 packages. Once the capacity of the 16 bins per week was filled, other packages would continue on without inspection. At this site, FDA had the capacity to inspect about 140 of the 3,000 packages set aside each week and the remaining packages, 2,800 or so, were released without inspection, as were some of the 140 which were deemed not suitable for holding.

At another IMB, CBP officials told us that they usually released packages containing prescription drugs that appeared to be a 90-day supply or less, which they felt was in line with FDA's personal importation policy. At this facility, FDA officials told us that each week, CBP turned over to them hundreds of packages for inspection, but FDA had the capacity to inspect about 100 of them. They returned many of the other packages without inspection and CBP, in turn, released them to the addressees.

At the express consignment facilities, CBP and FDA relied mainly on reviews of manifests of incoming packages to determine which to inspect. Packages could avoid inspection if manifest information was not accurate. Further, as you mentioned, FDA officials are not on site to coordinate with CBP on targeting activities or random inspections.

My third point is that processing requirements are time consuming and can hamper enforcement efforts. CBP and FDA typically have about two to three staff each to perform the inspections and prepare the paperwork at each location. Processing for these packages can strain available staff, and staff are tied up processing as opposed to inspecting. An average inspection can take anywhere from about 10 to 15 minutes if there is not much to inspect or it

is a known product, to 2 or more hours to fully investigate what is in the package. Similarly, CBP's seizure processes are time consuming, and because I need to sum up, I will not go into much detail on those.

I do want to mention one other thing here which I think is very important. At one IMB, as an alternative to seizure, CBP headquarters approved returning 123 bins containing roughly 40,000 packages of Schedule IV controlled substances, including Valium, pain killers, and antidepressants, to the sender. The 123 bins amounted to a processing backlog of a year or more. According to CBP officials, most of these packages were sent by two companies located in two countries. This stop-gap action avoided the need to fully process the packages and store them for possible forfeiture and destruction, but it is not consistent with policy. We plan to pursue this further in the coming weeks and to see how widespread this action might be.

The last point is that, and I think you made this point, Mr. Chairman, purchasing prescription drugs from Internet pharmacies isn't new and concerns about importation have existed for many years. Action to mitigate this issue are still evolving.

There have been task forces created in the last year in response to Congressional mandates. CBP created a task force which looks very similar to the task forces created in the late 1990's that you have mentioned in your opening statement. It is too soon to tell whether these new task forces will have any better success than the old task forces in addressing this problem.

In closing, CBP and FDA are charged with the responsibility of inspecting and interdicting these drugs and they both have many dedicated staff that try their hardest to do what they can with limited resources. Although initiatives are underway to help either interdict the drugs or prevent their importation, it is too soon to tell whether these are going to have any better success than those that were started in the late 1990's.

This completes my oral statement. I would be happy to address any questions you or other Members of the Subcommittee may have.

Senator COLEMAN. Thank you very much, Director Stana.

As I read the report and listen to the testimony, it is somewhat mind boggling that we have a system of substances coming into this country, many of which we know are legal. We know from spot checks and searches that there is a substantial volume of material that is counterfeit, dosages not correct, and instructions not there, particularly as we deal with foreign countries, certainly countries outside the U.S. and Canada. The information is a crap shoot. You don't know what you are getting. And yet we really don't have an effective system for monitoring and controlling that, do we?

Mr. STANA. The system that we have in place has simply been overrun by the volume of drugs coming in due to Internet purchases. There is a system in place as you are well aware. You have seen it at the mail branches and at the carrier facilities. But there just aren't enough people to manage it properly.

Senator COLEMAN. And I am not directly criticizing our folks who are out there making an effort. Now, I am going to talk about some areas where I do have concern a little later this morning, but I

sense it is kind of like sand castles against the tide. It can be as pretty as—I have seen some pretty nice sand castles on the beach, but the tide keeps coming in and just overwhelms it and overwhelms it. Is that a fair assessment?

Mr. STANA. Well, one of the frustrating things is that this is a problem that has been known for many years, and as I pointed out and you mentioned, we started in the late 1990's to focus on the issue, but for too long we have been discussing what needs to be done and not taking appropriate action. Now the problem is much larger and much more difficult to——

Senator COLEMAN. That is where I want to go next. Help me understand the period from 1999 to today. In 1999, there was testimony before a House Subcommittee, Dr. Janet Woodcock discussing FDA actions dealing with the sale of illegal drugs over the Internet. There are discussions of something called the web crawler. Let me back up. What is a web crawler?

Mr. STANA. I believe, and I am not a technical expert, but what a web crawler does is it identifies certain sites that shouldn't be used for illegal purchases.

Senator COLEMAN. Are you familiar with FDA's results from using the web crawler?

Mr. STANA. No, I am not. I think you might better address that to FDA.

Senator COLEMAN. Do you even know if a web crawler was actually accessed?

Mr. STANA. My understanding is they tried to use it, but it didn't meet with the success that they anticipated.

Senator COLEMAN. And clearly, we go from 1999, when we raised this issue, to today, in which certainly the volumes has increased exponentially, the volumes of access to illegal drugs. I am trying to understand what happened. I am trying to understand whether we started fast out of the gate and just slowed up, or whether we turned our attention elsewhere. Can you give me a kind of overview or summary of what happened in the efforts from 1999 and at what point it slowed up and what happened? Why aren't we in a better place today?

Mr. STANA. In 1999, FDA started with two task forces that looked similar to what was created just in the past few months. One had a working group on legal and regulatory issues. One had a working group on legal issues. Another had one on public education. And these are very similar to the kinds of working groups we have now.

On the positive side, what they did is they brought affected agencies together and they talked and to some extent coordinated, but there really was very little action taken there. It was more of a talking exercise, a coordination exercise. So not much has happened. And those efforts, while may be well intentioned, really didn't have much impact at the incoming facilities.

The more recent task forces have so far had maybe a little bit more impact in that there were a couple of blitzes done at three IMBs. They also did one at the border for incoming travelers. They posted Public Service Announcements. I was at a Giant a few days ago. There is a notice posted near the pharmacy there about the dangers of using Internet pharmacies. So it is having some impact.

But the fact remains that if you need to stop this importation of dangerous and risky drugs, these approaches, while useful, aren't having the kind of impact that is needed to really mitigate the problem.

Senator COLEMAN. My question or comment is probably better directed to the agency heads, but as a policy maker, I have to reflect upon the question of why I should have confidence today on the formation of a new task force and efforts when we walked down that path 5 years ago and the problem is worse today than it was then.

Mr. STANA. Well, there is so much that we just don't know about the size and nature of this problem. We knew that we didn't know it 5 years ago. We still don't know it today. We don't know how many packages are coming into the country. We don't know how many are getting by without inspection. We don't know how many resources it is going to take to mitigate the problem. One estimate I saw, although I didn't get behind the numbers so I can't vouch for its accuracy, stated there are about two million packages a year of illegal drugs coming into the country. That is a sizeable amount.

There is another estimate that each IMB site where FDA has its resources, instead of having three staff on each shift, needs ten staff on each shift. We haven't examined the basis for that figure, but it demonstrates that, clearly, there is a resource problem here.

Senator COLEMAN. Even if we were to increase the resources from three to ten, would it be fair to say that we would not have the capacity to investigate or review each and every parcel that came into the country, are the numbers simply too vast?

Mr. STANA. I don't know how many resources it would take to do that. Clearly, the law states that these packages are not to come into the country unless there are certain very careful prescribed exceptions that are met. But I don't have the number, whether 10 is the right number, 15 is the right number, or if it is a problem that 100 people couldn't solve.

Senator COLEMAN. I am just trying to look at the system we have, which is not unsystematic. Countries are highlighted that are known to be of greater risk, so it is targeted.

Mr. STANA. Right. It is a risk management issue.

Senator COLEMAN. You have got a risk targeted approach. But unfortunately, if a country is not a targeted country——

Mr. STANA. Right.

Senator COLEMAN [continuing]. You could be the worst business operator, the worst crook in the world, but if you are operating out of a country that is not targeted, you are essentially free from review at this time. Is that a fair statement?

Mr. STANA. That is correct at some mail branches, at some IMBs. It is totally targeted initially by country. That is the first cut. You might get picked up on a random search.

Senator COLEMAN. Talk to me about the random search. Are we talking needles in haystacks?

Mr. STANA. Yes, you are.

Senator COLEMAN. What are the chances of getting——

Mr. STANA. You are talking about gut feelings——

Senator COLEMAN. What is the mathematical chance of getting picked up in a random search?

Mr. STANA. Very small. I don't have the exact number, but very small.

Senator COLEMAN. Infinitesimal. Microscopic.

Mr. STANA. It would be very small, certainly less than 3 percent.

Senator COLEMAN. I would think less than perhaps——

Mr. STANA. One percent, perhaps.

Senator COLEMAN. Maybe a percentage of 1 percent.

Mr. STANA. But to amplify your underlying point, even in areas where CBP and FDA target countries, just because you are in one of the 70-some countries that CBP targets at one facility, that doesn't mean your package is going to be fully inspected because there are limits to the capacity. At the other IMB where inspection is a function of volume, if your package is in the 16 bins, it might be inspected, but the fact of the matter is, on average, of those 16 bins, your package in one of the bins is going to be inspected. The other ones are going to be returned without inspection.

Senator COLEMAN. What is your response to, or your analysis of, the different approaches per IMB? Would you suggest that it would make better sense to have a more uniform approach for the agency?

Mr. STANA. Yes. I think it would be beneficial to use a more consistent and uniform risk management approach from IMB to IMB that focuses in inspections, based on inspection statistics and experience—what are the more important packages to look at. Right now, we have an inconsistent policy.

FDA has just come up with an SOP which is intended to provide a uniform inspection process. The problem is, without more resources, all you are doing is creating a uniform process which in the end returns packages to the mail without inspection.

Senator COLEMAN. At one point, you talked about a situation, I forget the company, with a number of bins that were returned to sender.

Mr. STANA. Yes. That was that one IMB where there was about a year or more backlog of controlled substances. These were Schedule IV controlled substances. The staff at the facility felt that in the interest of the government they would not spend time processing these packages. As an alternative to seizure, they sent them back to the originating pharmacy. Clearly, a controlled substance is supposed to be seized. It is not supposed to be returned to sender without proper processing. They phoned headquarters and headquarters approved the return of the packages to the senders.

Now, by doing this, they missed a couple of opportunities. One, they missed opportunity to gather further intelligence on exactly who the sender, receiver, and shippers were. And second, when they do seize a package, they are supposed to tell the person who ordered it—the addressee—that he or she was performing an illegal act and the next time they do this the CBP will take action on it. That could act as a deterrent for future purchases. So they missed that opportunity, too.

Senator COLEMAN. When you talk about missed opportunity, was there anything they did in returning it to the sender that would have precluded that sender from reselling it, from reintroducing those drugs back into the marketplace?

Mr. STANA. Not that I am aware of.

Senator COLEMAN. So the sender sold it and made their money, I presume. There is no COD here. You are paying up front. So they made their money and then they received back the goods with the complete freedom to resell them again.

Mr. STANA. There is a possibility, unless there is something that happened that I am not aware of, there is a possibility they could be reintroduced to the market.

Senator COLEMAN. When you say something happening, was there any coordinated enforcement action against these sellers? Was there anything that identified this list of sellers and then asked folks to go back and to proceed with some action against them?

Mr. STANA. I am not aware of any. Records were not kept on these 123 bins and the 40,000 packages in them. What I know is they were predominately from two countries and they were from two companies within those two countries.

Senator COLEMAN. I find that of concern. It is like busting a drug dealer and giving him back his drugs without any follow-up. And I understand administratively we are faced with what to do with these things. But on the other hand, giving it back to somebody who is already breaking the law——

Mr. STANA. As you know—you visited the New York facility—there are seizure rooms with dozens and dozens of seized goods waiting for some sort of disposition. These were over and above that. But I didn't want to leave the impression that all controlled substances were returned to sender.

Senator COLEMAN. But there were. We are looking at a picture[1] taken at JFK. Approximately 20,000 boxes of suspected controlled substances seized by Customs are awaiting processing.

Mr. STANA. Right. It would look like that. There were 123 bins in an open area with bags in them that looked similar to those.

Senator COLEMAN. And we clearly don't have the resources to do those inspections, to process that.

Mr. STANA. Well, they said that it was a year, maybe 2 year's worth of processing backlog given the current required procedures and available staff.

Senator COLEMAN. Let me ask you a question. You talked about express facilities at one time. Are you talking about private operators?

Mr. STANA. Right, FedEx, DHL, UPS, those facilities.

Senator COLEMAN. And their representatives will be here and I appreciate that. They have manifests. Now, manifests means that somebody is declaring that this is a controlled substance——

Mr. STANA. Someone is to declare what good is inside, and certain characteristics like weight, volume, and so on.

Senator COLEMAN. So the sender, the wholesale, whoever is selling the drugs, would typically have to declare.

Mr. STANA. Yes.

Senator COLEMAN. But if they don't declare, then we are stuck with the same situation we see with Postal. There is no way to readily identify.

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[1] See Exhibit 14, which appears in the Appendix on page 299.

Mr. STANA. Well, again, they may be picked up in a random search, but it is not likely. The other thing is, because FDA is not on site at the same time CBP is—they work different shifts, FDA works primarily during the day and CBP works at night—they can't be there side-by-side to coordinate what these random searches might focus on.

Senator COLEMAN. But you are depending upon the credibility, the good word, the willingness of somebody to subject themselves to review and investigation by the nature of declaration, knowing that if they don't declare, then all they have got to do is gamble, and the odds are substantially in their favor because the odds of getting picked up in a random search are so small.

Mr. STANA. Any kind of cargo, whether it is ocean-going cargo, air freight, whatever, is subject to the same risk here. The veracity of manifests is a longstanding problem.

Senator COLEMAN. And particularly in an area where it would be different if there are manifests where you are not dealing with substances that are subject to seizure, that are potentially illegal. In fact, in the kind of spot searches that we have done, we have seen significant percentages of drugs which are controlled substances which are not in this country legally. So it is almost as if going across the border, you are telling the drug dealer, tell us what drugs you have.

Mr. STANA. Well, that is true, but in reviewing the manifests, the FDA people are also looking for other things, like certain structured shipments or a certain address they received a tip on. CBP inspectors might also have a gut feeling about a shipment where the weight doesn't match the description of the goods. So it is not strictly on the declared item, but that is a big part of the targeting.

Senator COLEMAN. I am looking, just trying to figure out if there are solutions here, trying to sort out the purpose of what we are doing here. One of the thoughts is to give Customs the ability to seize and destroy. So in other words, instead of sending back these 123 bins, if they could be identified as controlled substances which are, per se, illegal, they could have the ability for on-site destruction. Your reaction to that proposal?

Mr. STANA. Obviously, it would require a change in law. But at the same time, if that were enacted, it would certainly reduce the backlog and make the whole process more manageable. We haven't really examined all the pros and cons to it, but on the face of it, it would solve one problem. I don't know if it would create another.

Senator COLEMAN. I would, at some point, like you to be able to do that. Again, I am looking for solutions.

If there were a few other obvious things based on your study and your review, changes in the law that would improve our ability to provide a greater measure of safety for American consumers in this area?

Mr. STANA. Well, I think some of the initiatives that are underway are going to help, like consumer education, alerting people to the fact that this is just not getting the same drug at a bargain price, that there are health risks. Having looked at the table at the John F. Kennedy International Airport and saw what was on it, I would never put that stuff in my body. I think just getting that kind of word out is very important.

On the enforcement side, we talked about several options, including more people and maybe a summary destruction of illegal shipments. Another option is a summary return to sender; that wouldn't take the drugs out of the commerce chain, but it does make it more expensive for an Internet pharmacy to operate. There are other options that have been proposed that we are trying to get more information on, like working with the credit card companies, as you mentioned, to stop purchases from seemingly illegal sites, and identifying those sites that appear to be in safe countries but are actually located elsewhere and are selling dangerous drugs.

Senator COLEMAN. Aren't we also faced with the problem today of sites that are located in safe countries, located in Canada——

Mr. STANA. Or in the United States.

Senator COLEMAN [continuing]. Or the United States, but are getting their drugs from unsafe countries.

Mr. STANA. I don't know if U.S. pharmacy outlets are getting from third countries, but when we made our purchases of drugs from U.S.-based Internet pharmacies, we also found problems with the drugs. But your point is correct. There are Internet drug sites that mask their actual locations. I read about one site that posed as a Canadian site with Canadian flags on the web page but the orders were filled by a pharmacy in China.

Senator COLEMAN. And the consumer has no way to distinguish between an all-American Drugs-dot-com coming from Fiji or Thailand——

Mr. STANA. Not without a lot of sophisticated research. They can be pretty well masked. Of course, there are two dimensions to this problem and you mentioned them both. One is the well-intentioned consumer like you or me that just wants a bargain drug. The other involves, for example, the kid who wants to get high and sees ordering from the Internet pharmacies as an easy way to do it. Too often, we focus on the former, and that is part of a great national debate about trying to lower drug prices. But the latter is also very important and plays right into this issue.

Senator COLEMAN. In 1999, this issue was reviewed. Folks came before a House Committee, talked about task forces, talked about reviews, talked about web crawlers. We had a series of hearings. I believe Judiciary had a hearing just a couple weeks ago. What advice or direction would you give to some of the other witnesses who are coming before us from the FDA and Customs and Postal and the private folks? What advice do you give them to help raise the prospect of not coming back in another 5 years, because if we come back in another 5 or 6 years and I am still here, I am going to be very angry.

Mr. STANA. Well, I think that this problem grows exponentially. It doesn't grow on a straight line. With the growth on the Internet, I think you would not see anything but a tremendous growth in the future.

I think really that the core solution is getting a consensus and a commitment to address this problem and do what it takes to get on top of it. I don't know if FDA and Customs and now CBP have asked for more resources or if they haven't, whether any requests for more resources have been denied either by the past couple of administrations or by appropriators. But clearly, there has to be a

demonstrated commitment to address the problem. There are a lot of really hard-working people that are trying to do the best that they can with the resources they have. We don't want to create a cynacism because they are being put on the line with an impossible task that they are never going to have the resources to adequately addrss the problem.

Senator COLEMAN. I appreciate that, Director Stana. Thank you. Your testimony has been very helpful.

Mr. STANA. Thank you very much.

Senator COLEMAN. I would now like to welcome our second panel to today's hearing. Our second panel is comprised of representatives of the law enforcement and regulatory community, the Drug Enforcement Administration, the Bureau of Customs and Border Protection, the U.S. Postal Service, and the Food and Drug Administration.

I would like to welcome the Hon. Karen P. Tandy, the Administrator of the Drug Enforcement Administration; Lee R. Heath, Chief Postal Inspector for the U.S. Postal Service; Jayson P. Ahern, Assistant Commissioner at the Office of Field Operations at the Bureau of Customs and Border Protection; John M. Taylor III, the Associate Commissioner for Regulatory Affairs at the Food and Drug Administration; and finally William Hubbard, Associate Commissioner for Policy and Planning at the FDA.

As previously mentioned, the purpose of this hearing is to examine what role the FDA, the Bureau of Customs and Border Protection, the U.S. Postal Service, and DEA play in preventing the illegal importation of scheduled pharmaceuticals and pharmaceuticals that violate the Food, Drug, and Cosmetics Act, and whether the pharmaceuticals that are pouring into the United States from foreign sources are counterfeit, expired, unsafe, or illegitimate. Again, I appreciate all of your attendance at today's important hearing and am anxious to hear your observations on the current state of affairs.

But before we begin, pursuant to Rule 6, all witnesses that testify before the Subcommittee are required to be sworn. At this time, I would ask you all to please stand and raise your right hand.

Do you swear that the testimony you are about to give before this Subcommittee is the truth, the whole truth, and nothing but the truth, so help you, God?

Ms. TANDY. I do.

Mr. HEATH. I do.

Mr. AHERN. I do.

Mr. TAYLOR. I do.

Mr. HUBBARD. I do.

Senator COLEMAN. I think all the witnesses here are aware of the timing system. When the lights go from green to yellow, you have about a minute left to conclude. Your complete written statements will be entered into the record.

Administrator Tandy, we will have you go first, followed by Mr. Heath, Mr. Ahern, and finish up with Mr. Taylor and Mr. Hubbard. After we have heard all your testimony, we will proceed to questions. With that, Administrator Tandy, you may proceed.

TESTIMONY OF KAREN P. TANDY,[1] ADMINISTRATOR, DRUG ENFORCEMENT ADMINISTRATION

Ms. TANDY. Thank you, Chairman Coleman. The DEA appreciates your leadership on this issue, Mr. Chairman, as well as the other Members of the Subcommittee, and I thank you for the opportunity to discuss what is clearly a growing threat of on-line purchases of pharmaceuticals.

In the 21st Century, the Internet is becoming the cyber street corner where dangerous and addictive drugs are bought and sold. Pharmaceutical drugs are peddled by multi-million dollar organizations, albeit the same as Internet drug lords, who are as sophisticated as traditional drug cartels.

Prescription drugs are not the only drugs being peddled by criminals on the web. I want to share with you an operation that just concluded. It was conducted yesterday, and successfully so, by DEA along with my colleagues at this table from Homeland Security, Immigration and Customs Enforcement, FDA, U.S. Postal and Inspection Service. Together, we targeted on-line sellers of illegal designer drugs in Operation Web Trip. We arrested ten Website operators who were distributing highly dangerous designer drug analogs. DEA issued one restraining order, executed one search warrant, and obtained three voluntary terminations of five targeted Internet domains. Users refer to these analog drugs, designer drugs, as Foxy, Methoxy, or DIPT, and too many young people tragically believe that these designer drugs are legal substitutes for Ecstasy or LSD.

In reality, these drugs are research chemicals with no medical use, and when consumed, they produce hallucinogenic effects and users often exhibit violent behavior. These are volatile, powerful drugs that are not meant for human consumption. If users ingest as little as five milligrams too much, fatality can result.

The Websites that were targeted in Operation Web Trip sold substances that led to the fatal overdose of at least two people and many more non-fatal overdoses. This operation demonstrates that we together will shut down these Websites and arrest those behind them.

Rogue Internet pharmacies have also claimed too many unsuspecting victims. DEA's investigations have discovered 14 deaths or overdoses and 15 people who have entered treatment or sustained injuries from drugs obtained over the Internet. With the click of a mouse, consumers are buying controlled substances over the Internet without a legitimate prescription. Physicians associated with these Websites almost never establish a proper diagnosis through the use of accepted medical practice. In short, there is no authentic doctor-patient relationship. Visitors to these pharmaceutical Websites are, in essence, helping themselves to controlled substances. Consumers are subject to habit-forming drugs, dangerous drug interactions, and counterfeit or tainted products.

The Bush Administration has implemented a coordinated strategy announced this past spring to deal with the abuse of prescription drugs. For our part, DEA is targeting the diversion of drugs using the Internet by utilizing additional tools that Congress has

[1] The prepared statement of Ms. Tandy appears in the Appendix on page 202.

given to us. Appropriations for this fiscal year included 63 additional positions dedicated to our Internet initiative, which targets rogue pharmacies and affiliated doctors and has resulted in 91 active investigations involving the diversion of pharmaceutical controlled substances using the Internet, and those investigations cover some 537 Websites currently.

This fiscal year, we have shut down 25 Internet pharmacy organizations. Over $3.3 million has been forfeited, and 3.2 million dosage units have been seized. Eleven million dollars in assets are pending forfeiture currently.

In addition, Congress provided $6.3 million to DEA to put into place sophisticated technology to track down these rogue Internet pharmacy Websites. We are also using the Internet itself as a tool. DEA is working with major search engines and Internet service providers to warn consumers searching for controlled substances of the dangers, and we have recently established a link to DEA's home page that allows citizens in this country and others who access that home page to report suspicious Internet pharmacies, which is an initiative that has also brought us investigative leads.

The scope of this problem is too broad for DEA or any one of the single agencies before you to tackle alone. We are enlisting the support of the private sector, the legitimate businesses essential to the on-line trade in diverting pharmaceutical drugs through the Internet.

For example, we are working with FedEx and UPS, who are acutely aware that their businesses are being exploited and alert us with any unusual patterns. Similarly, consistent with my emphasis and this administration's emphasis on taking away the proceeds of the illicit drug trade, both Visa and MasterCard are assisting us in investigations and with financial leads. Both shippers and credit card companies have agreed to shut down sites determined to be conducting illegal activities.

And as this Subcommittee has noted, a significant aspect of the pharmacy problem is located abroad. The DEA is cooperating with our Federal and foreign counterparts and we have assumed a leadership role in the international forum on Internet diversion.

We look forward to working closely with you, Mr. Chairman, and with the Congress to ensure that the Controlled Substances Act addresses illegal Internet pharmacies as vigorously as we intend to address them through our enforcement efforts, and I would be happy to answer questions at the appropriate time. Thank you.

Senator COLEMAN. Thank you very much, Administrator Tandy. Mr. Heath.

TESTIMONY OF LEE R. HEATH,[1] CHIEF INSPECTOR, U.S. POSTAL INSPECTION SERVICE

Mr. HEATH. Good morning. As Chief Postal Inspector, I appreciate you giving me the opportunity to present the views of the U.S. Postal Service regarding this growing concern and the role the Postal Inspectors play in combatting it.

The responsibility for safeguarding approximately 200 billion pieces of mail a year and ensuring America's trust in the Postal

[1] The prepared statement of Mr. Heath appears in the Appendix on page 206.

system falls on the shoulders of the U.S. Postal Inspectors. I have submitted a written statement which highlights what we have done and continue to do with regards to illegal narcotics, child pornography, and other dangerous mailings. It outlines what we are doing and will do to better address today's issue.

There are numerous items prohibited from being sent through the mail under various sections of Title 18 of the U.S. Code. For instance, it forbids the mailing of lottery tickets or other gambling instruments. Customs agents open suspected foreign lottery mailings upon entry into the United States and then refer the mailing to us, since we have the primary enforcement jurisdiction. Using our existing authority, Postal Inspectors obtain destruction orders for this lottery mail to disrupt the operation.

We have met with the Postal Service General Counsel to explore applying our existing statutory authority to declare illegally mailed drugs in violation of the prohibition against dangerous mail. This strategy would enable us, working with FDA and Customs, to handle these items in a manner similar to what we do with lottery mailings.

To be successful, we must rely on the cooperative efforts of Customs and the FDA. Controlled substances may be mailed if they are not otherwise banned by Title 21 of the U.S. Code and are packaged in accordance with the Controlled Substance Act. Prescription drugs may be sent through the mail as long as the inner packaging is labeled to show the name and address of the dispenser and the label conforms to the other requirements. The outer wrapper has to be free of content markings.

This requirement creates an enforcement difficulty for Postal Inspectors acting alone. However, I am confident that we can overcome such challenges with the assistance of Customs and FDA using their existing authorities. Without these agencies, it is difficult, if not impossible, for us to articulate the probable cause necessary to secure a Federal search warrant based solely on the exterior appearance of the package or the mailing or the country of origin.

Since meeting with the Subcommittee on June 18, Postal Inspectors have met with our law enforcement and regulatory partners. We asked to be included in the standing working groups focusing on on-line drug sales.

We also conducted an assessment of the extent of the problem at the Miami, New York, Los Angeles, San Francisco, and Chicago International Mail Service Centers to develop strategies to address this problem with the interagency task forces. We proposed to the task force our intent to host a conference of the interested agencies from each of the International Service Centers to develop a strategy to combat this problem.

Finally, as the Chief Postal Inspector, I also serve as the Chairman of the Postal Security Action Group of the Universal Postal Union. The Universal Postal Union is the regulatory organization for all postal administrations, and the Postal Security Action Group is made up of approximately 75 international postal administrations. One of our major efforts since September 11 has been to promote and adopt measures which are designed to keep the mails of the world free from dangerous goods. I will obtain the necessary in-

formation from Customs and the FDA with regards to target countries and raise this issue with the other foreign postal administrations.

The Postal Inspection Service will do whatever it can to better address the problem of illegal drugs and illegally imported drugs in the mail. We remain greatly dependent on those agencies which have the primary jurisdiction in these matters and I am confident that we can work with them to overcome any obstacles.

I appreciate your recognition of the importance of this issue and the support shown by all of you. Thank you.

Senator COLEMAN. Thank you very much, Inspector Heath. Mr. Ahern.

TESTIMONY OF JAYSON P. AHERN,[1] ASSISTANT COMMISSIONER, OFFICE OF FIELD OPERATIONS, BUREAU OF CUSTOMS AND BORDER PROTECTION

Mr. AHERN. Good morning, Mr. Chairman, and thank you very much for the opportunity to testify here today. I would like to discuss with you CBP's ongoing efforts to address the ever-increasing trend of personal and bulk importation of pharmaceutical products and controlled substance into the United States.

Although the main focus of CBP has shifted to protecting the United States from terrorist attacks, CBP also enforces over 400 requirements from more than 40 agencies at our U.S. borders. These include the laws that prohibit the importation of illegal and unapproved pharmaceuticals that fall under the jurisdiction of the FDA, as well as those controlled substances that are under the jurisdiction of the Drug Enforcement Administration.

The issue of U.S. consumers buying prescription drugs from foreign sources have become a significant concern to CBP, and a growing number of Americans obtain their medications from foreign locations, often seeking out suppliers in Mexico and Canada, as well. However, the safety of the drugs purchased from these sources cannot be ensured.

CBP is concerned with several ways that pharmaceuticals are imported, including those that are purchased through the Internet and shipped through our international mail or express courier facilities, those carried by individuals across the U.S. borders, and also bulk shipments of adulterated or counterfeit pharmaceuticals. During the course of the past year, we have taken some steps to address each of these areas of concern.

Millions of packages, though, come through our mail and express courier facilities each year and thousands of these packages, particularly in the mail, are found to contain illegal and unapproved pharmaceuticals. Additionally, we have found bulk pharmaceutical shipments that were attempted to be imported through the mail, potentially indicating that these products could be making their way to pharmacy shelves.

The volume of the imported material brought into the United States via the mail is overwhelming. The international mail poses also several unique challenges to CBP, since it is not accompanied by any electronic manifest information.

[1] The prepared statement of Mr. Ahern appears in the Appendix on page 218.

While we do not have statistics on the total number of imports of controlled substances or pharmaceuticals that enter the country each year, the U.S. Postal Service estimates that over 400 million pieces of mail enter the United States through our international mail branches each year. It is also significant to note that during fiscal year 2003, Customs and Border Protection made over 24,000 seizures of mail, and during this period, of those 24,000, 12,353 were pharmaceutical and controlled substances.

At the express consignment facilities that we staff, there are over 46 million packages arrive, with Customs and Border Protection making over 4,900 seizures, of which 1,543 were related to pharmaceuticals or controlled substances.

In order to address some of these challenges, we recognize certainly there is a significant threat growing to the public's health and CBP has been working very cooperatively with the DEA, the FDA, the U.S. Immigration and Customs Enforcement, ICE, and the U.S. Postal Inspection Service, and now the offices of the National Drug Control Policies have become involved, as well. We have directed these issues related to the importation of prescription drugs and miscellaneous pharmaceuticals. The goals of this interagency working group are to create a strategy for enforcement, interdiction, and disposition of unlawful pharmaceuticals entering the United States and to develop proposals for joint enforcement operations at our ports of entry and mutually agreed upon policies to unauthorized importations.

Since a large percentage of pharmaceuticals and controlled substances arrive through the mail and by express consignment, a separate working group has also been created to address these areas. The working group was charged with reviewing and revising procedures used at international mail and express consignment operator facilities in addition to assessing resources used at these locations. CBP is currently working with the FDA to develop standard operating procedure for mail operations.

On the concrete results of the mail and express task force is the coordination of the effort that is being conducted at all of our international mail branches this year. The operation's goals, called Operation Safeguard, is to identify the type and the volume and the quality of the pharmaceuticals imported into the United States. This enforcement effort found the volume of pharmaceuticals shipped through the international mail to be enormous. We have also found that a significant number of these do not contain any active pharmaceutical ingredient but merely contain substances such as starch and sugar.

The latest blitz that was conducted in June uncovered a substantial volume of controlled substances, and of the packages that were examined, 46 percent are suspected to contain controlled substances and these products were seized.

The working group has also conducted regular meetings since January 2004 and several key accomplishments have also been created through the reimplementation of Operation Safety Cap, which is designed to look at passenger importations of pharmaceuticals from Mexico. Safety Cap was an agency-wide plan to enforce laws related to the importation of prescription drugs at the border. Both FDA and ICE also participated in this enforcement operation and

this plan continues to develop for further locations along the Southwest border, which we have done four to date. We will also turn to the North and look at crossings coming across the Northern border from Canada.

In conclusion, it is clear that the importation of the pharmaceuticals and controlled substances remains an overwhelming problem for Customs and Border Protection. We are committed to continue to work with the FDA, the DEA, ICE, and other regulatory agencies to develop a more practical and workable approach to solving this problem.

I want to thank you and the Members of this Subcommittee for including Customs and Border Protection in your review of importation of pharmaceuticals and I will be happy to take any questions later.

Senator COLEMAN. Thank you, Commissioner. Mr. Taylor.

TESTIMONY OF JOHN M. TAYLOR, III,[1] ASSOCIATE COMMISSIONER FOR REGULATORY AFFAIRS, U.S. FOOD AND DRUG ADMINISTRATION, ROCKVILLE, MARYLAND

Mr. TAYLOR. Mr. Chairman, before I begin, I would like to ask that some additional and updated enforcement cases be included in the record along with my written statement.[2]

Senator COLEMAN. Without objection.

Mr. TAYLOR. Thank you, sir. Mr. Chairman, I appreciate having this opportunity to discuss with you issues related to on-line pharmacies and importation of prescription drugs to the United States. Despite the many proposals that would legalize the importation of prescription drugs, FDA continues to have serious public health concerns about the importation of drugs outside the current safety system established by Congress under the Food, Drug, and Cosmetic Act.

When it comes to buying drugs absent our existing regulatory protections, FDA has consistently concluded that it is unable to endorse a "buyer beware" approach. Currently, new drugs marketed in the United States, regardless of whether they are manufactured here or in a foreign country, must be approved by FDA based on demonstrated safety and efficacy. They must be produced in inspected manufacturing plants that comply with good manufacturing practices, and the shipment and storage of these drugs must be properly documented and, where necessary, inspected.

Unfortunately, the drug supply is under unprecedented attack from a variety of progressively more sophisticated threats. For example, FDA's counterfeit drug investigations have risen fourfold since the late 1990's. At the same time, inadequately regulated foreign Internet sites have also become portals for unsafe and illegal drugs.

For example, FDA recently worked with domestic and international authorities to shut down a Website advertising FDA approved and safe European birth control pills and other drugs, but they were actually importing ineffective counterfeit products. FDA believes this Website and the four Websites that FDA knocked out

[1] The prepared statement of Mr. Taylor appears in the Appendix on page 227.
[2] Additional FDA Enforcement Actions appears in the Appendix on page 283.

in February 2004 that were selling contraceptive patches are indicative of the dangers consumers face when they purchase drugs over the Internet.

Consumers are exposed to a number of potential risks when they purchase drugs from foreign sources or from sources that are not operated by pharmacies properly licensed under State pharmacy laws. When consumers take such medications, they face the risk of subpotent, contaminated, counterfeit product, dangerous drug interactions, and/or suffering adverse events, some of which can be life threatening. More commonly, if the drugs are subpotent or ineffective, patients may suffer complications from the illnesses that their prescriptions were intended to treat without ever knowing the true cause.

Due to the huge volume of drug parcels entering the United States through international mail facilities and courier services, the requirements for notice and hearing, and FDA's limited resources, it is difficult for FDA to obtain and refuse the many mail imports consisting of individual small quantity shipments. As a consequence, tens of thousands of parcels that FDA is not able to review as a result of its limited enforcement resources and competing priorities are eventually released by FDA and the Bureau of Customs and Border Protection, even though the products contained in the parcels may violate FDA statute.

While we do not believe that this is an acceptable public health outcome, it is one which presents a significant challenge to the agency. We have responded to this challenge by employing a risk-based enforcement strategy, the refinement of which is ongoing, to target our existing resources effectively in the face of multiple import priorities, including homeland security and food safety.

To enhance our ability to effectively carry out this task and to assess the extent of the problems posed by imported drugs, CBP and FDA conducted import blitzes at four international mail facilities last summer. We found that 88 percent of the drug products we examined were unapproved or otherwise illegal. Examples of the potentially hazardous products encountered during the blitz included drugs never approved by FDA, drugs requiring careful dosing, drugs withdrawn from the market, drugs with clinically significant drug interactions, drugs with inadequate labeling, drugs inappropriately packaged, drugs requiring initial screening and/or close physician monitoring, and controlled substances.

CBP and FDA performed another round of blitzes at four international mail facilities and at several courier hubs in November 2003, resulting in similar findings. CBP and FDA continue to perform blitzes which help quantify the type of drugs coming into this country, identify the public health issues surrounding these products, and identify trends in illegal importation of unsafe drugs. The results enable us to strategically focus our investigatory and regulatory resources and drive our efforts to reevaluate, refine, and improve the programs and procedures used to ensure the availability of safe and effective drugs to U.S. consumers.

As a result of these efforts, the agency has finished drafting procedures that encompass the best and most effective practices identified from our operations around the country. These procedures will be used by all FDA personnel responsible for handling mail at

the international mail facilities and at the air courier hubs. We have implemented these new mail procedures in a staggered approach, starting with the international mail facilities located at JFK Airport and Carson, California. The air courier procedures will be implemented in a similar manner next month starting with the air courier hubs in Memphis and Louisville.

The completion of these procedures is significant because it represents a strengthening in the programs and procedures that are used to ensure the availability of safe and effective drugs to U.S. consumers. The procedures increase efficiency and consistency by providing well-defined steps for targeting packages for inspection and detention, and they also help CBP, DEA, Postal, and our other partners because they provide a better understanding of what products are of greatest concern to the agency, and they also make the process more transparent.

In closing, a large and growing volume of parcels containing foreign prescription drugs ordered by individuals from foreign sources are entering the United States. This volume represents a substantial challenge for the agency to adequately assess and process these parcels, resulting in an increased workload for agency field personnel. The new procedures, however, will help the agency target its limited resources in a manner that will best protect the public health from unsafe, illegal imported drugs, and drugs purchased from overseas Internet sites.

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

Senator COLEMAN. Thank you, Mr. Taylor.

For all the witnesses, there is a lot of information in your prepared statements and 5 minutes doesn't do justice to the range of concerns that you have identified and some of your suggestions for addressing those. So I just want you to know I appreciate that. I don't know if the audience, listening to 5 minutes, knows the extent to which you have been looking into these problems and trying to figure out a way to deal with them. But I do appreciate that.

Commissioner Hubbard.

TESTIMONY OF WILLIAM HUBBARD, ASSOCIATE COMMISSIONER FOR POLICY AND PLANNING, U.S. FOOD AND DRUG ADMINISTRATION, ROCKVILLE, MARYLAND

Mr. HUBBARD. Thank you, Mr. Chairman, and on that note, I am going to race through some exhibits that FDA has that I believe complement the very findings that you and GAO have made and also give you some results of some recent investigations that we have done.[1]

As you saw in New York, Customs is the initial screening organization for these drugs that turns it over to the FDA. We get presented with these huge bins——

Senator COLEMAN. Mr. Hubbard, I will let you take your time a little bit, too. I will extend your time.

Mr. HUBBARD. Great. Thank you. [Laughter.]

Senator COLEMAN. I grew up in Brooklyn, New York, spending my last 4 years in Minnesota, but the good news about growing up

[1] See Exhibit No. 33 which appears in the Appendix on page 351.

in Brooklyn is that you can talk fast. The bad news is, nobody understands you. [Laughter.]

Mr. HUBBARD. Thank you very much, Mr. Chairman. So FDA is presented with these huge bins of packages, and I have got some here before me. These are actual orders that patients have made, and let me just make up a scenario here.

They send me to New York and become one of these inspectors, and I have an M.D. degree and a pharmacy degree and a law degree, and I begin to open these packages, and maybe I can get through one bin in a day, but I can't make any reasonable judgments about these drugs. I can look at the name. I can look at the pill. But it doesn't tell me very much.

So I think to answer the question that you raised about more resources—a visual inspection with more resources will not actually solve this problem, we fear. And we are also very concerned that controlled substances are finding their way through with the prescription medications because of the difficulty of finding those, and as you saw in New York, there is a mountain of those sitting there waiting to be dealt with, as well.

Now, one of the things that we have recently done is ask a local computer security firm named Cyveillance to look at some of the sites that purported to be Canadian, which are generally believed to be the best of these pharmacies. So they use a web crawler, as you asked about, to examine sites and found 1,000 sites—1,009—that appeared to be Canadian. And then we did a random deeper analysis of 10 percent of those and found that almost half are offering controlled substances. Two-thirds or more are selling prescription distribution drugs. These are drugs like Accutane or something that FDA would only approve under very restricted use by certain doctors and pharmacists. They also lie and they say the drugs are FDA approved when, in fact, they are not, and they have liability disclaimers that say to the patient, we are not responsible if you are injured.

As an example, here is one, Discount Drugs of Canada. It appears to be very legitimate. We asked, where is it? They say they are in Manitoba. Who is the registrant of it? It is a Mr. Thuy. Where is he? He is in Vietnam. That concerns us. Why is the registrant of this site in Asia? They are selling not only drugs from Canada, they are offering drugs from Australia and Britain. So we see this almost inexorable dimunition of the source, and there are reports now of drugs coming from Chile, from Israel, from South Africa, and so the whole system, we fear, is degrading. And, of course, they are offering controlled substances like Meridia and restricted distribution drugs like the Somatropin that you see here.

And then lastly, these sites are essentially saying to the patient, sign away any right to sue us and attest to the fact that if you are injured, it is your responsibility, patient. No American drug store would ever do that.

We are also worried about an even slippery slope. As you see, this is a communication from a Pakistani drug manufacturer who is saying essentially to Canadian pharmacies, when you start running short of your supply of the good Canadian or American drugs, let us know. We will fill your pipeline with drugs that we make here in Pakistan.

One site that we and the DEA have been investigating is this one that offers to sell generic versions of Canadian drugs, and we have actually made some buys there and explored where they are. They are actually registered in China. But the postmark was Dallas, Texas. The return address was Miami, Florida. The credit card was billed to a business on the Island of St. Kitts. And the listed phone number for this site when we began to investigate where it really is was the South American country of Belize. Again, why if this is legitimate are these things all over the place?

And, of course, it is not legitimate. We actually bought drugs and tested them, Lipitor, Viagra, and Ambien, Ambien being a powerful sleep aid. We tested for potency. They failed. We tested them for so-called dissolution, to see if they would dissolve in the body and go into the bloodstream. Two failed. And they had impurities in most cases. In fact, in some cases, their potency was half-potent or double-potent. So, for instance, a senior citizen could take this Ambien thinking one pill was what he was supposed to take. It is double-potent. It could sedate him to the point of death, a very serious public health concern.

Now, as you know, part of the problem, Senator, is that the public officials are telling people to go buy these drugs because they are cheaper, and this is the Wisconsin site that Governor Doyle has put up. They use three Canadian pharmacies in British Columbia, in Alberta, and in Manitoba, as you see, Canada drugs, Granville Pharmacy, and Total Care. So recently, the Pharmacy Society of Wisconsin has been examining the actual purchases from those sites and they are finding that a third of the prescriptions from that site, and this is supposedly the site has been checked out by the State. It is supposed to be one of the better ones. A third of the prescriptions are not meeting the State's agreement. Two-hundred-and-thirty-seven impermissible drugs have been dispensed. Many of them were non-FDA approved drugs. And they had a specific requirement not to ship refrigerated drugs because that had been a problem.

So FDA then did its own examination to determine if, in fact, the Pharmacy Society results were accurate, and in fact, we found even worse, that in the case of Total Care Pharmacy, two-thirds of their prescriptions violated the State agreement. But unfortunately, Mayor Thomas Menino of Boston just yesterday announced a program to give employees of Boston drugs from Total Care Pharmacy, the very pharmacy that has been found to be violating the standards that had been established.

And even worse, in many cases, they are selling Americans generic drugs that they could have gotten here in the United States at a corner drug store cheaper than in Canada. So they could have gotten the regulated, FDA-approved drug here, and they are being sent to Canada to buy a drug that is actually more expensive and less regulated.

Last, I will just close with a couple of mentions of counterfeiting. These are two counterfeit drugs that are virtually identical in appearance and very difficult for the patient to distinguish between.

This is a Viagra die that a counterfeiter had been using. As you can see, it is quite filthy. You can see the Pfizer name upside down on the reverse side of the pill, the Viagra imprint.

This is a tableting machine. This is not what you would see in a licensed manufacturing organization.

This is how they dry the pills using light bulbs, as you see.

Now, this is the Viagra—this is their sophisticated packaging process. The blue pills on the bed are the Viagra and the bottles in the large plastic bags are to be inserted. I am not sure what the microwave oven is for.

This is again a packaging machine.

And then lastly, I will point out that a toilet is an effective porcelain vessel to make drugs. As you can see, that toilet is filled with them. But I don't think any of us believe that is the way to make good drugs, and so we are very worried that the counterfeiters will be able to use this mechanism, as you have pointed out, Mr. Chairman, to get these unsafe drugs into our system.

With that, I will end my presentation. Thank you.

Senator COLEMAN. Thank you very much, Commissioner Hubbard.

Let me start, and I am going to have questions for the panel, but just a statement about the work that the line folks have done. I have had a chance to be out at JFK, Customs and the FDA—I do have great respect for the work that your folks are doing out there. They are faced with a challenge of overwhelming proportion. I do have concerns about our ability to get our hands around this, whether in the 5 years from 1999 to today, did we move quickly enough in that period of time.

But I just want to say thank you to the folks on the front line. We have some issues that we have to deal with in terms of resources, whether this Congress is providing enough resources and whether we have worked in a coordinated enough approach. But I do want to let the folks on the front line know that we appreciate what they do.

How do you deal with the comments out there? And by the way, let me back it up and say I note you looked at Wisconsin's site. Minnesota has a similar site, and perhaps you are being kind to the Chairman and my governor by not commenting on the Minnesota site. I do recall in my review for this hearing that even the Minnesota site was one where one of the issues there was that site was providing drugs that were actually from another country. Now, apparently they provide notice to the customer that they are not getting Canadian drugs, but can somebody comment on that phenomena, that even those "legitimate" Canadian operations are at this point in the process of going elsewhere for their drugs? They are not American and they are not Canadian. They could be produced anywhere in the world. Any reflections on that?

Mr. HUBBARD. I think you are right. We pointed that out substantially because the sites often promise FDA-approved, U.S.-made drugs sold through Canada, and this trend of going to other countries is a slippery slope that we are very concerned about. And, in fact, it is happening. And while some do say that, others don't even say that. They just send the drug.

We had a case recently of a gentleman from Michigan who had ordered a drug from a Canadian pharmacy and was told he was going to get the U.S.-made, FDA-approved, Canadian-sold drug and it came from India. So he was lied to, and that is a concern, that in this case a senior citizen was duped into believing he was going to get the good drug and he didn't.

Mr. TAYLOR. It is directly attributable to supply and demand. One of the reasons why we conducted the blitzes is because there often is a lot of conjecture about what is out there and there is also a lot of conjecture about all the products being perfectly safe or all the products being harmful. And one of the things we have noticed is that, obviously, as the American consumers purchase more and more products over the Internet or through storefront pharmacies, the supply is dropping, and so these suppliers are having to look to other countries to backfill that supply. Our concern is that as they look at these other suppliers, that additional quality issues will arise, we will know even less about the origin of the products and how the products are manufactured.

Senator COLEMAN. How do you respond to the quip, "Where are the dead Canadians?"

Mr. TAYLOR. I am sorry, the——

Senator COLEMAN. How do you respond to the quip saying, "Where are—"

Mr. HUBBARD. Well, first of all, there are——

Senator COLEMAN. "Where are the dead Canadians?" With all of the concerns that we are raising here, we are not seeing lives being lost.

Mr. HUBBARD. There are injuries that have occurred from drugs bought by Americans from Canada. It is not a long list. But part of the problem, Mr. Chairman, is that there is no system in place to track injuries from these drugs. These drugs shouldn't even be here. So the health care system doesn't track them. And we have learned from patients, they tend not to tell anyone they are buying these drugs. They feel that maybe they have done something a little wrong and they don't admit it.

So let us say a patient gets a drug for his high blood pressure, it doesn't work, he has a stroke. They ask his doctor later and he said, "Well, my patient had the high blood pressure and he was stroke-prone," but maybe didn't know that the patient was getting not the legitimate drug but the foreign drug that wasn't working and caused his stroke.

Mr. TAYLOR. I think that is right. I mean, I think there is an additional facet to it, which is we don't always expect, quite frankly, to see gross negative health outcomes. However, our overarching concern is that a person is purchasing a drug with the expectation that it will treat or control the condition that they have, and if a drug is without any active ingredients, like the products that CBP tested, or like the counterfeit Lipitor that we dealt with last year, or like the contraceptive patches that were in my oral testimony, then the person's condition is not going to be treated or their depression is not going to be controlled. So that might not lead to mortality, but it certainly has a negative health impact that is not desirable.

Senator COLEMAN. I would also note at our last hearing where we dealt with the instance of dead Americans, a young man's family was involved in the testimony, and a tri-athlete whose wife didn't know that he was getting these drugs until he died. Perhaps she might not have known if certain information hadn't shown up. So I hear that quip again and again.

A question I would like you all perhaps to respond to. Knowing the extent of the problem or the extent of the challenge, was it 200 billion pieces, right, billion pieces of mail coming through this country? The percentage of stuff coming in from other countries, what was the figure there? Was it 400 million? Does anyone here envision, if you had access to whatever resources you needed, within reason, a system whereby we truly get our hands around this problem? Ms. Tandy.

Ms. TANDY. Mr. Chairman, if you liken this flow of pharmaceuticals coming into the United States as water through a faucet, my panel colleagues are at that downstream of the faucet trying to catch it all. What we are doing with DEA with the resources that were committed to us in the 2004 appropriation, we are focusing on turning the spigot off, which is attacking the organizations that are responsible for that flow.

It requires very sophisticated technology which we have in place now and are refining to identify these hundreds of rogue pharmacy Websites, many of which are outside this country. It is critical in order to truly get our hands around this to stop the spigot at the top and put those Websites out of business and those organizations that are responsible for that, put them in American jails for sending those drugs here.

Senator COLEMAN. Let me, before others respond, just to follow up on that. It has been highlighted here that you have sites that purport to have FDA approval, that have seals of approval. There have been some proposals to, in fact, require FDA approval in order for folks to operate. But assuming, do we have the authority today? Do we have the laws on the books today? If we were to put in place a system whereby there was bona fide FDA approval but you had folks who were counterfeiting that approval, who were fraudulently stating that they had FDA approval, do we have in place the legal mechanisms to go after and shut down these rogue operations?

Mr. TAYLOR. So far, a lot of our discussion has surrounded the issue of resources, but for FDA, it is not just resources. It is a question of adequate authorities. As Mr. Hubbard said, mere visual inspection of the product at the border is not going to—it is just not that useful in determining in a dispositive way whether a product is safe or not or whether it is approved or not. An important part of knowing the content of a product is knowing where it comes from and knowing its origins.

And yet when people ask, well, why doesn't FDA go and do a foreign inspection of some of these overseas pharmacies or overseas sites, what people don't understand is we don't have the jurisdiction to do those inspections. In order for us to do our foreign inspections, even the foreign inspections we do now as part of a new drug approval, we need the company to invite us in, and the incentive is that they invite us in and we do the inspection and their

product will get approved, and we need the country to allow us to come in, and there have been instances where we have been on a plane on our way to a facility and either the country or the company has decided they are not ready and we have had to turn around—so it is a question of resources and authorities that are necessary to really do a better job of controlling this problem.

Senator COLEMAN. Do you currently have the authority to, if you have a site that is fraudulently proclaiming that it has FDA approval, to shut down that site and to prosecute those for some sort of false representation?

Mr. TAYLOR. We do not have that authority. Sometimes we will—what we will do is sometimes we will talk to the Internet service provider and they will do it for us, depending on the evidence that we have in hand. Other times, we work with our partners at DEA or at ICE and they might have the administrative authority to shut down a site. But FDA does not have the authority to shut down a site. What we often do is we will either enjoin an operation, which will lead to the site shutting down, or we will indict or convict the people who are behind the site. But we don't have express authority to shut down the site.

Senator COLEMAN. Talking about authority, Commissioner Ahern, do you have the ability at this point to seize controlled substances? We have seen boxes of this stuff, there was one discussion of those being sent back, literally sent back to the illegal purveyor of this. What kind of increased authority do you need to immediately seize and destroy, and would you want that kind of authority?

Mr. AHERN. Thank you, Chairman. I would also like to answer the previous question, too, about the resource impact of this and is resource an acceptable solution to this problem.

I think, certainly, I am not certain you can throw enough resources given the volumes that we are dealing with, and I am not sure a resource response is the appropriate response for the government agencies. I think we need to take a very layered approach. I think it certainly is very appropriate to look at taking out the Websites, taking out the profiteers of this, and also I think a very layered approach with interdiction, investigation, intelligence, and public outreach. I think those are very key components that certainly is part of the task force, and by adding ONDCP recently onto the task force, we are getting that outreach part along with FDA.

But certainly to the question of authorities and to the referenced parcels that were returned to sender at JFK, I would like to respond to that directly. That is true, that there was the shipments up in JFK that were returned to sender. Most of those were Schedule IV as well as a lot of pharmaceuticals, as well. That was a 5- to 6-month backlog of detentions and seizures that were made at that point in time.

The people at JFK did not respond to policy of this organization and we have made the corrections with them to make sure that they know that they do not send return to sender on seizures. It should be affected at the borders.

However, I would like to state that for each one of those seizures that does occur, it requires about one hour of front-end processing at the mail facility to process those seizures, and that is why when

you had your opportunity to go up and take a look at the JFK mail facility, and what has been depicted here today in the hearing shows the volume actually of what is being stored and detained in our storage facilities there for processing, not all for FDA determination, or for Customs and Border Protection processing.

We have to do the same level of processing of that seizure because of the due process the individual importer is afforded under current law and procedure. We have to do the same long-form enforcement report as we would for if it was ten pounds of heroin or cocaine. We need to find a way to do consolidated seizure reports that could take the time involved with this processing down significantly, as well as move to a very efficient and effective summary forfeiture proceeding where we don't need to send the notice out but we can destroy these things on site and continue with the interdiction mission as part of that layered strategy.

Senator COLEMAN. In order to find that way, is that something that requires administrative changes or does it require legislature changes?

Mr. AHERN. For the summary forfeiture authority, we certainly need to have the legislative change to support that.

Senator COLEMAN. I look forward to working with you on those proposals.

Also in your testimony, you talked about interagency working groups. I reflected earlier in my opening statement, there were working groups formed in 1999. What is the difference between the working groups we have today and those that we had 5 years ago?

Mr. AHERN. I can't reflect back to 1999 and what might have not occurred under the group that was put in place at that point in time. I was not directly involved with that. I will tell you, looking back in history, shortly after this group was created, there were some operations that were conducted, not many. We also then had the 9/11 tragedy which certainly took the focus of the Border agency, certainly the agency that I am part of, and redirected our focus to preventing terrorists or implements of terrorism from coming into this country, and I think that was a very appropriate response from us for us at that time.

However, within the last several months, we have created these additional task forces to try to rejuvenate the collaboration that is necessary to achieve the layered approach with stopping this problem. It is not just a border interdiction problem. It is not just an investigative problem or a regulatory problem. We need to tackle this on all fronts.

I believe that the five working groups that are part of this have some comprehensive plans, and I would also submit that with the actions that have come out through the task force, special operations and blitzes that have been conducted as well as the laboratory and scientific services sampling reports, have shown the level of concern and I believe we will take these and continue to move forward with our action.

Senator COLEMAN. I would hope there would be some objective ways to measure progress here so we are not coming back in 5 years and asking the same question.

Mr. TAYLOR. Mr. Chairman, one objective measure is the work that we have done on procedures. One of the subgroups is just de-

voted to mail procedures and targeting. As part of our staggered approach, we have shared the procedures with DEA, Postal, and CBP. We welcome their comments. But more importantly, the information that was used to provide the framework for those procedures is part of our collaborative working relationship.

I agree with Jay. I think that the working group, and I wasn't around in 1994 either, but I think the working group has proven to be a springboard, if for no other reason we have a—it has made our working relationship here in Washington closer. If I need something, I can call Mr. Ahern or I can call Ms. Tandy's people inside or outside those meetings. It has been easier to involve more headquarters people as part of the subgroups.

And so one objective measure is the fact that after realizing the need for these mail procedures, we have introduced them. We will continue to refine them with the help of our partners. And then we will introduce the air courier procedures, again, in conjunction with our partners. So those are two small hallmarks that signify the robustness of what we are doing now.

Senator COLEMAN. And I would, Mr. Ahern, suggest a terrorist threat to what we are dealing with here, and we talked about this at the last hearing with Mayor Giuliani. You don't want to give anybody ideas, but it doesn't take rocket science to figure out that we are using extraordinary measures to protect our borders, to protect particularly people coming in, and we are doing things with cargo and other areas, understanding some of the challenges, to take a look at what is coming in. We are concerned about radioactive devices.

But the reality is that any terrorist network could set up an American A–Plus Number One Internet Drugs at bargain basement prices and flood this country with materials and drugs that could have a devastating impact and raise the level of fear. We shut off access to Canadian meat with the identification of one cow with BSE, and yet clearly we have a system here that is without controls, without the ability to, at this point, sufficiently prevent something like this from happening. So I would maintain there is a national security aspect to the availability of or the ease of getting these types of substances into the hands of American consumers.

Mr. AHERN. My comment to that is certainly I don't disagree with you. However, we certainly have to take a very risk-based approach and we know that there are concerns with people crossing our borders, coming into this country, as well as the threat posed by sea containers, as well as other cargoes coming into this country. So we do take a very risk-based, intelligence or information driven approach in our response with our resources.

To this point, there has been no active intelligence that indicates that this would present itself as a threat. Certainly, all the 400 million mail shipments coming into this country, as well as the half-a-billion people that cross our borders legitimately, as well as the sea containers and cargo opportunities, we look at as windows of opportunity and we take a very risk-based approach with addressing those threats. But certainly we haven't disregarded this as a potential at this point in time. There is no active intelligence that indicates that threat is present.

Senator COLEMAN. There is a system, is it VIPPS? There is a system that the pharmacy organizations have set up to provide some measure of bona fide, legitimate. Can someone talk a little bit about that?

Mr. HUBBARD. It is established by the National Association of Boards of Pharmacy and it has very high standards, and it basically says, if you want to sell drugs over the Internet and you meet all the requirements that a brick-and-mortar pharmacy would meet, you can receive this *Good Housekeeping* seal called a VIPPS seal. We believe it is a good idea.

There are two, of course, flaws in it. One is that the bad guys can fake the seal. And second, VIPPS cannot reach out into other countries. It is really for domestic Internet sites.

Senator COLEMAN. Is there anything that would preclude Canadian pharmacies from voluntarily adhering to the VIPPS standards?

Mr. HUBBARD. No. In fact, the National Association of Boards of Pharmacy has proposed to Minnesota that they work with them on inspecting Canadian pharmacies and making that very consideration. I don't believe we have heard back from the Minnesota officials on that recently, but FDA has expressed a willingness to be helpful in any way we can in that process.

Senator COLEMAN. Mr. Taylor.

Mr. TAYLOR. It is a good consumer outreach and education tool. A consumer can look at the site and know that the product is being dispensed pursuant to a legitimate State pharmacy license and that the products are FDA approved.

Senator COLEMAN. Help me understand this issue again. We have talked about how you can fake the seal. What are the consequences of falsely advertising FDA approval? Or what is the level——

Mr. HUBBARD. If you are a foreign Website, there is not much that can be done because your server is in another country. The business is in another country. I don't think any of us can reach to that country in any effective way. We try to work with other governments, but our actual legal authority doesn't reach there.

Mr. TAYLOR. Yes. If—I am sorry, Bill.

Mr. HUBBARD. There have been proposals in the past, bipartisan proposals, to at least require Websites to disclose who they are and where they are by both Republicans and Democrats in the House and Senate, and we have felt that concept has generally been a good one.

Mr. TAYLOR. That is because even though the overseas site might fall outside our jurisdiction, if there is a U.S. agent or a U.S. entity that is part of the business, then we can take action against them.

For example, we brought an injunction last year against RX Depot, which was a storefront pharmacy that was advertising FDA-approved products. In that case, we enjoined the American operation, which was essentially roughly about 80 other storefront pharmacies, and enjoined them from doing business. So even though we couldn't necessarily bring an action against the Canadian entities, we did deal with the domestic entity.

Senator COLEMAN. I would hope we would look at some way to substantially enhance the penalty and the ability to get compli-

ance, even those who are operating extraterritorially, that some action could be taken. I would anticipate that we are going to reach a point, I would hope, and certainly a proposal that Senator Gregg has offered and Senator Smith and I cosponsored that would require those who want to sell, Canadian and other pharmacies, to, in fact, be subject to FDA review and authorization and the same standards and that there be very strong penalties for those who fraudulently claim to have that kind of approval.

Let me ask, I just want to focus a little bit on some individual cases, and this goes to the enforcement actions for Mr. Taylor and Mr. Hubbard. Can you tell me who Eric Kaiser is? Does that name ring a bell?

Mr. TAYLOR. No, it does not, sir.

Senator COLEMAN. I am told that he is a registered owner of numerous Internet pharmacy Websites that offer Accutane, Prozac, Zocor without a prescription. Do you have any information on his actions and his response or lack of response to cease and desist letters, E-mails, etc.?

Mr. TAYLOR. Actually, it does—I know him in the context of some things that JFK has recently discovered and is looking into. It wasn't specifically with those products, but it was in another context.

Senator COLEMAN. I raise the question, using him as an example, and I may have one or two others for some of the other witnesses here, but again, it goes back to this ability to track down, to have some sort of effective control over folks who are operating illegally. If you identify somebody as the owner of an Internet pharmacy but they don't respond to letters, E-mails, etc., then you check down as you have shown here. You show them a Website registration that says it is registered in one place, but it doesn't correspond to a particular name. How do you follow up on this stuff? What are you doing to track down those people that you get a clear sense that they are abusing this process?

Mr. TAYLOR. Let me use the two examples in my oral testimony. For the contraceptive patches, that Website first appeared to be a U.S. Website. And by the way, this is a product that was brought to our attention by a consumer who received the contraceptive patches in a clear plastic bag, which caused warning bells to go off in her head. So she contacted the manufacturer who contacted us. There were tests and there is no active ingredient.

From there, we looked at the Website that she purchased the product from and had to, with the help of Immigration and Customs Enforcement and use of administrative subpoenas, and by working also with the Internet service provider, track the fact that there were actually five or six different levels—five or six additional Websites between the one that she was using and the one that was registered in India, where the products came from.

So to answer your question, there is a lot of interim investigatory work that is time consuming and requires not only good web crawling, but also good analytical skills to figure out the various links.

Once we realized that—and this case is still ongoing, so I don't want to go into a lot of detail—but once we realized where it was registered, we contacted the Customs officials overseas and the local authorities to enlist their aid. In some cases, the local govern-

ments have been helpful in helping us figure out where the person we are seeking is. In other cases, people have been less cooperative. We also utilize the in-country expertise of either Customs or DEA.

Now, I don't want to suggest this is easy. It is not. It is actually very difficult. And in some cases, we have people who are in countries where there is no extradition. But that is the general steps that we use to try and determine the location of someone who is operating outside the country.

Senator COLEMAN. I appreciate that.

Administrator Tandy, if I can just turn to one or two examples, and I think we have Exhibits 1 and 3,[1] over a 2-day period at JFK, our staff and I observed a shipment of 3,000 parcels of controlled substance from Amert, a single vendor in the Netherlands. That is one of the things that I noticed, that there were a number of parcels from single vendors containing illegal prescription drugs. When you see something like that, when you see massive quantities coming from single vendors, and I think that is Exhibit 1? I think there is another exhibit there which shows the same thing, single vendor, massive quantities.

What can you do to stop that company from continuing with these illegal drug transactions? What is your authority and what kind of action do you take?

Ms. TANDY. The process that we follow, once these vendors are identified, is to work with our foreign counterparts in law enforcement in the Netherlands or wherever the country is from whence these drugs have been shipped and to have our foreign counterparts assist us in the foreign-based piece of that investigation.

We do have long-armed jurisdiction under Title 21 as to Schedule I and Schedule II controlled substances. Schedules III, IV, and V, which often are what you see over the Internet, are not included under that long-armed jurisdictional statute.

Senator COLEMAN. And could you, for the record, describe the difference between Schedules I and II versus III, IV, and V.

Ms. TANDY. I say Schedule I, because under the statute it is covered, but Schedule I, of course, these are not medically accepted drugs. So you can set aside Schedule I.

Schedule II, there is a high risk of abuse of drugs in Schedule II. These are typically opioids.

Schedule III, which is where you have seen some of the deaths, would be Vicodin, which is not pure hydrocodone but is a mix of hydrocodone and acetaminophen.

So those schedules, the penalties are tiered by those schedules. Our authorities are cabined by the statute under the schedules.

Essentially, we have to rely on our foreign counterparts to assist us in further identification of these Websites because these are not brick-and-mortar locations and require sophisticated investigation in order to identify where they are really operating from. And then our foreign counterparts, we rely on to shut down those sites that are outside of our long-armed jurisdiction. We can always bring charges against these institutions, these Website companies, even though they are outside the country, for what they send into our country under the standard Title 21 process.

[1] See Exhibits 1 and 3 which appear in the Appendix on pages 286 and 288.

Senator COLEMAN. I believe that hydrocodone is pictured in this photo. Do you know if there was any follow-up with this, what are they, a Dutch operation, Amert, a Netherlands operation? Do you know if there was any follow-up on——

Ms. TANDY. I can tell you that we have a number of foreign-based Website investigations underway now, but I wouldn't be in a position to tell you any specifics about those investigations at the risk of compromising them.

Senator COLEMAN. Let me just introduce a last area of inquiry for you, and that is we talked about the web crawler. My understanding was in 1999, FDA purchased a web crawler. We are talking about it today. Help me understand why you believe the web crawler today will be more successful than the web crawler in 1999.

Ms. TANDY. I can't speak to FDA's web crawler. DEA just received funding in 2004 for what has been colloquially referred to as a web crawler. It is to conduct these on-line investigations. We have worked very diligently to put into place an on-line investigative tool that, as it is refined, is going to be the equivalent of essentially six Google search engines together that will go through these on-line pharmacies using specific information to try to connect the links to the various Websites to specific targets. So I don't know how this differs from what FDA attempted to do in 1999——

Senator COLEMAN. You have your own web crawler then?

Ms. TANDY. We have our own web crawler, which after today I won't refer to as a web crawler anymore. It will be the on-line investigations tool.

Senator COLEMAN. Mr. Heath, you talked about rogue pharmacies getting increased legal private scrutiny, and I believe some of the private operations, Google and Yahoo!, have been doing some things in regard to that. Does the Postal Service work with the private sector to address this issue of illegal sale of pharmaceuticals over the Internet? What kind? Because our next panel is going to be the private sector and I want to segue into that. Can you talk a little bit about that relationship?

Mr. HEATH. Absolutely. I think we have an excellent working relationship, especially with FedEx and UPS, not only to work on the illegal pharmaceuticals, but we share our intelligence and our methodologies with them, whether it is in the mail or in the private courier system, to target illegal narcotics, to target child pornography, and we certainly will do the same things with them with regard to this issue.

There is one other point I would offer up when we look here. Administrator Tandy has talked a lot about the highlights of the investigative effort they put in to addressing the problem. When we look at mailings or shipments, as would be reflected in this, if they are fresh, that is pretty good for an investigative and evidentiary purposes. I know at Miami and at JFK, there is a significant dated backlog of materials that were seized months and months ago.

I would suggest that along with Customs and Border Protection, FDA, that we take a look at using our enforcement authority with the destruction methodology to attack that backlog. If we can, in fact, demonstrate that there are multiple mailings from the same supplier, due to the dated nature, it is probably not going to be of

much benefit from an investigative nature, but I think we should try out our methodologies to try to destroy that.

As you mentioned, it does not make good sense to return it to the sender because it is only going to be sent back either to this country or to another country again.

Senator COLEMAN. Let me talk a little bit about your authority. Does the Postal authority have the ability to open packages without a warrant?

Mr. HEATH. No, sir.

Senator COLEMAN. So you have to turn to who in order to——

Mr. HEATH. We rely, especially on the international, the ones coming in from the foreign countries, we rely very heavily on Customs and Border Protection. They open the materials at the point of entry, and then for an enforcement process, once they have determined that it is an illegal product, then we can seek the destruction order.

Senator COLEMAN. What about the possibility of cross-designation to make it a little easier for you?

Mr. HEATH. Yes, sir, it definitely would.

Senator COLEMAN. I think it is something worth exploring.

I want to thank the members of the panel. We could go on and on. I do appreciate your efforts and your understanding of the nature of a growing problem and the importance of working together to address it. So again, I want to thank you for appearing before the Subcommittee.

I would now like to welcome our final panel to today's hearing. This panel is composed of representatives of the private sector.

I would like to welcome John Scheibel, Vice President for Public Policy at Yahoo!; Sheryl Sandberg, Vice President for Global Online Sales and Operations at Google; Joshua Peirez, Senior Vice President and Assistant General Counsel at MasterCard International; Steve Ruwe, Executive Vice President of Operations and Risk Management at Visa U.S.A.; Robert Bryden, Vice President of Corporate Security at Federal Express Corporation; and finally, Daniel Silva, Vice President and Director of Security at United Parcel Service.

The purpose of this panel is to examine the extent to which consumers can purchase dangerous and often addictive controlled substances from both domestic and international Internet sites and the role that Internet search firms, credit card companies, and package delivery firms can play in identifying rogue sites and preventing them from utilizing their services. I do appreciate everyone's testimony at this important hearing and am anxious to hear your testimony.

Pursuant to Rule 6, all witnesses before the Subcommittee are required to be sworn. At this time, I would ask you all to rise, raise your right hand.

Do you swear that the testimony you are about to give before this Subcommittee is the truth, the whole truth, and nothing but the truth, so help you, God?

Mr. SCHEIBEL. I do.

Ms. SANDBERG. I do.

Mr. PEIREZ. I do.

Mr. RUWE. I do.

Mr. BRYDEN. I do.

Mr. SILVA. I do.

Senator COLEMAN. As I am sure you are aware by now, we do try to have a timing system here, and for such a large panel, I would like to hold people to that. I will ask that folks limit their oral testimony to no more than 5 minutes, but I will make sure that your entire written testimony is entered into the record. When the light turns from green to amber, it gives you about a minute to sum up, so please follow that.

We will begin with Mr. Scheibel—we will have you go first this morning—followed by Ms. Sandberg, then Mr. Peirez, Mr. Ruwe, Mr. Bryden, and finish up with Mr. Silva, and after we have heard all the testimony, we will turn to questions. So with that, Mr. Scheibel, you may proceed.

TESTIMONY OF JOHN SCHEIBEL,[1] VICE PRESIDENT, PUBLIC POLICY, YAHOO! INC

Mr. SCHEIBEL. Chairman Coleman, thank you for the opportunity to testify on an extremely serious issue, prescription drug sales over the Internet.

Yahoo! is a leading provider of comprehensive on-line products and services to consumers and businesses worldwide. Yahoo! is the number one Internet brand globally and the most trafficked Internet destination worldwide.

Mr. Chairman, we appreciate your leadership in this critical area and we share your concern with protecting consumers. That is why, beginning in 2002, Overture, which later became a wholly owned subsidiary of Yahoo!, took its first preliminary steps to address this issue. At that time, Overture prohibited on-line pharmacies from advertising that prescription drugs could be purchased without a prescription.

Then in November 2003, we took industry-leading actions to better ensure that our sponsored search listings of on-line pharmacies meet high standards of integrity and accountability. Sponsored search is a program under which advertisers bid on search terms in order to get placement in search results. Only those listings relevant to a search term are permitted to enter or remain in the active database. These listings are clearly labeled "Sponsor Results" throughout the Yahoo! site.

As you mentioned, in November 2003, Yahoo! took the unprecedented action of removing all sponsored search pharmacy listings for prescription drugs as an interim step to developing 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 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. The on-

[1] The prepared statement of Mr. Scheibel appears in the Appendix on page 255.

line pharmacy qualification program employs a five-facet approach to enhance consumer trust in 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 join the program and comply with its terms in order to participate in the sponsored search marketplace.

Second, the advertiser is directed to Square Trade, 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 pharmacists. Unless Square Trade determines that the advertiser and its associated pharmacists 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, the NCPA, including certification that it will not provide prescription drugs without verifying the existence of a valid prescription from the person's health care practitioner and such prescription was not obtained solely by means of an online or telephone consultation.

Fourth, Square Trade, in a program administered in conjunction with the NCPA, regularly monitors the licensure status of participating pharmacies as well as responds to any complaints it receives regarding these pharmacies. Any negative action taken by the licensing entity or any complaints that are substantiated by Square Trade are reported to Yahoo! and the advertiser will be removed, as appropriate. Complaints will also be forwarded by Square Trade to the appropriate government licensing authority.

Finally, Yahoo! prohibits on-line pharmacies from advertising the most dangerous and abused prescription drugs, FDA Schedule II prescription drugs, in the Yahoo! marketplace.

Yahoo! believes that this five-pronged on-line pharmacy qualification program complements our mission of aligning the interests of consumers, advertisers, and Internet destination sites.

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.

Mr. Chairman, you have also asked for our comments on pending applicable legislation. S. 2464, introduced by Senators Coleman and Feinstein, precludes the sale of prescription drugs over the Internet absent disclosure by the site of identities and licensing information of the seller, pharmacist, or medical consultants. It also prohibits the sale of prescription drugs over the Internet absent a valid prescription, as that is described. This is a very thoughtful piece of legislation.

The bill would follow the lead of the Communications Decency Act by providing that an interactive computer service provider would not be liable under this bill on account of another person selling or dispensing prescription drugs, provided that the interactive computer service does not exercise corporate control over such person.

Senator Coleman, we applaud you for including this critical provision. It recognizes that telephone companies, Internet service pro-

viders, and Internet portals should not be liable for what others place on their sites or send over their lines.

Mr. Chairman, we at Yahoo! are proud of the steps that we have taken to create a safer environment for the on-line advertising of prescription drugs. Thank you for the opportunity to appear before you today.

Senator COLEMAN. Thank you, Mr. Scheibel.

Ms. Sandberg, I will take your testimony, and then I am going to have to recess. We have three stacked votes. So we will do Ms. Sandberg, recess for 45 minutes—I think that is what it will take—and be back here at noon, so if you can just plan your schedules accordingly. Ms. Sandberg.

TESTIMONY OF SHERYL SANDBERG,[1] VICE PRESIDENT, GLOBAL ONLINE SALES AND OPERATIONS, GOOGLE, MOUNTAIN VIEW, CALIFORNIA

Ms. SANDBERG. Good morning, Chairman Coleman. Thank you for inviting me to testify on this very important issue.

Google shares your concerns about the risks of on-line pharmacies and some of the unsafe products they sell. In my written testimony, I provided a detailed account of our policies and programs on this matter, so in view of the vote, will keep my oral comments very short.

Senator COLEMAN. Your testimony will be entered into the record as a whole, without objection.

Ms. SANDBERG. Thank you very much. Google's mission is to organize the world's information and make it universally accessible and useful. When a user, defined as someone who visits our site, goes to Google-dot-com or one of our 95 other domains, the user is able to search for information on over four billion web pages and over 880 million images.

We are dedicated to preserving the trust our users have placed in us. We always place the interests of our users first and their search for information, and that is the core value on which our company is built.

Like our search results, the goal of our advertising program is to provide users with useful information. Our users want information about pharmaceuticals and we know that providing relevant information from trusted sources can be critically important. We have received numerous E-mails from Google users who have found life-saving information through our Website.

We believe that advertising by licensed pharmacies, treatment and detox centers, and pharmaceutical manufacturers helps consumers locate services, compare options, and make cost-effective informed choices about their health. Our belief is supported by research showing that pharmaceutical-related advertising is strongly positive for consumers. However, we share your concerns that there are disreputable Internet sites, some of which are on-line pharmacies.

In response to the increasingly complex on-line pharmaceuticals market, we have taken proactive and aggressive steps to make sure that our advertising program provides users with relevant and safe

[1] The prepared statement of Ms. Sandberg appears in the Appendix on page 259.

information. In order for on-line pharmacies to advertise with Google, they must be certified by Square Trade, a leading third-party trust infrastructure company. Square Trade's licensed pharmacy program has been approved by the National Community Pharmacists Association.

By working with Square Trade, we require pharmacies that advertise on Google to be licensed, to maintain licensed pharmacists, to obey all applicable laws, rules, and regulations, to not provide prescription drugs unless they receive and verify a valid prescription, to make sure that prescription is not obtained online and not obtained over the phone, and also guarantee that they are only delivering medications through a provider that requires an adult signature for delivery.

Square Trade regularly monitors the licensure status of these pharmacies and we require that advertisers have a valid and current Square Trade ID before participating in our program. Through this process, we strive to permit only licensed pharmacies and pharmacists to advertise with Google. We are pleased to provide a means of connecting individuals with valid prescriptions to licensed pharmacies that can provide them cost-effective and convenient service. We are also proud that our Website helps people find information they need, information on education, rehabilitation, or other medical needs.

Thank you again for this opportunity to share our views. We are grateful for your leadership on this important issue.

Senator COLEMAN. Thank you very much, Ms. Sandberg.

Again, because of the three stacked votes, I will have to recess the hearing until approximately 12 o'clock. We may get started a little bit before that. This hearing is now recessed.

[Recess from 11:13 a.m. to 11:32 a.m.]

Senator COLEMAN. I am going to reconvene the hearing at this time. I apologize for the confusion but we have a series of three stacked votes and I probably have another 15 minutes in between this vote and the next vote. We do not have the entire panel in front of us but we have two of the witnesses, the carriers, here and I think it would be very helpful to get their testimony on the record. I am just not sure what time we are going to have for questioning but I think it is important to get the testimony on the record.

So with that, why don't we begin. Mr. Bryden, please begin your testimony.

STATEMENT OF ROBERT A. BRYDEN,[1] VICE PRESIDENT, CORPORATE SECURITY, FEDERAL EXPRESS CORPORATION, MEMPHIS, TENNESSEE

Mr. BRYDEN. Thank you, Mr. Chairman. Pleasure to be here with you today to talk about this important topic. I have submitted a statement and I would ask that you accept that for the record and I will make some short summary comments.

Senator COLEMAN. Without objection.

Mr. BRYDEN. Thank you, sir.

[1] The prepared statement of Mr. Bryden appears in the Appendix on page 266.

FedEx has been working with members of your staff and members of another committee in the House on this issue for almost 2 years now. We have met many times with the staff, and met with many of the Federal agencies numerous times. I feel like the research that we have done and the meetings that we have had have given us a good understanding of the scope of the problem and where our company fits within that problem.

I also think we have identified ways that we can assist the law enforcement agencies in doing, as you heard in earlier testimony, the virtually impossible task that they face in keeping these illegal drugs out of our country and out of the hands of children and people that should not have them. I think that we have discovered ways in this 2-year journey that we have been on that we can enhance our cooperation with law enforcement organizations. We have made those offers to law enforcement. We think we have something to offer to their investigations.

At the end of the day, we believe it is a law enforcement issue and that the technical issues involved in getting to the bottom of who is doing this shipping does require law enforcement power authority and through the use of subpoenas and so forth. But we are happy to cooperate in any way we can. We appreciate you having us here today and I look forward to answering questions that you may have.

Senator COLEMAN. Thank you Mr. Bryden. Mr. Silva.

STATEMENT OF DANIEL J. SILVA,[1] VICE PRESIDENT, DIRECTOR OF SECURITY, UNITED PARCEL SERVICE, ATLANTA, GEORGIA

Mr. SILVA. Chairman Coleman, my name is Dan Silva. I am the corporate security manager for UPS, and in that capacity I am responsible for security activities worldwide for the organization. I would like to thank you for the opportunity to participate here today.

You asked us to comment on three questions and I will do those in order. First, you asked about efforts that we have undertaken to preclude the delivery by UPS of illegal controlled substances and other pharmaceuticals purchased over the Internet. Let me first state that 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 lawful subpoena.

Additionally, 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 second, that display a UPS trademark or logo, so to avoid any appearance of sponsorship or endorsement.

[1] The prepared statement of Mr. Silva appears in the Appendix on page 269.

We have shared information about Internet pharmacy sites that we have gathered through our monitoring program with the FDA and DEA. Since much of the concern in this area arises from imported pharmaceuticals I would like to mention efforts we have undertaken with the Customs Service and 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 new 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.

Your second question relates to current efforts with the DEA and FDA to address the issue of illegal purchases of controlled substances. On an ongoing basis we respond to many subpoenas with information requested in support of ongoing investigations by these agencies.

Additionally, we have met twice this year with officials of FDA and DEA here in Washington to discuss ways in which we might further our cooperation concerning illegal pharmaceutical shipments. As I have already indicated, we have shared information about Internet pharmacies that we have identified through on-line pharmacy monitoring program with these agencies. These meetings with FDA and DEA officials have been productive and we will continue to meet as needed in the future.

The third question seeks our views on pending legislation regarding Internet pharmacies. We support legislation that would establish clear requirements for Internet pharmacies. In particular, we like provisions of the Coleman bill, S. 2464, that would require Internet pharmacies to be licensed. The requirements of S. 2464 are appropriate for ensuring 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, these requirements would provide more certainty that the products we are carrying meet the requirements of law and therefore meet our own tariff requirements.

We also support the goal of S. 2465. The criminal use of the Postal Service and carriers like UPS to unwittingly deliver fraudulently declared prescription drugs into the United States is an enforcement problem for Customs, FDA and DEA. UPS alone ships more than 3 billion packages a year, about 15 million of which are imported into the United States. We and other carriers have a limited ability to look behind the declarations supplied by the shipper in the manifest. S. 2465 would direct the attention of Federal agencies to this problem and we would gladly work with them, as we are already doing under the current law.

Thank you for the opportunity to share the views of UPS and I look forward to any questions that you may have.

Senator COLEMAN. Thank you, Mr. Silva.

For both you gentlemen, do Websites selling pharmaceuticals advertise the service of either Federal Express or UPS without authorization?

Mr. BRYDEN. They do.

Mr. SILVA. Yes, they do.

Senator COLEMAN. Help me get a better understanding of what you do to combat those situations where you have Websites selling. For instance, is there a way not to accept packages from these groups? What kind of ability do you have to react to or respond to folks that advertise selling pharmaceuticals with authorization?

Mr. BRYDEN. We have a group of attorneys who spend their full time every day looking for those types of infringements and then trying to find the right person to send cease-and-desist letters to. As you well know from this investigation, the problem of Internet pharmacies presents a particular problem because, in the main, people that are selling illegal drugs illegally into this country are not going to put their right name and address on the E-mail, on the Website. We have found Websites, as you saw testimony this morning where you would have a pharmacy pretending to be located in Canada and it would be linked to servers in several different countries, so there is no way for us to send cease-and-desist letters to that.

At the same time, it is very difficult to list shipping information with our customers because those Websites are not the ones that are shipping the drugs. They are putting in an order at another location, in the main, and then we are picking up at a completely different location not associated with a Website. So it is a difficult problem for us and, frankly, without subpoena power it is one that we are not finding we can make much headway into.

Senator COLEMAN. I believe Slide 26[1] is that one that had FedEx?

Mr. BRYDEN. Yes, sir, that is FedEx.

Senator COLEMAN. I believe this is one that was done without authorization. Do you have any knowledge——

Mr. BRYDEN. My written testimony which I submitted will substantiate for you, there are no Internet pharmacies that have the authority to use the FedEx logo.

Senator COLEMAN. Mr. Silva.

Mr. SILVA. The same is true for us. We have had some success with cease-and-desist letters. Eric Kaiser, a gentleman that you mentioned earlier, had somewhere in the vicinity of 30 sites. We have sent cease-and-desist letters. We have done that electronically. We have done that through certified mail. The mail got returned to us as undeliverable. But at the end of the day, all but one of his sites no longer mentions UPS.

Senator COLEMAN. What kind of assistance do you get from law enforcement? Use the *Kaiser* case as an example. What kind of assistance did you get?

Mr. SILVA. We provided the information to FDA and DEA. They were aware of Mr. Kaiser's existence through other sources. In that particular case they were already investigating it.

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[1] See Exhibit 26, which appears in the Appendix on page 311.

Senator COLEMAN. Mr. Bryden, you have had experience with the DEA; is that correct?

Mr. BRYDEN. Yes, sir, I spent 24 years with DEA.

Senator COLEMAN. Could you give an honest assessment from this side, now looking from the private sector, DEA's response to these matters, these issues?

Mr. BRYDEN. I can honestly say I am glad I was not a member of the law enforcement panel today. I just think they have a real uphill battle to climb.

I will say this, when I listened to all of the testimony from the law enforcement agencies today it struck me that we may be looking at the forest and not seeing the trees. What I mean by that is, on every one of these shipments that has been destroyed in New York and other locations, and the ones that are seized and are let into the country, there is data point that we are not doing much with. That is the recipient of the package. Anyone who ordered that drug over that Internet site committed an illegal act. I chagrin the fact that in this country we seem to have drifted away from holding people responsible for their actions. That may be an opportunity for the law enforcement agencies.

I am not suggesting, sir, that we put everybody in jail that bought drugs over the Internet. I am suggesting that they should perhaps get a letter from one of the law enforcement agencies saying, we have a package here. It has been seized. You violated the law when you did it. You are on notice. Then you can have a stairstep ladder of increasing penalties including fines. Because I just cannot—the testimony I heard today, I do not know how much resources it would take to get a handle on this, whether it is DEA or FDA, but if we start holding people accountable, that changes behavior. I have always believed as a law enforcement officer and I believe it now. That may be an opportunity.

Senator COLEMAN. We will get the credit card companies here, but it would occur to me, if somebody has got a series of credit card transactions, single individuals with multiple Internet pharmacies, there should be some way to deal with that.

Can you talk to me a little bit in the couple minutes I have left here, talk about the tracking systems. I raised the question about you are asking people to be honest. Maybe I have become cynical in my almost 2 years here, that if folks are sending illegal pharmaceuticals I doubt there is any incentive for them to honestly list on a manifest. Help me understand why you believe the manifest provides some way to control the system. You both use manifests; is that correct? Mr. Silva, why don't you start.

Mr. SILVA. Yes. When we are referring to Target Search, it is a targeting tool that enables Customs to use a number of data fields off of the manifest to search for any packages that travel into our facility. The value of it is intelligence. You heard some of the earlier testimony revolve around intelligence and that there seems to be a lot of intelligence out there. I do not know how much of it is actionable. I do not know how effective we are in fully utilizing the tools that have been deployed in some of the private courier companies to the maximum. The Target Search tool and the second brokerage operation support system tool afford these law enforcement agencies some tremendous resources. We do, believe it or not, get

shipments that come in that have either the generic name of the drug or are identified, and they do get picked off.

Mr. BRYDEN. Let me also say that the tracking and tracing capabilities that both UPS and FedEx have in order to help law enforcement can be used in other ways as well. For instance, if law enforcement comes to us with a name or an address, we can research that name and address and tell them how many previous times shipments have occurred. That helps them build conspiracy investigations.

The other thing that we use the manifest information for is if we get something that is manifested and it is supposed to weigh—let us say, it is a VCR. It is supposed to weigh 10 pounds, and it weighs one pound. That is a potential targeted package, we probably would open that package and take a look at it. We heard people refer to random searches. In FedEx, we do not like to do random searches. It is largely a waste of time. We like to do targeted searches, and I think my counterpart here at UPS feels the same way from a security standpoint. That is not to say we do not do random searches from time to time, but we teach our employees to look for suspicious packages. Weights that are different to the manifest, something that rattles when it should not rattle, quickly filled out shipping data on a bill of lading. Things like that enable us to catch more drugs and illegal things than a random search does.

Senator COLEMAN. I appreciate that.

Gentlemen, I will now recess till 12 o'clock. I do appreciate fitting your testimony in. It has been very helpful to me.

So this hearing is now recessed till 12 o'clock.

[Recess.]

Senator COLEMAN. This hearing of the Permanent Subcommittee on Investigations is called back to order.

I would note that during the recess, I actually got back between votes, reconvened the hearing for a brief period of time, had Mr. Bryden and Mr. Silva give their testimony, so we will now turn to Mr. Peirez for your testimony. You may begin.

TESTIMONY OF JOSHUA L. PEIREZ,[1] SENIOR VICE PRESIDENT AND ASSISTANT GENERAL COUNSEL, MASTERCARD INTERNATIONAL, PURCHASE, NEW YORK

Mr. PEIREZ. Thank you, Chairman Coleman. My name is Joshua Peirez and I am Senior Vice President and Assistant General Counsel at MasterCard in Purchase, New York. It is my pleasure to appear before you today to discuss the important issue of the sale of pharmaceuticals over the Internet.

MasterCard is a global organization that has licensed more than 23,000 financial institutions to use the MasterCard marks in connection with the issuance and acceptance of MasterCard cards. MasterCard requires that all licensees conduct business in accordance with all applicable laws. Any failure to comply with the law empowers MasterCard to assess stiff financial penalties and ultimately to suspend or terminate the licensee.

[1] The prepared statement of Mr. Peirez with an attachment appears in the Appendix on page 271.

MasterCard deplores the use of its systems for any illegal purposes, including for the illegal sale of pharmaceuticals. As you highlighted in your opening statement, Mr. Chairman, MasterCard has recently taken a number of steps to help prevent Internet pharmacies from accepting MasterCard cards for illegal pharmaceutical sales.

These steps include, first, issuing a global bulletin to all our licensees around the world, reminding them of their obligation to comply with all applicable laws and specifically highlighting Internet drug sales as risky transactions.

Second, working with our licensees to shut off more than 370 Websites from accepting MasterCard cards for the illegal sale of pharmaceuticals over the Internet.

Third, exploring new ways to protect the MasterCard system against use for any illegal activity.

And fourth, working with the DEA and the FDA in a collaborative fashion, as we always do with law enforcement.

The efforts we have undertaken to date represent important steps in demonstrating MasterCard's commitment to play an appropriate role in addressing this issue. These steps began about 8 months ago when we met with staff of this Subcommittee, as well as with staff of the House Energy and Commerce Committee. The meeting with your staff, Mr. Chairman, was particularly helpful in highlighting the scope of this problem and in clarifying some of the legal issues surrounding the Internet sale of pharmaceuticals, particularly the issues as they relate to controlled substances. We also met with staff of the DEA and the FDA at that time to exchange information and to explore ways in which MasterCard could be helpful to them in their efforts to enforce the law.

Since the time of our initial meeting with the Subcommittee staff, MasterCard's Merchant Security Team has been searching the Internet for Internet pharmacies that purport to accept MasterCard cards for illegal sales of controlled substances. We are pleased to report that, to date, these efforts have been successful in shutting off the acceptance of MasterCard cards at over 370 Websites.

Despite our success, the task has been made more difficult because it is not entirely clear that all these transactions are illegal, although the vast majority likely are. The lack of a clear prohibition has made it more difficult to educate our licensees around the world on this issue.

Additionally, because the DEA informed us that MasterCard and its employees are prohibited by law from knowingly making illegal buys, it has been difficult to identify the true nature of sales on a Website in some circumstances.

If Congress adopts a legislative solution to this issue, it would be helpful to reduce the confusion regarding a number of legal issues surrounding the sale of pharmaceuticals over the Internet. In particular, requiring pharmacies to be licensed or approved to sell over the Internet would be helpful in providing a clear understanding of whether particular pharmacy merchants are engaged in legal or illegal activities.

MasterCard requests that any statutory obligations on payment systems be carefully crafted to ensure they function appropriately

without creating undue liability on the payment systems for simply meeting their obligations under the law.

Mr. Chairman, thank you again for the opportunity to discuss these important issues and for the help your staff has provided to us. I would be glad to answer any questions you may have.

Senator COLEMAN. Thank you, Mr. Peirez. Mr. Ruwe.

TESTIMONY OF STEVE RUWE,[1] EXECUTIVE VICE PRESIDENT, OPERATIONS AND RISK MANAGEMENT, VISA U.S.A., INC., FOSTER CITY, CALIFORNIA

Mr. RUWE. Chairman Coleman, my name is Steve Ruwe. I am Executive Vice President of Operations and Risk Management for Visa U.S.A., Inc. Thank you for the invitation to participate in this hearing. Visa fully supports the Subcommittee's efforts to prevent illicit sales of prescription pharmaceuticals over the Internet.

The Visa payment system consists of Visa, which performs communication and settlement services for its member banks, and Visa's member banks that issue Visa payments cards or that acquire transactions from merchants that have accepted Visa payment cards. Visa and the Visa member banks 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 banks that acquire transactions from merchants do have a direct relationship with the merchants and the Visa rules require that these acquiring banks assume responsibility for certain aspects of their relationship with the merchants.

Because Visa cards are accepted worldwide, many of these banks, like the merchants that they service, are located in foreign countries.

Visa believes that the Visa payment system has responded effectively to the challenges posed by Internet transactions. Visa rules prohibit the use of Visa cards 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.

In the specific area of illicit sales of prescription pharmaceuticals over the Internet, Visa has met with representatives of the DEA and the FDA to discuss approaches to the problem of illicit transactions with Internet pharmacies. In March 2004, Visa reminded its member banks of their responsibilities to ensure that only legal transactions enter the Visa payment system and directed their attention to the list of controlled substances and problematic drugs maintained at the FDA and DEA Websites. Visa advised its member banks to consider relying on a reputable seal program, such as the VIPPS operated by the National Association of Boards of Pharmacy, as a means of identifying reputable Internet pharmacies.

In June 2004, Visa used the services of an outside firm to search the Internet for Websites selling controlled substances and accepting Visa payment cards. As a result of this monitoring effort, we have had discussions with some of our member banks regarding their merchants who appear to be involved in selling controlled substances. These member banks have conducted their own inves-

[1] The prepared statement of Mr. Ruwe appears in the Appendix on page 280.

tigations and have terminated or restricted the activity of merchants found to be selling controlled substances.

In May 2004, Visa updated its consumer Website to provide safety messages regarding the dangers of purchasing pharmaceuticals over the Internet and 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 cards for legal purposes.

We understand that S. 2493 would place additional responsibilities on the operators of payment card systems to prevent the use of payment cards in illicit Internet pharmacy transactions. Visa believes that, in many cases, the only parties that can actually determine the legality of the transactions are the parties in the transactions themselves.

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 reports or currency transaction report requirements, or where the illegality is so overt and egregious, such as child pornography, that Congress and law enforcement have enlisted the aid of third-party intermediaries to monitor the use of their facilities or services for policing illegal transactions.

In this regard, I note that imposing the cost of acting as law enforcement on financial institutions, communication channels, or other intermediaries for public purposes is effectively a tax on all the members of the public who use those services. In choosing alternatives, that tax must be measured against alternate expenditures that might accomplish the same purpose, such as hiring more law enforcement personnel.

With respect to S. 2493, we have reviewed this legislation and suggested technical changes. If these provisions are adopted, Visa will move aggressively to see that the Visa payment system compiles with any and all applicable requirements. Visa will continue to work with law enforcement to fight against illegal activity, including those involving Internet pharmaceutical sales. We will also continue to monitor the Internet for Internet pharmacies selling controlled substances.

We appreciate the opportunity to appear before you today and would be happy to answer any questions you may have.

Senator COLEMAN. Thank you, Mr. Ruwe.

I do want to compliment the folks here. You have clearly made an effort to try to deal with this situation. Unfortunately, as you listened to the prior testimony, it is simply not enough. We continue to be overwhelmed, and it is the nature of technology, nature of the ease of use of technology, and so we are presented with a challenge.

But Mr. Ruwe, you made the comment that it is helpful—let me step back. You made the comment that it is companies like Visa, MasterCard, the search engines, the folks that provide the transport, they are not required to know something is illegal. With all the commerce that you do, it may be difficult to do.

But what if, in fact, you knew that certain activities were not legal? So, for instance, if there were to be a requirement that pharmacists be licensed or approved to sell over the Internet and you have a list of those that you could easily enter. If you knew then that others were operating illegally, how would you respond to that and do you have any other examples of that kind of situation, where you know something is illegal but they are still using Visa, MasterCard? And I turn to our friends at Google and Yahoo! with the same question.

The question is, let us assume we had a situation where it would be illegal to sell drugs over the Internet unless you were licensed by the FDA, and we can get you a list of those groups that are licensed by the FDA. How would you respond to transactions from companies that are not licensed by the FDA which then are, per se, illegal operations?

Mr. RUWE. I believe if we had a list of the pharmacies that you believe to be legal and be registered and be approved, that we could manage that within our system, to make sure that they were the only ones that would be permitted to operate.

Senator COLEMAN. I am just trying to think, is there anology to something else you do today where you do those kind of runs, you have a list of these legal organizations and anything outside that is something that you wouldn't accept the transaction?

Mr. RUWE. I cannot think of an example that parallels that exact situation today. I mean, we do deal with the continual search for illegal activities, but nothing of the nature that is being proposed here.

Senator COLEMAN. Mr. Peirez.

Mr. PEIREZ. I am also not aware of such a list. However, we think that such a list could be highly effective and would be useful to us. I think it is the nature of the Internet that causes the problem in that activities may be perfectly legal in one jurisdiction and not in another. So by having a list like that we could provide to the banks located outside of the United States and tell them, look, if someone is not on this list, you cannot provide them the service to sell pharmaceuticals over the Internet to persons in the United States with a MasterCard card, we believe that is a very clear guideline and something that could be very effective in our system.

Senator COLEMAN. Another area, and again, I am trying to find analogies to things that you do already that would then be applicable to these kinds of situations. I know you have the capacity if a series of purchases are made, that generate some sort of suspicion that I have gotten a call about, was your card used so and so, and if the answer was no, you would take action. That has been proactive on your part. I didn't inquire, but you have gotten those kind of calls. So you have the ability in some way to monitor. I don't want to inquire into your security operations, but I presume you have that capacity.

On this issue of buying prescriptions over the Internet, in the instances where we had the tragedies or folks have died, often what you see is multiple sales over the Internet, multiple pharmacies within a short period of time of a range of prescription drugs, clearly something that would raise an eyebrow. Do you have the capac-

ity to kind of spot that kind of stuff and would that raise any red flags?

Mr. RUWE. I think the example you are referencing, Chairman, has to do with fraud. When I say fraud, I mean not fraud in the sense that the Internet pharmacy is doing something illegal or selling an illegal substance, but where these are unauthorized transactions where the true card holder did not initiate the transaction. In those cases, we have been successful at trying to identify those patterns, but those things are based on other factors, such as the amount of the transaction, where the transaction is taking place, and factors that would indicate patterns of unauthorized use as opposed to authorized use where they were buying something illegal.

Senator COLEMAN. And I understand the difference, but what I am trying to understand or to see if I can envision is where you could use the same process. You are looking at the activity of an individual card, and from whatever signals you have, things that raise a red flag, you are all of a sudden saying, hey, this may be fraud.

If we are dealing with the purchase of controlled substances in massive quantities from a range of different sites which then, if one checks back, are illegal sites, would you have the capacity to do the same thing, to raise a question about that and then perhaps deal with it?

Mr. PEIREZ. Mr. Chairman, you are asking a question about something we have thought quite a bit about. There are a couple of things I think that are important to understand. The examples you are raising are activities that are undertaken by the bank that has issued you your card in looking at your purchasing patterns, not an activity undertaken by MasterCard because we have no relationship with you. We don't even know who you are when your transactions run through our system.

Typically, the information that is contained in a transaction record does not include information on what is being purchased. It is simply where it is being purchased, which is not necessarily the name that you would see on a Website or on a URL. Typically, it would not be that type of a name through the system.

So it is something that we would like to explore a little more, but we think that it would not be nearly as effective as the list of registered pharmacies that we have spoken about previously.

Senator COLEMAN. Can I go back to the previous slide[1] that showed the Internet drug site that had the FedEx label and I believe had Visa or MasterCard.

This is a site, hydrocordone-dot-com, etc. What do you do here? They have got major credit cards accepted. This is one which we have concern about selling drugs illegally. And you have got masses of these. If something like this is brought to your attention, what can you do? Mr. Peirez, then Mr. Ruwe?

Mr. PEIREZ. Sure. Mr. Chairman, the first thing I will say is obviously we did see this exhibit earlier and we have already contacted our Merchant Security Team and asked them to begin an investigation into whether this site is still live and whether, in fact, it accepts MasterCard cards. Our experience has been sometimes

[1] See Exhibit 26, which appears in the Appendix on page 311.

the logo is there but the card cannot be used. What we can try to do is identify the bank that has contracted with this type of a merchant and if we can find that bank, we then follow up swiftly with the bank and have them either confirm that this is only legal activity, which in this case they will be highly pressed to do, or to shut off this merchant from accepting MasterCard cards, and that is the process we have used that has resulted in the successes I highlighted earlier in my testimony.

Senator COLEMAN. Mr. Ruwe.

Mr. RUWE. I think the process Mr. Peirez describes would be very similar to the one we would follow, as well. It would be necessary to reach out through the Visa member who signed that merchant to initiate the remediation.

Senator COLEMAN. Mr. Scheibel and Ms. Sandberg, I would like to inquire a little bit about Square Trade. That is your process for certifying vendors who are meeting certain standards. First, have you had a problem with unauthorized use of the Square Trade logo?

Mr. SCHEIBEL. Not to date.

Ms. SANDBERG. No, not to my knowledge, not to date.

Senator COLEMAN. You have a system in place if there is unauthorized use to then deal with that?

Mr. SCHEIBEL. Yes. In fact, it is a live seal, so it is harder for somebody to steal that seal than others.

Senator COLEMAN. If we can go to Slide 24,[1] please. On Slide 24, it is a Google site, no offense to Yahoo!. What you see is on the right hand side, that is your sponsored links. Those are the ones in which you have some controls, is that correct, Ms. Sandberg?

Ms. SANDBERG. That is correct.

Senator COLEMAN. And again, explain that to me the nature of what makes this sponsored link versus—I think in this search there were, if I can recall——

Ms. SANDBERG. A search listing.

Senator COLEMAN. Yes. If you look at a Google search for Vicodin, for instance, you will get 147,000 results. But then you have a listing of sponsored sites. Explain the difference.

Ms. SANDBERG. Sure, and everyone can see it on here. If you look on the left side, those are search results. Those are the result of our computers crawling the web, looking for information on over four billion web pages. On the right, noted as "Sponsored Links," and when you look at it online, they are colored, so you can tell that they are sponsored links, those are the results from our advertising program.

Senator COLEMAN. Just so I understand kind of how your system works, if somebody goes to a sponsored site, do you get something out of that? Is there a payment simply for visiting the sponsored site?

Ms. SANDBERG. Yes. It is an advertising relationship with the partner. The partner is signing up, registering as a Google advertiser. In the case of pharmaceuticals, they would need to be Square Trade verified. And then we are in a business relationship with them. They pay us for clicks to their site.

[1] See Exhibit 24, which appears in the Appendix on page 309.

Senator COLEMAN. There are, I think, 147,000 results for Vicodin. If one visits any of the unsponsored sites, does Google get anything there?

Ms. SANDBERG. No.

Senator COLEMAN. So the control you have is just over that limited number of sponsored sites, but there is nothing you can do to channel customers to go to the sponsored sites in which you have then some basis for checking credibility, whether they are using a process that would meet with concerns of law enforcement?

Ms. SANDBERG. We don't have any control. You are correct, Chairman, that we don't have any control over the search results. However, we do take proactive steps to let people know that we have the Square Trade program in place and let consumers know that these are verified, licensed pharmacies. We display that information on our Website and you can read about the program by clicking on those links.

Mr. SCHEIBEL. Mr. Chairman, in addition, on Yahoo!, the first links that a user will come to will be the sponsored links. So in this case, the most trusted parties, the people who we have worked with to try to create a safer environment for consumers will be the first links that a consumer comes to.

Senator COLEMAN. But for the massive number, the 140,000 or 149,000, what are those, alogarithmic searches?

Ms. SANDBERG. Yes.

Senator COLEMAN. In other words, if you have a word in there, this is the universe and Yahoo! and Google lets people access the universe.

Ms. SANDBERG. That is exactly right.

Senator COLEMAN. The known universe. That is it.

Ms. SANDBERG. That is right.

Senator COLEMAN. Do you have, just hypothetically, do you have the ability to block portions of alogarithmic searches?

Ms. SANDBERG. We do have the technical capability to remove things from the index, but given that we are an information company trying to provide all information to the world that is universally useful and accessible, that is done in only very limited circumstances.

Senator COLEMAN. What about child pornography?

Ms. SANDBERG. That is one example where it is done. The content there is illegal and it is removed from the index when we find it.

Senator COLEMAN. But is the issue of the illegality of the content or is illegal content here, too? I am trying to understand how you draw that line. I know these are tough questions. Can you help me understand how you draw that line? Clearly, you have illegal content, but there is something else. There is almost a moral equation that you are putting in here that says, this goes so far beyond the standards of what we can accept that you are willing to do that. Help me figure out how you draw that line.

Mr. SCHEIBEL. Two points, Mr. Chairman. The first is that when it comes to child pornography, the simple display of that information is illegal per se, as opposed to what we are dealing with here, which is commercial.

The second point is that when you type in a search term for many of these drugs, you will get as part of your results treatment centers, antidotes, information about the drug, problems with use and abuse of the drug, much of which is obviously very useful to consumers. So as to both Yahoo! and Google, we are search engines. We are in the business of facilitating access to information, and that is part of the information that we provide access to.

Senator COLEMAN. Let me go to Slide 25.[1] This shows the results from a research, again on Google, to purchase Vicodin last month. I think there were 129,000 hits on this. If you look at the sponsored links, you have, "Order Vicodin Online, $44.94 shipped, you save, 100 percent legal purchase." We don't know if this is a legal purchase, do we?

Ms. SANDBERG. Well, this advertiser that you are pointing to, the first one on the right, was verified by Square Trade as a licensed pharmacy and meets all of the requirements of Square Trade.

Senator COLEMAN. So from a Square Trade perspective, it is like whether—we get back to that basic question. Let me back it up. Does Square Trade then screen out those folks, for instance, who try to use—who fill out prescription on line?

Ms. SANDBERG. Square Trade——

Senator COLEMAN. Do they filter out——

Ms. SANDBERG. They make sure that you do not accept prescriptions obtained solely online or through the phone. That is part of their verification process.

Senator COLEMAN. Are there legal products that Google or Yahoo! refuses to accept advertising for?

Mr. SCHEIBEL. Yes. The Schedule II drugs, FDA Schedule II. Those search terms are not available, nor are the generic equivalent of those search terms.

Senator COLEMAN. Anything else?

Ms. SANDBERG. Yes. There are several legal products that we don't accept advertising for. We don't accept advertising for tobacco, as an example.

Senator COLEMAN. Can you tell me a little bit about your relationship with law enforcement? Have they approached you with guidance or assistance in this area? One of the challenges we have is technology is moving faster than the law, and obviously you are on the cutting edge of that. Can you help us understand a little bit about the relationship with law enforcement, what kind of assistance they have been seeking from both of you?

Mr. SCHEIBEL. Generally, Mr. Chairman, we work closely with law enforcement. We try to be responsive to their requests and it is a relationship that is evolving.

Senator COLEMAN. Ms. Sandberg.

Ms. SANDBERG. As well, we have worked closely with law enforcement on a number of issues. This is one of them. We were in conversations with the FDA as we were thinking through what to do in this area.

Senator COLEMAN. How does Square Trade deal with foreign Internet sites, for instance, Canadian Internet sites? Can you talk a little bit about what they do with them?

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[1] See Exhibit 25, which appears in the Appendix on page 310.

Mr. SCHEIBEL. Well, there is a distinction here. One is if you are other than a U.S. or Canadian company, you are not eligible for the sponsored search program on pharmaceuticals. With respect to Canadian companies, the requirements are just the same as in the United States. They have to be licensed by the regulatory body that would license them. And then there are several self-certification measures which we also require as part of the Square Trade program.

In addition, Canadian sites are not allowed to target U.S. consumers, and there is also a requisite statement, and I can read it to you, Mr. Chairman. "The FDA, due to the current state of their regulations, has taken the position that virtually all shipments of prescription drugs imported from a Canadian pharmacy by a U.S. consumer will violate the law."

Senator COLEMAN. Let me just back up one question. You talked about, I thought you said, Mr. Scheibel, about Schedule II drugs. Is hydrocodone a Schedule II?

Mr. SCHEIBEL. I believe it is.

Senator COLEMAN. And does either Google or Yahoo! block out or accept ads from Internet pharmacies selling hydrocordone?

Mr. SCHEIBEL. I don't believe we do. Now, let us draw a distinction. We do not allow pharmacies to bid on the search term. If they bid on another search term and that same pharmacy is selling the Schedule II, then we would go to DEA and verify that pharmacy is licensed to sell that drug.

Senator COLEMAN. Ms. Sandberg.

Ms. SANDBERG. We do allow licensed pharmacies to advertise on the majority of Schedule II terms. These are legal to be prescribed with a valid prescription and we make sure that they are done in accordance with the law.

Senator COLEMAN. One of the problems we confronted in our last hearing was young people using mom and dad's credit card and getting these drugs with a devastating impact. What are the type of things you can do to deal with that, if anything? Mr. Peirez, Mr. Ruwe, is that a problem that you see?

What I am trying to figure out is if there is—I keep coming back to whether you have the capacity to somehow look at the use of credit cards in dealing with on-line pharmacies that we know aren't legal or where they have the capacity to deal with large numbers of purchases of prescription drugs using your credit cards from operations that you know are questionable that have to raise a red flag. Just as you have the capacity to question large numbers of purchases for the sake of checking fraud, that seem to be suspicious, I am just trying to kind of hone in from a technical perspective. Are there ways in which you can work with us more effectively to stop some of the abuses of sale of drugs over the Internet to either young kids or to addicts?

Mr. PEIREZ. Mr. Chairman, we heard earlier the analogy to a running faucet and people talking about how difficult it is to try to control. I think the administrator from the DEA was discussing how difficult it is to try to deal with the water once it is coming out of the faucet, and MasterCard's focus on this particular issue has been on turning the faucet off. We are focused on the suppliers. We are not looking at individuals.

Frankly, there is no way for us to tell when a particular card is being used, if it is being used by the person who the card is issued to, their spouse, their child. We certainly would hope that parents don't make their cards available to their children. That is certainly something that they are educated on on a regular basis.

But in general, on this particular issue, we believe where we can be most effective is trying to control the suppliers from getting into the commerce stream using our cards. Obviously, there are other payment means that they will then turn to and can turn to, but we draw a very clear line on the legal and illegal activities. If it is illegal, we don't want it and that is where we are focused.

Senator COLEMAN. Mr. Ruwe.

Mr. RUWE. I think it does go back to the basic question of whether the transaction is legal or not. In terms of the individuals, I mean, there are now products in the market where a teenager could legitimately have a credit card in their possession, whether it might be a gift card, or in the case of Visa we have a "Bucks" card program. So it would be very difficult to manage it from that perspective, I believe.

But I would totally agree that there are further things that we could explore in terms of technology and working together with law enforcement to do our part and we would be most happy to entertain any of those things going forward.

Senator COLEMAN. How do you deal with gambling, for instance? Gambling sites present similar problems—not legal, overseas operations. For all of you, Mr. Ruwe, Mr. Peirez, do you accept transactions or do you screen any of those out?

Mr. RUWE. Gambling is a little easier, Chairman, because it is just illegal. So in our system, if they are coded as a gambling institution and they are coded as an Internet gambling institution, those transactions can be blocked, period. There is no distinction between a legal gambling institution and an illegal gambling institution, such as we are dealing with in the pharmacy example.

Senator COLEMAN. Mr. Peirez.

Mr. PEIREZ. It is pretty much the same answer as Mr. Ruwe. In that scenario, U.S.-based banks are able to recognize those codes for the Internet form of transaction and the gambling transaction and then block it. If they were to do that in this scenario, they would be blocking perfectly legal transactions, like if somebody is buying drugs on the Internet from Merck, Medco, or from Duane Reade or some other big pharmacy that does sell on the Internet. So you would be blocking legal transactions, which nobody wants in that scenario.

Senator COLEMAN. So if the FDA again were to have the capacity to distinguish between specifically approved legal versus illegal, you would have the capacity to block out the illegal?

Mr. PEIREZ. If we were provided with that list, frankly, it wouldn't have to be blocking transactionally. We would be blocking them from getting into the system in the first place.

Senator COLEMAN. I would be interested with FedEx and UPS. The problem there may be a little different in that your source of pickup may be different from the Website. But would that make a difference, if you had a list of places that are legal and anything outside of that, any sites or anything that are illegal, would you

have the ability to somehow on your system figure that out or filter that out?

Mr. BRYDEN. Mr. Chairman, I think a list would be useful if it was a list of the distribution sites offshore. If it were a list of the Internet sites without some linkage to the place that we would pick up a package, it would be less useful to us, but I think it would be useful to solving the overall problem.

Senator COLEMAN. Mr. Silva.

Mr. SILVA. I would agree with Mr. Bryden, but I would also say that might be valuable information for targeting.

Senator COLEMAN. I want to thank the witnesses here. This is a difficult area. It is a universe that is growing and expanding. I have a great respect for technology. I think it is the key to America's economic future. I respect what Yahoo! and Google do overall, but I am still troubled by the ability of folks to access clearly illegal operations with such ease. Perhaps the more that we can do to help consumers distinguish between the legitimate and the illegitimate, between the bona fide and the false, I think we would all be well served.

So I would encourage you to continue working with law enforcement, looking at your systems and seeing what we can do to ensure that we are not facilitating a process here that really has the potential and the reality of inflicting great harm on consumers in this country.

So again, I want to thank you for appearing. We will keep the record open for a period of 2 weeks for any additional questions.

With that, this hearing is now adjourned.

[Whereupon, at 12:37 p.m., the Subcommittee was adjourned.]

APPENDIX

United States General Accounting Office

GAO

Testimony

Before the Permanent Subcommittee on Investigations, Committee on Governmental Affairs, U.S. Senate

For Release on Delivery
Expected at 9:00 a.m. EDT
Thursday, June 17, 2004

INTERNET PHARMACIES

Some Pose Safety Risks for Consumers and Are Unreliable in Their Business Practices

Statement of Marcia Crosse
Director, Health Care—Public Health
and Military Health Care Issues

GAO-04-888T

GAO
Accountability*Integrity*Reliability
Highlights

Highlights of GAO-04-888T, a testimony before the Permanent Subcommittee on Investigations, Committee on Governmental Affairs, U.S. Senate

Why GAO Did This Study

As the demand for and the cost of prescription drugs rise, many consumers have turned to the Internet to purchase them. However, the global nature of the Internet can hinder state and federal efforts to identify and regulate Internet pharmacies to help assure the safety and efficacy of products sold. Recent reports of unapproved and counterfeit drugs sold over the Internet have raised further concerns.

This testimony summarizes a GAO report: *Internet Pharmacies: Some Pose Safety Risks for Consumers*, GAO-04-820 (June 17, 2004). GAO was asked to examine (1) the extent to which certain drugs can be purchased over the Internet without a prescription; (2) whether the drugs are handled properly, approved by the Food and Drug Administration (FDA), and authentic; and (3) the extent to which Internet pharmacies are reliable in their business practices. GAO attempted to purchase up to 10 samples of 13 different drugs, each from a different pharmacy Web site, including sites in the United States, Canada, and other foreign countries. GAO assessed the condition of the samples it received and forwarded the samples to their manufacturers to determine whether they were approved by FDA, safe, and authentic. GAO also confirmed the locations of several Internet pharmacies and undertook measures to examine the reliability of their business practices.

www.gao.gov/cgi-bin/getrpt?GAO-04-888T.

To view the full product, including the scope and methodology, click on the link above. For more information, contact Marcia Crosse at (202) 512-7119.

June 17, 2004

INTERNET PHARMACIES

Some Pose Safety Risks for Consumers and Are Unreliable in Their Business Practices

What GAO Found

GAO obtained most of the prescription drugs it sought from a variety of Internet pharmacy Web sites without providing a prescription. GAO obtained 68 samples of 11 different drugs—each from a different pharmacy Web site in the United States, Canada, or other foreign countries, including Argentina, Costa Rica, Fiji, India, Mexico, Pakistan, Philippines, Spain, Thailand, and Turkey. Five U.S. and all 18 Canadian pharmacy sites from which GAO received samples required a patient-provided prescription, whereas the remaining 24 U.S. and all 21 foreign pharmacy sites outside of Canada provided a prescription based on their own medical questionnaire or had no prescription requirement. Among the drugs GAO obtained without a prescription were those with special safety restrictions and highly addictive narcotic painkillers.

GAO identified several problems associated with the handling, FDA-approval status, and authenticity of the 21 samples received from Internet pharmacies located in foreign countries outside of Canada. Fewer problems were identified among pharmacies in Canada and the United States. None of the foreign pharmacies outside of Canada included dispensing pharmacy labels that provide instructions for use, few included warning information, and 13 displayed other problems associated with the handling of the drugs. For example, 3 samples of a drug that should be shipped in a temperature-controlled environment arrived in envelopes without insulation. Manufacturer testing revealed that most of these drug samples were unapproved for the U.S. market because, for example, the labeling or the facilities in which they were manufactured had not been approved by FDA; however, manufacturers found the chemical composition of all but 4 was comparable to the product GAO ordered. Four samples were determined to be counterfeit products or otherwise not comparable to the product GAO ordered. Similar to the samples received from other foreign pharmacies, manufacturers found most of those from Canada to be unapproved for the U.S. market; however, manufacturers determined that the chemical composition of all drug samples obtained from Canada were comparable to the product GAO ordered.

Some Internet pharmacies were not reliable in their business practices. Most instances identified involved pharmacies outside of the United States and Canada. GAO did not receive six orders for which it had paid. In addition, GAO found questionable entities located at the return addresses on the packaging of several samples, such as private residences. Finally, 14 of the 68 pharmacy Web sites from which GAO obtained samples were found to be under investigation by regulatory agencies for reasons including selling counterfeit drugs and providing prescription drugs where no valid doctor-patient relationship exists. Nine of these were U.S. sites, 1 a Canadian site, and 4 were other foreign Internet pharmacy sites.

Mr. Chairman and Members of the Subcommittee:

I am pleased to be here today as you discuss the safety of prescription drugs sold by Internet pharmacies.[1] As both the demand for and the cost of prescription medications have increased, the Internet has emerged as a growing marketplace for their purchase. Various types of pharmacies offer prescription drugs over the Internet, including those that require a patient to provide a physician's prescription and are sometimes associated with traditional chain drug stores, and other pharmacies that issue a prescription based on an online medical questionnaire or have no prescription requirement.

Like traditional pharmacies, Internet pharmacies are subject to state and federal statutes and regulations designed to ensure the safety and efficacy of the medications they dispense. However, the global nature of the Internet poses challenges for regulators. States have identified Internet pharmacies that do not comply with state pharmacy laws, but have reported difficulty locating, investigating, and taking action against the pharmacies when they are located beyond state borders. Federal agencies have also taken steps to stop illegal Internet sales of prescription drugs, including by prosecuting Internet pharmacies that dispense medications without a valid prescription. [2] The Food and Drug Administration (FDA) recently reported instances of drugs sold over the Internet that were improperly handled, such as improperly packaged drugs, drugs that were unapproved, and drugs that were not the authentic products consumers intended to purchase. Consumer complaints regarding the business practices of some Internet pharmacies have raised further concerns associated with the use of Internet pharmacies to obtain prescription drugs.

My testimony will summarize findings of a report we are releasing today that examines issues surrounding the availability and safety of prescription drugs sold over the Internet and the business practices of certain Internet pharmacies.[3] In a separate testimony, we are providing

[1]Throughout this testimony, each Internet Web site selling prescription drugs is referred to as an Internet pharmacy.

[2]See U.S. General Accounting Office, *Internet Pharmacies: Adding Disclosure Requirements Would Aid State and Federal Oversight*, GAO-01-69 (Washington, D.C.: Oct. 19, 2000).

[3]U.S. General Accounting Office, *Internet Pharmacies: Some Pose Safety Risks for Consumers*, GAO-04-820 (Washington, D.C.: June 17, 2004).

further details about our purchases of narcotics from Internet pharmacies.[4] At your request, Mr. Chairman, we examined (1) the extent to which certain prescription drugs can be purchased over the Internet without a prescription; (2) whether drugs sold by Internet pharmacies are handled properly, are FDA-approved, and authentic; and (3) the extent to which Internet pharmacies are reliable in their business practices. We attempted to place up to 10 orders for each of 13 targeted prescription drugs, each from a different Internet pharmacy.[5] (See table 1.) We generally attempted to purchase each of the 13 drugs both with and without a prescription, from a range of Internet pharmacies that purported or appeared to be located in the United States, Canada, and other foreign countries.[6]

[4]See U.S. General Accounting Office, *Internet Pharmacies: Hydrocodone, An Addictive Narcotic Pain Medication, Is Available Without a Prescription Through the Internet*, GAO-04-892T (Washington, D.C.: June 17, 2004).

[5]One of the drugs, Humulin N, is prescribed by physicians and is also available without a prescription. We included it among the drugs we ordered because of its special handling requirements.

[6]We determined the location of Internet pharmacies from which we received drug samples based on information contained in the pharmacy Web sites and the return addresses and postmarks on the packages we received. Throughout this testimony, Internet pharmacies from countries other than the United States or Canada are referred to as "other foreign Internet pharmacies."

Table 1: Prescription Drugs Selected for Purchase From Internet Pharmacies

Prescription drug	Condition treated	Remarks
Accutane®	Acne	Has special safety restrictions[a]
Celebrex®	Arthritis	--
Clozaril®	Schizophrenia	Has special safety restrictions[a]
Combivir®	HIV	--
Crixivan®	HIV	--
Epogen®	Anemia	Has special handling requirements
Humulin® N	Diabetes	Has special handling requirements
Lipitor®	High cholesterol	--
OxyContin®	Pain	Schedule II controlled substance, narcotic[b]
Percocet®	Pain	Schedule II controlled substance, narcotic[b]
Viagra®	Male sexual dysfunction	--
Vicodin®/hydrocodone	Pain	Schedule III controlled substance, narcotic[b]
Zoloft®	Depression	--

Source: GAO analysis of information from drug manufacturers and the Drug Enforcement Administration.

[a]Due to health risks associated with using this drug, there are special safety restrictions imposed on its use and distribution in the United States, such as a requirement that patients undergo certain medical tests and restrictions on the distribution of this drug to physicians with special training or expertise. Because of the health risks, FDA advises consumers not to purchase this drug over the Internet.

[b]The Controlled Substances Act established a classification structure for drugs and chemicals used in the manufacture of drugs that are designated as controlled substances. Controlled substances are classified into five schedules on the basis of their medicinal value, potential for abuse, and safety or dependence liability. Schedule I is reserved for the most dangerous drugs that have no recognized medicinal use, while Schedule V is the classification used for the least dangerous drugs.

We identified whether the samples we received contained a pharmacy label[7] with patient instructions for use and whether warnings were included on the labels or along with the packaging and made other observations about the manner in which the drugs were handled and the condition of the packaging. We forwarded the samples to the manufacturers of the drugs to determine whether they were FDA-

[7]The Federal Food, Drug, and Cosmetic Act defines "label" as the display of written, printed, or graphic matter upon the immediate container of any article and information required to be on the label must also be included on the outside container or wrapper, if any, of the retail package. *See* 21 U.S.C. § 321(k).

approved and authentic products, and identify any other safety concerns associated with the drugs or their handling.[8] We also undertook measures to examine the reliability of Internet pharmacy business practices, such as attempting to confirm the locations of certain Internet pharmacies and identifying the pharmacy sites currently under investigation by federal agencies.

We conducted our work from January through June 2004 in accordance with generally accepted government auditing standards and in accordance with the standards of the President's Council on Integrity and Efficiency.

In summary, we were able to obtain the majority of prescription drugs we targeted for purchase from a wide variety of Internet pharmacies without providing a prescription. We obtained a total of 68 drug samples—each from a different pharmacy in the United States, Canada, or other foreign countries—representing 11 of the 13 drugs we targeted for purchase. Drug samples received from other foreign pharmacies came from Argentina, Costa Rica, Fiji, India, Mexico, Pakistan, Philippines, Spain, Thailand, and Turkey. The samples included drugs with special safety restrictions, and as addressed in our companion statement, we were also able to obtain addictive narcotic painkillers. Among the Internet pharmacies from which we obtained drugs, 5 U.S. and all 18 Canadian pharmacies required the patient to provide a prescription, whereas the remaining 24 U.S. and all 21 other foreign Internet pharmacies issued prescriptions based on their own medical questionnaires or had no prescription requirements.

We identified several problems associated with the handling, FDA-approval status, and authenticity of the 21 drug samples received from other foreign Internet pharmacies, but fewer problems among the 47 samples received from U.S. and Canadian Internet pharmacies. None of the 21 samples from other foreign pharmacies included dispensing pharmacy labels that provided instructions for use, and only about one-third included warning information. Thirteen of the 21 samples displayed other problems associated with the handling of the drugs, such as 3 samples of a temperature-sensitive drug sent in envelopes without insulation, and 5 samples containing tablets enclosed in punctured blister packs, potentially exposing the tablets to damaging light or moisture.

[8]FDA has noted that chemical analysis of prescription drug samples may not always detect slight changes in the manufacturing process or different types or amounts of inactive ingredients, which can affect the comparability and thus therapeutic equivalence of drug samples.

Manufacturers reported that most of the drug samples from other foreign pharmacies (19 of 21 samples) were unapproved for the U.S. market because, for example, the labeling[9] or the facilities in which they were manufactured had not been approved by FDA; however, they reported that the chemical composition of all but 4 of the other foreign samples was comparable to the product we had ordered. Among the 4 exceptions, 2 samples were found to be counterfeit versions of the product we had ordered, containing a lesser amount of the active ingredient, and 2 samples had a significantly different chemical composition than that of the product we had ordered.[10] In contrast, all 47 of the drug samples we received from U.S. and Canadian Internet pharmacies included dispensing pharmacy labels, 41 included warning information, and none displayed evidence of mishandling. Like the samples from other foreign pharmacies, most of those from Canada were also unapproved for the U.S. market; however, manufacturers determined that the chemical composition of all were comparable to the product we had ordered.

Some Internet pharmacies—mostly other foreign pharmacies—were not reliable in their business practices. We did not receive six of the orders we placed and paid for, five of which were placed with other foreign Internet pharmacies and one of which was placed with a pharmacy whose location we could not determine. Also, we determined that several of the drug samples were sent from locations that raise questions, such as from private residences. We also observed Internet pharmacies that obscured details about the drugs sold, such as other foreign pharmacies from which we ordered brand name drugs, but then received a generic or foreign version of the drug. Finally, about 21 percent of the Internet pharmacies that sent us samples were found to be under investigation by the Drug Enforcement Administration (DEA) or FDA. Reasons for the investigations included allegations of selling adulterated, misbranded, or counterfeit drugs and providing prescription drugs where no valid doctor-patient relationship exists. Nine of these pharmacies were from the United States, one from Canada, and four from other foreign countries.

[9]The term "labeling" is broader than the term "label" and includes all labels and other written, printed, or graphic matter upon an article or its container or wrapper, or that accompanies the article. *See* 21 U.S.C. § 321(m).

[10]Under federal law, counterfeit drugs include those sold under a product name without proper authorization, which falsely purport or are represented to be a particular product. *See* 21 U.S.C. § 321(g)(2). Counterfeit products may include products without the active ingredient, with an insufficient quantity of the active ingredient, or with the wrong active ingredient.

Background

In the United States, the practice of pharmacy is regulated by state boards of pharmacy, which establish and enforce standards intended to protect the public. State boards of pharmacy also license pharmacists and pharmacies. 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 requirement that drugs be prescribed and dispensed by licensed professionals helps ensure patients receive the proper dose, take the medication correctly, and are informed about warnings, side effects, and other important information about the drug.

Under the Federal Food, Drug, and Cosmetic Act (FDCA), as amended, FDA is responsible for ensuring the safety, effectiveness, and quality of domestic and imported drugs. To gain approval for the U.S. market, a drug manufacturer must demonstrate that a drug is safe and effective, and that the manufacturing methods and controls that will be used in the specific facility where it will be manufactured meet FDA standards. The same drug manufactured in another facility not approved by FDA—such as a foreign-made version of an approved drug—may not be sold legally in the United States. Drugs are subject to other statutory and regulatory standards relating to purity, labeling, manufacturing, and packaging. Failure to meet these standards could result in a drug being considered illegal for sale in the United States.

The FDCA requires that drugs be dispensed with labels that include the name of the prescriber, directions for use, and cautionary statements, among other things. A drug is considered misbranded if its labeling or container is misleading, or if the label fails to include required information. Prescription drugs dispensed without a prescription are also considered misbranded. In addition, if a drug is susceptible to deterioration and must, for example, be maintained in a temperature-controlled environment, it must be packaged and labeled in accordance with regulations and manufacturer standards. Drugs must also be handled to prevent adulteration, which may occur, for example, if held under unsanitary conditions leading to possible contamination.

FDA-approved drugs manufactured in foreign countries, including those sold over the Internet, are subject to the same requirements as domestic drugs. Further, imported drugs may be denied entry into the United States if they "appear" to be unapproved, adulterated, or misbranded, among other things. While the importation of such drugs may be illegal, FDA has allowed individuals to bring small quantities of certain drugs into the United States for personal use under certain circumstances.

Most of the Targeted Prescription Drugs Were Purchased from Multiple Internet Pharmacies Without Providing A Prescription

We obtained 1 or more samples of 11 of the 13 drugs we targeted, both with and without a patient-provided prescription. Drug samples we received from other foreign pharmacies came from Argentina, Costa Rica, Fiji, India, Mexico, Pakistan, Philippines, Spain, Thailand, and Turkey. Most of the drugs—45 of 68—were obtained without a patient-provided prescription. These included drugs for which physician supervision is of particular importance due to the possibility of severe side effects, such as Accutane, or the high potential for abuse and addiction, such as the narcotic painkiller hydrocodone.[11] (See table 2.)

[11]We purchased generic hydrocodone because it was much more readily available than the brand name drug Vicodin.

Table 2: Prescription Drugs Ordered and Received from Internet Pharmacies

Drug ordered	Orders placed[a]	Drug samples received[b]	Drug samples obtained without a prescription provided by the patient
Accutane	10	6[c]	3
Celebrex	10	9	7
Clozaril	9	0	0
Combivir	6	5	1
Crixivan	6	6	2
Epogen	1	1	0
Humulin N	7	4	3
Lipitor	10	9	6
OxyContin	1	1	1
Percocet	0	0	0
Viagra	10	9	7
Vicodin/hydrocodone	10	9[d]	9
Zoloft	10	9	6
Total	**90**	**68**	**45**

Source: GAO.

Note: The samples were shipped by FedEx (24), UPS (3), the U.S. Postal Service (39), and other couriers (2). Payments were made using Visa and MasterCard credit cards.

[a]Does not include attempted orders that were not accepted. We did not reach our goal of placing 10 orders for each drug because we could not always locate 10 sources from which we could purchase the drugs in a manner consistent with our methodology's protocols.

[b]We did not receive a drug sample for every order placed. Reasons included the drug being out of stock, a requirement that physicians prescribing certain drugs be part of a registry, and pharmacy requests for follow-up information we could not provide. In several instances, we could not determine why an order placed was not received.

[c]Includes one sample we could not link to an order we placed.

[d]Although we placed orders for Vicodin, we did not receive any samples of the brand name version of the drug; all nine samples received were of the generic equivalent hydrocodone.

Although most of the samples we received were obtained without a patient-provided prescription, prescription requirements varied. Five U.S. and all 18 Canadian pharmacies from which we obtained drug samples required the patient to provide a prescription. The remaining 24 U.S. pharmacies generally provided a prescription based on a general medical questionnaire filled out online by the patient. Questionnaires requested information on the patient's physical characteristics, medical history, and condition for which drugs were being purchased. Several pharmacy Web

sites indicated that a U.S.-licensed physician reviews the completed questionnaire and issues a prescription. The other foreign Internet pharmacies we ordered from generally had no prescription requirements, and many did not seek information regarding the patient's medical history or condition. The process for obtaining a drug from many of these pharmacies involved only selecting the desired medication and submitting the necessary billing and shipping information. (See table 3.)

Table 3: Prescription Requirements of Pharmacies from which We Obtained Samples

Prescription requirement	U.S. Internet pharmacies	Canadian Internet pharmacies	Other foreign internet pharmacies
Prescription from patient's physician must be provided	5	18	0
Web site provides prescription based on questionnaire	24	0	3
No prescription required	0	0	18

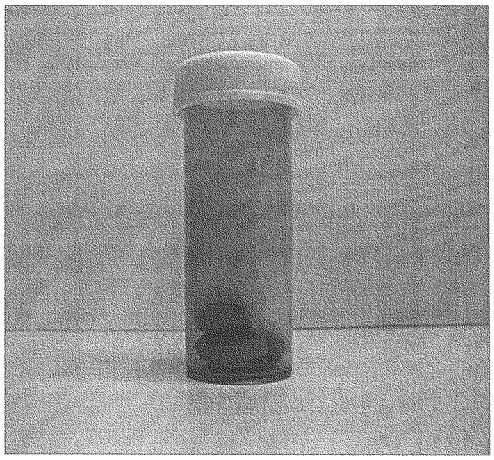
Source: GAO.

Most Problems Identified among Drug Samples Received from Other Foreign Internet Pharmacies

None of the 21 prescription drug samples we received from other foreign Internet pharmacies included a dispensing pharmacy label that provided patient instructions for use, and only 6 of these samples came with warning information.[12] Lack of instructions and warnings on these drugs leaves consumers who take them at risk for potentially dangerous drug interactions or side effects from incorrect or inappropriate use. For example, we received 2 samples purporting to be Viagra, a drug used to treat male sexual dysfunction, without any warnings or instructions for use. (See fig. 1.) According to its manufacturer, this drug should not be prescribed for individuals who are currently taking certain heart medications, as it can lower blood pressure to dangerous levels. Additionally, two samples of Roaccutan, a foreign version of Accutane, arrived without any instructions in English. (See fig. 2.) Possible side effects of this drug include birth defects and severe mental disturbances. Compounding the concerns regarding the lack of warnings and patient instructions for use, none of the other foreign pharmacies ensured patients were under the care of a physician by requiring that a prescription be submitted before the order is filled.

[12]One of the samples we received from other foreign pharmacies included a dispensing pharmacy label; however, this label lacked patient instructions for use.

Figure 1: Drug Sample Received Without Any Warnings or Instructions



Source: GAO.

Note: Sample purporting to be Viagra® arrived without any warning information or instructions for use.

Figure 2: Drug Sample Received Without Any Instructions in English

Source: GAO.

Note: Sample of Roaccutan®, a foreign version of Accutane®, arrived without instructions for use in English.

We observed other evidence of improper handling among 13 of the 21 drug samples we received from other foreign Internet pharmacies. For example, 3 samples of Humulin N were not shipped in accordance with manufacturer handling specifications. Despite the requirement that this drug be stored under temperature-controlled and insulated conditions, the samples we received were shipped in envelopes without insulation. (See fig. 3.) Similarly, 6 samples of other drugs were shipped in unconventional packaging, in some instances with the apparent intention of concealing the actual contents of the package. For example, the sample purporting to be OxyContin was shipped in a plastic compact disc case wrapped in brown packing tape—no other labels or instructions were included, and a sample of Crixivan was shipped inside a sealed aluminum can enclosed in a box labeled "Gold Dye and Stain Remover Wax." (See fig. 4.) Additionally, 5 samples we received were damaged and included tablets that arrived in

punctured blister packs, potentially exposing pills to damaging light or moisture. (See fig. 5.) One drug manufacturer noted that damaged packaging may also compromise the validity of drug expiration dates.

Figure 3: Drug Sample Shipped Improperly

Source: GAO.

Note: Despite the requirement that Humulin®N be stored under temperature-controlled and insulated conditions, samples we received were shipped in an envelope without insulation.

Figure 4: Drug Samples Shipped in Unconventional Packaging

Source: GAO.

Note: Sample purporting to be OxyContin® was shipped in a plastic compact disc case wrapped in brown packing tape—no other labels or instructions were included.

Source: GAO.

Note: Sample of Crixivan® was shipped inside a sealed aluminum can enclosed in a box labeled "Gold Dye and Stain Remover Wax."

Figure 5: Drug Sample Received in Damaged Packaging

Source: GAO.

Note: Sample of Crixivan®, a moisture sensitive drug, arrived in punctured blister packs.

Among the 21 drug samples from other foreign pharmacies, manufacturers determined that 19 were not approved for the U.S. market for various reasons, including that the labeling or the facilities in which they were manufactured had not been approved by FDA.[13] For example, the manufacturer of one drug noted that 2 samples we received of that drug were packaged under an alternate name used for the Mexican market. The manufacturer of another drug found that 3 samples we received of that drug were manufactured at a facility unapproved to produce drugs for the U.S. market. In all but 4 instances, however, manufacturers determined that the chemical composition of the samples we received from other foreign Internet pharmacies was comparable to the chemical composition of the drugs we had ordered. Two samples of one drug were found by the

[13]The manufacturer of one of the remaining two samples determined it was approved for the U.S. market and the manufacturer of the other sample could not make a determination.

manufacturer to be counterfeit and contained a different chemical composition than the drug we had ordered. In both instances the manufacturer reported that samples had less quantity of the active ingredient, and the safety and efficacy of the samples could not be determined. Manufacturers also found 2 additional samples to have a significantly different chemical composition than that of the product we ordered.

In contrast to the drug samples received from other foreign Internet pharmacies, all 47 of the prescription drug samples we received from Canadian and U.S. Internet pharmacies included labels from the dispensing pharmacy that generally provided patient instructions for use and 87 percent of these samples (41 of 47) included warning information. Furthermore, all samples were shipped in accordance with special handling requirements, where applicable, and arrived undamaged. Manufacturers reported that 16 of the 18 samples from Canadian Internet pharmacies were unapproved for sale in the United States, citing for example unapproved labeling and packaging. However, the samples were all found to be comparable in chemical composition to the products we ordered. Finally, the manufacturer found that 1 sample of a moisture-sensitive medication from a U.S. Internet pharmacy was inappropriately removed from the sealed manufacturer container and dispensed in a pharmacy bottle.

Table 4 summarizes the problems we identified among the 68 samples we received.

Table 4: Problems Observed Among Prescription Drug Samples Received

Pharmacy location	No pharmacy label with instructions for use (23 samples)	No warning information (21 samples)	Improperly shipped or dispensed (4 samples)	Unconventional packaging (6 samples)	Damaged packaging (5 samples)	Not approved for U.S. market (35 samples)	Counterfeit or otherwise not comparable to product ordered (4 samples)
Canadian		Celebrex (2) Zoloft (2)				Accutane (3) Combivir (3) Crixivan (3) Humulin N (1) Lipitor (2) Viagra (1) Zoloft (3)	
Other foreign	Accutane (3) Celebrex (3) Combivir (1) Crixivan (2) Humulin N (3) Lipitor (3) OxyContin (1) Viagra (2) Zoloft (3)	Accutane (2) Celebrex (3) Crixivan (2) Lipitor (3) OxyContin (1) Viagra (2) Zoloft (2)	Humulin N (3)	Accutane (1) Celebrex (1) Crixivan (2) OxyContin (1) Viagra (1)	Accutane (2) Celebrex (1) Crixivan (1) Lipitor (1)	Accutane (2) Celebrex (3) Combivir (1) Crixivan (1) Humulin N (3) Lipitor (3) OxyContin (1) Viagra (2) Zoloft (3)	Accutane (1) OxyContin (1) Viagra (2)
U.S.	Celebrex (1) Zoloft (1)	Lipitor (1) Zoloft (1)	Crixivan (1)				

Source: GAO and drug manufacturers.

Notes: Drug names indicated are those that GAO ordered. The samples we received were not the brand name drugs we ordered in all instances.

Drug samples do not add to 68 because some samples exhibited more than one problem.

Some Internet Pharmacies Were Not Reliable in Their Business Practices

We observed questionable characteristics and business practices of some of the Internet pharmacies from which we received drugs. We ultimately did not receive six of the orders we placed and paid for, suggesting the potential fraudulent nature of some Internet pharmacies or entities representing themselves as such.[14] The six orders were for Clozaril, Humulin N, and Vicodin, and cost over $700 in total. Five of these orders were placed with non-Canadian foreign pharmacies and one was placed with a pharmacy whose location we could not determine. We followed up with each pharmacy in late April and early May of 2004 to determine the

[14]The National Association of Boards of Pharmacy has also reported receiving complaints from consumers who state they have provided payment to various Internet pharmacies, but have not received the products ordered.

status. Three indicated they would reship the product, but as of June 10, 2004, we had not received the shipments. Three others did not respond to our inquiry.[15]

We determined that at least eight of the return addresses included on samples we received from other foreign Internet pharmacies were shipped from locations that raise questions about the entities that provided the samples. For example, we found a shopping mall in Buenos Aires, Argentina, at the return address provided on a sample of Lipitor. Authorities assisting us in locating this address found it impossible to identify which, if any, of the many retail stores mailed the package. The return address for a sample of Celebrex was found to be a business in Cozumel, Mexico, but representatives of that business informed authorities that it had no connection to an Internet pharmacy operation. Finally, the return addresses on samples of Humulin N and Zoloft were found to be private residences in Lahore, Pakistan.

Certain practices of Internet pharmacies may render it difficult for consumers to know exactly what they are buying. Some non-Canadian foreign Internet pharmacies appeared to offer U.S. versions of brand name drugs on their Web sites, but attempted to substitute an alternative drug during the order process. In some cases, other foreign pharmacies substituted alternative drugs after the order was placed. For example, one Internet pharmacy advertised brand name Accutane, which we ordered. The sample we received was actually a generic version of the drug made by an overseas manufacturer.

About 21 percent of the Internet pharmacies from which we received drugs (14 of 68) were under investigation by regulatory agencies. The reasons for the investigations by DEA and FDA include allegations of selling controlled substances without a prescription; selling adulterated, misbranded, or counterfeit drugs; selling prescription drugs where no doctor-patient relationship exists; smuggling; and mail fraud. The pharmacies under investigation were concentrated among the U.S. pharmacies that did not require a patient-provided prescription (nine) and other foreign (four) pharmacies. One Canadian pharmacy was also included among those under investigation.

[15]We received no notice from federal agencies indicating that our drug samples had been seized, nor did the Internet pharmacies we contacted about unreceived shipments indicate they had received such notification.

Concluding Observations

Consumers can readily obtain many prescription drugs over the Internet without providing a prescription—particularly from certain U.S. and foreign Internet pharmacies outside of Canada. Drugs available include those with special safety restrictions, for which patients should be monitored for side effects, and narcotics, where the potential for abuse is high. For these types of drugs in particular, a prescription and physician supervision can help ensure patient safety. In addition to the lack of prescription requirements, some Internet pharmacies can pose other safety risks for consumers. Many foreign Internet pharmacies outside of Canada dispensed drugs without instructions for patient use, rarely provided warning information, and in four instances provided drugs that were not the authentic products we ordered. Consumers who purchase drugs from foreign Internet pharmacies that are outside of the U.S. regulatory framework may also receive drugs that are unapproved by FDA and manufactured in facilities that the agency has not inspected. Other risks consumers may face were highlighted by the other foreign Internet pharmacies that fraudulently billed us, provided drugs we did not order, and provided false or questionable return addresses. It is notable that we identified these numerous problems despite the relatively small number of drugs we purchased, consistent with problems recently identified by state and federal regulatory agencies.

Mr. Chairman, this concludes my prepared statement. I would be pleased to respond to any questions you or other Members of the Subcommittee may have at this time.

Contacts and Acknowledgments

For future contacts regarding this testimony, please call Marcia Crosse at (202) 512-7119. Other individuals who made key contributions include Randy DiRosa, Margaret Smith, and Corey Houchins-Witt.

United States General Accounting Office

GAO

Testimony

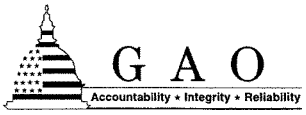
Before the Permanent Subcommittee on Investigations, Committee on Governmental Affairs, U.S. Senate

For Release on Delivery
Expected at 9:00 a.m. EDT
Thursday, June 17, 2004

INTERNET PHARMACIES

Hydrocodone, an Addictive Narcotic Pain Medication, Is Available Without a Prescription Through the Internet

Statement of Robert J. Cramer
Managing Director, Office of Special Investigations



GAO-04-892T

Mr. Chairman and Members of the Subcommittee:

I am pleased to be here today to summarize the results of our investigation of some of the business practices of certain U.S. Internet pharmacies that sold narcotics without a prescription. Our testimony is part of a larger body of work GAO has performed that is the subject of a report and additional testimony we are releasing today that examines issues surrounding the availability and safety of prescription drugs sold over the Internet and the business practices of certain Internet pharmacies.[1] We conducted our work from March 2004 through June 2004 in accordance with quality standards for investigations as set forth by the President's Council on Integrity and Efficiency.

At your request, Mr. Chairman, we attempted to obtain information about the sources of hydrocodone[2] that we purchased without a prescription from eight U.S. online pharmacies. Hydrocodone is an addictive narcotic pain medication, and illicit use of this drug has increased significantly in recent years. We contacted one of the pharmacies that had sold us hydrocodone in an attempt to determine the relationship between the Internet site and the pharmacy that dispensed the narcotic and to find out what role a physician may have played in facilitating our purchase. We also spoke to a physician who actually prescribed the narcotic for one of our purchases and appears to be operating an Internet drug business that caters almost exclusively to individuals purchasing hydrocodone. Although the Internet Web site and the physician have taken some measures to disguise their operation as a legitimate enterprise, their business practices suggest otherwise.

We determined the location of the pharmacy that we contacted based on the return address on the package in which the sample was delivered. Further, posing as a relative of the customer who had purchased hydrocodone from this Internet pharmacy, one of our investigators spoke to the pharmacist who dispensed the drug as well as the prescribing physician. Subsequently, we conducted surveillance of the office where the physician processes Internet drug orders.

[1]U.S. General Accounting Office, *Internet Pharmacies: Some Pose Safety Risks for Consumers*, GAO-04-820 (Washington, D.C.: June 17, 2004); *Internet Pharmacies: Some Pose Safety Risks for Consumers and Are Unreliable in Their Business Practices*, GAO-04-888T (Washington, D.C.: June 17, 2004).

[2]Hydrocodone, a Schedule III controlled substance, is the generic version of Vicodin.

In summary, we found that (1) one can purchase hydrocodone from certain Web sites on the Internet without providing a prescription or being examined by a physician; and (2) the Internet pharmacies from which we made our purchases of hydrocodone charge significantly higher prices for the drug than walk-in pharmacies. We concluded that those who participate in Internet drug operations that operate in this manner appear to be in the business of knowingly servicing, and profiting from, individuals who may purchase pain medication for illicit purposes.

Purchases of Narcotic Pain Medication Without Prescriptions

We obtained hydrocodone from eight domestic Web sites on which we placed orders without submitting a prescription or undergoing an examination by a physician. Six purchases, each from different Web sites, were dispensed by a single pharmacy located in a Southeastern state. The two remaining purchases were ordered from two separate Web sites and were dispensed by separate pharmacies located in states in the Southeast and Southwest.

We obtained the hydrocodone online by completing questionnaires on which a GAO staff member (the "customer") claimed that he had pain. In addition, he claimed that his doctor had prescribed hydrocodone for the pain, but that he had recently lost his health insurance and could not return to his doctor for a new prescription. Five Web sites sent the narcotic after receiving our order and credit card payment information. We received telephone calls from the three other suppliers before our order was completed. They asked questions about our purported need for the hydrocodone and prior use of the drug.

In our attempt to determine the relationship between the Internet site and the pharmacy that dispensed the narcotic, and to find out what role a physician may have played in facilitating our purchase, we contacted one of the pharmacies that had sent us hydrocodone. We also contacted the physician who "prescribed" a 30-day supply of the narcotic without seeing or speaking to the customer and without any confirmation from a physician that the customer had previously been under a doctor's care or had received a prescription for pain relief.

This specific purchase originated on February 26, 2004, when the customer, posing as a patient experiencing pain, used a pseudonym to place an order for hydrocodone. Customers are advised on the site that they are required to (1) fill out an online questionnaire, (2) receive a phone call from a medical professional to discuss the customer's medical condition to

determine if he or she is approved for the drug, and (3) undergo a complete physical examination. If approved, the medication is billed to the customer's credit card.

Despite the claims on the Web site that customers must satisfy these requirements, we obtained the hydrocodone without undergoing a physical examination or producing any tangible evidence showing treatment by a doctor in the past. Indeed, the customer simply completed the online questionnaire and spoke by telephone to the physician's representative, who offered the customer two options for satisfying the physical examination requirement: (1) for $199, the customer could visit a physician at one of two clinics in the area where the customer lived; or (2) for $49, the representative would fax or e-mail paperwork that the customer could take to his own physician to fill out and return to the pharmacy's physician. In addition, the representative told the customer that if he chose and paid for one of these two options with a credit card during their telephone conversation, the physician would immediately issue a 30-day prescription so that he could get his medication right away.

The customer told the representative that he needed to think about both options. However, the representative reemphasized that if he chose either the $199 or the $49 option and paid for it immediately, he could get his 30-day supply of hydrocodone right away. The customer then chose the $49 option and gave the representative his credit card information. After the transaction was complete, the representative reviewed the information that the customer submitted online and said that he would receive e-mails from her and from the Web site containing paperwork and information on how to pay for the medication.

The customer then asked if he needed to set up an appointment for a consultation with the physician, and the representative replied that she had already completed the consultation. Later that day, the customer received the paperwork and an e-mail link for a payment site. He went to the site and used his credit card to pay a total of $190 for his initial 30-day supply of hydrocodone.

Subsequent Investigation

Subsequent to receipt of the hydrocodone, a GAO investigator, posing as a relative of the customer, contacted the pharmacy listed on the return address of the package in which it was delivered. The pharmacist confirmed that he had sent the drug and explained that he has a business

relationship with the Web site on which we ordered it, and with a physician who sent a prescription for it to the pharmacist.

The investigator then telephoned the physician who confirmed that he prescribed the hydrocodone. The physician claimed that he never writes prescriptions for new medications for patients and that he always confirms that the patient has been on the medication in the past. The investigator asked whether the doctor had actually spoken with his relative, and the physician responded that one of his associates had in fact spoken to him. He said that he has a staff of several people who make such telephone calls to confirm that the customer has been on the medication in the past. He repeatedly asserted that the staff calls and speaks with the customer's physician who previously prescribed the medication. However, he confirmed that the telephone number his staff had called with respect to our purchase was simply the telephone number of the customer himself, not that of a physician.

The physician indicated to our investigator that he was handling his Internet drug business from a clinic he operates. When asked the name of the clinic, he indicated that it is part of a health care network and gave a name that does not correspond to the name of any existing health care network we could find or to any actual medical practice with which the physician is in fact affiliated. He said to our investigator, "90 percent of our business is for hydrocodone." He acknowledged that he currently provides prescriptions for five different Internet drug sites and disclosed that he previously wrote prescriptions for two Web sites that have been shut down.

When asked about the possibility of children buying narcotics through him, the physician claimed that the need for a credit card is the "safeguard" to prevent that from happening and that "a kid shouldn't have a credit card." However, he admitted that "parents call [him] all the time saying that their children have gotten hold of their credit cards." While he stated that the system can be used by customers to purchase drugs for illicit purposes, he repeatedly stressed that his online pharmacy business offers "a service for patients who don't have insurance, who can't afford to go and see a doctor."

However, this assertion is patently false. To the contrary, the customer paid a total of $190.00, and an additional $49.00 "consultation" fee, for 60 tablets of hydrocodone that can be purchased for an average price of about $26.00 at local retail pharmacies at which we inquired. Thus, we paid nearly ten times the ordinary retail price of the drug because we did not

have a prescription. The Drug Enforcement Administration provided us with information that the "street price" or illegal sales price of the hydrocodone we bought online is about $5 to $6 per pill. Thus, we paid slightly less than the street price for the drug from this source. The prices we paid for hydrocodone at the other seven Web sites from which we ordered it were also significantly higher than the retail price at local pharmacies. Overall, we paid the eight online pharmacies prices that were 3 to 16 times the price charged for hydrocodone at local pharmacies.

During our visit to the site where the physician purports to operate a clinic, we saw no evidence of a health clinic. The site is a one-room storefront set up with several computers and telephones. The only individuals we saw going to or leaving the storefront appeared to be employees, and there was no sign on the premises indicating that the business was health related. When one of the employees was asked what kind of business is operated at the location, she responded that they do "computer consultations."

Concluding Observations

Our investigation revealed that customers can purchase hydrocodone, a potentially dangerous and addictive controlled substance, from certain domestic Internet sites that do not require prescriptions. These Web sites appear to purposely cater to hydrocodone customers who are willing to pay a substantial markup for the painkillers because they do not have prescriptions. As a result, these sites appear to be in the business of profiting from illicit drug use rather than providing a safe, inexpensive alternative source of drugs for customers.

Submission Of

THE HONORABLE RUDOLPH W. GIULIANI

Chairman & CEO
Giuliani Partners LLC

Hearing Before The

U. S. Senate Permanent Subcommittee on Investigations

BUYERS BEWARE: THE DANGERS OF PURCHASING PHARMACEUTICALS OVER THE INTERNET

June 17, 2004

Giuliani Partners LLC
Examination and Assessment of
Prescription Drug Importation From Foreign Sources
To the United States

Interim Findings
May 11, 2004

INTRODUCTION

The availability of safe, effective and reasonably priced medications for all Americans is at the center of an important, ongoing debate regarding our health care system. As the costs of medicines have increased, so has the focus of pricing on this debate. Individuals and even local and State governments have sought alternative means to obtain necessary medicines at lower costs, and these initiatives have further narrowed the debate to the value of importing Canadian or foreign medicines into the United States.

However, the safety and efficacy of these same imported medicines has received less attention and focus and is often overshadowed or even ignored by the pricing issue. From the outset, there is little dispute that the high price of many prescription medicines becomes an impediment to access. And while the price of today's medicines exist in part to provide for the development of tomorrow's cure, patient access should be expanded by exploring methods for lowering costs for those in need.

Giuliani Partners LLC has been retained by the Pharmaceutical Research and Manufacturers of America (PhRMA) to evaluate the risks, if any, associated with the importation of Canadian and foreign medicines.

In recognition of the public health implications associated with importation, and at the request of Congress, the United States Department of Health & Human Services has convened a Task Force on Drug Importation to examine these very concerns. Acknowledging the importance of this issue to the public, the Task Force is working with great alacrity to provide its recommendations to HHS. Giuliani Partners LLC will be providing the Task Force with a more detailed report encompassing our preliminary findings and conclusions as part of our effort to inform this critical debate and to assist the Task Force in its work. For now, we have made a series of interim findings that are worth discussing today to widen the lens through which the issue of the importation of drugs is viewed, and consequently address the equally important issues of safety and risk in the Task Force's assessment.

It is important to note from the outset that there appears to be a fundamental misunderstanding about the source of the less expensive drugs at the center of this discussion. Initially, this debate was framed around "re-importation" – in other words, the importation (from Canada) of medicines manufactured under U.S. Food and Drug Administration (FDA) oversight and now available at a lower cost via Canada. Under such a system, a patient could reasonably assume that the medicine

was safely and properly manufactured under FDA oversight without corruption in the supply chain. However, that is not necessarily what is occurring. Instead, U.S. patients are receiving medicines from foreign countries (albeit ordered through Canada or sources purporting to be Canadian based) that were manufactured or re-packaged without any oversight by the FDA or Health Canada (the Canadian FDA counterpart).

Indeed, several U.S. States that provide links to websites for their citizens to order "Canadian" drugs have graphic disclaimers disavowing any warranty about the product and relinquishing the state government from any legal liability with regard to the product or care from the on-line pharmacy. In some instances, the Canadian pharmacy website requires the patient to sign a waiver that denies the patient any legal recourse in the U.S. for harm caused by these imported drugs. The current U.S. regulatory process, while not perfect, protects patients seeking medicines from U.S. pharmacies. This raises an important question that must be reviewed when assessing the relative risks associated with obtaining imported medicines against the potential rewards of lower prices.

Product Quality: What Is In Our Medicine?

When a patient seeks to fill a particular prescription for a particular medicine, there is an assumption that the medicine is in the exact form, quality, potency and dosage as directed by the patient's physician. Anything less constitutes a risk to that patient's health and well-being.

Based upon our review to date, we have found that some patients who believe they are purchasing re-imported Canadian medicines are in fact receiving non-FDA approved drugs from foreign countries that are not at all what they claim to be. There is significant evidence that patients have received drugs through the internet that are past their expiration date, are sub-potent (or, in some cases, more potent than indicated), contain the wrong dose, are contaminated or clearly counterfeited, are not properly stored or shipped (i.e. medicines that require constant refrigeration or others that must be protected from freezing) among other problems. We have found that medicines ordered over the internet that purport to be manufactured under FDA oversight or delivered through Canadian pharmacies are in fact manufactured in countries such as Pakistan, China, Iran, Singapore and many others. The fundamental question of product quality and integrity must be at the center of this important discussion.

Set forth below is an outline of the review we have undertaken. Significant questions are raised regarding the level of safety for patients and indeed for our nation from the relaxation of importation controls. It is vital that the Task Force and others carefully and thoughtfully consider all of these legitimate concerns so that our health care system can be as safe, effective and accessible as possible.

SYSTEMIC ISSUES

The American system for manufacturing, distributing and selling prescription medicines is significantly regulated and often referred to as the "gold standard."

Notwithstanding this fact, however, there are identifiable weaknesses in this process that can compromise the quality and integrity of our medicine supply.

The Distribution Chain

On its face it appears that the distribution chain for prescription medicines in the United States is fairly straightforward – manufacturers sell their products to wholesalers, who in turn sell the products to retail pharmacies or stores, who in turn dispense medicines to patients with prescriptions. It is not until the system is studied in greater detail that one begins to appreciate both the complexities and the vulnerability of the distribution chain and the potential for exploitation or abuse.

Some contributing factors are as follows:

- Wholesalers or distributors are primarily regulated by the states with no uniform standards across state borders. States have a comparatively small number of investigators to monitor the licensed wholesalers; thus, given the sheer number of wholesalers, oversight is minimal.

- There are thousands of "secondary" pharmaceutical wholesalers in addition to McKesson, AmerisourceBergen and Cardinal Health (the "big three") involved in the distribution of prescription medicines. As reported in The Washington Post, there are more than 6,500 small wholesalers nationwide.

- There is no uniform mechanism, i.e., a chain of custody or "pedigree," to track the medicine from point of manufacture to point of sale; the FDA has not implemented the pedigree requirement that was mandated by law in 1988.

- Repackaging is a vulnerable point in the process and can provide an opportunity for counterfeit or non-FDA approved products to compromise the system.

Report of the Florida Grand Jury

Two years ago the State of Florida convened a statewide Grand Jury to examine the safety of prescription drugs in Florida and to analyze the sale and resale of prescription drugs in the wholesale market. The report, released in February 2003, found an overwhelming need for tighter regulation and oversight of the pharmaceutical distribution industry. Many of those interviewed by Giuliani Partners indicated that the problems identified in the Florida Grand Jury Report are pervasive throughout the United States. A summary of the Grand Jury's findings follows.

- Oversight of the system is lax.
    - Minimal background checks are required for licensing wholesalers and warehouse operators were found to be uneducated amateurs, some with criminal records.
    - Corrupt wholesalers are neither investigated nor prosecuted.
    - Despite existing requirements, drugs are being distributed with either incomplete or, in many cases, non-existent pedigree papers to document the products' supply chain history.

- Inspection of wholesaler operations by the appropriate authorities and oversight by responsible agencies is spotty at best.

- Funding for oversight agencies is inadequate.
  - The Florida Bureau of Statewide Pharmacy Services employs only nine field inspectors to inspect 422 wholesalers statewide.

- Product quality is compromised.
  - Widespread problems with the quality and integrity of the secondary wholesale drug supply were found to include:
    - expired drugs re-labeled with falsely extended dates
    - previously dispensed medicines
    - illegally imported drugs
    - sub-potent drugs
    - drugs that contained an entirely different substance from the one listed on the container's label

- Health risks are significant.
  - The mainstream market is compromised by corrupt, secondary wholesalers. Diverted drugs are often combined with counterfeit medicines or re-labeled or repackaged. Then, these compromised drugs enter the mainstream market through corrupt secondary wholesalers and are dispensed by legitimate pharmacies, hospitals or clinics. By way of example, a father in Michigan who thought he was injecting his son with a growth hormone later found that the vials actually contained insulin. These drugs were traced to a legitimate pharmacy in Orlando, Florida.

- Incentives for counterfeiting and diversion are considerable.
  - The huge profits derived from these activities rival those of illicit narcotics traffickers, while the penalties are minor by comparison.

Challenges to Oversight and Enforcement

There are challenges associated with the oversight and enforcement of our current laws with regard to ensuring that medicines being purchased or sold in this country are FDA-approved, safe and effective.

- The current volume of parcels of drugs coming into this country through the mail (it is estimated to be more than 10 million packages annually) and the increasing volume of internet purchases make meaningful inspection by the FDA almost impossible.

- The FDA has less than 100 investigators to deal with drug importation issues nationwide, and its investigative authority is limited relative to its ever-increasing law enforcement responsibilities. For example, the FDA has no administrative subpoena authority in order to facilitate the conduct of its investigations; thus it must either partner with another investigative agency or request subpoenas from the local United States Attorney's office.

- Investigating and prosecuting counterfeit drug cases or illegal internet sales cases are not, with few exceptions, a priority for the federal or state law enforcement agencies.

- The penalties are comparatively low for engaging in this kind of activity – the current penalties for FDA violations are approximately 3 years.

- The technologies being advanced as mechanisms to ensure an imported drug shipment is safe and effective are not foolproof, and, in some instances, not yet available.
    - Electronic Track and Trace – most agree that these technologies, e.g., using bar coding or radio frequency identification (RFID) chips that could track drug products in real time throughout the system and then provide an electronic pedigree, are still very costly when available.
    - Counterfeit resistant technologies that include covert and overt packaging and labeling techniques, such as holograms, watermarks, color shifting inks or fluorescent inks, as well as chemical agents, are widely used by the industry already. However, they can be easily duplicated and, therefore, must be changed on a periodic basis.
    - "Unit of Use" packaging, which is a container closure system designed to hold a specific quantity of drug product for a specific use and dispensed to a patient without any modification except for appropriate labeling, does eliminate the need for some repackaging; however, there are packaging and cost issues for the manufacturers, and some drugs do not lend themselves to such packaging.
    - Authentication testing, while not a technology *per se*, is also an option when determining the integrity of a pharmaceutical product. It is a complicated, time consuming and costly process, however, and can be performed only by the original manufacturer. There are no available tests that can be conducted "in the field" to ascertain whether a product is real or fake.

These factors, among others, make it a high profit, low risk business for the counterfeiters or those involved in circumventing the laws in supplying medicines outside the traditional distribution chain, and, therefore, it may be appealing to organized crime and terrorist organizations.

PRODUCT QUALITY

Weaknesses in the existing system already threaten the quality and integrity of the nation's drug supply. Despite best efforts, the evidence we have seen thus far supports the notion that the drug supply is indeed vulnerable. Some examples are as follows:

Random Examinations Conducted by the FDA and U.S. Customs and Border Protection

The FDA and U.S Customs and Border Protection conducted a number of random inspections or "blitzes" at several mail ports in the fall and early winter of 2003.

- In the first inspection, 1,153 drug products were examined and 1,019 or 88% were not approved by the FDA; the drugs came from countries such as India, Thailand, and the Philippines.

- In the second exam, 1,982 parcels were examined and 1,728 or 87% were not approved; 16% of those shipments were from Mexico.

- Many of the drugs examined during these visits were non-FDA approved for many reasons, including:
    - improper labeling, e.g., there were no instructions for proper use;
    - the presence of controlled substances;
    - potentially recalled drugs, e.g., drugs that had been withdrawn from the market for safety reasons;
    - animal drugs not approved for human use;
    - drugs requiring risk management and/or restricted distribution (e.g., initial screening or periodic monitoring); drugs with clinically significant drug interactions; or drugs requiring careful dosing; and
    - required special storage conditions for certain drugs were violated.

Portal Visits

In order to gain an appreciation for the scope of the problem, United States mail facilities were visited to observe the volume and nature of the packages allegedly containing prescription drugs entering the United States. A number of the observations follow.

John F. Kennedy Airport Mail Facility

At the invitation of United States Senator Norm Coleman, former New York City Mayor Rudolph W. Giuliani and former New York City Police Commissioner, Bernard B. Kerik, accompanied the Senator on a visit in March, 2004 to the US Mail facility located at JFK Airport. Customs officials advised that approximately 40,000 packages of suspected drug shipments are received each day from the postal service for review and inspection. Based upon information, the FDA focuses on "countries of interest" and visually inspects 500 to 700 parcels per day. Thus, the majority of packages are sent on to the addressee uninspected. The following was learned:

- Drugs purported to be Xanax, Valium (Diazepam), Lorazapam, Vicodin (all controlled substances) and Lupron were observed; there were numerous packages from the Netherlands, Brazil, Pakistan, as well as other countries.

- Many of the drugs contained in the parcels were non-FDA approved because they were inappropriately packaged, expired, mislabeled or otherwise noncompliant.

- The sheer volume of shipments overwhelms Customs and FDA; FDA has only 6 staff members assigned to JFK.

- Although much of what is inspected is non-FDA approved, few parcels are actually detained. The processing requirements to detain a shipment are

cumbersome and time consuming. The rules require the FDA to send a notice to the addressee of the package. If the person does not respond or the response is insufficient, the package must then be returned to the sender (manufacturer). This process varies significantly from the way controlled substances or narcotics are handled. Such drugs can be destroyed without further processing.

Miami International Mail Branch Facility Visit in March 2003

Giuliani Partners was provided with a Congressional staff report regarding a similar review of the Miami facility in March 2003. The findings of the bipartisan Congressional report were consistent with the findings of this review:

- Congressional staff witnessed "thousands of shipments of foreign drugs" being processed; the packages were from countries such as Honduras, Costa Rica as well as Great Britain; and the packages purportedly contained "valium" (diazepam), Reteina (Ritalin), Zolipedem, and Ciprofloxacin.

- The volume of drugs coming through the mail facilities is too great to allow for any meaningful inspection.

- Parcels are only visually inspected; there is no testing as to the quality or integrity of the product.

- FDA and Customs detain very limited numbers of questionable drugs coming into the facility because of the cumbersome nature of the detention process.

<u>The Increase in Counterfeit Drugs</u>

- Most of those interviewed by Giuliani Partners agreed that:

    - The number of incidents involving counterfeit medicines is increasing;
    - The increased use of internet sale and purchase is exacerbating the problem;
    - The counterfeiting techniques are becoming more sophisticated and harder to detect;
    - There are vulnerabilities in the current distribution system that contribute to the problem; and
    - Opening the borders for wholesale importation will worsen the problem.

- The former Commissioner of the FDA, Dr. Mark McClellen, testified before the U.S. Senate Committee on Commerce, Science and Transportation on March 11, 2004 that the FDA has seen its number of counterfeit drug investigations increase four-fold since the late 1990's. "Although counterfeiting was once a rare event, we are increasingly seeing large supplies of counterfeit versions of finished drugs being manufactured and distributed by well funded and elaborately organized networks."

- On its website, the World Health Organization (WHO) states that while the true extent of the problem of counterfeit drugs is difficult to know or measure,

they have estimated that at least 8% – 10% of the world's total drug supply is counterfeit.

- An August 30, 2002 Washington Post story cites the Shenzhen Evening News in reporting that an estimated 192,000 people died in China in 2001 because of counterfeit drugs. Another news story reported that as much as 50% of China's drug supply is counterfeit (Investor's Business Daily dated October 20, 2003).

Reported Incidents of Adverse Effects

Without question, the most frequently asked question by proponents of importation is "who is really being harmed by the purchase of medicines from outside of the United States?" There appears to be no easy answer to the question. Because receipt of imported medicines is unregulated, there are no systems in place to effectively monitor whether injuries result from the taking of compromised medicines. When complications arise from taking imported medicines and a patient does consult with his or her doctor or reports to an emergency room, no one is asking the question 'where do you purchase your prescription medicines?" Patients are also reluctant to report adverse reactions that may be attributable to medicines illegally purchased from outside the country.

Given these circumstances, coupled with the systemic challenges discussed earlier, it is difficult to ascertain the actual source of an imported drug. The following are some examples of actual incidents where people taking medicines with undocumented origins were adversely affected as a direct result of taking the prescription drugs. These cases represent the dangers of obtaining drugs from sources outside of the United States' closed system.

- In La Mesa, California, Ryan T. Haight, 18, died in his bedroom of an overdose after taking narcotics obtained on the internet. After his death, his parents found a bottle of the painkiller Vicodin in his room with a label from an out-of-state pharmacy. An investigation by federal drug agents showed that the teenager had been ordering addictive drugs online and paying with a debit card his parents gave him to buy baseball cards on eBay. (Washington Post, October 19, 2003)

- In Sacramento, California, James Lewis, 47, a former triathlete, shopped the world for painkillers that flowed unimpeded from pharmacies in South Africa, Thailand and Spain. His wife discovered him dead of an overdose on the living room couch. (Washington Post, October 19, 2003)

- A 15-year-old paraplegic boy went into convulsions and died after taking a non-FDA approved drug called Lincocin which had been smuggled in from Mexico. (Los Angeles Times, March 10, 2001)

- Juris Abolins, 43, used painkillers off and on for years to treat pain from kidney stones. His roommate found him slumped on his bedroom floor dead. An autopsy revealed the presence of controlled substances in his blood stream.

Relatives found a Federal Express slip for drugs purchased from a website in Tijuana, Mexico. (Washington Post, October 19, 2003)

THE INTERNET

Over the past several years, hundreds of websites have appeared on the internet selling prescription medicines. While some sites provide legitimate prescription services, many sites are illegitimate and pose significant risks to all patients who use them.

Private Investigation Regarding Internet Purchases

A security and investigative firm based out of New York City, Beau Dietl & Associates, conducted an investigation regarding the importation of foreign medicines and reported its findings in December 2003. The results were disturbing:

- More than 1400 websites were identified as selling prescription drugs.
- 352 of those sites did not require a prescription when ordering.
- 142 of 170 orders were placed without a prescription and at the time of the report, 79 orders were filled without a prescription.
- Many of the medicines received were not only shipped in improper packaging but came from foreign countries such as Pakistan.
- An order for Ciprofloxacin was placed, received and tested. It was determined to be only 65% potent.
- The investigation found that website operators were often difficult to identify and trace; and some of those identified were found to have questionable backgrounds:
    - One website owner/operator was a convicted felon;
    - Other website owners could not be traced because the registration information was false;
    - Many sites failed to comply with legal requirements – doctors wrote prescriptions without ever meeting the patient; and one internet doctor was a convicted sex offender.
- Websites were easily established with no minimum qualifications, standards, or oversight.
- Once the websites were established, emails were received from various suppliers offering to provide medications from "several countries," or "bulk meds from Pakistan" for resale in the U.S. market.

The results of this investigation offer a troubling snapshot of the nature of the internet pharmaceutical business.

The CASA White Paper

The National Center on Addiction and Substance Abuse at Columbia University, under the direction of Joseph Califano, former Secretary of the Department of Health, Education and Welfare, the predecessor of the U.S. Department of Health and Human Services, released a study in February 2004 regarding the sale of controlled, dangerous and addictive prescription drugs in America. It looked particularly at internet sales and teamed with the same New York City investigative firm to conduct the review. CASA characterized its findings as "alarming."

During a one-week period of observation, the firm identified a total of 495 web sites offering Schedules II through V controlled substance prescription drugs. Examples of the controlled substances available online included painkillers, stimulants, and nervous system depressants.

- Of the 157 sites selling controlled substance prescription drugs on the internet
  - 90% (141) did not require a prescription
  - 4% (7) required that a faxed prescription
  - 2% (3) required that a mailed prescription
  - 4% (6) made no mention of prescriptions

- Of the sites, 47% disclosed that the drugs would be coming from outside the United States; 28% stated the drugs would be shipped from a US pharmacy; and 25% gave no indication where the drugs would be coming from.

- The analysis determined that there were no mechanisms in place to block children from purchasing these drugs.

Canada – The Implications of Importation

It is generally agreed that prescription medicines purchased by Canadians in a Canadian drug store are safe and effective. Like the United States, Canada has a system of regulatory controls over its medicine supply. However, the same cannot be said for the drugs that are being imported to Canada and then exported. In fact, the Canadian government is not inspecting those medicines that are being imported to Canada and then exported to the United States. The Canadian government has clearly stated that it would not be responsible for the safety and quality of prescription drugs exported from Canada into the United States or any other country. Furthermore, the Canadian Food and Drug Act does not apply to any packaged food, drug, cosmetic or device not manufactured for consumption in Canada and not sold for consumption in Canada.

With respect to the question of drug supply capacity, it is undisputed that Canada does not have supply sufficient to provide for its residents and Americans as well. (In 2002, 3.1 billion prescriptions were filled in the U.S. compared to 335 million prescriptions filled in Canada.)

According to information provided by Industry Canada, a department of the Canadian Federal Government, from September 2002 to September 2003, there was a significant increase in drugs imported into Canada from the following countries:

- Singapore up 30%
- Ecuador up 198%
- China up 43%
- Iran up 2,753%
- Argentina up 221%
- South Africa up 84%
- Thailand up 52%

Prudential Financial, Inc. released similar findings, stating that Canadian internet pharmacies were increasingly obtaining their product from other countries such as Bulgaria (exports to Canada up 300%), Singapore (up 101%), Argentina (up 171%), South Africa (up 114%), Pakistan (up 196%), as well as others. Further, some Canadian pharmacies, such as Canadameds.com, have publicly indicated that because of the increasing demand from the United States, they are turning to Great Britain for prescription drugs.

THE POTENTIAL FOR EXPLOITATION BY NARCOTICS TRAFFICKERS, ORGANIZED CRIMINALS AND TERRORISTS

The terrorist attacks of September 11, 2001 demonstrated how vulnerable this country is to those who have total disregard for human life or who mean us harm. Since that time, the United States has invested billions of dollars to protect our borders. Despite all that has been done, we have not focused on the vulnerability of the nation's medicine supply as a potential target. The present controlled system of importation and inspection is open to exploitation and abuse. Any further removal of controls, much less the total opening of the borders to foreign drugs, would create a situation that terrorists, drug dealers and organized criminals might well use to their advantage. It seems counter-intuitive to contemplate opening our borders with regard to our medicine supply when in all other aspects of border security and protection, we as a country are looking for ways to tighten security.

A July 22, 1998 story in Insurance Day, while reporting on pill piracy and the World Health Organization's efforts to confront pharmaceutical fraud, stated that "Interpol believes that this aspect of the drug trade is closely connected with the narcotics cartels and that the profits generated by it are in part used to finance international terrorism." The article further stated that Interpol had been following the global counterfeit drug racket for some time and based its belief on evidence uncovered by police in North America and Western Europe.

Further, in her book, Funding Evil, How Terrorism is Financed – and How to Stop It, Rachel Ehrenfeld makes numerous references to the fact that terrorists use counterfeiting activities as a means to fund their terrorist acts. While counterfeit prescription drugs are not specifically referenced, the use of illegal drugs to fund such activities is well documented.

GlobalOptions Inc. identified the potential terrorist threats to America's medical supply in its work, An Analysis of Terrorist Threats to America's Medicine Supply. In sum, it identified three potential threats. First, the "mere infiltration of terrorists in the counterfeit drug market poses a threat to the public." Terrorists could easily produce and sell harmful prescription drugs. Second, terrorist groups could use the profits raised through the sale of counterfeit or diverted drugs to fund their activities. And third, terrorists could use poisoned drugs as a method of attack or, worse, as a weapon of mass destruction.

This study cited numerous examples of links between counterfeiting activities of various types and terrorist groups, where such groups were using the proceeds from these sales to fund their terrorist activities. In particular, the authors pointed to the following:

- The activities of the Irish Republican Army in the early 1990's in Florida that included the manufacture of a counterfeit drug product used to treat livestock. Proceeds from this operation were used to purchase guns;

- An international drug ring raised millions of dollars for Hezballah. The report states that the terrorist group's operatives legitimately purchased large quantities of pseudoephedrine in Canada, smuggled it into the United States, and produced "speed."

THE CONCLUSION

After conducting a preliminary, independent review of the issues associated with the wholesale importation of prescription medicines, it is evident that the existing pharmaceutical system is open to significant exploitation of counterfeit, diluted or adulterated drugs coming into the United States. The limitations of our system should be addressed before it is opened to wholesale importation.

The Health and Human Services Task Force on Drug Importation is currently considering all of these issues. The Task Force should be allowed to complete its mission as Congress directed before any major statutory changes are contemplated. Given the seriousness of this issue and its implications for the health and safety of Americans, a thorough and well-informed analysis is necessary.

Our interim findings can be summarized as follows:

- Although the current pharmaceutical manufacturing and distribution system is comprehensive and regulated, counterfeit or otherwise adulterated products still penetrate the market.

- There are serious questions as to the quality and safety of the medicine products coming into the United States from foreign sources.

- There are no minimum standards and little or no regulation regarding the operations of internet pharmacies.

- There are identifiable weaknesses in the current pharmaceutical distribution chain (e.g., the "secondary" wholesale distribution market and the lack of a drug pedigree)

- The agencies responsible for enforcing the existing laws and regulations are already overwhelmed with the current volume of non-FDA approved prescription medicines coming into the United States.

- The potential exists for the use of the nation's medicine supply as a vehicle for terrorist activity.

- There are serious implications for Canadians with the current demand on their drug supply.

As noted previously, this review and these findings are preliminary. However, the issues discussed herein strongly suggest that no action be forced on the FDA or other government oversight agencies until the HHS Task Force has completed its analysis. In the meantime, the public should be made aware of the risks associated with importing medicines from outside the United States. As the importation debate continues, it is vital that all aspects of this important public health issue be carefully assessed. We should not minimize the potential risks surrounding importation.

Statement on Importation of Prescription Drugs

by
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Submitted to
Senate Subcommittee on Investigations
"Drug Importation"

Thursday, June 17, 2004

Mr. Chairman and members of the committee, I appreciate the invitation and opportunity to testify on issues relating to importation of prescription drugs. My name is Marv Shepherd, and I am the Director of the Center for Pharmacoeconomic Studies, College of Pharmacy, The University of Texas at Austin. I have studied the issues surrounding drug importation since 1994.

Several congressional bills have been introduced to make drug importation a safe practice and make drug importation a cost-effective alternative for Americans. In addition to these legislative efforts, the Medicare Prescription Drug Improvement and Modernization Act of 2003, Public Law 108-173 (MMA) has directed the Secretary of Health and Human Services (HHS) to make a thorough examination of drug importation.

One method of prescription drug importation is importation by individuals. I stand opposed to this type of methodology because it puts Americans at tremendous risk. It bypasses professional medical supervision and safe medication use procedures and protocols. There are no double checks on prescription drug accuracy, no checks on drug-drug, or drug-disease interactions, there is virtually no counseling, and patients do not have access to professionals to get critical drug questions answered.

The potential for problems is particular serious for those who obtain their prescription drugs via the internet because of the many fraudulent internet pharmacy sites located outside of the U.S. For example, prescriptions ordered via the internet from what are purportedly to be Canadian pharmacies may in fact not be located in Canada and many times drug products are supplied by a pharmacy providers outside of the Canada. Recent news stories have revealed that one Canadian company is now forwarding the prescriptions on to a British pharmacy.[1] I am also aware of situations in which Americans believe they are receiving American made prescription drugs from Canada when in reality these drugs are coming from a variety of other countries. For example, a recent article in *Scrip* reports that one Canadian Internet Pharmacy Provider

(Canadapharmacytrust.com) is shipping pharmaceuticals which were made in Mexico to U.S. residents. The article goes on to say that the drug products were not approved by Health Canada nor the FDA.[2]

Furthermore, my research shows that in 2003 Canada imported pharmaceuticals from over 80 countries. Canada does have federally negotiated mutual recognition agreements with 18 Western European countries on Pharmaceutical GMPs (Good Manufacturing Practices). But as noted, Canada is importing drugs from more than just these countries including Ecuador, Mexico, Brazil, and China. From 2002 to 2003, Canadian imports from India have increase 109%, Singapore 72%, Mexico 50%, Italy 282%. Even though U.S. pharmaceutical exports to Canada have increased nearly one billion dollars since 1999, as a proportion of all Canadian imports, U.S exports to Canada have been decreasing. In 2000, U.S. drugs comprised 55% of all Canadian drug imports, but in 2003 it has dropped to 43%. Drug importation to Canada is now greater than what Canada manufactures.

The personal importation of pharmaceuticals is growing enormously and, in my opinion, is out of control. There are no guarantees that legislators, regulators and pharmacists can provide the information necessary to consumers on whether the imported prescription drugs they are receiving are adulterated, counterfeit, or approved for use in the United States. There is also no way for local pharmacists to determine whether the medication is safe and effective.

I understand the plight of individuals unable to afford much needed prescription drugs and support the goal of lowering drug costs for the American consumer. However, the anticipated savings importation programs may generate is uncertain because of factors such as price differentials for specific drugs in and out of the United States, the availability of product for importation, the additional importation overhead costs required, plus the profit taking by the intermediaries in the importation process.

One of the potential negative consequences of a program that permits pharmacies and wholesalers to import prescription drugs is the development of a two-tiered drug system of drugs based on product cost and source. If states base their reimbursement to pharmacies on an importation-based acquisition cost, pharmacies would have to establish a dual inventory system, one system for U.S. made drugs and another system for imported drugs. More importantly, drug importation is a direct threat to our generic drug industry. Drug importation may destroy the incentive for generic drug development.

All of us are aware of the potential for drug counterfeiting. Drug counterfeiting is a world-wide problem. No country is immune from this threat. However, drug importation, especially personal importation, only opens this door wider. Counterfeiters go where the money is and the U.S. is an excellent target for pharmaceutical fraud, deception and counterfeiting. We have been fortunate that more people haven't been hurt or killed by these products. I have said and continue to say it is only a matter of time before some horrific tragedy involving imported pharmaceuticals occurs.

I believe that until more data are available as to the likely impact of importation on the cost of drugs, the impact on our drug distribution system and the risks posed to American citizens, I am opposed to proposals which allow for the importation of prescription drugs. The Health and Human Services is now intensively investigating this issue; I urge you and others to let these professionals do their work, receive and study their report and then make the right decisions. To develop a drug importation scheme in haste without the input from their report may be more costly than any of us in this room want to expend or face.

Thank you again for this opportunity and I look forward to answering any questions that you may have.

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[1] Associated Press, "U.K. Pharmacy Filling U.S. Prescriptions," *New York Times*, May 2, 2004.
[2] "Mexican Drugs Shipped to US via Canada, say Consumers," *Scrip: World Pharmaceutical News*, No 2942, April 9, 2004, p 17.

Drug Importation Analysis: Comparison of the Canadian Pharmaceutical Market Size with the U.S. and Implications for Drug Importations

By
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Submitted to:
Representative John D. Dingell
Ranking Member
House Committee on Energy and Commerce

And

Senator Norm Coleman
Chairman
Senate Permanent Select Committee on Investigations

Submitted to the
Senate Subcommittee on Investigations
June 17, 2004

Introduction

This report was written in response to a request from the Ranking Member of the House Committee on Energy and Commerce, John Dingell and Chairman of the Senate Permanent Select Committee on Investigations, Norma Coleman. The letter request was written March 5, 2004. The request asked for descriptive information about the size of the Canadian pharmaceutical market. Specifically, the requests were:

1. How large roughly is the Canadian pharmaceutical market and how does it compare to the U.S. market?
2. What percentage of the drugs used in Canada are made in the U.S. (or is a U.S. form located overseas)? Of this figure, what percent of these drugs are consumed by Canadians, and thus what percent are theoretically available for the purpose of re-importation?
3. To the extent determinable, what is the status of this residual supply? Is it approaching exhaustion? Or is it already exhausted? If demand in this area ultimately exceeds supply, what are the implications of this situation?

In examining the questions, one can see that all three are interrelated. In fact, to determine the size of the pharmaceutical market, the amount of pharmaceuticals imported needs to be determined which to some extent addresses the second question, which is: what is the percentage of drugs used by Canada made in the U.S. In essence the general formula to calculate the size of the Canadian pharmaceutical market is as follows:

Canadian Drug Supply = (Amount of Drugs Manufactured in Canada) - Amount of Drugs Exported which were made in Canada) + (Amount of Drugs Imported – Drug Imports that were Exported) + Amount of Drugs Exported but were Re-imported

For this report, this formula was simplified to the following:

Apparent Domestic Canadian Drug Market = Manufacturing Drug Shipments + Total Drug Imports – Total Drug Exports

Data Sources, Commodity/Industry Codes and Exchange Rates

A variety of data sources were used for this report. However, the primary sources for Canada were obtained from Statistics Canada's Survey of Manufacturing (ASM) for Canada's Pharmaceutical and Medicine Manufacturing (NAICS 3254).[1] In addition, Canadian pharmaceutical manufacturing statistics were obtained from Canada's Business and Consumer site strategies.gc.ca. This site is produced by Industry Canada which is a Department of the Canadian Federal Government.[2] The primary source for U.S. data was the Foreign Trade Division of the U.S. Census Bureau[3] and the United States

[1] http://www.ic.gc.ca/canadian_industry_statisitics/cis.nsf/idE/cis3254datE.html
[2] http://www.strategis.ic.gc.ca/
[3] http://www.ita.doc/gov/td/industry/otea/industry_sector/tables_naics/325412.htm

International Trade Commission.[4] As mentioned many data sources were also utilized and they will be referenced appropriately in the report.

Pharmaceutical manufacturing, import and export commodity codes were used to specify commodity and industry identification.[5] The designated commodity code used most often in this report was HS 3004 and is titled: "medicaments-put up in measured doses or packed for retail use." This designation was used because it was believed that this would accurately reflect drug products for consumer use rather than using an overall pharmaceuticals and medicines product code which may cover bulk pharmaceuticals. However, at times an industry code was used and when this was done the NAICS (North American Industry Classification System) code was employed. The NAICS code used for pharmaceutical and medicine manufacturing was NAICS 325410.

The financial amounts expressed in the report will be in U.S. dollars, unless otherwise specified. When converting Canadian dollars to U.S. dollars, Table 1 denotes the exchange rates employed for each year. At times, it is difficult to determine if over-the-counter drug (OTC) products are included in the amounts provided by Canada or the U.S. Plus, in Canada some products sold as OTCs are prescription drugs in the U.S. Also, for the analyses on pharmaceutical manufacturing output, importation and exportation, the analyses were conducted for products designated in measured dosing units or packaged for retail use (Code HS3004).

Table 1
Canadian to U.S. Dollar Exchange Rates

Year	Exchange Rate
1997	1.38
1998	1.48
1999	1.49
2000	1.49
2001	1.55
2002	1.57
2003	1.40

Source:http://www.bankofcanada.ca/en/exchange.htm

Methods Employed to Determine the Size of the Canadian Pharmaceutical Market

Three approaches were used to determine the size of the Canadian pharmaceutical market. The first approach was to determine the dollar value of drug products manufactured by pharmaceutical manufacturers (brand and generic drugs manufactured) add the amount of drug products imported, and subtract the amount of Canadian drugs exported. The second approach was to determine the number of prescriptions filled in Canada and the third approach was to determine the total amount of drug expenditures in

[4] http://dataweb.usitc.gov/scripts/user_set.asp
[5] http://strategis.ic.gc.ca/sc_mrkti/tdst/tdo/tdoDefinitions_30.php accessed March 5, 2004.

Canada. The latter approach is commonly referred to as the market size because it reflects retail, clinic and hospital expenditures or the total amount expended on pharmaceuticals in Canada by public and private payers. However, the number of prescriptions dispensed approach does offer an insightful method because it eliminates drug price differences between countries.

The differences between these approaches are distinctive. As mentioned, the drug expenditure approach does include markups on the drug product from the retail pharmacies, wholesalers and other outlets. Thus, this method provides the total dollar volume expended on drug therapies in Canada. The first method provides drug costs from the manufacturer or drug cost as reported upon importation or exportation (FOB value). Both methods are relevant for a comparative analysis with the U.S.

Canadian Pharmaceutical Manufacturing

Table 2 denotes the annual pharmaceutical and medicine manufacturing reported by the Strategis web site. Manufacturing data were only available through 2001.

Table 2
Canadian Pharmaceutical and Medicine Manufacturing (NAICS 3254)
(Value in Billions of U.S. Dollars)

Year	Value ($billions)
1997	3.529
1998	3.219
1999	3.319
2000	3.670
2001	4.387

http://strategis.ic.gc.ca/sc_mrkt/tdst/tdo/tdo.php#tag accessed March 11, 2004.

Using the data provided by Statistics Canada from their Annual Survey of Manufacturers (ASM), Table 3 presents pharmaceutical and medicines manufacturing (NAICS 325410). These statistics are the total value of drug manufacturing shipments of the industry. This is the value of the goods produced by pharmaceutical manufacturers in Canada. **In using Table 3 the values within the column labeled manufacturing shipments is the one used to represent the drug shipments from the facility.** Also, the data sites do not provide a breakdown by drug name; this information is considered proprietary and not for distribution. Nor does the ASM information breakdown the product as to whether or not the product was manufactured in measured dosage units or packaged for retail use. This information can be very useful because one can determine to what extent products are bulk pharmaceuticals or products in measured dosage forms or packaged for retail use. The site provides a total dollar amount of the drug shipments from Canadian drug manufacturing facilities.

Table 3
Annual Pharmaceutical and Medicine Manufacturing Output and Revenues (Value in Billions U.S. Dollars)

Year	Manufacturing Shipments	Value Added*	Total Revenues
1997	$3.529	$2.557	$4.347
1998	$3.219	$1.824	$4.122
1999	$3.319	$1.812	$4.563
2000	$3.670	$1.946	$4.966
2001	$4.387	$2.258	$6.258

Source: http://www.ic.gc.ca/canadian_industry_statistics/cis.nsf/idE/cis3254datE.html accessed March 11, 2004.

*Value-added is the measure of net output. Value-added is the gross outputs less the inputs such as cost of materials and supplies, fuel, electricity) which have been used to develop the product.

Exportation of Pharmaceuticals Manufactured in Canada

As expected not all drugs manufactured in Canada, stay in Canada for Canadian use. Some drug products are exported. Table 4 depicts the amount of pharmaceuticals in measured dosage forms or packaged for retail use which were exported to the U.S. or other countries. (Note Canadian drug import and export data can be categorized into products in measured dosage forms or products packaged for retail use).

The results in Table 4 show that vast majority of drug products exported from Canada were shipped to the U.S. Also, the proportion of drug exports to the U.S. has more than tripled since 1999. Pharmaceuticals made in Canada and exported to "other countries" has been under $300 million since 1999 and when compared to those products exported to the U.S. are relatively small.

Lastly, based on the dollar amounts of drugs manufactured in Canada (Table 3), 19.5%, 20.0% and 23.0% of the pharmaceuticals manufactured in Canada were exported in 1999, 2000, and 2001 respectively. To summarize, approximately one-fifth of the drugs manufactured in Canada were exported and U.S. received approximately 80% of these exports. ***Please note that these export figures do NOT include pharmaceuticals obtain via pharmacy internet providers and shipped to U.S. residents.***

Table 4
Trend in Canadian Drug Exports to the U.S. and Other Countries for Pharmaceuticals in Measured Dosage Forms or Packaged for Retail Use Which Were Manufactured in Canada
1999-2003
(Value in Thousands of U.S. Dollars)

Year Exported to	1999 (%)	2000 (%)	2001 (%)	2002 (%)	2003 (%)
U.S.	$411,595 (63.4%)	$544,347 (72.4%)	$853,909 (84.6%)	$904,392 (81.8%)	$1,456,495 (84.4%)
Other Countries	$237,241 (36.6%)	$207,019 (27.6%)	$155,914 (15.4%)	$200,848 (18.2%)	$269,427 (15.6%)
Total	$648,836 (100.0%)	$751,366 (100.0%)	$1,009,823 (100.0%)	$1,105,240 (100.0%)	$1,725,921 (100.0%)

Source: http://strategis.gc.ca/sc_mrkti/tdst/tdo/tdo/.php

Canadian Drug Importation

The next step in this process is to determine the amount of pharmaceuticals Canada imports. Table 5 shows the dollar amount and proportion of Canadian drug imports which were packaged for retail use or in measured dosage forms from the U.S. and "other countries" from 1999 through 2003.

Since 1999, total pharmaceutical imports by Canada have increased 101.6% from $2.347 billion to $4.732 billion. U.S. drug imports to Canada have increased 67.2% from $1.254 billion to $2.097 billion and Canadian imports from all other countries have increased 141.1% from $1.093 billion to $2.635 billion from 1999 to 2003.

Even though the U.S. drug exports to Canada have increased nearly a billion dollars since 1999 (Table 5), the percentage of U.S. made drugs being imported by Canada has been decreasing. In 2001, the U.S. proportion of Canadian imports was nearly 56%, but in 2003 it declined to 44.3%. It needs to be noted that not all U.S. made pharmaceuticals exported to Canada are FDA approved. Also information provided by the U.S. government on U.S. exports does NOT include product name nor does it include whether or not the product is FDA approved. Both the Canadian and U.S. government authorities will not release specific product names; they are classified as proprietary information.

The trend depicted in Table 5 indicates that Canada is importing more drugs and since 2000 more and more drugs are non-U.S. made pharmaceuticals. Figure 1.0 graphically depicts the shift in the proportion of Canadian drug imports from the U.S. and other countries. Later in this report, a more detailed analysis will be presented on what countries are exporting drug products to Canada.

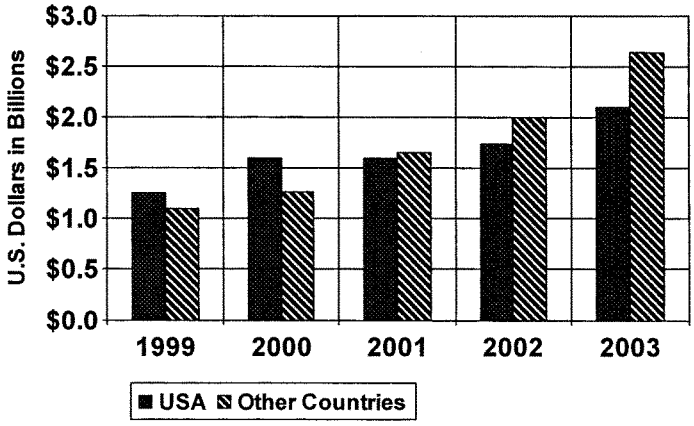
As stated, it needs to be reiterated that both U.S. and Canadian importation and exportation information sources will not reveal pharmaceutical product names and the quantity by product names. This information is considered proprietary by the company and is to be protected by the governmental agencies. This limitation certainly weakens this section of the analysis in that it makes the analysis less definitive. One will not be able to determine Canadian product surpluses or shortages by product name.

Table 5
Trend in Canadian Drug Imports from the U.S. and Other Countries for Pharmaceuticals in Measured Doses or Packaged for Retail Use 1999-2003
(Value in Billions of U.S. Dollars)

Year Exporting Source	1999 (%)	2000 (%)	2001 (%)	2002 (%)	2003 (%)
U.S.	$1.254 (53.4%)	$1.602 (55.9%)	$1.598 (55.7%)	$1.733 (49.2%)	$2.097 (44.3%)
Other Countries	$1.093 (46.6%)	1.265 (44.1%)	$1.646 (44.3%)	$2.000 (50.8%)	$2.635 (55.7%)
Total	$2.347 (100.0%)	$2.867 (100.0%)	$3.245 (100.0%)	$3.733 (100.0%)	$4.732 (100.0%)

Source: http://strategis.gc.ca/sc_mrkti/ accessed March 12, 2004.

Figure 1.0 Trend in Canadian Drug Imports for Drugs Packaged for Retail Use 1999-2003
U.S. Dollars



Source: http://strategis.gc.ca/sc_mrkti/ accessed March 12, 2004.

Total Drugs Exported from Canada

Like Canadian manufactured pharmaceuticals, not all drug products imported by Canada remain in Canada. Some Canadian imported pharmaceuticals are exported. The term "re-exports" (The U.S. term is "foreign exports") is used to designate drug products which were imported by Canada, but latter were exported. ***Please note that re-exports do not include drugs purchased by U.S. residents from Canadian internet pharmacy providers. Also none of the export data from Canada include drugs shipped by Canadian internet pharmacy providers to U.S. residents nor does the export data include drugs purchased by U.S. residents who drive to Canada and return to the U.S. with pharmaceuticals.***

Table 6 depicts the total amount of pharmaceuticals exported from Canada from 1999 through 2003. This total includes the total dollar amount of drugs exported which are manufactured in Canada, plus the Canadian exports from drugs which have been imported into Canada. Table 6 depicts products which are in measured dosage forms and drug products packaged for retail use. It does not include bulk pharmaceuticals.

Table 6
Trend in Total Canadian Drug Exports* for Pharmaceuticals in Measured Dosage Forms or Packed for Retail Use
1999-2003**
(Values in Thousands of U.S. Dollars)

Year Country	1999 (%)	2000 (%)	2001 (%)	2002 (%)	2003 (%)
To U.S.	$428,064 (64.0%)	$592,708 (73.8%)	$902,531 (85.0%)	$967,492 (81.9%)	$1,541,163 (84.5%)
To Other Countries	$240,738 (36.0%)	$210,796 (26.2%)	$159,625 (15.0%)	$214,221 (18.15)	$282,970 (15.5%)
Total Canadian Exported Drugs	$668,802 (100.0%)	$803,505 (100.0%)	$1,062,156 (100.0%)	$1,181,713 (100.0%)	$1,824,133 (100.0%)

Source: http://strategis.gc.ca/sc_mrkti/ accessed March 12, 2004
* Total drug exports from Canada include the pharmaceutical exports from drugs manufactured in Canada plus Canadian drug imports which have been exported.
** Table does NOT include drugs shipped from Canada to the U.S. via Canadian internet pharmacy operations nor does it include drugs purchased by U.S. residents in Canada and brought back to the U.S.

In 2003, Canada exported $1.824 billion of pharmaceutical products. This is an increase of 172.7% since 1999. The majority of drugs exported from Canada were shipped to the U.S. In 2003, $1.541 billion of the Canadian exports came to the U.S, whereas only $285 million went to other countries. Close to 85% of the Canadian drug exports come to the U.S. ***Again it must be emphasized that that none of these export figures include pharmaceuticals shipped to U.S. residents from Canadian internet pharmacy***

operations nor drugs purchased in Canada by U.S. residents and brought back to the U.S.

Estimates of U.S. Resident Purchases of Canadian Drugs

Dollar estimates as to the extent Canada provides drugs to U.S. residents vary. For 2003, IMS has estimated that U.S. residents purchased $1.1 billion of drugs last year from Canada.[6] But, in another analysis, IMS estimates drug sales from Canadian internet sites and foot-traffic at $700 million.[7] Canadian internet pharmacy providers are the primary sources, but do not under estimate of number of U.S. residents traveling to Canada to purchase drugs. One indicator of the growth of Canada supplying drugs to U.S. residents is the growth in the number of Canadian internet pharmacy providers. In 1999, there were10 Canadian internet providers, now the estimate ranges from 120 to130 Canadian internet operations supplying drugs to U.S. residents.[8]

Apparent Domestic Canadian Market

As noted earlier, the apparent Canadian domestic market for drug products is calculated by summing the manufacturing shipments and total drug imports and subtracting total Canadian drug exports. The formula is as follows:

Apparent Domestic Market = Manufacturing Shipments + Total Imports – Total Exports

Please interpret this value with caution, because the "apparent market" and real domestic market are different. The value placed on products at the border and at the manufacturer's level may be different than the domestic market value. Plus, various other factors play a role in this difference including freight handling charges, and mark-ups from various handlers of the product.

Also, this calculation does not take into account the amount of drugs being supplied by Canada to U.S. residents via the Canadian internet pharmacy providers or by U.S. residents traveling to Canada to purchase drug products. Without this deduction, the figure from the above formula will give a market size, but it may not reflect the amount of drugs used primarily by Canadians.

Another problem in determining apparent market size is that the Canadian pharmaceutical manufacturing data has all shipments from the manufacturing facilities. This includes bulk pharmaceuticals, chemicals, along with products in measured doses. This means that other product forms such as bulk pharmaceuticals manufactured are included in the data with the finished drug products (products in measured dosage forms and packaged for retail use). Thus, to make the variables uniform, information on drug

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[6] "Rx Sales Jump 11%, Top $200Billion", *America's Pharmacist*, April 2004, 10.
[7] Saatsoglou Paul "Pharmaceutical Reimportation: magnitude, Trends and Consumers," Supplement to *Managed Care*, Vol.13. No. 3, March 2004.
[8] Carlisle, Tamsin, "What's Left for Canadians If Americans Buy Their Drugs" *Wall Street Journal*, November 4, 2003.

imports and drug exports must also include these "other products" or bulk pharmaceuticals along with the prepared dosage form drugs and pharmaceuticals packaged for retail use. The previous import and export tables only had data on pharmaceuticals which were in measured dosage units or packaged for retail use. Table 7 presents the information on Canadian manufactured shipments, pharmaceuticals imported and drugs exported with "bulk" pharmaceuticals added to the drugs in measured dosage forms or packaged for retail use.

Table 7
Canadian Pharmaceutical Manufacturers' Production, Amount of Pharmaceutical Imports and Exports and the Apparent Market Size
1999 through 2003
(Value in Billions of U.S Dollars)

Canadian Product Source and Exports	1999	2000	2001	2002	2003
Manufacturer Shipments	$3.319	$3.670	$4.387	Not Available	Not Available
Total Imports	$3.423	$4.014	$4.546	$5.116	6.399
Total Exports	$1.131	$1.248	$1.490	$1.625	$2.400
Apparent Market Size	$5.611	$6.436	$7.443	----------	----------

Source: http://strategis.ic.gc.ca/sc_mrkti/

Using the above formula and the most recent pharmaceutical manufacturing data available from Canada Statistics depicted in Table 6, the Canadian apparent domestic market for 2001 was $7.443 billion ($4.387 + $4.546 – 1.248 = $7.443). However, remember this figure includes some bulk pharmaceuticals. Also remember, this figure does not include distribution charges, wholesaler charges and mark-ups at the retail or hospital level. Theoretically, this figure represents the ingredient costs of drugs to be distributed to various health care provider outlets in Canada including internet pharmacies and other pharmacies providing drugs to the U.S. residents. Thus, this figure cannot be considered as only meeting the needs of Canada. Canadian drug products which are being shipped to U.S. residents need to be subtracted.

Deduction of Canadian Drugs Being Purchased by U.S. Residents

As mentioned, the estimations for U.S residents obtaining drug products from Canada through Canadian internet pharmacy providers and other Canadian retail outlets range from $700 million to $1.1 billion. If it is assumed that markups through the distribution chain range from 18% to 25%,[9] then the amount of drug costs shipped to U.S. residents

[9] "Trend 2002: The Pharmacy Report" Analysis of Canadian community pharmacies produced by Taro Pharmaceuticals and McKesson Canada, 2002, p 38.

runs from $525 million (.75 x $700 million) to $902 million (0.82 x 1.1 billion). When you subtract this figure from the apparent domestic market of $7.443 billion it leaves an estimated Canadian market size range of $6.541 billion to $6.918 billion. **Thus, when you take into account the Canadian drugs being purchased by U.S. residents, the Canadian drug market approaches $7 billion.** Remember, this does not include markups or dispensing fees throughout the Canadian drug distribution chain.

The $7.443 billion dollar figure represents pharmaceuticals available for sale in Canada, including products distributed to hospitals. Even though hospitals may not be a source of pharmaceuticals for U.S. residents, hospital purchases were not deducted from the $7.443 billion calculated market size because hospitals represent a portion of the Canadian pharmaceutical market. For informational purposes only, Canadian hospitals purchased $1.16 billion of drugs in 2000, $1.34 billion in 2001 and $1.49 billion in 2002. These figures are in Canadian dollars;[10] the U.S. dollar equivalent amounts are: $779 million in 2000, $865 million in 2001 and $949 million in 2002.

Separation of Bulk from Retail Packaged or Drugs in Measured Doses

When you subtract the import figures from Table 6 from the total import figures in Table 7 you will obtain the amount of bulk pharmaceuticals imported or pharmaceuticals not in measured dosage units or packaged for retail use. This same methodology can be used for calculating Canadian bulk exports of pharmaceuticals (subtract figures of total exports, found in Table 6, from total exports reported in Table 7). The results show that in 2003 there was a total of $1.667 billion of imported bulk pharmaceuticals ($6.399 - $4.732 = $1.667). A total of 69.26% (4.732/6.399) of the Canadian drugs imported were in measured dosage forms or packaged for retail use in 2003. For pharmaceuticals exported by Canada in 2003, the amount for bulk pharmaceuticals is estimated to be $576 million ($2.4 billion – $1.824 billion = $576 million). Pharmaceuticals in measured doses or packaged for retail use represent 76.0% of the Canadian pharmaceutical exports. This the analysis shows that drug products imported by Canada and exported by Canada are primarily products in measured dosage units or products packaged for retail use.

Comparison to the U.S. Pharmaceutical Market

In comparison to the U.S. pharmaceutical market, the Canadian market is relatively small. Using U.S. Department of Commerce, Bureau of Census data, Table 8 presents U.S. pharmaceutical manufacturers' production, U.S. imports and U.S. exports of pharmaceuticals. Table 8 also includes the U.S. apparent pharmaceutical market size employing the same formula as previously used.

[10] "The Canadian Pharmaceutical Market," IMS Report, IMS Health Incorporated, 2003, p 13.

Table 8
U.S. Pharmaceutical Manufacturers' Production, Amount of Pharmaceutical Imports and Exports and the Apparent Market Size
1999 through 2003
(Value in Billions of U.S Dollars)

U.S. Product Source and Exports	1999	2000	2001	2002	2003
Manufacturer Shipments	$72.751	$80.038	$93.779	Not Available	Not Available
Total Imports	$9.801	$10.131	$13.506	$19.368	Not Available
Total Exports	$7.662	$9.175	$11.375	$11.220	Not Available
Apparent Market Size	$74.89	$80.994	$95.910	----------	----------

Source: U.S. Department of Commerce: Bureau of the Census; International Trade Administration http://www.ita.doc.gov/td/industry/otea/industry_sector/tables_naics/325412.htm accessed March 29, 2004

The latest data available from the U.S. Department of Commerce for pharmaceutical manufacturing was 2001 and it shows that U.S. pharmaceutical manufacturers produced $93.779 billion dollars of pharmaceutical products. However, in reality, the pharmaceutical manufacturing industry produced a total of $100.068 billion worth of shipments, but the Department of Commerce did not classify all shipments as pharmaceutical shipments. Some of these other shipments may have been diagnostic testing supplies, other chemicals or products not classified as pharmaceuticals.

U.S. drug imports were $13.506 billion and of this total, $12.447 billion was for pharmaceuticals packaged for retail use or in measured dosage forms. The U.S. pharmaceutical industry exported $11.377 billion worth of pharmaceutical products. Using these figures and the apparent market formula, the apparent U.S. market size was found to be $95.910 billion in 2001.

The Canadian apparent pharmaceutical market size (Table 7) in comparison with the U.S. apparent market size (Table 8) is much smaller than the U.S. In 2001, the U.S. market size was $95.910 billion whereas the Canadian market size was $7.443 billion. Based on this approach, the U.S. pharmaceutical market size is approximately 13 times larger ($95.910 billion/ $7.443billion = 12.89) than the Canadian. As a matter of interest, the U.S. pharmaceutical exports are greater than the total Canadian market size in 2001.

Other Comparative Methods

Another approach to compare Canadian pharmaceutical market size to the U.S. is to examine the amount each country spends on pharmaceuticals annually. But, before this

analysis it was decided to compare the number of prescription filled annually for each country. Of course there is huge difference in the population of Canada when compared to the U.S. and thus the number of prescriptions will be reflective of the population differences. In Canada, the 2003 population was 31,629,700.[11] For the U.S., the population in 2003 was 290,810,000.[12] Thus, one can expect a large difference in number of prescriptions dispensed between the countries.

Number of Prescriptions Comparison

This approach on comparing the number of prescriptions does assume that the quantity of the drug per prescription (Number of dosage units per prescription) is the same for each country. Table 9 presents the total number of prescription dispensed per year from 1999 through 2002 for Canada and U.S. In examining the results it can be seen that the U.S. prescription drug market is approximately 10 times larger than the Canadian market based on the number of prescriptions dispensed. It is unknown if the number of prescriptions dispensed by Canadian internet pharmacies to U.S. residents is included in these figures.

Table 9
Number of Prescriptions for U.S. and Canada from 1999 trough 2002
(Numbers is Thousands)

Country	1999	2000	2001	2002
Canada*	264,376,000	285,530,000	306, 184,000	326,219,000
U.S.	2,707,000,000	2,865,000,000	3,009,000,000	3,138,000,000

* Source: IMS Health
**IMS Health and National Association of Chain Drug Stores Economics Department
http://www.nacds.org/user-assets/PDF_files/dollar-Sales.pdf

On average, in 2002 there were approximately 8,590,260 prescription drugs in the U.S. dispensed per day (3.138 billion/365). When you divide the total number of prescription drugs dispensed in Canada, 326,219,000, by 8,590,000 prescriptions per day, **the results show that if U.S. residents were to purchase all their prescription drugs in Canada, the annual supply of Canadian drugs would be exhausted in 38 days (37.94 days)** and this assumes no drug supply for the Canadians. Of course, this assumes that the quantities of the drug per prescription are equal between countries and prescribing patterns are similar.

When you calculate the number of prescriptions dispensed per person for 2002, the results show 10.4 prescriptions per person were dispensed for Canada (326.219 million Rxs/31.361 million people) and 10.9 prescriptions per person were dispensed for the U.S.

[11] http://www.statcan.ca/english/Pgdb/demo02.htm accessed March 23, 2004.
[12] http://eire.census.gov/popest/data/states/tables/NST-EST2003-01.php accessed May 5, 2004.

(3.138 million Rxs/287.973 million people). Thus, both countries utilize approximately the same number of prescriptions per capita.

Canadian Drug Expenditures

In regard to prescription drug expenditures, Table 10 depicts the annual dollar expenditures for prescription drugs for Canada and the U.S. These data reflect public funded programs and private expenditures for drug products from both countries. The data in Table 10 are expressed in U.S. dollars. In Canadian dollars, the annual expenditures for Canada were as follows: $10.239 billion for 1999, $11.728 billion in 2000, $13.297 billion for 2001 and $14.572 billion for 2002.[13] The Canadian expenditures for 2001 and 2002 were forecasted. It must be mentioned that various estimates exist for the size the of the Canadian retail pharmacy market. It was decided to use information from the Canadian Institute of Health Information because of its completeness.

Table 10
Trends in Canadian and U.S. Drug Expenditures
1999-2002
(Volume in Billions of U.S. Dollars)

Country	1999	2000	2001	2002
Canada*	$6.871	$7.871	$8.643 (forecast)	$9.282 (forecast)
U.S.**	$125.758	$145.611	$164.143	$182.712

*Source: "Drug Expenditures in Canada 1985 – 2002," Canadian Institute for Health Information, 2003, 66.
**Source: IMS Health and National Association of Chain Drug Stores Economics Department http://www.nacds.org/user-assets/PDF_files/dollar-Sales.pdf

The comparisons in Table 10 reflect not only the difference in size of the populations and drug markets, but they also reflect the difference in drug prices at the retail level between the countries. Thus, the comparisons show a larger difference in market size than the previous analyses.

Summary of Comparative Analysis

The results show that the U.S. pharmaceutical market is much larger than the Canadian market. The Canadian drug market which is used by the Canadians is approximately $7.0 billion whereas the U.S. market is approximately $95 billion when using governmental data on product costs from manufacturer and importation evaluations. This is a 13 fold difference. Based on the number of prescription filled, the Canadian annual prescription

[13] "Drug Expenditures in Canada 1985 – 2002," Canadian Institute for Health Information, 2003, 66.

drug supply would only last 38 days in the U.S. This is a nine fold difference and based on the pharmaceutical expenditures there is a 19 fold difference.

Extrapolation of Older U.S. Residents Drug Use and the Canadian Drug Supply

In the United States, people 65 years of age or older have approximately 28 prescriptions dispensed per year in the U.S.[14] This 28 days may seem like a lot, but this number is heavily dependent on quantity of the medication dispensed for each prescription. If a prescription is written for a 90-day supply then only four prescriptions are needed per year. Thus, and person on five chronic medications and each prescription was written for a 90-supply, the total number of prescription dispensed per year would be 20. Most medications for the treatment of chronic conditions are written for 90-day quantities. Thus the average of 28 prescriptions pre year sounds reasonable for people 65 years of age or greater.

In 2001, people 65 years of age or greater accounted for 30.352 million people in the U.S.[15] Using the 28 prescriptions per year average, the estimated number of prescriptions annually to serve this population is approximately 979.776 million (28Rxs/year x 30.352 million). As documented earlier, Canadian pharmacies dispensed 306 million prescriptions in 2001. Based on these facts, to supply just half of the U.S. elderly population and provide enough pharmaceuticals to take care of the Canadian needs, Canada will need to increase their total drug supply by 2.5 times. Notice that this estimate does not account for other population groups which may want to obtain their pharmaceuticals from Canada and only includes half of the U.S. elderly.

Other Issues Canadian Drug Importation

As noted earlier in Table 5, the U.S. provides 44.3% of Canadian imported pharmaceutical products. The remaining come from a variety of countries. Canada does have mutual pharmaceutical manufacturing agreements with 18 countries which are primarily located in Western Europe. And in fact, Canada does import a large amount of pharmaceuticals from these countries. However, in examining the importation data, Canada is also importing pharmaceuticals from over 100 countries some of which include China, Mexico, Ecuador, Brazil, India, and Hong Kong and Singapore.[16] Table 10 depicts the dollar amounts of Canadian imported pharmaceuticals, the exporting country and the year.

From 2002 to 2003, there was a 26.1% increase in drug imports for Canada. For the previous two years, annual increases have been around 13%. One item of interest in looking at Table 10 is the fluctuations in the amount of drug imports by year for some countries. There have been major changes in sources of pharmaceutical products by year.

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[14] "Cost Overdose: Growth in Drug Spending for the Elderly 1992-2010," Families USA, July 2000, 6.
[15] http://www.census.gov/statab/www/poppart.html accessed May 4, 2004.
[16] http://strtegis.ic.gc.ca/sc_mrkti/tdst//tdo/tdo.php accessed March 28, 2004.

For example, Ireland exported close to $200 million in 1999, but decreased exports to $41 million the following year and in 2003 it was approaching $700 million.
It is also worth noting that some of these countries have had a tremendous increase in the amount of pharmaceuticals being exported to Canada in recent years. It can be hypothesized that this is most likely a response to the increase demand from U.S. residents and perhaps supply shortages in Canada. For example, since 2001 Canadian imports from the U.S. have increased 31.2%, from Ireland 231%, Italy 282%, Mexico 50%, Singapore 72%, and India 109%. Recently, *Script* reported that a Vancouver internet pharmacy provider is "openly selling U.S. citizens prescription medicines that allegedly come from Mexico and are not approved by either Health Canada or the U.S. FDA." [17] Some Canadian internet providers are on record of stating that they will find creative ways of obtaining drug products to meet U.S. demands, if U.S companies will not meet their needs. It is this type of information that has many U.S. authorities worried about the quality of imported drug products.

Table 10 Trend in Imported Canadian Pharmaceuticals in Measured Doses or Packed for Retail Use by Country by Country 1999-2003

	1999	2000	2001	2002	2003
United States (U.S.)	1,254,311,235	1,602,008,338	1,598,438,598	1,733,050,587	2,097,199,943
Ireland	199,447,738	41,383,925	206,071,951	438,399,420	682,506,549
United Kingdom (U.K.)	147,666,168	182,909,940	257,198,969	311,863,991	406,414,553
Germany	92,112,130	324,150,542	356,652,961	280,232,330	340,642,981
Sweden	159,062,746	224,446,299	262,215,121	336,302,278	305,074,422
France (incl. Monaco, French Antilles)	101,646,463	105,826,201	114,740,886	154,768,473	260,583,813
Switzerland	171,650,097	155,339,689	165,800,110	171,872,184	163,654,400
Italy (includes Vatican City State)	16,858,740	23,555,031	26,806,935	42,065,631	102,533,237
Denmark	56,155,279	49,668,111	52,488,721	65,472,723	82,957,897
Belgium	26,455,563	33,723,485	40,465,406	36,711,166	60,140,262
Netherlands	39,107,967	44,530,184	50,122,282	58,355,308	57,979,106
Australia	14,953,982	14,939,756	36,394,430	36,151,382	35,165,129
Spain	13,091,102	10,416,578	14,910,734	17,418,756	30,416,629
Mexico	9,439,259	9,969,995	16,814,478	15,857,350	25,276,253
Japan	17,903,970	4,943,085	1,875,572	10,922,853	20,125,762
Israel	6,756,619	9,339,424	14,500,995	18,724,538	18,014,407
Austria	1,749,807	1,422,486	4,270,600	7,632,486	13,673,762
Singapore	1,821,849	907,911	2,767,210	1,492,924	4,904,130
Finland	1,830,886	2,137,776	2,302,451	2,932,492	3,571,742
India	3,857,686	5,929,390	1,583,930	5,324,872	3,316,641
China	2,701,437	1,813,780	7,203,586	2,314,027	2,972,456
Ecuador	238,567		–	1,515,374	2,687,887
Norway	12,286	27,310	269,611	411,524	1,884,032
Hungary	2,907,423	4,992,093	4,084,945	3,089,237	1,869,047
Slovenia	1,127,537	663,901	918,000	1,341,894	1,770,403

[17] Mexican Drugs Shipped to US via Canada, say Consumers," *Scrip World Pharmaceutical News*, No 2942, April9, 2004, 17

Hong Kong	957,953	1,568,652	1,496,071	908,142	1,341,165
Brazil	5,820	452	1,157,341	4,516,057	1,123,451
Thailand	145,345	213,158	615,460	498,154	929,496
New Zealand	1,209,685	598,183	929,712	832,210	918,626
Portugal	45,594	25,158	77,360	614,000	615,668
Re-Imports (Canada)	722,391	4,459,855	303,333	1,253,379	610,008
South Africa	181,974	354,573	228,272	328,601	314,778
Malta	--	--	185,703	260,136	279,898
Taiwan (Taipei)	37,770	371,060	52,462	195,534	255,240
Korea, South	109,533	122,401	505,488	151,197	149,042
Cuba	--	136,548	176,682	120,583	139,486
Argentina	50,424	54,011	36	3,598	75,480
Colombia	137	24	5	13,847	73,936
Luxembourg	8,175	35,509	146,136	--	59,934
Poland	273	8,084	--	12,472	41,396
Guyana	1,921	5,341	29,607	29,526	41,115
Czech Republic	954	3,368	625	205	40,005
Greece	321,373	23,839	29,923	31,248	19,220
Bolivia	--	--	--	--	12,324
Costa Rica	1,309	834	--	82,058	6,965
Philippines	2,080	58,749	777	1,003	4,151
Iceland	--	381,483	2,758	--	3,572
Panama	2,920	29,019	--	30	2,582
Iran	23,682	49,288	--	--	2,355
Niger	--	10,945	--	--	2,101
United Arab Emirates	2,206	1,313	1,852	4,788	2,032
Sri Lanka	79	407	120	675	1,886
Guatemala	--	--	10	--	1,871
Pakistan	2,759	4,788	482	1,605	1,682
Malaysia	1,875	2,128	8,352	32,560	1,655
Macau (Macao)	--	--	--	--	1,100
Vietnam	--	--	147	190	564
Indonesia (includes East Timor)	10,823	--	76	420	507
Jamaica	--	21	2,069	1,084	480
Uruguay	--	35,446	--	1,975	417
Tunisia	--	--	--	31	332
Slovakia	92,671	284,569	10	2	331
Lebanon	--	--	--	--	326
Kenya	--	--	307	25	288
Paraguay	--	--	--	--	257
Saudi Arabia	9	--	--	415	233
Russia	73	96	63	24	222
Trinidad and Tobago	457	895	9,222	3,586	213
Albania	--	--	--	--	171
American Samoa	--	--	--	--	170
Fiji	--	--	--	360	156
Venezuela	349	--	--	19	143
Nigeria	--	--	2	187	128
Bahamas	229	32	--	531,477	124
Chile	66,101	4,370	2,805	131,537	122
Turkey	5,095	14,848	--	125	113

Ukraine	--	50	246	2,874	110
Bermuda	--	74	141	1,207	108
Ghana	--	--	136	146	51
Barbados	14,216	13	4,184	6,348	49
Jordan	202	100	170	46	49
Morocco	--	--	--	44	16
Saint Lucia	--	--	--	--	14
Romania	--	--	--	81	13
Dominica	--	--	--	--	10
Côte-D'Ivoire (Ivory Coast)	17	--	1	--	7
Peru	1,141	2,583	962	82	3
Bulgaria	20	12,567	10	20	1
Egypt	--	1,522	--	--	1
Grenada	--	--	--	363,306	--
Croatia	214,731	73,630	77	20,504	--
Yugoslavia - Serbia and Montenegro	--	--	--	2,499	--
Seychelles	--	--	--	636	--
British Virgin Islands	--	--	--	106	--
Dominican Republic	61	--	--	61	--
Nepal	--	--	--	20	--
Kuwait	--	--	--	10	--
Syria	--	--	32	2	--
El Salvador	--	--	56	1	--
Georgia	--	544	56,631	--	--
Cameroon	21	--	5,634	--	--
Latvia	--	--	1,691	--	--
Guinea	--	--	1,093	--	--
Netherlands Antilles	--	--	552	--	--
Honduras	--	50	46	--	--
Brunei Darussalam	--	--	14	--	--
Belize	344	14,054	--	--	--
Central African Republic	--	1,658	--	--	--
Cyprus	--	24	--	--	--
St. Helena	20	20	--	--	--
Gabon	--	13	--	--	--
Sudan	1,112	--	--	--	--
Sierra Leone	874	--	--	--	--
Qatar	75	--	--	--	--
Mali	18	--	--	--	--
TOTAL (ALL COUNTRIES)	2,347,111,427	2,868,986,530	3,244,933,426	3,733,187,908	4,732,413,392

Source of data: Statistics Canada
Report Date: 04-May-2004
http://strategis.gc.ca/sc_mrkti/tdst/tdo/tdo.php?headFootDir=%2Fsc_mrkti%2Ftdst%2Fheadfoot&naArea=9999&lang=30&searchType=BL&toFromCountOUPED#tag

Conclusion

Using today's realities and from a practical perspective, it does not appear reasonable for Canada to meet the drug needs for many in the U.S. This is especially true if U.S. pharmaceutical manufacturers limit their shipments of pharmaceuticals to Canada and the demand for Canadian continues to escalate. It seems reasonable to project that a shortage of prescription drugs will occur in Canada with the rising demand from U.S. residents. Evidence of this has already appeared in many newspapers across the country. To meet the demand of U.S. residents, Canada will have to either expand their manufacturing capabilities or import more pharmaceuticals. And, it appears that the latter approach appears to be the strategy in place.

Even if pharmaceutical manufacturers were to continue their drug shipments to Canada, the drug distribution infrastructure of Canada needs to be developed to handle the expected increased volume. Innovative methods are available to mediate the logistical supply chain issues and the drug control concerns, but the cost of developing such systems may offset the savings generated. Just the logistical development for a drug recall protocol and the re-labeling of drug products which do not meet FDA labeling standards will add costs to the system. Canadian and U.S. firms along with governmental agencies will probably have to invest heavily in their infrastructure and personnel if they were to assume such a venture.

In writing this report other questions have arisen that need to be addressed in regard to importing pharmaceuticals from Canada. These include:

- What are the most popular drugs being imported from Canada?
- Who is purchasing drug products from Canada? In other words, what are the demographic characteristics of people now obtaining drug products from Canada?
- What are the top 20 drug products used by Americans 65 years of age or older? Are these available in Canada and are these products being imported?
- What drug products are being imported by Canada and what country and what firm is supplying the product? Are these products approved by the Health Canada or the U.S. FDA?
- To what extent do U.S. residents travel to Canada to purchase pharmaceuticals? What is the demographic profile of these customers? Are products purchased by traveling to Canada different than products purchased through Canadian internet providers?
- Are Canadian internet pharmacy providers by-passing the Canadian importation declaration process and obtaining drug products which are not approved by Health Canada nor reported?
- How many Canadian internet providers have facilities working "off-shore" and providing drugs to U.S. residents?
- What changes in the drug distribution infrastructure need to be made to accommodate Canadian drug importation?
- How could products be directly shipped from U.S. manufacturers to U.S. wholesalers or warehouses while the purchasing agreements pass through Canadian firms? This would eliminate distribution, storage and drug custody problems.
- Will cost savings be captured by middlemen in the distribution or will they passed on to consumers or buyers?

STATEMENT
OF

ELIZABETH CARR

Before The
U.S. Senate Permanent Subcommittee on Investigations
Hearing On
BUYER BEWARE: THE DANGER OF PURCHASING PHARMACEUTICALS OVER THE INTERNET
June 17, 2004

☆ ☆ ☆

Good morning Chairman Coleman and Senator Levin. Thank you for the opportunity to speak to you today. My name is Elizabeth Carr and on April 10, 2003, I lost my husband to an overdose of Darvon, a controlled substance. My husband, Jim, purchased this drug and others over the Internet from rogue pharmacies located in South Africa, Thailand, Spain and other foreign countires.

Jim and I were married in 1996. He moved from Los Angeles to accept a job in Sacramento, California. This was a significant climate change for him as he was used to very mild weather in Los Angeles. My husband was a former tri-athlete and marathon runner. He also loved to mountain bike. Through these activities, he dislocated his hip and had to have operations on both knees.

By 2002 it was painful for him to even take a brisk walk and he said it was always worse in the winter. In January of 2003, Jim told me he was going to purchase some codeine for his pain over the Internet. I didn't think much about it at the time because codeine was in cough syrup when I was growing up. He never told me how much he was taking and because he worked at home, I never saw the packages coming in the mail. However, by the end of March, I grew concerned because I could see a change in his demeanor. I confronted Jim about this and asked him to stop, which he agreed to do.

On the day before my husband died, he was behaving very disoriented when I got home from work. When I quizzed him about what was wrong, he explained that he decided to turn to Darvon to wean himself off the Codeine. This was the first time he had taken the drug Darvon. He went to sleep that night and never woke up.

The autopsy showed that Jim had eight times the recommended dosage of Darvon in his system. After Jim died, I received five packages in the mail that Jim had purchased weeks before he died. By comparing his credit card statements, the dates posted on the packages, and the dates the packages arrived, I ascertained that the time from order to receipt from these pharmacies took several weeks. In fact, all five packages were from overseas and none had a pharmacy label. Some had instructions but most of the instructions were not in English. One of the packages even had a green tag attached on the outside that said "Sweets."

As I continued to go through my husband's things, I found all kinds of empty pill containers. I also looked into his computer activities and discovered that he had done quite a bit of research on different kinds of drugs and how to get them. Some websites required him to fill out a short questionnaire before he could get the medication, while others did not require anything. All the overseas pharmacies required payment in credit card form and were shipped via U.S. mail.

After Jim's death, I worked with the California Medical Board to try to hold someone accountable for the delivery of these substances to my husband. However, there was nothing the California Medical Board could do because the only documents I could provide for them did not implicate doctors licensed in California. They told me something needed to be done at the federal level.

That is why I am here today Senator Coleman. I am here to tell you what is happening to real people not just numbers or statistics on a piece of paper. This problem affects everyone in our society in one way or another and something must be done to stop these companies from making money off of people's trust, need, or lack of awareness.

Thank you.

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STATEMENT
OF

FRANCINE HAHN HAIGHT

Before The
U.S. Senate Permanent Subcommittee on Investigations
Hearing On
BUYER BEWARE: THE DANGER OF PURCHASING PHARMACEUTICALS OVER THE INTERNET
June 17, 2004

☆ ☆ ☆

Good Morning.

My name is Francine Hahn Haight. My daughter, Natalie and my son Jeremy are present and sitting behind me. I am very grateful for this opportunity to speak before this Subcommittee and to share what has happened to our family. I am the Mother of 3 beautiful children. I am extremely sorry to say that one of them died.

I am here to tell you about my son, Ryan Thomas Haight. Ryan was born on December 28, 1982, and died on February 12, 2001. Ryan died of an overdose of narcotics he had easily purchased on the Internet. A medical doctor, Dr. Robert Ogle, that he never saw prescribed them to him over the Internet. An Internet pharmacy, Clayton Fuchs of Mainstreet Pharmacy, mailed them to our home. He was only 17 when he purchased the narcotics, and he was only 18 when he died.

Ryan was an incredible boy. From the time he was little, I always believed that he would make a difference in this world. He was very intelligent and excelled in school. He loved math and science. He was always at the top of his class, was a Gate student in the elementary years, and then went on to take honors classes. He was an A student maintaining a 4.0 or above during his years in high school. He was looking forward to going to college. He loved his family and we did many things together. He had traveled quite a bit, loved Hawaii and the Caribbean. Ryan loved to hike, see the National Parks, and always looked forward to holidays and gatherings of the family. He was athletic. In Elementary school he played Little League Baseball, starting with T-ball and ending to be a top player in the Majors and making the All Star Team. He also started playing Open Junior tennis tournaments, and went on to play Varsity tennis for 3 years in high school. Had he not died his senior year, he would have been a 4 year Varsity Letterman in tennis. He loved to snow ski, snow board, water ski, knee board, and attempted all sports with great enthusiasm. He loved to play billiards, go bowling, and play Ping-Pong. He was competitive, and competed on a swim team when he was young, and loved to play Nintendo and other video games. Ryan loved using the computer. He used the computer to play games against his friends, to compete in Fantasy Baseball where you pick your teams, and he loved to chat with his friends on line. He loved to trade baseball cards on Ebay. Ryan was taking a computer graphics class in high school. He was considering a possible career designing software or doing

something with computers. But all his hopes and dreams died when he discovered he could buy drugs on the Internet. He was curious about the party scene, went to Rave parties with friends, and started to experiment with drugs. He was encouraged to experiment with drugs from an Internet chat room. Someone in this chat room told him where you could buy drugs and how to buy them on the Internet. He found that you could buy powerful narcotics on the Internet, very easily, right out of his own house. It was like buying candy in a grocery store.

On February 11, 2001, Ryan had worked a full day at a retail store. He came home around 8pm and said he was hungry. I had made him his favorite chicken soup in the crock pot. He told me his back was bothering him from moving plants in the nursery at work. Since it was cold and raining outside, rather than use the outside spa, he asked if he could use mine. He used my bath around 10 PM for about 30 minutes, got out and after talking to him for a few minutes about work he said he would like to just relax in his sister's room and play video games. His sister, Natalie, was away at college, he missed her, and felt comfortable using her room for the television and video games. About an hour later, just after Midnight, I went to say goodnight to him in his room. He was just getting into bed and said he was going to listen to some music. Ryan loved all kinds of music, Rap, techno, and we shared a common interest and love for classic rock. I loved it that he enjoyed listening to the Eagles and the Beatles with me. I told him I loved him as I do every night, hugged him and he said...."love you too."

The next morning, was a holiday, President's Day, so it was not unusual for Ryan to sleep in. I had 12 women showing up that evening for dinner and to play Bunco, so I had many things to do to get ready. My housekeeper, who had lived in with us for many years, came to the house that morning to clean. I told her I was going to a few stores to get things for that night, and that Ryan was sleeping, but should get up soon and to call me if she or he needed anything. I got home after 3pm and noticed Ryan's car still in the driveway. It had not moved and I immediately felt something was wrong. I ran into his room, and found that Ryan was not breathing. I could not believe what I saw. I knew he was dead. I call 911, and tried to do CPR. I screamed and cried.....and screamed and cried...and prayed for him to come back to life. I remember a paramedic pulling me off him...and looking me into my eyes and saying.....OH MY GOD, I am So Sorry. There is nothing we can do.

I thought, HOW, HOW, HOW could this happen? What happened? The next thing I know, a sheriff is showing me a bottle. A bottle of Hydrocodone, Vicodin. On the bottle it says Mainstreet Pharmacy. He also shows me a bottle of Morphine. I thought, no way.....these are controlled prescription drugs. He said he found the drugs after searching his room. These are drugs under lock and key in hospitals. How did he get them? How?

We parents often worry about our children. When they are little we worry they will fall and get hurt. But as they become teenagers we worry even more. We worry that they will drink alcohol and drive and get in a car accident. We worry that they will smoke cigarettes and marijuana. We worry that they will try illegal street drugs, such as cocaine, LSD, heroin and

others. We worry about porn, and strangers they might meet on the Internet. But never, did I worry about buying prescription drugs on the Internet.

After Ryan died, a friend of Ryan's called and told his father he got the drugs off the Internet. Never did I think you could so easily get prescription drugs on the Internet. I was in shock. Being an RN, I always thought that controlled substances were under lock and key. Ryan was encouraged to obtain powerful narcotics that required nothing but filling out a simple questionnaire on the Internet. That week, Ryan's dad gave Ryan's computer to the DEA and the investigation started. I have assisted in helping with the prosecution of these Internet drug dealers. They are just as bad, if not worse, than the drug dealers on the street. Since then, from the evidence they got from the Internet, Clayton Fuchs and Dr. Robert Ogle were found guilty and pleaded guilty of selling drugs illegally on the Internet. An autopsy report shows that Ryan died from a drug overdose of Hydrocondone, Vicodin which was prescribed by Dr. Ogle and sent to him from Mainstreet Pharmacy. Why did they sell these drugs to my son? They both said they "did it for the money." Dr. Ogle had been to prison twice. Once he served three years in a federal penitentiary for illegally prescribing Quaaludes, a hypnotic sedative. Another time for theft. But he still easily got his medical license back. He should never get his medical license again. I think Ryan, as most kids would, thought that since a doctor was prescribing the drug, it is a legal drug obtained with a prescription, then it must be safe. The drug was delivered to our home, with no instructions, no safety precautions, no adverse reactions attached. Ryan received these drugs without ever seeing the doctor, and never had any follow up. The pharmacy delivered these "controlled substances with no instructions and no questions asked."

These money hungry, drug pushers of doctors and pharmacies have got to be stopped. They are making millions of dollars and are only concerned about the money.....they do not care about he person ordering them.

There are over 500 rogue pharmacies on the Internet as I speak. Tighter regulations on our Internet need to be enforced with high penalties. I continue to receive emails from these pharmacies on a daily basis. What our public to not know...is just because it says, United States pharmacy does not mean it is in the U.S. In fact, when you click on the site, it goes to Mexico. Our seniors think they can buy from Canadian pharmacies and save money. What they do not know, is that when they click on something that says Canada, it actually takes them to Africa or India. Drugs are being distributed daily like candy, and it's very dangerous. These Internet sites can lead to an increase in drug addiction, and lead to more deaths.

RyansCause is an organization I have started. Reaching Youths Abusing Narcotics. Saying No to Drugs is not enough. We are losing this war against drugs. President Bush in his State of the Union Address a few months back, mentioned that drug use in our youth is down. He might be right about street drugs, but he did not mention the increased usage of prescription drugs. Prescription drug usage is up. My hope is that with tighter restrictions on the Internet and more public awareness we could save lives. I want to get RyansCause brochures into every high school classroom. I want to talk and educate our youth and parents. This tragic death could have

happened to anyone. Ryan was the boy next door. We need to fight this war against drugs and save others.

With tighter regulations on the sales of prescription drugs on the Internet, it will make our increasingly technological world more safe. I want to thank Senator Feinstein and Senator Coleman in introducing legislation to improve the safety of buying prescription drugs on the Internet. Internet pharmacies should be required to identify their business, pharmacist and physicians. Pharmacies should be prohibited from distributing drugs to consumers with a prescription based solely on an online questionnaire. The state Attorney's General should have the ability to shut down rogue websites, nationwide, rather than just in their individual jurisdictions. Severe punishment should be served to those that break this law. These laws will not bring Ryan back. Our grief continues and extends beyond the immediate family. Ryan's grandparents, aunts and uncles, cousins and friends feel Ryan's death very deeply. Ryan will never see Jeremy play his clarinet, or take him out for ice cream. Ryan will never be here to talk for long hours with his best friend, his sister Natalie. I will not see him graduate from college, attend his wedding, and be grandmother to his children. But we continue to water our white roses, and drink our Sprite with no ice in his memory. Ryan will be forever missed and will remain in our hearts forever. Thank you for allowing me to tell his story in front of this Subcommittee.

# # #

United States Government Accountability Office

GAO

Testimony

Before the Permanent Subcommittee on Investigations, Committee on Governmental Affairs, U.S. Senate

For Release on Delivery
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PRESCRIPTION DRUGS

Preliminary Observations on Efforts to Enforce the Prohibitions on Personal Importation

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

GAO-04-839T

GAO
Accountability·Integrity·Reliability

Highlights

Highlights of GAO-04-839T, a testimony before the Permanent Subcommittee on Investigations, Committee on Governmental Affairs, U.S. Senate

July 22, 2004

PRESCRIPTION DRUGS

Preliminary Observations on Efforts to Enforce the Prohibitions on Personal Importation

Why GAO Did This Study

American consumers are increasingly drawn to the convenience, privacy, and cost advantages that might be accrued by purchasing prescription drugs over the Internet. However, there is growing concern about the safety of the drugs and the lawfulness of shipping the drugs into the United States through international mail and private carriers. Under current law, the importation of prescription drugs for personal use is illegal, with few exceptions. 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. According to the agencies responsible for enforcing these laws, prescription drugs imported for personal use generally do not meet these requirements. The Department of Homeland Security's U.S. Customs and Border Protection (CBP) and the Department of Health and Human Service's Food and Drug Administration (FDA) are responsible for inspecting and interdicting unapproved prescription drugs that are being illegally imported via the U.S. mail or private carrier.

This testimony reflects our preliminary observations from ongoing work to assess federal efforts to enforce the prohibitions on personal importation of prescription drugs.

www.gao.gov/cgi-bin/getrpt?GAO-04-839T

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

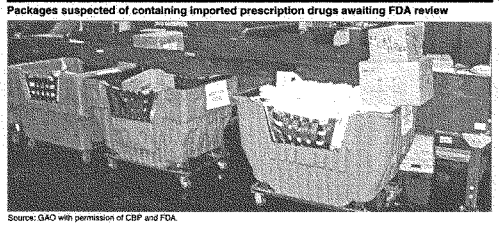
What GAO Found

CBP and FDA officials said that the volume of imported adulterated, misbranded, or unapproved prescription drugs is large and increasing, but complete data do not exist to document these observations. FDA officials said 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. GAO's recent report on a sample of drugs purchased from Internet pharmacies echoed these concerns.

CBP and FDA officials at mail and private carrier facilities inspect and interdict some packages that contain prescription drugs. However, according to officials, because of resource constraints, many other packages containing prescriptions drugs are either not inspected and are released to addressees or are released after an inspection. CBP and FDA target certain packages for inspection based on the packages' countries of origin and whether the packages are suspected of containing certain prescription drugs. However, packages that are not targeted typically bypass inspection and are released to addressees without an assessment of their contents or admissibility. FDA officials have acknowledged that tens of thousands of packages, containing drug products that may violate current laws and pose health risks to consumers, have been released. They said that time-consuming processing requirements and resource constraints limit their ability to perform more inspections.

Agency efforts to deal with imported prescription drugs are evolving. Two interagency task forces were established to study prescription drug importation and address related law enforcement issues, respectively. Also, to overcome differences in the way officials target and interdict shipments of unapproved prescription drugs at various mail and private carrier facilities, FDA has begun implementing new procedures to promote more uniformity across facilities. It is too soon to tell if these efforts are sufficient to address various health, safety, and law enforcement issues associated with the importation of prescription drugs.

Packages suspected of containing imported prescription drugs awaiting FDA review



Source: GAO with permission of CBP and FDA.

Mr. Chairman and Members of the Subcommittee:

I appreciate the opportunity to be here today to participate in this hearing on prescription drug importation. American consumers are increasingly drawn to the convenience, privacy, and cost advantages that might be accrued by purchasing over the Internet such prescription drugs as Valium, cholesterol-lowering drugs, and Viagra. However, there is growing concern, reported in the media and elsewhere, that persons who purchase prescription drugs from Internet pharmacies, particularly those pharmacies located in foreign countries, run the risk of taking drugs that may be compromised or not the authentic product they intended to purchase. Thus, American consumers may be exposed to potential health and safety risks. Furthermore, consumers may also be violating the law, unknowingly or intentionally, by having these drugs shipped into the United States through the international mail and private carriers.

Under current law, the importation of prescription drugs for personal use is illegal, with few exceptions. 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, as defined in the Controlled Substances Act,[1] 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.

My testimony today reflects our preliminary observations from ongoing work to assess federal efforts to enforce the prohibitions on personal importation of prescription drugs, which was requested by the Chairman and Ranking Minority Member of this Subcommittee and the Ranking Member of the House Energy and Commerce Committee. Much of our work to date has focused on the efforts of the Department of Homeland Security's U.S. Customs and Border Protection (CBP) and the Department of Health and Human Service's Food and Drug Administration (FDA) to

[1]The Controlled Substances Act establishes a classification structure for certain drugs and chemicals that are designated as controlled substances. This structure places controlled 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. Prescription drugs that are also controlled substances, such as Valium or codeine, fall in schedules II through V.

inspect and interdict prescription drugs that are being imported via the U.S. mail or private carrier, such as FedEx or DHL, for personal use. In this statement, I make the following points:

- CBP and FDA officials said that the amount of unapproved prescription drugs illegally entering the country is large and increasing. The overall healthfulness and safety of these imported drugs is not assured, and limited testing showed that some of these drugs pose risks to consumers.
- CBP and FDA interdict some packages that contain prescription drugs, but many other packages containing these drugs are released to addressees—either not inspected and released or released after inspection. According to CBP and FDA officials, this is because of resource and other constraints.
- CBP and FDA officials told us that their respective requirements for inspecting and processing violative materials can be time-consuming and in some cases hamper their enforcement efforts.
- Agency efforts to address issues concerning the importation of prescription drugs are evolving, but it is still too early to tell whether these efforts will adequately address every aspect of the law enforcement and safety issues associated with the importation of these drugs.

My testimony is based on our ongoing review of federal laws and agency policies, procedures, and practices related to personal importation of prescription drugs; visits to three international mail facilities operated by the U.S. Postal Service and two private carrier facilities; and interviews with officials from CBP, FDA, the Department of Justice's Drug Enforcement Administration (DEA), the U.S. Postal Service, and the Department of Homeland Security's U.S. Immigration and Customs Enforcement. We did the work reflected in this statement from March to July 2004 in accordance with generally accepted government auditing standards. We plan to finish our work and issue a report later this year. Additional information on our scope and methodology can be found in appendix I.

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 13 International Mail Branches (IMBs) located at U.S.

Postal Service 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 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 IMBs 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.[2] Under the act and implementing regulations, this includes foreign versions of FDA-approved drugs because, 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 permit personal importation of prescription drugs that do not contain controlled substances under specified circumstances, such as importing for treatment of a serious condition a small quantity, generally not more than a 90-day supply, of a

[2]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. §§ 811, 812 §§ 351, 352, 355.

drug not available domestically.[3] The importation of unapproved 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 also controlled substances, such as Valium or codeine. (See app. II for general description of controlled substances.) Under the act, the importation of controlled substances is prohibited unless the importer is registered with DEA, and such registration is generally not available for importation for personal use. 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.[4]

CBP inspects packages for prescription drugs on behalf of DEA and FDA. Upon inspection, CBP is to seize illegally imported controlled substances on behalf of DEA.[5] 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.[6] CBP is to turn over

[3]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.

[4]21 U.S.C. 956(a), 957(b)(1)(C); 21 C.F.R. 1301.26. The controlled substance must be in the original container in which it was dispensed to the individual. The individual must declare that it is possessed for personal use or for an accompanying animal and provide the trade or chemical name and schedule of the substance. If the traveler is a U.S. resident, he or she may bring no more than 50 dosage units of the substance without a prescription.

[5]19 USC § 1595a(c)(1)(B); 19 C.F.R. §§ 162.23, 145.59, 145.58, 12.36. Schedule I and II controlled substances are subject to summary forfeiture.

[6]19 CFR §§ 162.31, 162.32, 162.45, 162.45a, 162.46, 162.47, 162.63.

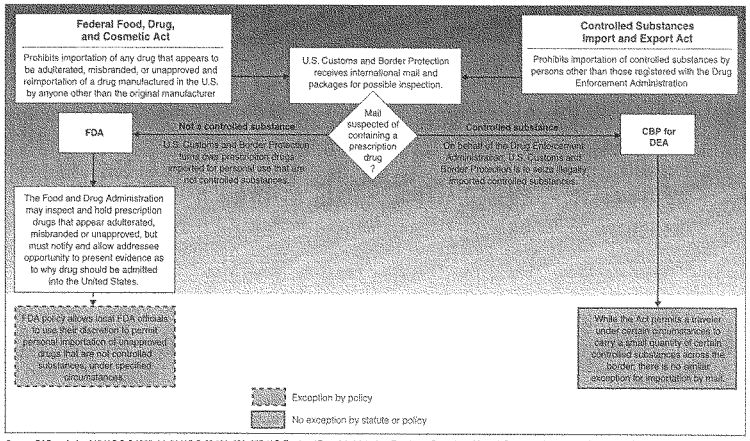
packages suspected of containing prescription drugs that are not controlled substances to FDA.[7] FDA investigators may inspect such packages and hold those that appear to be adulterated, misbranded, or unapproved, but must notify the addressee and allow that individual the opportunity to present evidence as to why the drug should be admitted into the United States.[8] If the addressee does not provide evidence that overcomes the appearance of inadmissibility, then the item is refused admission.

Figure 1 illustrates the two acts that specifically govern the importation of prescription drugs into the United States. It also presents the roles of FDA, DEA, and CBP in implementing those acts.

[7] 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. Downloaded May 18, 2004.

[8] 21 U.S.C. § 381(a); 21 CFR §1.94.

Figure 1: Acts Governing the Personal Importation of Prescription Drugs into the United States and FDA, DEA, and CBP Roles Implementing Those Acts



Source: GAO analysis of 19 U.S.C. § 1595a(c); 21 U.S.C. §§ 381, 958, 957; U.S. Food and Drug Administration, Regulatory Procedures Manual, Chapter 9, Subchapter: Coverage of Personal Importations.

Volume of Prescription Drug Imports Is Said to be Large and Increasing, and the Health and Safety of these Drug Imports is Not Assured

CBP and FDA officials said that the volume of unapproved prescription drugs illegally imported through the IMBs or carrier facilities is large and steadily increasing. However, complete data do not exist to document this observation. During special operations, CBP and FDA have attempted to determine the volume of imported prescription drugs entering through selected IMBs. Generally, these were one-time, targeted efforts to identify and tally all of the packages containing prescription drugs at certain time periods. The limited data collected have shown wide variations in volume. For example, CBP officials at one IMB estimated that approximately 3,300 packages containing prescription drugs entered the facility in one week. In 2004, CBP officials at another IMB determined that 4,300 packages containing prescription drugs entered the facility in one day. While these data may provide estimates regarding the volume entering selected IMBs for certain time periods, the data may not be representative of other time periods or projectable to other locations.

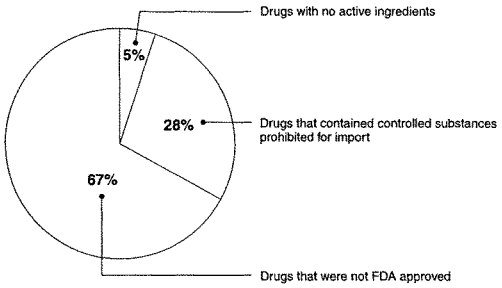
FDA officials have stated that they cannot provide assurance to the public regarding the safety and quality of drugs purchased from foreign sources, which are largely outside of their regulatory system. Additionally, FDA officials indicated that consumers who purchase prescription drugs from foreign-based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

CBP and FDA have conducted special operations to do limited assessments of the nature of some imported prescription drugs, and these operations have raised questions about the safety of some of the drugs analyzed. For example, during an operation undertaken in 2003 at four IMBs, CBP and FDA inspected 1,153 packages that contained prescription drugs.[9] According to a CBP report, 1,019, or 88 percent, of the drug products were violative because they were prohibited for import, including Lipitor (a cholesterol-lowering drug), Viagra, and Propecia. A CBP laboratory analyzed 180 drug samples. This analysis showed that the majority of the drugs were never approved by FDA. Furthermore, the operation showed that many of the unapproved drugs could pose safety

[9]According to CBP officials, packages shipped through four IMBs 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 historical experience.

risks. The samples included drugs that were withdrawn from the U.S. market for safety reasons; animal drugs not approved for human use; and drugs that carry risks because they require careful dosing, initial screening, or periodic patient monitoring. In addition, other drugs tested were found to contain controlled substances prohibited for import, and some of the drugs contained no active ingredients. Figure 2 illustrates the results of the CBP laboratory analysis.

Figure 2: Results of CBP's Laboratory Analysis of 180 Imported Drugs



Source: GAO analysis of CBP information.

In a recent report and testimony before this Subcommittee, we found that prescription drugs ordered from some foreign-based Internet pharmacies posed safety risks for consumers.[10] Specifically, we identified several problems associated with the handling, FDA approval status, and authenticity of 21 prescription drugs samples purchased from Internet pharmacies located in several foreign countries—Argentina, Costa Rica, Fiji, Mexico, India, Pakistan, Philippines, Spain, Thailand, and Turkey. Our work showed that most of these drug samples, all of which we received via consignment carrier shipment or the U.S. mail, were unapproved for the

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

U.S. market because, for example, the labeling[11] or the foreign manufacturing facility, methods, and controls were not reviewed by FDA. Of the 21 samples:

- None included dispensing pharmacy labels that provided instructions for use, and only about one-third included warning information.
- Thirteen displayed problems associated with the handling of the drug; three samples that should have been shipped in a temperature-controlled environment arrived in envelopes without insulation; and five samples contained tablets enclosed in punctured blister packs, potentially exposing them to damaging light or moisture.
- Two were found to be counterfeit versions of the products we ordered, and two had a significantly different chemical composition than that of the product we had ordered.

We found fewer problems among 47 samples purchased from U.S. and Canadian Internet pharmacies. Although most of the drugs obtained from Canada were of the same chemical composition as that of their U.S. counterparts, most were unapproved for the U.S. market. We stated that it was notable that we identified numerous problems among the samples received despite the relatively small number of drugs we purchased, consistent with problems recently identified by state and federal regulatory agencies.

Some Packages Containing Prescription Drugs Are Interdicted, but Others Are Released

Our work thus far shows that while CBP and FDA interdicted some packages that contain prescription drugs, other similar packages were released—either not inspected and released or released after inspection. CBP officials told us that certain packages were targeted for inspection. However, packages that were not targeted typically bypass inspection and are released to the addressee without an assessment of their contents or admissibility. Many packages that were held by CBP officials for FDA at the IMBs were also subsequently released to the addressee. FDA has acknowledged that tens of thousands of packages have been released, although they may contain drug products that violate current laws and pose health risks to consumers. FDA officials at the IMBs said that the

[11]The term "labeling" is broader than the term "label" and includes all labels and other written, printed, or graphic matter upon an article or its container or wrapper, or that accompanies the article. See 21 U.S.C. § 321(m).

packages were released to the addressee because FDA investigators were unable to process the volume of packages turned over to them. FDA headquarters officials told us that this occurred because of limited available resources relative to the volume of unapproved prescription drugs entering the country.

Packages Not Targeted for Inspection and Released

According to CBP and FDA officials at the IMBs we visited, CBP and FDA use various approaches to target certain incoming international mail packages for inspection. These include targeting packages from certain countries and/or packages suspected of containing certain prescription drugs. For example, at one IMB we visited, FDA provided CBP with a list of targeted countries—the composition of which changed periodically. A recent list targeted seven countries and specific areas in one other country. FDA officials asked that CBP hold the packages they suspected of containing prescription drugs that were from the targeted countries. Typically, CBP officials told us that when packages containing prescription drugs were detected, but were not from one of the targeted countries, they were released to the addressee without an assessment of their admissibility. Accordingly, CBP officials stated that packages containing prescription drugs unapproved for import were released daily without FDA review.

According to CBP and FDA officials at the carrier facilities we visited, packages containing prescription drugs sent through these facilities may also be released without inspection. Unlike packages at IMBs, packages arriving at carrier facilities we visited were preceded by advance manifest information, which included the shipper's declaration describing the contents and its value. CBP and FDA officials review the manifest information to target packages for inspection before their arrival. Agency officials at two carrier facilities we visited told us that FDA officials were not typically on-site and electronically reviewed the manifests and targeted incoming packages declared as prescription drugs. FDA officials noted that packages containing prescription drugs could potentially avoid their review if the manifest information was not accurate. CBP and FDA officials told us there were no assurances that the shipper's declarations were accurate. For example, CBP and FDA officials at the carrier facility found eight packages containing a human growth hormone—unapproved for import—that were inaccurately manifested as glassware.

Packages Released after Inspection

FDA officials said that some packages that were inspected and determined to contain prescription drugs at the IMBs were released because they could not process them. For example, at one IMB, CBP officials held 16 bins containing roughly 3,000 packages for FDA investigators on a weekly

basis. However, the FDA officials estimated that in one week, they could open and fully inspect about 140 packages. In making the decision regarding what to inspect, two FDA investigators considered whether the packages contained prescription drugs considered to be an enforcement priority, including injectable drugs and certain controlled substances, such as steroids. The FDA officials told us that they typically released packages that did not contain a priority drug, even though the packages were believed to contain other prescription drugs that were not approved for import. Figure 3 shows bins containing packages of suspected prescription drugs being held for FDA review and possible inspection.

Figure 3: Bins Containing Packages of Suspected Prescription Drugs Being Held for FDA Review and Possible Inspection.

Source: GAO with permission of CBP and FDA.

At another IMB, CBP officials said that they usually released packages containing prescription drugs that appeared to be a 90-day supply or less—in line with one of the criteria in FDA's personal importation policy.[12] For example, after viewing an x-ray image of a package, CBP performed a visual inspection of the outer container of a medication, labeled as a treatment for ulcers,[13] determined that it appeared to contain 90 pills, and released it. At this same facility, FDA officials told us that every week CBP turned over to FDA hundreds of packages. CBP told us that these packages contained quantities of prescription drugs that appeared to be more than a 90-day supply. However, the FDA officials stated that they were able to process a total of approximately 20 packages per day. As a result, the FDA officials told us they returned many of the packages to CBP, citing an inability to process every package. The CBP officials said that most of the returned packages were released to the addressees. For example, CBP officials told us that several packages suspected of containing generic Viagra, unapproved for import, were returned by FDA and were released.

Officials Said Process Requirements Are Time-Consuming and Can Hamper Enforcement Effort

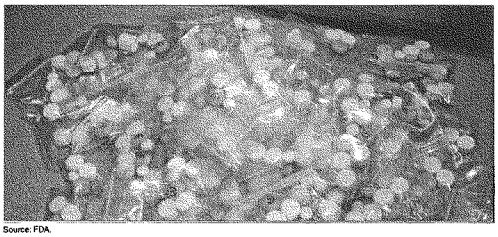
FDA officials told us that for packages found to contain prescription drugs, processing requirements are time-consuming and can hamper their ability to process all of the packages that are detained by CBP. FDA processing requirements include identifying the drugs, measuring the volume, entering this information into a FDA database, taking pictures of the drugs, preparing the drugs for temporary storage, and sending notification to the addressees to provide evidence regarding the admissibility of the drug. Processing time varies depending on the quantity and variety of drugs in the package.

In addition, processing time increases if research is required to determine the drug type. For example, FDA officials at one IMB stated that some prescription drugs are not immediately identifiable, particularly when shipped without labels or with labels in a foreign language. Figure 4 illustrates an example of drugs that was sent without labeling.

[12]For a description of some of the other criteria in FDA's personal importation policy, see note 3 and the accompanying text.

[13]This medication was labeled as a Canadian drug, although it had a New Zealand return address.

Figure 4: Drugs Sent without Labeling.



Source: FDA.

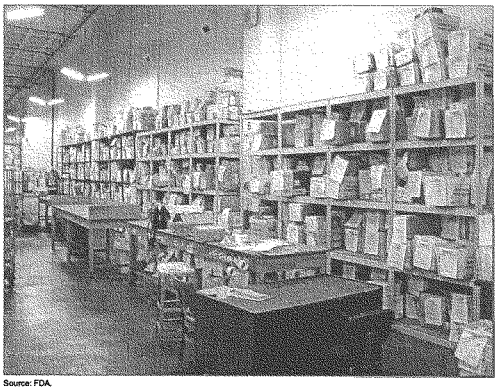
FDA officials at the IMBs we visited stated that considering these many factors, processing a single package can take anywhere from a few minutes to several hours. FDA officials who are responsible for reviewing manifest information for drugs shipped through the private carriers stated that it can take several days to process a package, particularly if they need to obtain additional information regarding the shipment.

FDA headquarters officials said that packages that contain prescription drugs that appear to be unapproved for import cannot be automatically refused and returned because of the statutory requirement that FDA hold the package and give the addressee the opportunity to provide evidence of admissibility. Officials said that this requirement applies to all drug imports with few exceptions. According to FDA investigators, in most instances, the addressees did not present evidence to support the drugs' admissibility, and the drugs were ultimately provided to CBP or the U.S. Postal Service for return to sender.

CBP officials at two IMBs told us that they could not turn over all packages they suspected of containing prescription drugs because FDA officials were not able to process all of the packages. FDA officials at one IMB stated that the processing time affected the number of packages they could inspect and was the reason many of the packages that were held up by CBP were ultimately released to the addressee without inspection. A FDA headquarters official stated that considerable storage space is needed to hold the detained packages, while the notice, opportunity to respond, and the agency's decision are pending. For example, one FDA IMB official told us that space limitations have affected the number of packages they

are able to store, including those packages held on-site awaiting a response from the addressee. Figure 5 shows drugs stored at one IMB as they pass through FDA's process, including those awaiting addressees' responses.

Figure 5: Drugs in Storage as They Pass through FDA's Process at One IMB



Source: FDA

Processing requirements for controlled substances can also be burdensome if an IMB receives a high volume of controlled substances in the mail. According to CBP officials, the seizure process requires that CBP inspectors record the contents of each package—including the type of drugs and the number of pills or vials in each package—before it is turned over to seized property staff for possible investigation by Immigration and Customs Enforcement, forfeiture, and eventual destruction. CBP officials at one IMB told us that in recent months they have observed substantial increases in the volume of prescription drugs containing controlled substances being sent through the international mail because, in their view, of the increased incidence of consumers ordering drugs over the Internet. Although CBP officials had been seizing substantially more of these drugs in recent months, they had also accumulated a sizable backlog

of controlled substances awaiting seizure because, according to officials, they did not have the resources to begin the seizure process. By June 2004, CBP at this IMB had accumulated 123 bins of mail, containing over 40,700 packages of Schedule IV controlled substances—including the tranquilizer Valium, antidepressants, and painkillers. Figure 6 shows some of the bins of controlled substances that were being held awaiting formal seizure, as of May 14, 2004.

Figure 6: Controlled Substances Accumulated and Awaiting Seizure at One IMB

Source: GAO with permission of CBP and FDA.

According to CBP officials at this facility, as the controlled substances continued to accumulate, they became concerned that they would not be able resolve the backlog. In June, a CPB official said that CBP IMB officials asked CBP headquarters for permission to send the products back to the senders as an alternative to seizure, and to keep these drugs from entering U.S. commerce. According to this official, CBP's headquarters office granted them permission to send most of the drugs back to the

sender because the backlog would have taken months to resolve.[14] One CBP official said that the ability to return the controlled substances enabled CBP to clear the backlog in two to three weeks rather than the one to two years they projected it would have taken had CBP been required to begin seizure proceedings for each item. Officials at the facility said that they are now seizing controlled substances as they arrive at the facility.

Agency Efforts to Address the Importation of Prescription Drugs Are Evolving

Our preliminary work revealed a number of efforts, including interagency initiatives that are being undertaken in response to concerns raised about the importation of prescription drugs. For example, 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 and submit a report to Congress (P.L. 108-173). The conference report (House Report 108-391) enumerated questions to be addressed in this study including, among other things:

- assessing the scope, volume, and safety of unapproved drugs, including controlled substances, entering the United States via mail shipment; and
- estimating agency resources, including additional field personnel, needed to adequately inspect the current amount of pharmaceuticals entering the country.

In February 2004, the Secretary of Health and Human Services appointed a task force, chaired by the Surgeon General, on drug importation. It included members representing the department, CBP, DEA, Department of Justice trial attorneys, and the Office of Management and Budget. Between March and May, the task force held public hearings to gather information to address the questions posed by Congress. According to an FDA official, as of July 2004, the task force staff was reviewing the testimony from the public hearings and the comments sent to the Federal Register docket to answer the questions posed in the conference report. The official said that the task force report is expected to be completed by this fall so that the

[14]According to a CBP official, most of the drugs returned were Schedule IV controlled substances. They said that a small number of the packages contained nonschedule prescription drugs that were referred to FDA. Also, CBP seized a small number of items that did not have a return address.

Secretary of Health and Human Services can meet his December 2004 deadline for reporting to Congress.

In addition, a CBP official told us that CBP is leading an interagency pharmaceutical task force, established in January 2004 to address various law enforcement issues related to the importation of prescription drugs and miscellaneous pharmaceuticals. The task force, which includes managers and senior managers from CBP, FDA, DEA, the Office of National Drug Control Policy, U.S. Immigration and Customs Enforcement, as well as legal counsel from the Department of Justice and other agencies, meets every two months. According to the CBP official, the task force has established five interagency working groups designed to tackle specific issues identified by the task force. The working groups, which meet more frequently, are focused on improving information sharing and law enforcement targeting criteria, increasing public awareness of potential dangers of imported pharmaceuticals, reviewing and enhancing mail and express mail consignment procedures, working cooperatively with industry, and legal issues. The groups report the results of their enforcement efforts to the task force, which makes suggestions for future efforts.

Our preliminary discussions with CBP about the activities of the working groups revealed initiatives currently under way by two of the groups. In one instance, the working group on mail and express mail consignment procedures has been involved in recent interagency enforcement operations at selected international mail facilities. During these operations, the interagency group targeted and found mail containing nonscheduled prescription drugs as well as controlled substances. According to the CBP official, these operations resulted in investigations of commercial shipments of the prescription drugs by agents from the task force and working group and helped the law enforcement agencies identify Internet addresses for purposes of future investigations. The CBP official told us that, in another instance, the working group focused on increasing public awareness of the potential dangers of imported pharmaceuticals had developed public service announcements that are to be posted on the Internet. Appendix III shows one of these announcements that was recently posted on the CBP web site.

Individual agencies are also taking steps to enhance their ability to deal with inspection and interdiction issues associated with imported prescription drugs. As discussed earlier, during our visits to the three IMBs, we noted that CBP and FDA officials at those facilities had adopted different approaches for targeting and interdicting prescription drugs. FDA

headquarters officials also recognized this and in response indicated that a more uniform approach was needed. According to these officials, FDA has drafted a set of standard operating procedures that will apply to the handling of imported prescription drugs consistently across the 13 International Mail Branches. FDA officials said that these procedures have been developed to apply to the handling of prescription drugs nationwide, but will also give officials at individual facilities some flexibility to adopt procedures that address uniquely local conditions. FDA headquarters officials told us they have begun implementing the procedures at selected IMBs and plan to implement them at more locations. FDA officials also said that they were developing a similar set of standard operating procedures that would apply to the inspection and interdiction of imported prescription drugs at the consignment carrier facilities. CBP officials told us that CBP expects that these guidelines will also discuss CBP responsibilities for handling imported prescription drugs.

In closing, Mr. Chairman, it has been discussed in the media and elsewhere that American consumers are purchasing prescription drugs for importation in increasing numbers. Our preliminary observations indicate that CBP and FDA face considerable challenges inspecting and interdicting these drugs to help ensure compliance with current law. Currently data are unavailable to estimate the volume of prescription drugs entering the country, and the overall health and safety risks of these drugs are unknown. CBP and FDA are inspecting and interdicting some of the unapproved prescription drugs that are entering the country, but others bypass inspection and are sent to consumers who purchased them, often because, according to CBP and FDA officials, time-consuming processing requirements and staffing constraints limit their ability to perform more inspections. Although agencies like CBP, FDA, and DEA have begun initiatives to deal with various aspects of the drug importation issue, it is too early to tell whether these efforts will adequately address every dimension of the law enforcement and safety issues associated with the importation of prescription drugs.

This concludes my prepared statement. In the next several weeks we plan to follow up with CBP and FDA officials on their plans to enhance their enforcement activities. I would be pleased to answer any questions you and the Subcommittee members may have.

GAO Contacts and Staff Acknowledgments

For further information about this testimony, please contact Richard Stana, Director, Homeland Security and Justice Issues, on (202) 512-8777 or at stanar@gao.gov. Major contributors to this testimony included John Mortin, Yelena Harden, Barbara Stolz, Frances Cook, and James Russell.

Appendix I: Scope And Methodology

To understand importation restrictions and enforcement requirements, we reviewed current federal laws on the importation of prescription drugs and controlled substances. We reviewed current CBP and FDA policies, procedures, and guidance related to prescription drugs and controlled substance importation. We reviewed applicable importation and interdiction data from CBP and FDA. We conducted interviews with officials at CBP, FDA, U.S. Postal Service, U.S. Immigration and Customs Enforcement, and DEA.

To understand inspection procedures, we visited three IMBs in Chicago, Los Angeles, and New York and two carrier facilities in Cincinnati (for the DHL Corporation) and in Memphis, (for the FedEx Corporation). We judgmentally selected these facilities based on the overall number of packages processed at the facilities and their geographic dispersion. At these locations, we observed inspection and interdiction practices; met with CBP and FDA management, inspectors, and investigators to discuss issues related to inspection, manifest reviews, and pharmaceutical importation volume; and reviewed relevant documents on inspection and interdiction procedures. At the IMBs we also met with officials from the U.S. Postal Service regarding mail handling and processing procedures.

We did the work reflected in this statement from March to July 2004 in accordance with generally accepted government auditing standards.

Appendix II: General Description of the Controlled Substance Schedules I-V

The drugs and drug products that come under the Controlled Substances Act are divided into five schedules. A general description and examples of the substances in each schedule are outlined below in table 1.

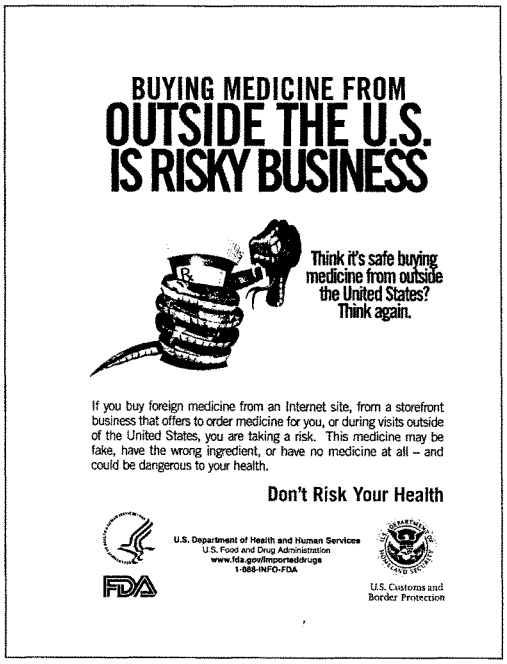
Table 1: General Description of Controlled Substance Schedules I-V

Schedule	Description of substances in the schedule	Examples
I	Substances that have no accepted medical use in the United States and have a high potential for abuse.	Heroin, lysergic acid diethylamide (LSD), marijuana, and gama hydroxybutyric acid (GHB)
II	Substances that have a high potential for abuse with severe psychic or physical dependence liability—certain narcotic, stimulant, and depressant drugs.	Opium, morphine, codeine, methadone, and meperidine (Demerol)
III	Substances that have a potential for abuse that is less than those in Schedules I and II and include compounds containing limited quantities of certain narcotic drugs and non-narcotic drugs.	Anabolic steroids; derivatives of babituric acid (except those listed in another schedule); benzphetamine; and any compound, mixture, preparation or suppository dosage form containing amobarbital, secobarbital, or pentobarbital
IV	Substances that have a potential for abuse that is less than those listed in Schedule III.	Barbital, alprazolam (Xanax), Cathine— constituent of the "Khat" plant, and Diazepam (Valium)
V	Substances that have a potential for abuse that is less than those listed in Schedule IV and consist primarily of preparations containing limited quantities of certain narcotic and stimulant drugs.	Pyrovalerone (Centroton, Thymergix)

Source: GAO analysis of Drug Enforcement Administration information.

Note: Schedule I substances are not the subject of this report.

Appendix III: CBP Public Service Announcement Posted on the Internet



BUYING MEDICINE FROM
OUTSIDE THE U.S.
IS RISKY BUSINESS

Think it's safe buying medicine from outside the United States? Think again.

If you buy foreign medicine from an Internet site, from a storefront business that offers to order medicine for you, or during visits outside of the United States, you are taking a risk. This medicine may be fake, have the wrong ingredient, or have no medicine at all – and could be dangerous to your health.

Don't Risk Your Health

U.S. Department of Health and Human Services
U.S. Food and Drug Administration
www.fda.gov/importeddrugs
1-888-INFO-FDA

FDA

U.S. Customs and Border Protection

Testimony of

Karen Tandy
Administrator

Drug Enforcement Administration

Before the

Permanent Subcommittee on Investigations
Committee on Governmental Affairs
United States Senate

July 22, 2004

Chairman Coleman, Senator Levin, and distinguished Members of the sub-committee, thank you for the opportunity to discuss the problem of illicit or "rogue" online pharmacies, which illegally sell dangerous and addictive controlled substances over the Internet. On behalf of the men and women of the Drug Enforcement Administration, thank you for your interest in this significant threat to public health and safety.

Introduction

The Internet has brought drug dealers from the back alleys directly into every American home wired for email and the World Wide Web. Extremely dangerous, addictive, and potentially life-threatening drugs are now sold illegally every day, just one click beyond virtually every email box. These drugs are peddled by multimillion dollar organizations every bit as sophisticated as international cartels.

For the consumer, buying these drugs over the Internet without a legitimate prescription is no safer than taking drugs offered to you by a street corner hustler. Narcotics sold over the Internet have led to deaths, overdoses, and addiction nationwide. Rogue Internet pharmacies pose an immediate threat to lives and health across the country, and the Attorney General and I have made it a priority for the Drug Enforcement Administration to aggressively identify and pursue these organizations.

The Problem of Rogue Internet Pharmacies

Purchasing controlled substances online is simple: someone looking for a drug of choice can simply type its name into a search engine, pick from numerous sites offering it, fill out a brief questionnaire, and then click to purchase. Often, persons are not even looking for drugs but are solicited to buy them by unrelenting "spam" emails. In either case, the physician associated with the website, typically in a business relationship with the pharmacy, almost never has a valid doctor-patient relationship under accepted medical practices.

There is no physical examination, no discussion with the consumer of the diagnosis and the evidence for it, no discussion of the risks and benefits associated with various treatment options, no verification of the information provided, and no follow up care by the physician. The pharmacist then dispenses the controlled substance with an invalid prescription and without the needed and required underlying physician-patient relationship. Acting together, the physician and pharmacist dispense controlled substances without a legitimate medical need, resulting in widespread self-medication over the Internet.

The risks of self-medication are obvious: addiction to habit-forming substances, dangerous drug interactions, use of counterfeit or tainted products, and adverse reactions to medications that are prescribed without a medical purpose. Pharmacists and doctors that participate in dispensing controlled substances without valid prescriptions essentially become Internet-based drug lords.

Some pharmacy owners have 25 or more specific sites, which are heavily advertised through spam e-mails and on the web. This makes finding and accessing these pharmacies easier. Total annual sales for some website operators are estimated at as much as $50 million, with profits of $30 million to $40 million. One case currently under indictment seeks forfeiture of $125 million from the website owner.

The real toll of these rogue Internet pharmacies is not in these numbers, however, but in victims across the country. Investigations have discovered 14 deaths or overdoses and 15 persons who have entered rehabilitation or sustained injuries from drugs obtained over the Internet. The tragic case of Ryan Haight, whose mother has testified before you, is nationally known. Ryan died at the age of 18 from an overdose of painkillers, including Vicodin, he ordered over the Internet without a legitimate prescription while a 17 year old minor. Sadly, these cases are only examples of a rapidly spreading problem and must be dealt aggressively.

Dealing with the Illicit Internet Pharmacy Problem

The non-medical use of prescription drugs has become an increasing widespread and serious problem in this country; one that calls for immediate action. President Bush has set forth a coordinated strategy with the problem of illegal diversion and abuse of prescription drugs, including rogue internet pharmacies, in the *National Drug Control Strategy for 2004.* The Office of the National Drug Control Policy and other key federal agencies are embarking on a comprehensive effort to insure that potentially addictive medications are dispensed and used safely and effectively though improved outreach to responsible businesses used to facilitate the on-line pharmacy trade, enhanced investigation and enforcement and greater public education.

The DEA currently has 91 active investigations involving the diversion pharmaceutical controlled substances using the Internet that cover 537 websites. This fiscal year, we have shut down 25 Internet pharmacy organizations; over $3.3 million has been forfeited and 3.2 million dosage units seized. $11 million is pending forfeiture.

The DEA is increasing staffing and resources dedicated to the problem of diversion over the Internet to improve our capacity to identify and stop illicit Internet pharmacy operations, and working more closely with agencies and companies inside and outside the government to coordinate and improve our efforts.

Specifically, appropriations for this fiscal year included an increase of 63 positions dedicated to our Internet initiative. We expect this enhancement of specialized investigators to have an immediate impact on Internet crime. Another key goal is to enhance our ability to find illicit Internet pharmacies, both online and in physical world, and find the organizations behind them using sophisticated technology. Congress provided $6.3 million in funding for this project, which is now becoming operational, and beginning to provide intelligence relating to ongoing investigations.

The DEA is also working to use the Internet itself as a tool to counter "rogue" pharmacies. The ease of obtaining some controlled substances over the Internet has dangerously misled the public. The DEA is working with major search engines and Internet service providers to warn consumers searching for controlled substances that they are in fact dangerous drugs. We have also established a link to the DEA's Internet homepage to allow citizens to report suspicious Internet pharmacies, an initiative which has already provided us with leads.

The scope of the problem of "rogue" Internet pharmacies is too broad and far reaching for DEA or any single agency to tackle alone. We are building partnerships and working with other regulatory agencies to enlist the support of legitimate businesses essential to the online trade. We are working closely with the National Association of Boards of Pharmacy and the Federation of State Medical Boards to build bridges with Internet Service Providers (ISP), credit card companies and shippers.

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 investigations with valuable tracking information on origin and destination of shipments. They are acutely aware that their businesses are being exploited and alert us to any unusual patterns. Similarly, consistent with my emphasis on taking away the proceeds of all illicit drug trade, we have met with both Visa and Master Card to explain their role in policing the activities of the vendors using their services. They fully assist us in all aspects of investigations and with financial leads. Both shippers and credit card companies understand how their companies can facilitate online drug dealing and have agreed to shut down sites when their customers have been determined to be conducting illegal activities.

The importance of our partnerships is best illustrated by a recent example. Last week, the DEA worked with Ebay to remove illegal steroids that had been improperly listed for sale on their website. The sellers were offering several types of Schedule III anabolic steroids to the highest bidder, which had managed to avoid detection in online "filters" Ebay had set up in cooperation with the DEA. Once noted, these harmful steroids were taken off their website immediately. We continue to work with them daily on illegal steroids offered by individuals via their website. While Ebay, of course, is not an illicit pharmacy website, our work demonstrates the successes we have had working with the private sector.

The DEA is also committed to working closely with our Federal partners. An interagency task force we participate in with Customs and Border Patrol, Immigration and Customs Enforcement and the Food and Drug Administration recently coordinated an "import blitz" to target imported pharmaceuticals arriving at the 13 U.S. international mail facilities at JFK Airport in New York. Of 325 packages sampled, 132 contained controlled substances, including codeine products, Valium, Xanax, steroids and Hydrocodone, which had illegally arrived from Spain, India, the Netherlands, Belgium, Romania, Slovenia, Mexico, Argentina and Brazil.

As the Subcommittee has noted, a significant aspect of the pharmacy problem is located abroad. The DEA has staffed critical overseas offices with diversion investigators to cooperate with our foreign counterparts on these matters. In addition, the DEA has assumed a leadership role in the international forum on Internet diversion. In March of 2000 and again in 2004, the United States introduced resolutions to the Commission on Narcotic Drugs of the United Nations Economic and Social Council emphasizing the importance of the Internet as a global diversion problem. These resolutions, which were overwhelmingly adopted, urge signatories to develop well-coordinated and focused policies to terminate Internet sites that fraudulently sell controlled drugs.

Continuing Challenges

Ultimately, it will also be necessary to address the problem of illicit Internet pharmacies within the regulatory structure of the Controlled Substances Act. Currently, no special DEA registration is required for online pharmacies, nor are online pharmacies required to report the nature or volume of their business in controlled substances. Such requirements would allow us to identify legitimate online pharmacies and persons operating and promoting them, to gather information pointing to patterns of abuse, and to punish "rogue" online pharmacies.

There is not a discrete legal or regulatory prohibition on using the Internet to advertise the illegal sale of controlled substances (as there is for other advertisements offering to sell Schedule I controlled substances).

We look forward to continuing to work closely with Congress to ensure that the Controlled Substances Act ultimately will address the problem of "rogue" Internet pharmacies as vigorously as we intend to address them through our enforcement efforts.

Conclusion

Mr. Chairman, I want to reiterate that "rogue" Internet pharmacies pose a significant threat to lives and health across the country and pursuing these organizations is a top priority for the DEA. At the same time, it is important to emphasize that caution and awareness are also important ways to protect the public. I would be happy to answer any questions.

Statement of Lee R. Heath
Chief Inspector
of the
United States Postal Inspection Service
on the Purchase of Pharmaceuticals Over the Internet
Before the Permanent Subcommittee on
Investigations
of the
Committee on Governmental Affairs
U.S. Senate

July 22, 2004

On behalf of the United States Postal Inspection Service, thank you for raising America's awareness of the dangers posed by the importation of drugs via online orders. As Chief Postal Inspector, I appreciate your giving me the opportunity to present the views of the United States Postal Service regarding this growing concern and the role Postal Inspectors have in combating it.

The responsibility for safeguarding 200 billion pieces of mail a year and ensuring America's trust in the postal system falls on the shoulders of U. S. Postal Inspectors. Congress empowered the Postal Service "to investigate postal offenses and civil matters relating to the Postal Service." Through its security and enforcement functions, the Postal Inspection Service provides assurance to American businesses for the safe exchange of funds and securities through the U.S. Mail; to postal customers of the "sanctity of the seal" in transmitting correspondence and messages; and to postal employees of a safe work environment.

As one of our country's oldest federal law enforcement agencies, founded by Benjamin Franklin, the United States Postal Inspection Service has a long, proud and successful history of fighting criminals who attack our nation's postal system and misuse it to defraud, endanger, or otherwise threaten the American public.

Postal Inspectors work closely with U.S. Attorneys, other law enforcement agencies, and local prosecutors to investigate postal cases and prepare them for court. There are approximately 1,900 Postal Inspectors stationed throughout the United States who enforce roughly 200 federal laws covering investigations of crimes that adversely affect or fraudulently use the U.S. mail and postal system. Primary among those are statutes that protect the sanctity and security of the mail. Last year, Postal Inspectors made over 11,000 arrests. Over fifteen percent of those arrests were related to prohibited items in the U.S. mail.

What Can Be Mailed?

There are numerous items prohibited from being sent through the mail under various sections of Title 18. For instance, 18 USC § 1302 forbids the mailing of lottery tickets or other gambling instruments. The Postal Inspection Service works with Customs and Border Protection (CBP) agents to stop foreign lottery materials at their point of entry into the United States. With the assistance of the Postal Service's Law Department, Postal Inspectors obtain mail destruct orders allowing Customs and the Postal Inspection Service to destroy the illegal lottery materials. For years, the American public and businesses have been plagued with fraudulent mailings from West Africa, commonly referred to as "419" letters, offering the addressees great riches and "financial opportunity." Over the years, working closely with CBP agents, Postal Inspectors have intercepted and destroyed in excess of 5 million of these fraudulent solicitations through mail destruction orders.

Another illustration of Title 18 prohibitions is found in 18 USC § 2251 - 2252, which involves the sexual exploitation of children. The Postal Inspection Service was the first federal law enforcement agency that recognized the need to combat child exploitation and has been dedicated to keeping child pornography out of the mail stream and bringing those engaged in the sexual exploitation of children to justice. The Postal Inspection Service has successfully investigated and dismantled several of the largest domestic and international child pornography rings in recent years. Moreover, this year marked the sixth consecutive year that Postal Inspectors were recipients of the prestigious National Exploited Children's Award by the National Center for Missing and Exploited Children. In addition, a Postal Inspector received top honors among the other award recipients and was named "Officer of the Year", at a Congressional Breakfast held on Capitol Hill. This was the fourth such "Officer of the Year" award given to Postal Inspectors in the past six years. No other law enforcement agency has achieved such acclaim.

Title 18 USC §§ 1715 and 1716 forbid the mailing of firearms, bombs, and other injurious articles such as poisons, flammable materials, and all other articles, compositions or material which may kill or injure another or injure the mails. Although bombs in the mail are not common occurrences, the Postal Inspection Service considers the investigation of mail bombs among its highest priorities and maintains a high degree of expertise to successfully investigate these potentially deadly crimes when they do occur. Postal Inspectors also regularly coordinate and conduct mail bomb and explosive screening operations at large national and international events. Firearms and certain poisonous animals are allowed to be sent through the mail under very limited circumstances. Specifically, firearms can be sent to law enforcement and military personnel and from manufacturer or dealer to manufacturer or dealer, and poisonous insects such as scorpions may be sent through the mails for the purpose of making anti-venom products.

18 USC § 1716(f) bans all alcohol products from the mail. As an example of recent enforcement activity in this area of our jurisdiction, last year, Senator Ted Stevens from Alaska contacted the Postal Inspection Service over his concerns that alcoholic beverages were being mailed into "dry" villages in rural Alaska. In many of these villages the rate of alcohol related homicides, felony assaults, rapes, and other serious crimes were 50% higher than the national average. At the request of Senator Steven's office, the USPIS partnered with the Alaska State Troopers and conducted a mail interdiction effort known as "Operation Safe Village." Postal Inspectors continue to work with the Alaska State Troopers on the issue, having initiated an alcohol prevention campaign aimed at educating the Alaskan public regarding the high crime rates associated with alcohol and the unlawful use of the mail to distribute alcohol.

The Postal Service has incorporated the prohibitions and restrictions of 18 USC §§ 1715-1716 in the Domestic Mail Manual (DMM), sections C021-C024. This information is available to the public in hard copy and on the Postal Explorer website at http://pe.usps.gov.

The shipment of hazardous materials through the mail is closely regulated. The DMM sets forth the circumstances under which hazardous materials such as explosives, corrosives, gases and flammable liquids are allowed to be shipped through the mail, if at all, at DMM C023. Postal Service regulations and the lists of which perishable and hazardous materials may and may not be mailed are set forth in great detail in Publication 52, *Hazardous, Restricted and Perishable Mail*. Sections 481-487 of that publication pertain to the mailing of controlled substances and other drugs and make explicit reference to the Controlled Substances Act. These publications are available to the general public, and the Postal Service has an extensive hazardous materials training program for its employees.

The Postal Service has promulgated regulations in the DMM sections C021 – C024 setting forth prohibitions and restrictions on mailability of certain types of substances. For instance, DMM C023.4 sets forth the narrow circumstances under which flammable and combustible liquids may be sent through the mail, describing in detail the acceptable flashpoints and container requirements. DMM C023.7 defines toxic substances, bans them from international mail and sets forth the limited circumstances under which authorized parties may send toxic substances through the mail, such as from a manufacturer or dealer to licensed physicians, surgeons, dentists, pharmacists, and druggists (*see* DMM C023.7.3).

Many controlled substances are not banned outright. 21 USC §§ 801-802 and 812 and the regulations set forth in 21 C.F.R. Part 1300 *et seq.* describe the circumstances under which various controlled substances can be mailed or shipped via common carrier. Controlled substances may be mailed if they are not banned by 21 USC §§ 801-802 and are packaged in accordance with the Controlled Substances Act. Prescription drugs may be sent through the mail as

long as the inner packaging is labeled to show the name and address of the dispenser and the label conforms with the requirements of the Food, Drug and Cosmetics Act (FDCA) and other Food and Drug Administration (FDA) requirements, and the outer wrapper or packaging is free of markings that indicate the nature of the contents. *See* DMM C024.11.2. It is the latter requirement that creates enforcement difficulties, since there is no way to identify the contents based on the outer wrapper and mail under seal cannot be opened without a federal search warrant. The only exception to this warrant requirement exists when CBP personnel exercise their warrantless search authority on inbound foreign mail at the border.

The DMM regulations mirror the relevant sections of Title 21. The DMM defines a controlled substance as "any anabolic steroid, narcotic, hallucinogenic, stimulant, or depressant drug in Schedules I through V of the Controlled Substances Act, 21 USC § 801, and 21 C.F.R. 1300 *et seq.* *See* DMM C024.11.1. The DMM also states that "[i]f distribution of a controlled substance is unlawful under 21 USC § 801 or implementing regulation in 21 C.F.R. 1300, then distribution of such matter by mail also is unlawful under 18 USC § 1716. In addition to the controlled substances themselves, the DMM also addresses the issue of the mailability of drug paraphernalia. "It is unlawful to use domestic or international mail to transport drug paraphernalia." *See* DMM C024.12.1. If an item is not permitted in the mails, the Postal Inspection Service is empowered to investigate those involved in its shipment and to seek appropriate civil or criminal penalties through the U.S. Attorney's Office or the USPS Judicial Officer Department. However, there are significant legal as well as practical obstacles which limit the ability of the Postal Inspection Service to make the initial determination that a prohibited item has been mailed. Fourth Amendment privacy rights present a challenge with regard to mail sealed against inspection. It is difficult, if not impossible, to articulate the probable cause necessary to secure a search warrant on the basis that the exterior appearance or country of origin has led one to believe a violation of law has occurred. Further, the number of search warrants which would be required for effective enforcement would significantly burden the court system.

Background of Prohibited Mailings Narcotics Investigations Conducted by USPIS

The Postal Inspection Service has been proactively investigating and removing illegal drugs from the mail for more than 25 years. Postal Inspectors regularly work in concert with federal, state, and local law enforcement agencies and arrest approximately 1,400 suspects annually for trafficking drugs through the mail. Thousands of pounds of illegal drugs are seized from the domestic mail stream each year. These seizures include marijuana, cocaine, heroin, anabolic steroids, methamphetamine, and other illegal drugs. To ensure the integrity of

the mail and to protect the American public from illegal drugs, Postal Inspectors conduct numerous national and local drug interdictions every year.

Recently, the Postal Inspection Service led an investigation that resulted in the dismantling of an international Internet drug organization. The organization was responsible for manufacturing, smuggling and distributing controlled substances, prescription medications, and counterfeit medications throughout the world. Postal Inspectors arrested the organization's "King Pin," along with several others, on federal charges related to smuggling; introduction of misbranded drugs into interstate commerce; distributing counterfeit drugs; dispensing drugs without a prescription; mail and wire fraud; and, money laundering. The investigation, conducted in partnership with the Bureau of Immigration and Customs Enforcement (ICE) and the FDA determined the organization advertised the illegal products through a web site registered in another country and mailed an estimated 100,000 Express Mail, Priority Mail, and Global Express parcels containing illegal pharmaceutical drugs to approximately 60,000 customers.

Similar past investigations include the April 2003 federal indictment and arrest of Dr. Alberto Alvarez, a Tijuana, Mexico, physician, in San Ysidro, California. Dr. Alvarez was identified by Postal Inspectors as a significant Internet distributor of Oxycontin. Postal Inspectors made undercover purchases of Oxycontin and Hydrocodone. Over 900 Express Mail labels attributed to Alvarez were identified. Dr. Alvarez used Priority Mail, Express Mail and Federal Express to ship the controlled substances ordered from his web site to the customers. He was subsequently convicted and sentenced to one year in federal prison. In another case, Postal Inspectors, working with ICE agents, arrested an Emerald Isle, North Carolina, man this past March for illegally receiving an international mail parcel containing 900 codeine pills. The pills had been mailed from an Internet pharmacy in Australia. As part of the Internet pharmacy's advertisement, it stated, "if the ordered items are seized by Customs, contact the company and the merchandise will be re-sent free of charge."

The Postal Inspection Service partners with organizations such as the Organized Crime Drug Enforcement Task Forces (OCDETF) and the High Intensity Drug Trafficking Area (HIDTA) Task Forces in an effort to reduce the drug flow into and through the United States. This year, the Postal Inspection Service is broadening its role in the law enforcement interdiction and intelligence community through a new partnership with COBIJA (which means "blanket" in Spanish), a HIDTA-sponsored interdiction program that facilitates intelligence sharing and interdiction coordination among federal, state, and local law enforcement agencies.

In addition to drugs, the shipment of hazardous materials through the mail is closely regulated. The DMM sets forth the circumstances under which hazardous materials such as explosives, corrosives, gases and flammable liquids are allowed to be shipped through the mail, if at all, at DMM C023. Postal

Service regulations and the lists of which perishable and hazardous materials may and may not be mailed are set forth in great detail in Publication 52, *Hazardous, Restricted and Perishable Mail.* Sections 481-487 of that publication pertain to the mailing of controlled substances and other drugs and make explicit reference to the Controlled Substances Act. These publications are available to the general public, and Postal Service has an extensive hazardous materials training program for its employees.

What Can Be Mailed Internationally?

The Postal Service educates the public and foreign postal administrations about limits on prohibited items in international mail.

The Postal Service educates its customers about outbound mail prohibitions by publication of country lists in the International Mail Manual (IMM), which is available to the general public as hard copy and on line via the Postal Explorer public web site at http://pe.usps.gov. These listings, alphabetical by country, reproduce the Listings of Prohibited Items that each Universal Postal Union (UPU) member country submits to the International Bureau, which serves as the UPU secretariat. For example, the IMM Country Listings identify country-specific prohibitions on shipment of substances such as butane lighters, radioactive materials, perishable infectious biological substances, live plants and animals, tobacco, foodstuffs containing saccharine, and human remains.

The U.S. government also educates foreign postal administrations about restrictions for importation of articles to the United States. The State Department has the primary responsibility for maintaining the relationship with the UPU, but USPS does fill an advisory role. The Postal Service assists in maintaining and updating a U.S. List of Prohibited Items, which is published by the UPU International Bureau. This list identifies the importation requirements for foreign mailers. Country lists are shared with foreign postal administrations, thereby enabling them to educate foreign mailers about U.S. import restrictions. In addition, the UPU maintains a copy of the publication on its website, http://www.upu.int.

With respect to the U.S., its listing identifies numerous import prohibitions, including explosives, flammable materials, poisons, narcotics, opium, opiates and the derivatives thereof, any narcotic, hallucinogenic, stimulant, or depressant drug listed as a controlled substance, adulterated or misbranded drugs, new drugs, biological products, infectious substances, and serums. It also notes that articles of that nature can be admitted conditionally, under limited circumstances, as set forth in the U.S. List Part II §§ 2.6–3.3.

As information, controlled substances are not banned *per se* from importation into the United States. The Food, Drug and Cosmetic Act (FDCA) does allow importation of drugs under certain circumstances. Postal Service management is

consulting with the Food & Drug Administration on possible updates to the U.S. Listing of Prohibited Items to ensure that current restrictions as embodied in the FDCA are reflected in the U.S. Listing.

Jurisdictional Authorities of the USPIS

Neither the Postal Inspection Service nor the U.S. Postal Service has the authority to stop packages from other countries at the border, open them and either return them by mail to the originating country or destroy them. The Postal Inspection Service does not have the authority to enforce the FDCA by intercepting drug shipments from other countries and either destroying them or sending them back. U.S. Customs and Border Protection (CBP), now part of the Department of Homeland Security, has control of U.S. Borders. Customs officials are empowered to open inbound international mail without a warrant, and under certain circumstances, may also open outbound international mail. At the border, all searches are inherently reasonable because they are border searches (see *United States v. Ramsey*, 431 U.S. 606; 97S.Ct. 1972 (1978)).

Unlike the Customs Service, the Postal Inspection Service is not charged with protecting the Nation's border. In most circumstances, if a Postal Inspector seeks to search a package, the Inspector must first obtain a federal warrant and meet the Fourth Amendment's probable cause standard. The mere fact that a package originates in another country is unlikely to rise to the level of probable cause necessary to obtain a warrant. 18 USC § 1716(d) makes reference to poisonous drugs and medicines and empowers the Postal Service to draft rules and regulations. While the Postal Service might use this authority to draft regulations allowing the Postal Inspection Service more explicit authority to investigate the shipment of drugs from other countries, section 1716 cannot be interpreted as allowing the Postal Service to draft rules overriding the Fourth Amendment by allowing the Postal Inspection Service to seize shipments from any foreign country without a warrant.

Responsibility for enforcement of FDCA rests with Health and Human Services and Customs. Title 21 provides that if drugs are intercepted by Customs, they are to be transferred to HHS, specifically the FDA. If HHS determines that the article cannot legally be imported to the United States, then Customs can destroy the shipment or arrange for it to be returned. *See* 21 USC § 381(a). The FDCA does not authorize the Postal Inspection Service to act on behalf of the FDA and Customs to enforce the Act. While the Postal Inspection Service could open an investigation in response to a consumer complaint or request from FDA, the Postal Inspection Service is not authorized to seize the mail and destroy it.

Neither the FDCA nor the relevant sections of Title 18 and Title 39 grant the Postal Inspection Service the independent authority to seize and search the mail for foreign originating drug shipments or to destroy or return pharmaceuticals.

Role of USPIS in Enforcement of Illegal Drugs Identified at the Border

On June 15 of this year, the Postal Service was contacted by the staff of the Senate Permanent Subcommittee on Investigations and asked what role it plays in the safeguarding of American consumers from unapproved or dangerous drugs imported into the United States. As the law enforcement and security arm of the Postal Service, representatives of the Postal Inspection Service met with staffers and described the criminal investigative programs designed to keep illegal drugs out of the U.S. mail. Our enforcement activities to date have focused on illegal drugs already present in the domestic mailstream versus the identification of illegal drugs identified at the border unless one of the other federal agencies with border responsibilities, such as Customs or FDA, notifies the Postal Inspection Service and requests that we work collaboratively with them.

Here is an example of the type of case involving illegal drugs in the mail that the Postal Inspection Service worked in collaboration with other agencies. During the recent June 17 hearing before the Senate Committee on Governmental Affairs, Francine and Bruce Haight testified to the February 12, 2001 death of their 18-year-old son Ryan Haight who died from a combination of hydrocodone, morphine and other drugs. Both the hydrocodone and the morphine were purchased over the Internet. Doctor Robert Ogle, the 56-year-old general practitioner whose name was found on a bottle of hydrocodone in Ryan Haight's room, was held financially responsible for Ryan's death and ordered to pay $2 million in damages to the boy's parents, Francine and Bruce Haight.

Texas pharmacist Clayton Fuchs, who owns an online pharmacy, was also sued by the Haights and named in the lawsuit as having sold hydrocodone to their son. In 2001, Fuchs was arrested and later convicted on charges of dispensing a controlled substance subsequent to an investigation conducted by Postal Inspectors, DEA and the Oklahoma Bureau of Narcotics. He was also convicted of money laundering and operating a criminal enterprise. Along with Fuchs, another Texas pharmacist, Waldrick Lemons, 30, was arrested and convicted on charges of conspiracy to dispense a controlled substance.

Ogle and another Texas physician who wrote prescriptions for Fuchs' online pharmacies pled guilty to charges of conspiracy to illegally distribute a controlled substance and money laundering; a third pled guilty only to the first charge. In a related case, Oklahoma doctor Ricky Joe Nelson is serving time for prescribing addictive narcotics over the Internet. He was arrested by Postal Inspectors in Fort Worth subsequent to an investigation conducted by the Postal Inspection Service together with DEA, IRS and Oklahoma Bureau of Narcotics. At the time of his arrest, Nelson was writing prescriptions at a rate of 300 per day, most often for hydrocodone and diazepam. In February 2001, his narcotics registration

number was suspended by the state for providing false information on his renewal application in 2000.

The type of online pharmacy operated by Fuchs is what is often described as a "rogue" pharmacy. Rogue pharmacies are unlicensed online operations that make most of their money not by selling maintenance drugs to fixed income older Americans but by pushing highly addictive narcotics like hydrocodone or dangerous diet drugs over the Internet. The online pharmacy business run by Clayton Fuchs did roughly 75 percent of its sales in hydrocodone. Between January 1, 2000, and March 30, 2001, his business generated about $5.6 million in controlled-substance sales. Federal prosecutors are seeking full restitution of the amount. Rogue pharmacies have recently come under increasing legal and public scrutiny. Executives of the Internet search engine Google announced earlier this year they would no longer accept advertising from unlicensed pharmacies, following similar decisions by Yahoo and Microsoft.

The Postal Inspection Service is painfully aware of Ryan Haight's story and that of a young life brought to a premature end as a result of prescription drugs purchased through the Internet prescribed by an anonymous doctor. Our agency, along with our law enforcement partners, helped bring justice to the Internet pharmacy operator, the physicians linked with Ryan's death, and several other physicians guilty of similar crimes. It is a hollow victory, however, as no measure of justice will return to the Haights their son's life. As explained to the Subcommittee, the Postal Inspection Service was pleased to have participated in this investigation and will always be willing to apply our resources to egregious crimes of this nature, especially as the use of the Internet grows.

Since the Congressional Hearings of 2001, the Postal Inspection Service was aware that prescription drugs were being illegally imported into the United States, We recognized at the time that Customs and FDA had primary jurisdiction over these matters, but to the extent the mail was used, the Postal Inspection Service would participate in a supportive role. Since then, the Postal Inspection Service has participated in several joint investigations regarding the online ordering of drugs.

In response to the Subcommittee's recent findings citing the number of illegal drugs or illegally imported drugs that enter the U.S. mail despite enforcement efforts by Customs and FDA, the Postal Inspection Service has re-examined our role for the specific purpose of determining what more can be done. Since meeting with the Subcommittee on June 18, the Postal Inspection Service has met with its law enforcement and regulatory partners, and developed a strategy for the immediate future and resolved to continue jointly seek long-term solutions.

Specifically:

- We advised Postal Inspection Service executives of the Subcommittee's concerns and of our commitment to provide whatever assistance our jurisdiction permits.

- We met with the agencies which have primary jurisdiction (DHS, DEA, FDA and Customs) in this matter and joined their interagency working group to explore new enforcement strategies that emphasize a multi-agency approach.

- We asked our field divisions to immediately contact their local interagency counterparts and assess the extent of the problem at the Miami, New York, Los Angeles, San Francisco and Chicago International (Mail) Service Centers (ISCs). Between July 6 and 15, Postal Inspectors met with CBP and FDA personnel at these ISCs and conducted reviews. During their review of the ISCs, we were able to determine that CBP was able to readily identify illegal drugs and illegally imported pharmaceuticals in the mail through a variety of methods which include x-ray, maintaining lists of target companies and countries, and by an external examination of the mail piece. Mail that was identified as containing suspected illegal drugs or illegally imported drugs was staged for FDA to make a determination if a violation of the Controlled Substance Act or Food Drug and Cosmetic Act existed. FDA inspected a portion of the suspect mail and followed their established protocols.

- We asked our field divisions to determine which, if any, state or local Internet drug task forces they participated in. We determined that the Postal Inspection Service supports state and local enforcement efforts through a number of activities ranging from participation in enforcement task forces to providing investigative attention to leads referred to us by state regulatory personnel. This includes participation in or support of local chapters of the High Intensity Drug Trafficking Area Task Force (HIDTA) and the National Association of Drug Diversion Investigators, Inc (NADDI). We support DEA sponsored diversion programs in our local field divisions where our assistance has been requested due to the use of the U.S. mail. We also assist other federal, local and state agencies involved in investigations in which the U.S. mail plays a role in the furtherance of the crime.

- We will explore with Customs and Border Protection the feasibility of cross-designating U.S. Postal Inspectors with Custom's authority to conduct warrantless searches of incoming parcels or letters suspected of containing illegal drugs. This authority will be requested for specific inter-agency operations only.

- We assisted Postal management in initiating consultations with the FDA on possible changes to the U.S. country listing in the Universal Postal Union Listing of Prohibited Items to clarify importation prohibitions on pharmaceuticals.

- The Chief Postal Inspector as President of the Postal Security Action Group (PSAG) will request that body of the Universal Postal Union to assist the United States to better identify and prevent the importation of illegal drugs through the international mail. A more direct and specific cooperative effort will be sought from those countries identified as being source countries for illegal drugs.

- Building upon the success we have had in Fraud and Child Exploitation, we have proposed initiating a joint nationwide prevention campaign in conjunction with our law enforcement and regulatory partners. A program will be designed to raise the public's awareness to the dangers this problem presents. Prevention and education campaigns greatly enhance enforcement programs, because through education we get to the root of the problem.

- Finally, we met with members of the Postal Service Office of General Counsel to explore the feasibility of applying certain elements of our jurisdiction as an alternative remedy. Specifically, we discussed the possibility of exercising our authority under Title 39, USC, 3001 (normally used to intercept and destroy lottery matter) by linking it to Title 18, USC, 1716 which prohibits the mailing of dangerous substances. The legal authority for exercising this option is, however, not free from doubt and may be subject to a challenge. Nevertheless, it offers us the opportunity to explore the possibility of using existing enforcement vehicles in the context of illegal importation of pharmaceuticals. An additional complication is that we do not have independent authority to open inbound mailpieces or to make determinations regarding violations of the FDCA. We rely on the authority of Customs and Border Protection to open the mailpieces suspected of being illegally imported and would have to rely on the FDA to identify those items which might violate the FDCA.

Conclusion

The Postal Inspection Service will do whatever it can to better address the problem of illegal drugs and illegally imported drugs in the mail. We recognize that this must be accomplished within our current jurisdictional and statutory authorities, as well as given our limited resources and as other responsibilities allow. Moreover, we will remain greatly dependent on those agencies which have primary jurisdiction in these matters. We have already begun seeking new avenues to address the problem. Investigative efforts traditionally have focused on illegal drugs as outlined in Schedule One through Four of the Controlled Substance Act. The Postal Inspection Service has memorandums of

understanding (MOUs) with other federal law enforcement and regulatory agencies to deal with illegal drugs in the mail, and an effective investigative program that demonstrates our commitment in this area. With regard to the illegal importation of drugs, we have no existing MOUs but are working with our law enforcement and regulatory partners to establish effective working relationships, specifically to address the illegal importation of items that violate the Controlled Substance Act.

We rely on our law enforcement and regulatory partners who have primary jurisdiction to take the lead in addressing the issue of non-Scheduled drugs in the mail, illegally imported controlled substances, or any drug illegally obtained or dispersed in the mail. The Postal Inspection Service does, however, and will continue to support our partners by assisting with investigations and supplementing their resources in critical areas and at critical times.

Working to reduce the opportunities where the U.S. Postal Service can be used for illegal purposes is a crucial element in our fight to keep the U.S. mail free of illegal drugs and safeguarding consumers from dangerous substances. As always, we will do our part to remove from society criminals who use the mail for illegal purposes. We appreciate your recognition of the importance of this issue and the support shown by you and your staff.

STATEMENT OF JAYSON P. AHERN

U.S. SENATE COMMITTEE ON GOVERNMENT AFFAIRS

PERMANENT SUBCOMMITTEE ON INVESTIGATIONS

BUYER BEWARE: THE DANGER OF PURCHASING PHARMACEUTICALS OVER THE INTERNET

JULY 22, 2004

INTRODUCTION:

Mr. Chairman, members of the Committee, thank you for this opportunity to testify. I am Jayson P. Ahern, Assistant Commissioner, Office of Field Operations at the Bureau of Customs and Border Protection (CBP). Today I would like to discuss with you CBPs ongoing efforts to address the ever-increasing trend of personal and bulk importation of pharmaceutical products and controlled substances into the United States.

Although the main focus of the CBP has shifted to protecting the United States from terrorist attacks, CBP also enforces over 400 requirements for more than 40 other federal agencies at U.S. borders. These include the laws that prohibit the importation of illegal or unapproved pharmaceuticals that fall under the jurisdiction of the Food and Drug Administration, or FDA as well as those controlled substances that are under the jurisdiction of the Drug Enforcement Administration or DEA.

The issue of U.S. consumers buying prescription drugs from foreign sources has become a significant concern to CBP. A growing number of Americans obtain their medications from foreign locations, often seeking out suppliers in Mexico and Canada. However, the safety of drugs purchased from these sources cannot be ensured. Drugs produced outside the United States may be counterfeit. Counterfeiting can apply to both brand name and generic products, where the identity of the source is deliberately and

fraudulently mislabeled in a way that suggests that it is the authentic approved product. An individual who receives a counterfeit medication may be at risk for a number of dangerous health consequences since these products may not contain the drug's active ingredient, may contain an insufficient quantity of the active ingredient or may have been produced with the wrong active ingredient.

CBP is concerned with several ways that pharmaceuticals are imported, including those that are purchased through the Internet and shipped through our international mail or express courier facilities; those carried into the United States by individuals transiting our land borders; and bulk shipments of adulterated or counterfeit pharmaceuticals. During the course of the past year we have taken several steps to address each of these areas of concern.

Millions of packages come through mail and express courier facilities every year. Thousands of packages, particularly in the mail, are found to contain illegal and unapproved pharmaceuticals. We also estimate that 10 million people cross the land border annually carrying the same unapproved products. Additionally, we have found bulk pharmaceutical shipments that were attempted to be imported through the mail, potentially indicating that these products could be making their way to pharmacy shelves.

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

The volume of imported material brought into the United States via the mail is overwhelming. This international mail poses several unique challenges to CBP since it is not accompanied by any electronic manifest information. One of the results of not having any electronic means of capturing data related to mail is that we do not have any precise measurement of the number of pieces of mail, much less the content, that enters into the United States each year. This is one of the reasons that CBP is working closely with the United States Postal Service and with foreign postal administrations to look at ways to capture data electronically that would be useful for enforcement and tracking purposes. The FDA has estimated that there could well be over 5,000,000 imports per year of

pharmaceuticals through the mail. While CBP does not have any confirmation of this number, it is a significant concern and we are working on a strategy to address pharmaceutical imports into the United States.

While we do not have statistics on the total number of imports of controlled substances or pharmaceuticals that enter the country each year, the USPS estimates that over 400,000,000 pieces of mail enter into the United States through the International Mail Branch (IMB) locations each year. It is significant that during Fiscal Year 2003, CBP made over 24,000 seizures and collected $4,415,086 in duty and user fees at our IMB facilities. During this period there were 12,353 pharmaceutical and controlled substance seizures that were made.

INTERAGENCY WORKING GROUP

In order to address what is clearly a growing threat to the public's health, CBP has been working cooperatively with the DEA, the FDA, the U.S. Immigration and Customs Enforcement (ICE), the United States Postal Inspection Service (USPIS), the Office of National Drug Control Policy (ONDCP), and Department of Justice (DOJ) attorneys in a working group directed at addressing issues related to the importation of prescription drugs and miscellaneous pharmaceuticals. The goals of this interagency working group are to create a strategy for enforcement, interdiction, and disposition of unlawful pharmaceuticals entering into the United States; develop proposals for joint enforcement operations at ports of entry and mutually agreed upon policies relative to unauthorized importations.
To address these very large goals, the working group developed five sub-groups to address the importation of pharmaceuticals and controlled drugs. These sub-groups are 1) targeting and data analysis, 2) public outreach, 3) industry outreach, 4) a group to review and revise procedures used at international mail and express consignment operator facilities and 5) a legal working group.

The work group is working on increasing public awareness of the dangers of foreign-made drugs by pooling agency resources to communicate a unified message. This is being done through several different means. Draft messages to the public developed by FDA are currently being reviewed by each organization for possible co-branding (i.e. CBP and DEA would authorize their emblems to be printed on the messages) and dissemination to the public. The work group is also working with the

Office of National Drug Control Policy (ONDCP) to raise the issue of drug importation safety to the highest levels.

Since a large percentage of pharmaceuticals and controlled substances arrive through the international mail or are carried by Express Consignment Operators, a separate work group was created to coordinate each of the regulatory authorities resources in these areas. The work group was charged with reviewing and revising procedures used at international mail and express consignment operator facilities in addition to assessing resources used at these locations.

The working group is also designing a valid sampling methodology to determine the number of pharmaceutical shipments being imported through each IMB and has established local pharmaceutical coordinators at each of these locations. In addition, CBP is working with FDA to develop a Standard Operating Procedure for mail operations.

OPERATION SAFEGUARD

One of the concrete results of the mail and express work group is the coordination of an enforcement effort that is being conducted at all of the International Mail Branch locations during the course of this year. The operation's goals are to identify the type, volume, and quality of pharmaceuticals imported into the United States.

Based on an enforcement effort named "Operation Safeguard" that we have carried out over the last couple of years, we have found the volume of pharmaceuticals shipped through international mail to be enormous. We have also found that a significant number of these do not contain an active pharmaceutical ingredient, but merely contain substances such as starch or sugar. Other problems include expired materials, unapproved products, improper usage instructions, and products made in facilities not under proper regulation. The vast majority of the pharmaceuticals that enter the U.S. via the mail do so in a manner that, according to the FDA, violates present FDA or other requirements. Additionally, we have found that many parcels contained different types of pharmaceuticals that, if taken simultaneously, could cause dangerous interactions. Individuals not under the direct supervision of a physician could easily purchase these products. Thus, we cannot assume that these products would be used properly.

The CBP Offices of Trade Compliance and Facilitation (OTCF) and Laboratories and Scientific Services (LSS) conducted "Operation Safeguard" blitz operations at several of the International Mail Branches (IMBs). These three-day blitzes were conducted between September 2000 and November 2003, at IMBs located at Oakland, Ca.; Dulles, Va.; Miami, Fl., New York (JFK); San Francisco, Ca.; and Carson, Ca., Buffalo, N.Y., Seattle, Dallas, Tx. and Chicago. Beginning in July 2003, the FDA participated in these blitzes with CBP. An average of 100 parcels per day were sampled at each of the IMBs. While the countries of shipment and the types of pharmaceutical shipments varied between IMBs, the prevailing conclusion of each blitz operation was that a serious health issue related to the safety of imported pharmaceuticals had been uncovered. The final assessment concluded that, "Although many drugs obtained from foreign sources claim, and may even appear to be the same as FDA-approved medications, these examination showed that many are of unknown quality/origin or are controlled substances." Some highlights from each blitz include:

Dulles & Oakland

- 80% of the sampled packages were considered personal use (generally not more than a 3-month supply) with the remaining 20% being quantities clearly intended for commercial distribution
- Of the 391 different pharmaceuticals sampled, none were manufactured for the U.S. market.
- Approximately 50% of these were foreign manufactured "gray market" versions of drugs available in the U.S.
- Numerous examples of expired product, unlabeled product packaged in unmarked plastic bags, labeling in foreign languages.
- Products found which can cause serious illness or death because of dangerous drug interactions, allergic reactions, contradictions, or improper dosing

Miami, New York, San Francisco, & Carson

- A total of 1,153 imported shipments that appeared to contain drugs were examined over the course of the four operations
- 88% were violative, the majority because they contained unapproved drugs
- Most frequent drugs examined: Lipitor, Viagra, Synthroid, and Propecia

- Drugs arrived from different countries
    1. Canada – **15.8%**
    2. India – **14.3%**
    3. Thailand – **13.8%**
    4. Philippines – **8%**
    5. The remaining **48.1%** were from various countries

Buffalo, Dallas, & Seattle

- A total of 1,713 imported drug shipments were examined over the course of the three operations
- The overwhelming majority were violative because they contained unapproved drugs (Per FDA)
- Found drugs that were subject to recall in Canada that were also the subject of an FDA consumer alert (Serevent "Diskus" and Flovent "Diskus")
- 80.9% of the drugs shipped from Canada; 16.8% from Mexico, with the balance from the United Kingdom, Thailand, Taiwan, Japan and the Netherlands
- Most frequent drugs found were Lipitor, Premarin, Fosomax, Synthroid, and Zocor
- Approximately 8% of the shipments were subjected to laboratory analysis
- Lab findings – 5 shipments were controlled substances and the remainder were gray market versions of U.S. pharmaceuticals or drugs that were never approved by the FDA

Throughout the upcoming 12 months, a series of three-day blitz operations will be conducted at the International Mail Branches (IMBs). The focus of these blitzes will be to evaluate the type, volume and quality of pharmaceutical products being shipped in the International mail packages.

The first of these blitzes was conducted at the Buffalo IMB during the period May 18-20, 2004. During this period:

- 128 packages containing pharmaceutical, medical, or vitamin products were documented.
- The majority of these products were either person-to-person shipments of vitamins, herbal products and/or cosmetics; business to person sales of supplements and cosmetics and supplements and

herbal products being returned from Canada to the U.S. manufacturer for a refund.

- Seven of these packages were detained by CBP and sent to the LSS laboratory in Chicago for testing. Lab result expected in approximately 2 weeks
- Fifty eight packages were referred to FDA for a compliance determination.
- Two products detained appeared to contain a controlled substance.

Operation Safeguard, JFK, NY IMB, June 29 – July 1, 2004

Forensic Scientists from Laboratories and Scientific Services (LSS) deployed to Jamaica, NY the week of June 28, 2004 to conduct Operation Safeguard at the JFK Airport International Mail Facility. Also participating in the operation were special agents from ICE Headquarters and the local SAIC office; investigators from the local DEA offices and investigators from the FDA.

International mail arriving at the JFK facility from various countries was examined for pharmaceutical products. The concentration of the examinations focused on the countries of Mexico, Netherlands, India and Spain. LSS documented three hundred (300) packages that contained a pharmaceutical product. Additional packages were examined that did not contain pharmaceuticals or other items of interest. Of the 300 packages, 27 were taken to the LSS laboratory in Newark for detailed chemical analysis.

With regard to specific trends or issues, this operation uncovered a substantial volume of controlled substances. Of the packages, 46% are suspected to contain controlled substances. These products were seized by CBP officers.

OPERATION SAFTEY CAP

The working group has conducted regular meetings since January, 2004, and has achieved several key accomplishments since its inception, including conducting a joint interagency enforcement operation, known as "Operation Safety Cap", which was designed to look at passenger importations of pharmaceuticals from Mexico.

Operation Safety Cap was an agency-wide plan to enforce laws related to the importation of prescription drugs at the border. Both FDA and ICE participated in the enforcement operation. The plan consisted of a public outreach period advising individuals entering the United States of existing pharmaceutical importation restrictions at the ports of Andrade, Yuma, Tecate, San Luis and Calexico followed by an enforcement effort at each of the port locations. The purpose of Operation Safety Cap was to evaluate compliance with laws related to the importation of prescription drugs by individuals entering the United States at five land border locations.

Operation Safety Cap was conducted February 12, 2004 through February 27, 2004. The operation was divided into two phases, a public outreach campaign (February 12th through February 22nd) and an enforcement action (February 23rd through February 27th). The public outreach campaign was designed to inform the public, through flyers and posters, of the dangers of consuming pharmaceuticals produced outside our borders. The flyers that were handed out were designed by both CBP and FDA.

During the enforcement effort, each location was instructed to randomly sample 100 individuals entering the United States utilizing the Customs Automated Operational System (CAOS). Undeclared pharmaceuticals were to be seized and declared pharmaceuticals exceeding personal use exemption quantities were to be detained. Subsequently, entire seizures/detentions were to be sent to the CBP lab for testing. Medication not found to be in violation of CBP law by our lab was forwarded to FDA for a final disposition determination.

During the course of the operation there were several troubling instances of returning U.S. residents receiving different medications than the ones that they thought that they were being prescribed. In one instance a prescription that was labeled as penicillin was found to be amoxicillin. This difference could potentially prove to be dangerous to someone who had an allergic reaction to different types of antibiotics. In another instance there was no active ingredient in the unmarked, undeclared bottle that was brought into the U.S. The seizure/detention rate was significant enough to warrant additional enforcement efforts at land border ports of entry.

CONCLUSION

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

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

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

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
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STATEMENT OF

JOHN M. TAYLOR, III

ASSOCIATE COMMISSIONER FOR

REGULATORY AFFAIRS

U.S. FOOD AND DRUG ADMINISTRATION

BEFORE THE

PERMANENT SUBCOMMITTEE ON INVESTIGATIONS

COMMITTEE ON GOVERNMENTAL AFFAIRS

UNITED STATES SENATE

JULY 22, 2004

Release Only Upon Delivery

INTRODUCTION

Mr. Chairman and Members of the Subcommittee, I am John M. Taylor, Associate Commissioner for Regulatory Affairs at the U.S. Food and Drug Administration (FDA or the Agency). With me is Mr. William K. Hubbard, Associate Commissioner for Policy and Planning at FDA. We appreciate having this opportunity to discuss with you the issues relating to the importation of prescription drugs into the United States and the use of the Internet to facilitate the sale of these drugs.

At FDA, our statutory responsibility is to assure the American public that the drug supply is safe, secure, and reliable. For more than 60 years, the Federal Food, Drug, and Cosmetic (FD&C) Act has ensured that Americans can be confident that, when they use an FDA-approved drug, the medicine will be safe and effective and will work as intended in treating their illness and preventing complications. In carrying out this responsibility, FDA also works to do all we can under the law to make medicines accessible and help doctors and patients to use them as effectively as possible, through such steps as expanding access to generic medicines, reducing the time and cost of showing that new medicines are safe and effective, and providing up-to-date information for health professionals and patients to obtain the benefits and avoid the risks associated with powerful medicines. That is the primary mission of the thousands of dedicated staff, including leading health care experts, doctors, economists and scientists who work tirelessly at FDA in public service for the American people. FDA remains strongly concerned about unapproved, imported pharmaceuticals whose safety and effectiveness cannot be assured because they are outside the legal structure and regulatory resources provided by Congress.

IMPORTATION OF PRESCRIPTION DRUGS

Sixty-five years ago, Congress responded to widespread instances of unsafe drugs by directing FDA to implement a system for assuring that Americans have a drug supply they can trust will not harm them. Over forty years ago, Congress required that legal drugs be proven to be effective as well, because modern medicines – when they are produced, distributed, prescribed, and used properly – should not only be safe but effective in the treatment of disease. More recently, in 1988, Congress enacted the Prescription Drug Marketing Act (PDMA) to establish additional safeguards to prevent substandard, ineffective, or counterfeit drugs from entering the U.S. Under PDMA, it is illegal for anyone other than the drug's original manufacturer to re-import a prescription drug into the U.S. that was manufactured in the U.S. This law was enacted with strong bipartisan support because of high-profile cases of unsafe and ineffective drugs entering the U.S. in large volumes. In one instance, over 2 million unapproved and potentially unsafe and ineffective Ovulen-21 "birth control" tablets from Panama were distributed into the U.S. as American goods returned. In another case, a counterfeit version of Ceclor, a widely used antibiotic at the time, found its way into the U.S. drug distribution from a foreign source. Over the years, FDA's dedicated professional staff has employed PDMA and other authorities to build a drug safety infrastructure to ensure that Americans enjoy the highest-quality drug supply in the world.

Unfortunately, the drug supply is under unprecedented attack from a variety of increasingly sophisticated threats. This is evident in the recent significant increase in efforts to introduce counterfeit drugs into the U.S. market. FDA has seen its number of counterfeit drug investigations increase four-fold since the late 1990s. Although counterfeiting was once a rare event, we are increasingly seeing large supplies of counterfeit versions of finished drugs being manufactured and distributed by well-funded and elaborately organized networks. At the same time, inadequately regulated foreign Internet sites have also become portals for unsafe and illegal drugs. For example, FDA recently worked with domestic and international authorities to shut down a website that was advertising "FDA-approved" and safe "European" birth control pills and other drugs, but was actually responsible for importing ineffective, counterfeit drugs. Evidence strongly suggests that the volume of these foreign drug importations is increasing steadily, presenting an increasingly difficult challenge for Agency field personnel at ports-of-entry, mail facilities, and international courier hubs, and our laboratory analysts and border and law enforcement partners.

FDA is doing its best to use its limited international authorities to stop the increasing flow of violative drugs into this country, but the task is daunting. Each day, thousands of individual packages containing prescription drugs are imported illegally into the U.S., simply because the sheer volume has grown to exceed the capability of FDA field personnel to properly process. FDA's Office of Regulatory Affairs has inspectors working in the field who perform investigations pertaining to imported prescription drugs, a job that is not limited to inspections at ports-of-entry.

SAFETY CONCERNS RELATING TO IMPORTATION

FDA remains concerned about the public health implications of unapproved prescription drugs from entities seeking to profit by getting around U.S. legal standards for drug safety and effectiveness. Many drugs obtained from foreign sources that either purport to be or appear to be the same as U.S.-approved prescription drugs are, in fact, of unknown quality. Consumers are exposed to a number of potential risks when they purchase drugs from foreign sources or from sources that are not operated by pharmacies properly licensed under state pharmacy laws. These outlets may dispense expired, subpotent, contaminated or counterfeit product, the wrong or a contraindicated product, an incorrect dose, or medication unaccompanied by adequate directions for use. The labeling of the drug may not be in English and therefore important information regarding dosage and side effects may not be available to the consumer. The drugs may not have been packaged and stored under appropriate conditions to prevent against degradation, and there is no assurance that these products were manufactured under current good manufacturing practice (cGMP) standards. When consumers take such medications, they face risks of dangerous drug interactions and/or of suffering adverse events, some of which can be life threatening. More commonly, if the drugs are subpotent or ineffective, they may suffer complications from the illnesses that their prescriptions were intended to treat, without ever knowing the true cause.

Patients also are at greater risk because there is no certainty about what they are getting when they purchase some of these drugs. Although some purchasers of drugs from foreign sources may receive genuine product, others may unknowingly buy counterfeit copies that contain only inert ingredients, legitimate drugs that are outdated and have been diverted to unscrupulous resellers, or dangerous sub-potent or super-potent products that were improperly manufactured. Furthermore, in the case of foreign-based sources, if a consumer has an adverse drug reaction or any other problem, the consumer may have little or no recourse either because the operator of the pharmacy often is not known, or the physical location of the seller is unknown or beyond the consumer's reach. FDA has only limited ability to take action against these foreign operators.

The Agency has responded to the challenge of importation by employing a risk-based enforcement strategy to target our existing enforcement resources effectively in the face of multiple priorities, including homeland security, food safety and counterfeit drugs. However, this system, as it works today, is already overwhelmed by the number of incoming packages, and this presents a significant ongoing challenge for the Agency.

Recent spot examinations of mail shipments of foreign drugs to U.S. consumers revealed that these shipments often contain dangerous or unapproved drugs that pose potentially serious safety problems. In 2003, inspectors found that the majority of the packages examined in these "blitzes" contained illegal, unapproved drugs. Last summer, FDA and the U.S. Customs and Border Protection agency (CBP or Customs) conducted blitz examinations on mail shipments at the Miami and New York (JFK) mail facilities in July, and the San Francisco and Carson, California, mail facilities in August. In each location, the agencies examined packages shipped by international mail over a 3-day time span. Of the 1,153 shipments examined, the overwhelming majority (1,019 packages, or 88 percent) contained unapproved drugs. The drugs arrived from many countries. For example, 16 percent entered the U.S. from Canada; 14 percent were from India; 14 percent came from Thailand, and 8 percent were shipped from the Philippines.

A second series of import blitz exams, conducted in November 2003, also revealed potentially dangerous, illegally imported drug shipments. Of the 3,375 products examined, 2,256 or 69 percent were violative. FDA found recalled drugs, drugs requiring special storage conditions and controlled substances. These blitz exams were performed at the Buffalo, Dallas, Chicago and Seattle international mail facilities and, for the first time, the private courier hubs at Memphis and Cincinnati. Canadian parcels appeared most frequently (80 percent of the mail parcels), while 16 percent were from Mexico, and the remaining 4 percent came from Japan, the Netherlands, Taiwan, Thailand and the United Kingdom.

Examples of the potentially hazardous products encountered during the exams include:

- Unapproved drugs such as 1) alti-azathioprine, an immunosuppressant drug that can cause severe bone marrow depression and can be associated with an increased risk of infection and cancer development; and 2) human growth hormone, which can have serious side effects if used inappropriately or in excessive doses.

- Controlled substances – FDA and Customs found over 25 different controlled substances, including Diazepam; Xanax; Codeine; Valium, Lorazepam, Clonazepam and anabolic steroids.

- Drugs withdrawn from the U.S. market for safety reasons such as Buscapina, which appears to be the drug dipyrone, removed from the market in 1977 due to reports of association with agranulocytosis -- a sometimes-fatal blood disease.

- Improperly packaged drugs shipped loose in sandwich bags, tissue paper or envelopes.

- Animal drugs not approved for human use such as Clenbuterol, a drug approved for the treatment of horses but also known as a substance of abuse in the "body building" community and banned by the International Olympic Committee.

- Potentially recalled drugs -- Serevent Diskus and Flovent Diskus medicines from Canada for the treatment of asthma. Shortly after the blitz, certain lots of the Canadian versions of these drugs were recalled in Canada.

- Drugs requiring risk management and/or restricted distribution programs -- for example, Canadian-manufactured isotretinoin, which in the U.S. is subject to a stringent risk management plan, under which prescribers are required to screen, educate and monitor patients to avoid certain serious risks such as birth defects.

- Drugs with inadequate labeling such as those with missing dosage information or labeling that is not in English.

INTERNET DRUG SALES

With greater and greater frequency, consumers are using the Internet to access health related information and products. Sales of consumer products over the Internet have grown rapidly, including the sale of drugs. The growth in online drug sales by reputable pharmacies has provided significant benefits to consumers. Many managed health care organizations are searching for ways to achieve cost savings and are turning to online prescription plans as a means of providing quality service at a lower cost.

A number of online drug websites, however, present risks to purchasers and unique challenges to regulators, law enforcement officials and policy makers. FDA is concerned about the public health implications of unlawful Internet drug sales, and we are responding to these concerns as we develop and implement risk-based strategies to protect the public health. FDA monitors the Internet to evaluate the quality of products and information being offered, and we encourage consumers to remain vigilant about their purchases and to rely on reputable Internet sites. But we remain concerned about consumers directly purchasing foreign unapproved drugs through the Internet, because

of the Agency's continued concerns that there is not sufficient information or means to assure that these products are as safe and effective as products sold within the United States.

In the context of prescription drug sales over the Internet, the private sector also has an important role in consumer education and in providing assurances to consumers about the quality of products and services they offer. Our challenge is to make sure that the protection for consumers who purchase prescription drugs in cyberspace is just as strong as the protection consumers enjoy when they purchase drugs at their corner pharmacy. Rapid technological developments have magnified the challenges we face. As electronic commerce embraces global markets, we need to acknowledge the need to assure safety and effectiveness regardless of the jurisdiction in which a U.S. consumer resides or the location of the pharmacy.

Benefits of Online Drug Sales

The Internet is rapidly transforming the way we live, work, and shop in all sectors of the economy. In the health sector, telemedicine allows people in remote areas to access the expertise of doctors in the nation's finest health centers. The Internet permits individuals to obtain extensive medical information to help them understand health issues and treatment options. Millions of Americans used the Internet last year to find medical information, either in documentary resources or through online discussions with health professionals. Conducting research regarding health concerns is the sixth most common reason that people use the Internet, according to the market research firm, Cyber Dialogue Inc.

The sale of most consumer products over the Internet has grown rapidly in recent years, including the sale of prescription medications. Prescription drug sales over the Internet can provide tremendous benefits to consumers. These benefits are many and include:

- Access to drugs for the disabled or otherwise homebound, for whom a trip to the pharmacy can be difficult;
- The convenience of shopping 24 hours a day; and a wide selection of pharmaceutical products;
- Privacy for those who don't want to discuss their medical needs in a public place.

FDA is aware that many reputable Internet pharmacies provide consumers seeking prescription drugs with a measure of safety, privacy and convenience. They can provide detailed information on drug interactions, and may e-mail customers if the drug they ordered has been recalled, a cheaper generic version of the drug becomes available or to remind them of prescription renewals. Some also sell drugs for less than traditional "brick-and mortar" pharmacies. Hyperlinks and search programs provide online customers with written product information and references to other sources of health information more easily than in the traditional storefront. Finally, as data sharing standards are developed and adopted, and the use of computer technology to transmit prescriptions from doctors to pharmacies expands, a reduction in prescription errors may be possible.

While online pharmaceutical sales are important for some customers, brick and mortar pharmacies can offer benefits and services that are often not available through the Internet, such as quick access to prescription drugs needed for immediate treatment. These pharmacies will undoubtedly remain an essential component in the delivery of effective health care.

In matters relating to pharmaceutical sales over the Internet, the challenge for government at both the state and Federal level is to develop and implement policies that will allow legitimate electronic commerce to flourish while continuing to assure safety and efficacy of these products. Consumers must have confidence that safeguards for online consumers are as least as protective as those at brick and mortar pharmacies.

Concerns About Online Drug Sales

As beneficial as this technology can be, the Internet also has created a marketplace for the sale of unapproved drugs, prescription drugs dispensed without a valid prescription, or products marketed with fraudulent health claims. Consumers may have difficulty identifying which sites sell legitimate products. As FDA considers the issues related to online drug sales, we recognize that there are various types of websites engaged in drug sales. Many sites focus on selling prescription drugs and are referred to by some as "Internet pharmacies." These sites offer for sale either FDA-approved prescription drug products, or in some cases, unapproved, illegal versions of prescription drugs. While Internet sites operated by legitimate, properly licensed pharmacies provide genuine benefits to consumers, sites that are unlicensed or otherwise engaged in the illegal dispensing of prescription drugs pose a serious potential threat to the health and safety of American citizens. In many cases, FDA cannot provide consumers with assurance that drugs purchased over the Internet were manufactured under cGMP requirements, even if the website appears to be based in the U.S. While the increase in "Internet pharmacies" engaged in illegal sales is seen as a potent threat, FDA believes that some of the non-pharmacy sites are also harmful. We have moved aggressively against these types of sites that unlawfully offer unapproved drug products, products making fraudulent health claims, or drugs for recreational use.

Patients who buy prescription drugs from an illegitimate site are at risk of suffering adverse events, some of which can be life threatening. These risks include potential side effects from inappropriately prescribed medications, dangerous drug interactions or drug contamination. Patients are also at risk because they often don't know what they are getting when they purchase some of these drugs. Although some patients may purchase genuine product, others may unknowingly buy counterfeit copies that contain inert ingredients, legitimate drugs that are outdated and have been diverted to illegitimate resellers, or dangerous sub-potent or super-potent products that were improperly manufactured.

FDA is concerned about the proliferation of sites that substitute a simple online questionnaire for a face-to-face examination and patient supervision by a health care

practitioner. According to the American Medical Association, a health care practitioner who offers a prescription for a patient he or she has never seen before, based solely on an online questionnaire, generally does not meet the appropriate medical standard of care. Four years ago, the Federation of State Medical Boards, Special Committee on Professional Conduct and Ethics found that "Prescribing of medications by physicians based solely on an electronic medical questionnaire clearly fails to meet an acceptable standard of care and is outside the bounds of professional conduct." This statement is especially important in light of the primary responsibility of states in regulating the practice of medicine. FDA is concerned that the use of such questionnaires may jeopardize the privacy of a patient's medical records, as online pharmacies may not properly secure data and/or comply with privacy practices required of entities covered by the Health Insurance Portability and Accountability Act.

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

"Canadian Generics" Website

A recent example illustrates some of the dangers associated with the purchase of prescription drugs from rogue pharmacy sites. Within the last six months, FDA has examined two web sites having identical web pages headlined "Canadian Generics" which were identified through spam e-mails sent to consumers. FDA has purchased prescription drugs from both of these sites, and has found that these drugs and the manner in which they are sold pose potential threats to the health and safety of consumers.

There is at least one Canadian flag on every page of these sites, as well as the words "Canadian Generics." The web sites say, "Order Canadian to get the biggest discounts!" Both of the URLs from which the orders were placed suggest the sites are located in, and operated out of, Canada. Despite these representations, however, we determined there is no evidence that the dispensers of the drugs or the drugs themselves are Canadian. The registrants, technical contacts, and billing contacts for both web sites have addresses in China. The reordering website for both purchases and its registrant, technical contact, and billing contact have addresses in Belize. The drugs were shipped from Texas, with a customer service and return address in Florida.

FDA purchased drugs described by the website as generic Viagra, generic Lipitor, and generic Ambien. None of these products, however, has a generic version approved in the U.S. or Canada. Both times, to obtain the drugs, an FDA investigator posed as a

consumer and filled out an on-line questionnaire. The investigator was never asked to provide a prescription. After each purchase, the drugs arrived packaged in heat-sealed plastic bags within a manila envelope.

Ambien is a controlled substance with a substantial potential for addiction. In addition, for both purchases, FDA's "consumer" said in the on-line questionnaire that he is taking erythromycin. The use of Viagra with erythromycin is contraindicated and, more importantly, there is a warning on the approved labeling for Lipitor about concurrent administration of Lipitor with erythromycin. Despite these critical safety issues, the website operators sent the drugs anyway.

The drugs received from the second purchase were tested in an FDA laboratory. All three samples failed, using the brand-name manufacturer's methodology. While all three samples had some level of active ingredient, the "generic" Lipitor and Viagra were found to be subpotent, while the "generic" Ambien was found to be superpotent. Two of the three drugs failed the dissolution parameters of the brand-name drugs. The third drug passed the dissolution testing, but only because it was superpotent. Two of the three samples also failed purity testing, while all three samples failed the USP criteria for content uniformity.

Consumers can, and should, be cautious when purchasing drugs online. There are legitimate sites that dispense drugs based on valid prescriptions. Consumers should check with their State Board of Pharmacy or the National Association of Boards of Pharmacy to see if the online pharmacy possesses a valid pharmacy license and has met state quality standards.

One means that consumers have at their disposal to protect themselves is the Verified Internet Pharmacy Practice Sites, or VIPPS system, developed by the National Association of Boards of Pharmacy (NABP) in choosing online pharmacies with which to do business. This program, which verifies the legitimacy of Internet sites dispensing prescription drugs, provides a "seal of approval" to sites that apply and meet state licensure requirements and NABP's standards. Although participation in the VIPPS program is voluntary, the Agency believes this program is an example of one that is helpful in assuring consumers that the Internet site they are using is reputable.

USE OF THE INTERNET TO BYPASS REGULATION

The unique qualities of the Internet, including its broad reach, relative anonymity, and ease of creating new or removing old websites, pose new challenges for the enforcement of the FD&C Act and state laws regulating the practice of medicine and the practice of pharmacy. FDA has found that many Internet sites are actually comprised of multiple related sites and links, thereby making investigations much more complex and resource intensive. The global nature of the Internet creates special problems for effective law enforcement. Different approaches to drug approval and marketing in foreign countries further complicate law enforcement issues for U.S. officials. FDA and other U.S.

government agencies must try to work with foreign governments to share information and to develop mechanisms for cooperative law enforcement, but this is a difficult task.

FDA Authority

The types of unlawful conduct that can occur when drugs are sold over the Internet are similar to unlawful activities that occur in other contexts. Under the FD&C Act, FDA has the legal authority to take action against:

- The sale, distribution or importation of an adulterated or misbranded drug;
- The sale, distribution or importation of an unapproved new drug;
- The sale or dispensing of a prescription drug without a valid prescription; and
- Counterfeit drugs.

When the Internet is used for an illegal sale, FDA, working with the Department of Justice (DOJ), must establish the grounds for a case, develop the same charges, and take the same actions as it would if another sales medium, such as a storefront or a magazine, had been used. FDA has investigated and referred numerous cases for criminal prosecution and initiated civil enforcement actions against online sellers of drugs and other FDA-regulated products, particularly sellers of drugs not approved by the Agency.

State Regulation of the Practice of Medicine and Pharmacy

The states have enacted laws regulating the practice of pharmacy and the practice of medicine to protect patients from harm resulting from the use of unsafe drugs, and the improper practice of medicine and pharmacy. Under many of these laws, to receive a prescription drug, a licensed health care practitioner who determines the appropriate treatment and issues a prescription for an FDA-approved drug generally must examine a patient. The prescription may also authorize refills. The patient then has the prescription filled by a registered pharmacist working in a licensed pharmacy that meets state standards.

Even with these Federal and state systems in place, the Internet provides ample opportunities for circumventing established safeguards. The speed, ease, and anonymity of ordering products on the Internet can attract unscrupulous sellers. Individuals not licensed to sell prescription drugs can easily create websites that appear to represent legitimate pharmacies. The fact that operators can quickly change the location and appearance of their Internet site makes enforcement all the more difficult.

Safeguards are not always maintained when drugs are purchased over the Internet. A health care practitioner may not examine the consumer prior to the purchase of drugs online. A patient-doctor relationship may not be established. Unfortunately, attempts to stop some U.S. doctors and online pharmacies from issuing online prescriptions without a physical examination have not always been successful. States face many obstacles when it comes to regulating online pharmacies. State pharmacy and medical boards have

limited resources for enforcement and state regulations may not fully address the Internet context. Many states have not yet fully determined how to address the issues that arise from online prescribing.

Jurisdictional Challenges

Online drug sales pose unique challenges for regulatory and law enforcement agencies at the state, Federal and international level. Internet technology can obscure the source of the product as well as provide a degree of anonymity to those responsible for selling and shipping the product. The parties to a transaction can be dispersed geographically and usually never meet. Thus, the regulatory and enforcement issues cross state, Federal, and international jurisdictional lines.

The sale of drugs to U.S. residents via foreign websites is an extremely challenging area. Medications sold on the Internet that may be legal in foreign countries may not be approved for sale in the U.S. Products not approved for sale in the U.S. often do not conform to the cGMP and quality assurance requirements in U.S. laws and regulations, and it is illegal for a foreign pharmacy to ship such drugs into the U.S. Foreign sales pose the most difficult challenge for U.S. law enforcement because the seller is not within U.S. boundaries. Although FDA may have jurisdiction over a resident in a foreign country who sells in violation of the FD&C Act to a U.S. resident, from a practical standpoint, the Agency working with DOJ has a difficult time enforcing the law against foreign sellers, when they are hard to reach and outside our borders. As a result, the Agency's efforts typically focus on requesting the foreign government to take action against the seller of the product, or asking the CBP to stop the imported drug at a U.S. port-of-entry.

STATE-ENDORSED PHARMACY SITES

Recently, several governors and mayors have proposed to create systems whereby their employees and/or constituents could be directed to Canadian pharmacies for purchasing Canadian drugs. FDA has spoken with a number of such officials about our concerns, and many have declined to proceed and have turned to other legal, proven ways to safely reduce drug costs. However, some states and localities, including the state of Minnesota and the state of Wisconsin have proceeded to establish state-run websites linking citizens to entities dispensing drugs purportedly from Canada.

Recent research by the state of Minnesota pointed out significant problems related to purchasing non-FDA approved pharmaceuticals from foreign Internet pharmacies. Minnesota State health officials observed even Canadian pharmacies that participate in the Canadian Internet Pharmacy Association engaging in problematic practices during a single, voluntary, pre-announced "visit." The officials noted dozens of safety problems, such as:

1) several pharmacies used unsupervised technicians, not trained pharmacists, to enter medication orders and to try to clarify prescription questions;

2) one pharmacy had its pharmacists review 100 new prescriptions or 300 refill prescriptions per hour, a volume so high that it would have been impossible to assure safety;
3) one pharmacy failed to label its products, instead it shipped the labels unattached in the same shipping container, even to patients who received multiple medications in one shipment; and
4) drugs requiring refrigeration were being shipped un-refrigerated with no evidence that the products would remain stable.

At least one of the Canadian pharmacies visited by Minnesota health officials dispensed many drugs that apparently were not even of Canadian origin, and many of the drugs were obtained from prescriptions that had been written and rewritten across multiple Canadian provinces. These types of systematic safety problems would generally be clear regulatory violations that would not be tolerated under the comprehensive system of Federal and state regulation of drug safety in the U.S.

Similar problems have become evident in the operation of the state of Wisconsin's Prescription Drug Resource Center. In reviewing the reports submitted by the three Canadian pharmacies linked to the Wisconsin website, the Pharmacy Society of Wisconsin has identified serious breaches of the agreements under which the pharmacies participate in the state program. The Society found that of the 765 prescriptions dispensed by the pharmacies, 316 (over 41%) violated the state agreements. Specifically, 127 of the dispensed drugs were products not approved by FDA or available in the U.S., while 189 of the drugs were products not authorized by the state program. In six instances, the pharmacies improperly sent drugs requiring refrigeration through the mail. Additionally, one of the Canadian pharmacies advised the state that it intended to obtain drugs from a European supplier, even though that was specifically prohibited by its agreement. Responding to these reports, the Wisconsin Department of Health and Family Services sent letters to the three pharmacies on April 27, 2004 ordering them to cease these prohibited practices. In reaction to these reports, the executive director of the Wisconsin Pharmacy Society, which is the professional association representing licensed pharmacy practitioners in the state, concluded that "no one in Wisconsin has any real idea what these Canadian businesses are doing."

Significant safety issues surfaced when representatives of New Hampshire Governor Craig Benson visited the Canadian Internet pharmacy known as CanadaDrugs.com, located in Winnipeg, Manitoba. The "terms of service" for CanadaDrugs.com requires purchasers to agree that they "will not be liable for damages arising from personal injury or death" from the use of drugs sold by the pharmacy. Under this practice, the consumer has no recourse for injuries arising from the use of drugs from this shipper. Additionally, the website allows patients to send in their prescriptions by fax, when the practice is illegal under the law in New Hampshire and other states. CanadaDrugs.com is "accredited" only by the Internet and Mail order Pharmacy Accreditation Commission, which is a voluntary body with no legal standing and no Federal or state regulatory or enforcement authority.

FDA ACTIONS TO PROTECT PUBLIC HEALTH

FDA has long been engaged in taking steps to minimize the dangers to public health posed by the sales of drugs on the Internet. In July 1999, FDA adopted, and has since been implementing, an Internet Drug Sales Action Plan, which includes five key areas of activity:

- Engaging in public outreach and education;
- Partnering with professional organizations;
- Coordinating action with state and other Federal agencies;
- Cooperating internationally; and
- Enhanced enforcement tailored to the Internet environment.

Public Education

FDA's "Buying Rx Drugs Online" education program is a multi-media campaign, which is centered on FDA's website: http://www.fda.gov/oc/buyonline/default.htm, which can be accessed from FDA's home page. The website includes information for consumers, including tips and warnings on how to spot health fraud, frequently asked questions (FAQ's) and where to report suspected "rogue" sites. The page is one of the most frequently visited on FDA's website, and we are currently logging approximately 60,000 complaints a month in the mailbox.

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

Professional Outreach and Partnering

FDA continues to interact with organizations representing state regulatory and law enforcement bodies, consumers, health care practitioners and industry. These cooperative relationships include the following organizations:

- The National Association of Boards of Pharmacy
- The Federation of State Medical Boards
- The National Association of Attorneys General
- The American Medical Association
- The American Pharmaceutical Association
- The National Consumers League
- The American Society of Health-Systems Pharmacists
- The National Association of Chain Drug Stores

- The National Community Pharmacists Association
- Pharmaceutical Security Institute

Coordination with State and Federal Agencies

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

FDA has increased coordination with other governmental bodies and meets regularly with other Federal agencies and state officials to share information, discuss the roles and responsibilities of the parties regarding online drug sales and identify opportunities for partnering in enforcement actions. FDA maintains strong working relationships with DOJ, including the Drug Enforcement Administration (DEA) and Federal Bureau of Investigation (FBI), the U.S. Postal Inspection Service, CBP, the Office of National Drug Control and Policy (ONDCP) and other appropriate Federal and state agencies. FDA believes that cooperation among Federal agencies is particularly critical to address the sale of drugs to U.S. residents by foreign sellers.

FDA is also involved in the effort to combat an increase in the abuse of prescription drugs, which is evident in the increasing illegal sales of controlled substances on the Internet. In announcing the President's National Drug Control Strategy for 2004, ONDCP has brought together the efforts of FDA, Federal substance abuse prevention and treatment agencies, and law enforcement to bear on the factors contributing to rising prescription drug abuse. The Strategy incorporates education of medical professionals and consumers, outreach to businesses involved in Internet commerce, pharmaceutical manufacturers, and pharmacies. The new program includes a range of activities designed to reduce the abuse of prescription drugs, and includes the use of web crawler/data mining technology to identify, investigate and prosecute "pill mills" -- Internet pharmacies that provide controlled substances illegally.

In conjunction with DEA, FDA will implement additional investigative efforts and enforcement actions against the illegal sale, use, or diversion of controlled substances, including those occurring over the Internet. Many of these e-pharmacies are foreign-based and expose the purchaser to potentially counterfeit, contaminated, or adulterated products.

Enhanced Enforcement

Since 1999, FDA has aggressively expanded its investigation and enforcement activities relating to Internet drug sales because we believe that illegal online drug sales pose a significant public health risk. FDA has initially focused its enforcement activities in the following areas:

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

Through the use of various search tools and by upgrading its data handling capabilities, FDA has increased its capability to monitor the Internet and identify sites that potentially violate the FD&C Act. These actions help the Agency to better understand the type and extent of unlawful conduct on the Internet and to more accurately assess whether its enforcement efforts have had an impact on illegal behavior. FDA has reviewed thousands of websites and identified hundreds involved in the sale of drug products. But this remains a daunting task and each day new sites are identified.

Since 1999, FDA has reviewed potential enforcement actions and coordinated case assignments through the use of a case assessment or "triage" team with representatives from the Office of Enforcement and OCI within the Office of Regulatory Affairs (ORA), the Center for Drug Evaluation and Research (CDER), the Office of Chief Counsel (OCC) and the Office of Policy. Under the triage process, when FDA obtains leads on sites that potentially violate the FD&C Act from internal Internet monitoring activity, state, other Federal or foreign law enforcement agencies, consumers, Congress, or the press, the triage team evaluates leads and decides whether they should be pursued through a civil or criminal investigation. Priority is given to cases involving unapproved new drugs, health fraud, and prescription drugs sold without a valid prescription and products with the potential for causing serious or life-threatening reactions. The triage team makes referrals, when appropriate, to various offices within FDA for follow-up.

The triage process results in a better coordination of criminal and civil enforcement actions at the appropriate Agency components and reduces overlapping effort. This process helps to ensure that decisions are made in a timely way. The Agency seeks an appropriate balance in terms of achieving a maximum deterrent effect while taking action, if needed, to remove harmful products from the market. The team will continue to oversee Internet-related enforcement activities while they are being investigated, and will ensure that they are brought to appropriate conclusion.

OCI, working with OCC, is responsible for investigations of pharmacy sites and other Internet drug sites whose operations involve potential criminal activity. The Investigative Analysis Branch analyzes the information collected by OCI. After the suspect sites are researched, and possible violations are identified, the OCI field offices receive assignment for investigative work, which often includes undercover buys. Further investigation determines the bona fides of the pharmacy and doctor(s), and examines the relationship between the patient and doctor and the doctor and pharmacy.

OCI has ongoing cooperative relationships with CBP, DEA, FBI, the Postal Inspection Service and appropriate state law enforcement and regulatory agencies, and this has enhanced their investigative capabilities with regard to Internet drug sales.

The following examples of recent enforcement actions taken by FDA illustrate the serious risks to the public health posed by fraudulent or illegal drug sales utilizing the Internet.

Counterfeit Contraceptive Patches

On February 4, 2004, the FDA issued a press release warning the public about an Internet site selling contraceptive patches that contained no active ingredient, thereby providing no protection against pregnancy. The website's domain name, www.rxpharmacy.ws, is registered to American Style Products of New Delhi, India. That firm was also listed in the return address of mail parcels containing the bogus contraceptive patches. The website also sold other products that purported to be versions of FDA-approved drugs. FDA is currently analyzing these other products as well, and has urged consumers to treat any drugs purchased from this firm as being suspect. The FDA also sought and obtained the cooperation of the U.S. based Internet service provider (ISP) in discontinuing service to this website.

The bogus contraceptive patches were promoted on the website as Ortho Evra transdermal patches, which are FDA approved, and made by Johnson & Johnson's Ortho-McNeil Pharmaceutical, Inc. subsidiary. Instead of receiving the advertised Ortho Evra patches, customers received patches without the active ingredient necessary to make the patches effective. Moreover, the patches were sent in simple plastic zip-lock bags without identifying materials, lot numbers, expiration dating or any other labeling information needed to safely and effectively use this prescription product.

On February 12, 2004, FDA also obtained the cooperation of a U.S. based Internet Service Provider in discontinuing service for three additional foreign Internet sites associated with www.rxpharmacy.ws. The three newly discovered Internet sites involved were www.usarxstore.com, www.europeanrxpharmacy.com, and www.generic.com. These sites also sold other drugs that purported to be the same as FDA-approved drugs, but were in fact from unknown sources and of unknown safety and efficacy.

The FDA believes these four websites are indicative of the dangers consumers face when they purchase pharmaceuticals off the Internet. The content of each of these websites was written in perfect English, and to the average US consumer, these websites may appear to be of domestic origin. On closer inspection, none of the websites listed a physical address, telephone number or other identifiers. In fact, all four websites appear to be controlled by largely unknown business entities in various parts of the world, who sell questionable and dangerous products to unsuspecting consumers for pure profit motives.

FDA's Office of Criminal Investigation is working with Johnson & Johnson and the Department of Homeland Security's Bureau of Immigration and Customs Enforcement (ICE) to combat illegal/counterfeit drug imports, to include those facilitated by the Internet. These criminal investigations are ongoing.

NoPrescriptionpharmacy.com (Alden L. Sears)

The National Association of Boards of Pharmacy forwarded information to OCI that a website called NoPrescriptionpharmacy.com was offering for sale numerous controlled and non-controlled prescription drugs such as Clenbuterol, Clomid, Valium and Viagra without any apparent requirement for on online consultation or a doctor's prescription. Based upon this information, two separate undercover orders were made from the website. In both instances, although money orders were negotiated, no products were received despite numerous e-mail inquiries. In August 2003, search warrants were executed at the domain registrant's residence, during which time numerous anabolic steroids were seized. The domain registrant, Alden L. Spears, was arrested and charged with mail fraud. The defendant pled guilty and was sentenced on April 26, 2004. This case was investigated by both OCI and the U.S. Postal Inspection Service.

Genapharm.com

On March 9, 2004, Hadi M. Ghandour, owner of Genapharm, Inc. of Austin, Texas, pled guilty to four counts of conspiracy to introduce misbranded and unapproved new drugs into interstate commerce, counterfeiting human growth hormone, and possessing controlled drugs with intent to distribute. Ghandour admitted to engaging in a conspiracy to sell unapproved, misbranded, counterfeit and Schedule I controlled drugs from 1999 to 2001. Ghandour sold these drugs through Genapharm, Inc. and Bioscultpt Technologies, Inc., and through an Internet website, www.genapharm.com.

The drugs included:

- 1,4 Butanediol, which converts into gamma hydroxybutyric acid or GHB, a Schedule I Controlled Substance, when metabolized by the human body;
- Counterfeit human growth hormone;
- 4 Bromo-2, 5-dimethoxyphenethylamine (2CB or Nexus), a Schedule I Controlled Substance;
- BZP, which if combined with 1-(3-trifluoromethylphenyl) piperazine (TFMPP), has stimulant and hallucinogenic effects similar to 3,4-methylenedioxymethamphetamine (MDMA), or ecstasy, a Schedule I Controlled Substance; and
- Tiratricol, tri-iodothyroacetic acid (TRIAC), a potent thyroid hormone.

Two other persons involved in these offenses were previously convicted and sentenced. Ghandour faces up to five years in prison and a fine of $250,000 on each count. The investigation was conducted by FDA/OCI and the DEA, with assistance from the Dallas District Office of FDA and the Texas Department of Health.

Vinci-online.com

On August 5, 2003, Christian Frederic Finze pled guilty to charges relating to various counts of conspiracy, distribution, and importation of controlled substances as a result of a case initiated by OCI in July 2000 after Finze was identified as the principal for Vinci-online and CFF Pharma Consult. The website domain used by the defendant, Vinci-online.com, was found to be registered to CFF Pharma Consult, a German business established by the defendant to ship drugs from Germany to customers in the U.S. These shipments included 7,200 units of flunitrazepam, commonly known as Rohypnol or the "date rape drug." Flunitrazepam is not approved for manufacturing or distribution in the U.S. Vinci-online.com also offered other pharmaceutical drug products for sale via its website including controlled substances, antibiotics, anti-allergenics, weight loss medications, steroids, and hormones. Several undercover purchases of prescription drugs were made from the website without providing prescriptions. These purchases were in response to instructions on the website that consumers should place orders via e-mail. Following the e-mail purchase request, an invoice was generated instructing the purchaser to send a money order or cashier's check to Vinci American Ltd. in Las Vegas, Nevada. The products that were received as a result of these on-line purchases were sent from Germany and displayed and contained German labeling. Moreover, the products were shipped from Germany into the U.S. through the use of forged and fraudulent documents designed to deceive employees of Customs and FDA. Finze is awaiting sentencing.

Joan Davis a.k.a. Joan Smith, a co-defendant in the case, pled guilty on September 17, 2003. She was sentenced on February 9, 2004 and received 37 months' confinement and 36 months' probation.

Rx Clinic

On December 3, 2003, a 108-count indictment charging ten individuals and three companies with illegally selling controlled substances and other prescription drugs over the Internet was unsealed. The indictment charges that the defendants used an "online ordering process" to allow consumers to order prescription controlled substance drugs over the Internet, through such websites as www.get-it-on.com, without ever seeing a doctor. Defendants were charged with, among other things, conspiring to unlawfully distribute Schedule III and IV controlled substances (including weight-loss drugs Bontril, Ionamin, Phentermine, Adipex, and Meridia) without a legitimate medical purpose and outside the usual course of professional practice. Defendants include Vineet (Vincent) K. Chhabra of Florida, an owner, operator, and officer of the businesses, and Sabina S. Faruqui of Florida, an officer, manager, and operator of the businesses. Also indicted were five physicians, a pharmacist, and a partner of Chhabra's who co-owned and operated some of the websites. Various defendants are charged with money laundering, and the indictment seeks forfeiture of $125 million. Several defendants are charged with violating the FD&C Act by introducing into interstate commerce misbranded prescription drugs, including Bontril, Meridia, Xenical, and Viagra.

On December 19, Marvin Brown, a physician, and Luke Coukos, a pharmacist, entered guilty pleas to charges related to this case. Brown, a retired obstetrician-gynecologist, relinquished his DEA controlled substance registration, and turned in his licenses to practice medicine in Ohio and Massachusetts. Brown pled guilty to conspiracy to dispense and distribute controlled substances, and admitted that in the course of the conspiracy he authorized more than 22,056 prescriptions for Schedule III and IV controlled substance diet drugs. Coukos pled guilty to conspiracy to dispense and distribute controlled substances and to introduce into interstate commerce prescription drugs without the prescription of a practitioner licensed by law to administer prescription drugs. Coukos admitted that he personally dispensed at least 43,066 Schedule III and IV controlled substance prescriptions, and at least 9,055 prescriptions for non-controlled prescription drugs. Coukos was sentenced on March 12 to 60 months' incarceration and a $140,318 fine. In April, two other physicians and one other pharmacist charged in the Indictment pled guilty to conspiracy to distribute and dispense controlled substances, and await sentencing.

Kwikmed

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

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

The indictment alleged that during the course of the conspiracy the defendants and others generated sales in excess of $28 million that was billed to consumers as charges for prescription drugs, doctor consultations, and shipping. The indictment charges defendants with violations of the FD&C Act, as well as conspiracy, mail fraud, and money laundering. The charges were the result of an investigation by FDA and the U.S. Postal Inspection Service.

On October 2, 2003, William J. Clemans, a physician, pled guilty to five felonies for his involvement with these Internet websites. In his plea, Clemans admitted that generally a physician did not review questionnaires before drugs were shipped to customers.

Charges to which Clemans pled included: 1) conspiracy, 2) introduction of misbranded drugs into interstate commerce, 3) failure to register a drug manufacturer, 4) mail fraud, and 5) conspiracy to commit money laundering. Clemans also agreed to forfeit $600,000.

On December 16, 2003, Adalberto Robles Guzman, a physician also charged in this case, entered a guilty plea to two felony counts for tax evasion. In the plea agreement, Robles admitted he omitted from his tax return over $100,000 of income received from Kwikmed. Two other defendants who were owners of Kwikmed, Inc. have also pled guilty to conspiracy, introduction of misbranded drugs into interstate commerce, mail fraud, money laundering and failure to register an establishment in which drugs are manufactured; prepared; propagated; compounded; and processed.

Norfolk Men's Clinic

On February 16, 2002, a Federal jury in Alabama convicted Anton Pusztai and Anita Yates of charges arising out of the operation of an online pharmacy that illegally sold prescription drugs over the Internet to consumers. On June 18, 2002, Pusztai and Yates were sentenced respectively to more than 15 and 6.5 years in prison. Pusztai, an Australian citizen, and Yates, a resident of Clanton, Alabama, were convicted of conspiracy to commit violations of the FD&C Act, conspiracy to commit money laundering, mail fraud, dispensing misbranded drugs, and operating a drug repackaging facility not registered with FDA.

From fall 1998 to the summer of 2000, the defendants operated a website called Viagra.au.com, also known as Norfolk Men's Clinic, and related sites, that sold a variety of prescription medications. The case has been appealed to the Eleventh Circuit and is awaiting a decision. This case was investigated by FDA/OCI with assistance from State and local law enforcement.

Storefront Pharmacies

FDA has taken recent actions against so-called "storefront pharmacies," which are generally walk-in businesses, sometimes associated with Internet sites, which assist U.S. consumers in ordering prescription drugs from Canadian or other foreign pharmacies and facilitate the filling of these orders. FDA is concerned about these domestic operations that are not properly licensed under state pharmacy laws, and expose consumers to a number of potential risks. As of November 2003, twenty-two states have taken, or are prepared to take, regulatory actions against storefront pharmacies that facilitate illegal imports of prescription drugs from Canada.

Rx Depot Inc.

DOJ and FDA filed an injunction on September 11, 2003, to stop Rx Depot Inc. from causing the importation of prescription drugs from Canada in violation of U.S. law. The Agency brought the suit because the storefront chain posed a risk to public health by importing unapproved prescription drugs and drugs that may only be imported by

the U.S. manufacturer. Earlier in the year, FDA issued a warning letter to Rx Depot in conjunction with the Arkansas State Board of Pharmacy, but the company's response was inadequate. These drugs posed a public health risk because they do not have the same assurance of safety and efficacy as drugs regulated by FDA. Rx Depot and similar companies have incorrectly stated that FDA condones their activities and that their prescription medications are "FDA approved."

On November 6, 2003, Federal District Court Judge Claire V. Eagan, U.S. District Court for the Northern District of Oklahoma, granted a preliminary injunction to immediately prevent the defendants from importing prescription drugs from Canada, because the importation of such unapproved drugs was a clear violation of the FD&C Act. In addition to its unequivocal findings of law, the court found that these companies could not assure the safety of the drugs they have been importing and, as a result, in violating the law, have put Americans at risk. The court stated that "unapproved prescription drugs and drugs imported from foreign countries by someone other than the U.S. manufacturer do not have the same assurance of safety and efficacy as drugs regulated by the Food and Drug Administration." The court continued, "Because the drugs are not subject to FDA oversight and are not continuously under the custody of a U.S. manufacturer or authorized distributor, their quality is less predictable than drugs obtained in the United States."

CanaRx

On September 16, 2003, FDA issued a warning letter to CanaRx notifying the firm of our concerns about supplying prescription drugs from unregulated sources and making unwarranted claims about these products. Specifically, FDA's warning letter stated that CanaRx runs an Internet website and mail operation that illegally causes the shipment of prescription drugs from a Canadian pharmacy into the U.S., thereby exposing U.S. consumers to risky imported drug products. This potential risk is compounded by the fact that CanaRx makes misleading assurances to consumers about the safety of its drugs.

An FDA investigation of this firm showed that CanaRx operates a drug purchasing arrangement that channels drugs through companies that are not U.S. licensed pharmacies and does not consistently use shipping practices necessary to ensure its drugs are safe and effective. For example, FDA has evidence demonstrating that CanaRx shipped insulin, a product that should be stored under refrigeration, in a manner that did not satisfy the storage conditions specified in FDA approved labeling, and which could potentially compromise the safety and effectiveness of the insulin. CanaRx's response to the Agency's warning letter was inadequate, and on November 6, 2003, FDA sent a second letter reiterating our concerns about the potential safety of the product, and the firm's business practices. The investigation is ongoing.

Expedite-Rx, SPC Global Technologies, and Employer Health Options

On January 22, 2004, FDA issued a warning letter to Expedite-Rx, a technological interface, SPC Global Technologies, Ltd., a pharmacy benefits manager, and Employer

Health Options, Inc., a pharmacy benefits manager, all of Temple, Texas, notifying them that it considers their drug import program to be illegal and a risk to public health. The letter accuses the firms of facilitating illegal imports of prescription drugs from Canada and misleading the public about the drugs' safety. Expedite-Rx, which does not hold a Texas Pharmacy license, was directed by the Texas State Board of Pharmacy last July to "immediately discontinue receiving/processing prescription drug orders." FDA is reviewing information received from the three firms in response to the Warning Letter.

Internet Sales Facilitators

Last fall, the popular Internet search engines Google and Yahoo, as well as Microsoft's MSN website announced that they will stop accepting advertising from unlicensed pharmacies. America Online Inc. has said it has restricted sales of illegal drugs beginning approximately two years ago.

Increasingly over the last few years, search engines have become cluttered with links to rogue Web sites. Consumers merely type in a drug name and are linked to an array of Web sites selling prescription drugs, including controlled substances. Unlicensed pharmacies selling narcotics and other prescription drugs pay Internet search engines to link their advertisements to keywords typed in by those who use the search engines. Many of these drug sellers are located offshore and many sell prescription drugs without a valid prescription. FDA has strongly encouraged online search engines and other advertising outlets to assist in identifying and removing access to illegitimate pharmacies. The Agency has been in contact with search engines to provide information and assist them in understanding the effect on public health of accepting such advertising.

As these actions indicate, FDA intends to work closely with its partners in the individual states in support of their efforts to curtail illegal and potentially dangerous operations, especially when they involve misleading claims about drug safety. FDA has been working closely with states and private sector entities like the online search engines to address the problem of illegal Internet pharmacy issues over the past four years to protect the public health.

DRUG COUNTERFEITING

Counterfeiting of prescription drugs is a growing global concern. In fact, counterfeiting of drugs is commonplace in many countries.

In the ongoing debate over drug importation, the term "counterfeit drug" has been widely used in different contexts to mean different things. Some use the term as a catch-all to refer to all unapproved new drugs that are imported into the US. Others use it to refer to so-called "foreign versions" of FDA-approved drugs (i.e., versions of FDA-approved drugs that are not approved in the U.S. but are approved in the foreign country in which they are sold).

In fact, the term "counterfeit drug" is defined in the Food, Drug, and Cosmetic Act (Act), and it describes a narrow set of drugs. In section 201(g)(2) of the Act, "counterfeit drug" is defined as "a drug which, or the container or labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, or device, or any likeness thereof, of a drug manufacturer, processor, packer, or distributor other than the person or persons who in fact manufactured, processed, packed, or distributed such drug and which thereby falsely purports or is represented to be the product of, or to have been packed and distributed by, such other drug manufacturer, processor, packer, or distributor.

Note that a key element in this definition is the idea of fraud or deceit. The provision is aimed at products that are labeled as something other than they are. Thus, any product that is labeled or embossed with a drug trade name must be the precise product so identified or it is a counterfeit. For example, an article labeled as Viagra that is not in fact the genuine Pfizer product is a counterfeit. It makes no difference whether the counterfeit drug is an effective, chemically indistinguishable version of Pfizer's. So long as the trade name is used on the label without authorization to suggest the product is something that it is not, the product is counterfeit.

In contrast, an unapproved new drug that is not falsely labeled is not counterfeit. This includes "foreign versions" of FDA-approved drugs that are labeled with their approved foreign labeling. Again, the key distinction is the element of fraud. Suppose, for example, that a Canadian pharmacy dispensed into the U.S. a Canadian version of Paxil called "Proxy," which was manufactured by the "ACME Company" and approved for sale in Canada but which was not FDA-approved for sale in the U.S. Whether that drug was also counterfeit within the meaning of section 201(g)(2) of the Act would depend on how it was labeled. If the pharmacy labeled the Proxy as "Paxil", which is the trade name of an FDA-approved drug manufactured by GlaxoSmithKline, then the drug would be a counterfeit because the unauthorized use of the trade name would falsely suggest to the consumer that the drug he or she received was in fact GSK's FDA-approved product. If, however, the drug were labeled as Proxy that was manufactured by ACME, the product would not be counterfeit because there would be no false indication that the drug at issue was in fact FDA-approved Paxil. Even though the US consumer might think of the product as Paxil-like, the fact that the product label did not misrepresent the product's true identity would keep it outside the technical definition of a counterfeit.

In sum, the term "counterfeit drug" has a precise legal definition. Virtually all drugs that are imported by individual consumers into the U.S. are unapproved new drugs, but not all of them are counterfeit. To determine whether a drug is a "counterfeit," investigators look at the drug and at its label and packaging. If the drug is embossed or labeled with a trade name or identifying mark that suggests it is a genuine FDA-approved product, the drug itself is examined more closely. If the drug has not in fact been manufactured, packaged, processed, or distributed by the person(s) identified on the tablet or labeling, and thereby falsely represents that fact, then the drug is a counterfeit within the meaning of the Act.

In the U.S., Federal and state authorities have kept counterfeiting of drugs to a minimum because of our extensive system of laws, regulations and enforcement. As a result, Americans have a high degree of confidence in the drugs they obtain from their local pharmacy. In recent years, however, FDA has seen growing evidence of efforts by increasingly well-organized counterfeiters, backed by increasingly sophisticated technologies and criminal operations, intent on profiting from drug counterfeiting at the expense of American patients. FDA has seen its counterfeit drug investigations increase to over 20 per year since 2000, after averaging only about five per year through the late 1990's. From October 1996 through June 2004, FDA's Office of Criminal Investigations (OCI) has opened approximately 113 counterfeit drugs cases. These investigations have so far netted 77 arrests and 42 convictions.

To respond to this emerging threat, FDA convened a Counterfeit Drug Task Force that received extensive comment and ideas from security experts, Federal and state law enforcement officials, technology developers, manufacturers, wholesalers, retailers, consumer groups, and the general public. Based on these comments, on February 18, 2004, FDA issued a report that contains specific steps that can be taken now and in the future to protect consumers from counterfeit drugs and secure the U.S. drug supply chain.

The report's framework describes how to strengthen our drug safety system against modern counterfeit threats through a multi-layered strategy that includes modern anti-counterfeiting technologies. Promising developments such as "track and trace" technologies that cannot be forged like a paper drug pedigree, and verification tools built not only into tamper-resistant drug packaging but also into the drugs themselves will make our job of verifying the legitimacy of drug products much easier. FDA is working to speed the availability of these anti-counterfeiting technologies, but these technologies have not yet been proven, and they are intended to complement and reinforce an underlying system for assuring the safety and effectiveness of prescription drugs.

Thus, anti-counterfeiting technologies hold great promise for strengthening our legal drug distribution system, but to be effective they must be used in conjunction with effective legal authorities.

Reporting of Information on Counterfeit Drugs by Manufacturers

In another move to respond to the increase in counterfeit drug cases and to strengthen the Agency's and industry's collaboration in those situations where counterfeit drugs are suspected, on April 22, 2003, the Pharmaceutical Research and Manufacturers of America (PhRMA), which represents the country's major research-based pharmaceutical and biotechnology companies, announced the adoption of a voluntary program to report suspected instances of drug counterfeiting to FDA. The information provided by PhRMA members under this program will assist FDA in carrying out its responsibilities to protect the safety and integrity of the nation's drug supply. It will enhance the Agency's ability to detect quickly and remove counterfeit drugs from the marketplace.

Under this program, PhRMA member companies have agreed to notify OCI within five working days of determining that there is a reasonable basis to believe that a product has been counterfeited. The program also applies to counterfeits discovered in foreign countries if there is clear evidence that the counterfeits are intended for distribution in the U.S. Drug manufacturers already conduct their own investigations of suspected distribution of counterfeit drugs. This formal collaborative agreement will strengthen FDA's ability to assure the safety and effectiveness of drugs used by U.S. consumers. The reporting program went into effect on May 1, 2003 and has already led to some useful tips. To date, thirty-five (35) voluntary counterfeit reports have been submitted to the Agency since this agreement with PhRMA was put in place.

Recent Counterfeit and Misbranding Cases

Counterfeit Viagra

On January 9, 2004, a federal grand jury in Los Angeles indicted Khoa Twan Do (a.k.a. Chris Do) of Glendale, California on charges of trafficking in counterfeit Viagra tablets that were manufactured in the People's Republic of China. This individual allegedly conspired with a manufacturer in Beijing to import at least 40,000 counterfeit Viagra tablets into the United States. He then arranged to have the bogus Viagra tablets shipped to his business in Glendale, the location from which he would resell the counterfeit product. He had told his Beijing supplier that the counterfeit tablets needed to "look like the real thing" because "I can find many customers who want the real thing."

This individual was charged with one count of conspiracy, one count of trafficking in counterfeit goods and one count of selling a counterfeit drug. The three counts in the indictment carry a maximum possible penalty of 18 years in federal prison and a fine of more than $2 million.

Steven Gabriel Moos

On June 3, 2004, DOJ announced the indictment of Steven Gabriel Moos, an Oregon physician, on multiple criminal charges including the unlawful importation of misbranded drugs and human growth hormone; falsifying information submitted to DEA; and unlawfully obtaining controlled substances. The indictment stemmed from a multi-Agency investigation which uncovered that Moos had allegedly attempted to import drugs from China which were labeled as vitamin supplements, prednisone or blood pressure medicine but were "misbranded" to appear to be Viagra. Moos also allegedly imported misbranded human growth hormone that was not legitimately manufactured or packaged. According to the indictment, neither of these products included necessary warnings on safe used or contraindications for use; and the lack of appropriate labeling posed significant patient safety concerns.

Moos had been placed on probation by the Oregon Board of Medical Examiners in March 2000 due to his intended prescription practices. Moos allegedly later filed DEA registration forms misrepresenting his status to practice medicine. After the Board of

Medical Examiners acted to further suspend Moos' license to practice medicine in January 2003, Moos allegedly misrepresented his status to drug manufacturers and wholesalers to unlawfully maintain his access to a supply of controlled substances. This investigation was conducted by OCI, FBI, DEA and HHS/OIG. Assistance was provided by the Oregon Board of Medical Examiners and the Oregon Department of Justice Medicaid Fraud Unit.

Alliance Wholesale Distributors/Local Repack Inc./Phil & Kathy's

On September 15, 2003, FDA announced the seizure of all drug products labeled in a foreign language and/or labeled as repacked by Phil and Kathy's, Inc., d.b.a. Alliance Wholesale Distributor and/or Local Repack, Inc. of Richton Park, Ill.

FDA acted to prevent these drug products from entering the U.S. drug distribution system because there was no assurance that they were safe or effective. Many of the products received and repackaged at Local Repack were of unknown origin and their storage and handling was unverifiable. Local Repack repeatedly failed to comply with cGMP requirements. In addition, many drugs at Local Repack's facility were misbranded. These drugs posed a potentially serious or even life-threatening risk to patients who use them.

FDA inspections conducted after an August 1999 Warning Letter to Local Repack revealed significant and continuing violations. A series of inspections and other recent evidence revealed numerous deficiencies including the failure to properly handle customer complaints, discrepancies surrounding the signatures of quality control employees, records indicating the review and approval of repackaging operations before the operations were completed, incomplete or missing repackaging records, duplicate and inconsistent repackaging records for the same batch, and unreliable receiving and distribution records for drugs.

The September seizure followed the July 9, 2003, seizure of more than 4,500 bottles of prescription drugs that were being repackaged by Local Repack stemming from an investigation of counterfeit Lipitor. Many of the products seized in July were marked with expiration dates to permit them to be sold after similar U.S.-approved drugs would have expired. For example, Portuguese-labeled product that Local Repack labeled as Lipitor had expiration dates well beyond the two-year limit that is based on stability studies performed under the new drug application (NDA) approved in the U.S. for Lipitor. Furthermore, none of these products were shipped to Local Repack in authentic, original manufacturer's packaging with appropriate labeling.

On April 8, 2004 Phil and Kathy's signed a consent decree agreeing to operate in full compliance with FDA's regulations. Under the consent decree, Phil and Kathy's is prohibited from manufacturing, labeling and distributing any article of drug until it meets certain conditions, the most important of which is the FDA's determination that the firm's repackaging operations comply with cGMPs. In addition, Phil and Kathy's agreed not to repackage any foreign-labeled drugs or drugs that are in any manner inconsistent with FDA's standards for approval.

MEDICARE IMPORTATION STUDY AND TASK FORCE

Last year, when Congress enacted the Medicare Modernization Act, it recognized these safety issues and included language that authorizing a program of drug importation, but only if the Secretary of Health and Human Services could certify that implementation of the program would not compromise the safety of the U.S. prescription drug supply. At the same time, Congress directed the Secretary to conduct a comprehensive study and prepare a report to Congress on whether and how importation could be accomplished in a manner that assures safety. The Department of HHS is currently working on that analysis and the Secretary has created an intergovernmental task force, chaired by Surgeon General Richard Carmona, to steer this effort to completion.

The taskforce includes representatives from FDA, the Centers for Medicare and Medicaid Services, CBP, and DEA. The taskforce has brought together a wide variety of stakeholders to discuss the risks, benefits and other key implications of importing drugs into the U.S., and to offer findings to the Secretary on how to best address this issue in order to advance the public health. The statutory language and the conference report provide detailed, comprehensive requirements for the importation study. As an integral part of the study process, the task force held a series of six meetings to gather information and viewpoints from consumer groups, health care professionals, health care purchasers, industry representatives and international trade experts, and a public docket for comments was opened as well.

CONCLUSION

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

The vigilance of FDA and Customs inspectors is an important tool in detecting imported products that violate the FD&C Act. Given the available resources and competing priorities facing these agencies, however, experience shows that inspectors are unable to visually examine many of the parcels containing prescription drug products that arrive through the mail and private courier services each day. The growing volume of unapproved imported drugs, which often are generated from sales via the Internet, presents a formidable challenge.

The nature of Internet technology presents law enforcement and policy makers with unique challenges. FDA is grappling with these challenges, and we must strive to

carefully balance consumer access to information and products with protecting the public health. We are aggressively using our existing educational, compliance and enforcement tools to combat the proliferation of unsafe or fraudulent pharmaceuticals on the Internet, and we will continue to evaluate what changes in our procedures, regulations, or the law might be appropriate to enhance our efforts. Our goal is to ensure that the protections afforded to consumers who purchase drugs from their corner drugstore also extend to consumers in the electronic marketplace.

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

Additional FDA Enforcement Actions

Christopher Lamoreaux

On July 15, 2004, a federal jury found Christopher Lamoreaux of Anaheim, CA guilty of two counts of mail fraud for defrauding his employer by accepting secret kickbacks for negotiating a contract to purchase Lipitor and Bextra from a Missouri pharmaceutical firm. Lamoreaux was formerly the president and CEO of NuCare Pharmaceuticals, Inc., a licensed repackager of pharmaceuticals located in CA that supplies drugs to urgent care facilities, indigent clinics, and occupational health clinics. In late 2002, Lamoreaux had negotiated a contract with Albers Medical, Inc., on behalf of NuCare under which NuCare purchased Lipitor and Bextra on consignment from Albers, repackaged the drugs at its facility, and then shipped the drugs to Med-Pro, another repackaging company located in Lexington, Nebraska. Lamoreaux was paid a 5 percent commission on the profits NuCare earned through these transactions. In addition, Lamoreaux secretly received more than $115,000 in illegal commissions from Albers. The additional commissions were paid to Consulting Ventures LLC, a business entity created by Lamoreaux in January 2003 and which was set up by Lamoreaux to allow him to personally profit from this contract. Lamoreaux faces a sentence of up to 40 years in federal prison without parole, plus a fine up to $500,000. This case was investigated by the Food and Drug Administration's Office of Criminal Investigations.

Counterfeit Viagra Dispensed by California Pharmacies

On June 30, 2004 FDA released a statement alerting pharmacies and the public of a small number of confirmed reports involving counterfeit Viagra after Pfizer, the legitimate manufacturer of the drug, reported to FDA that counterfeit product had had been dispensed by two pharmacies in California.

Counterfeit Viagra

On June 23, 2004 Khoa Twan Do, also known as Chris Do, pled guilty to charges of conspiracy, trafficking in counterfeit counterfeit goods, and a felony violation of the Federal Food, Drug and Cosmetic Act. In pleading guilty, the defendant admitted that he conspired with a manufacturer in Beijing to import thousands of counterfeit Viagra tablets into the United States, which he would then resell. He had told his Beijing supplier that the counterfeit tablets needed to "look like the real thing" because "I can find many customers who want the real thing."

The defendant is scheduled for sentencing in September, 2004. He faces a maximum possible penalty of 18 years in federal prison and a fine of more than $2 million.

David Palumbo

On June 16, 2004, an indictment was unsealed in San Diego, CA that charged David Palumbo, a bodybuilder and editor-in-chief of Rx Muscle magazine, with conspiring to unlawfully distribute human growth hormone and traffic in counterfeit goods. According to the indictment, Palumbo obtained counterfeit Serostim and sold it to bodybuilders who did not possess lawful prescriptions for the drug. The indictment further alleged that Palumbo sent his payments in cash by commercial interstate carriers such as Federal Express, often contained within the pages of a copy of the bodybuilding magazine he edited. The source of the counterfeit Serostim for Palumbo proved to be Bill Young who pled guilty on February 19, 2003 to trafficking in counterfeit goods. The counterfeit Serostim produced by the defendants in this case was identified by the fact that the hologram on the box was a sticker, rather than an imprint on the box itself. Palumbo faces 5 years in custody and/or a $250,000 fine.

Omega Pharmaceuticals

On June 9, 2004 Omega Pharmaceuticals, a wholesale distributor of prescription drugs, pled guilty to selling and holding for sale counterfeit prescription drugs. On February 25, 2003 OCI agents seized multiple bottles of eleven types of purported prescription drugs after executing a federal search warrant at the Daphne, Alabama office of Omega. The seized prescription drugs included Viracept made by Agouron Pharmaceuticals; Videx EC and Sustiva made by Bristol-Meyers Squibb; Crixivan made by Merck; Retrovir, Ziagen, and Trizivir made by Glaxo Smith Kline; Prilosec made by Astra Zeneca; Zyprexa made by Eli Lilly; and Kaletra and Norvir made by Abbot Laboratories. Forensic analysis subsequently confirmed that the drugs seized from Omega were, in fact, counterfeit. Records seized during the search of Omega's office verified that the company was in the business of buying and selling prescription drugs throughout the country. As part of the plea agreement, Omega agreed to the destruction of all of the drugs seized by the FDA. The company is scheduled to be sentenced in October, 2004 and faces a fine of up to $200,000

Domperidone

On June 7, 2004 FDA issued warning letters to a number of companies (http://www.fda.gov/bbs/topics/ANSWERS/2004/ANS01292.html) stating that all drug products containing domperidone (whether compounded or not) violate the Federal Food, Drug, and Cosmetic Act because they are unapproved new drugs and misbranded. In addition, distribution within the U.S., or importation of domperidone-containing products, violates the law. FDA informed the warning letter recipients that further violations of the Act may result in enforcement actions including seizure and injunction.

The Agency also issued an Import Alert that warns FDA field personnel to be on the lookout for attempts to import this drug so that it can be detained and refused admission into the U.S. if appropriate.

FDA took these actions because it has become aware that some women who breastfeed and/or pump breast milk are purchasing this drug, domperidone, from compounding pharmacies and from sources in foreign countries to increase breast milk production. Domperidone may increase the secretion of prolactin, a hormone that is needed for lactation.

Although domperidone is approved in several countries outside the U.S. to treat certain gastric disorders, it is not approved in any country, including the U.S., for enhancing breast milk production in lactating women and is also not approved in the U.S. for any indication.

TESTIMONY OF JOHN SCHEIBEL

VICE PRESIDENT, PUBLIC POLICY

YAHOO! INC.

BEFORE

PERMANENT SUBCOMMITTEE ON INVESTIGATIONS

COMMITTEE ON GOVERNMENTAL AFFAIRS

JULY 22, 2004

Chairman Coleman, Senator Levin and Members of the Subcommittee, thank you for the opportunity to testify on the extremely serious issue of 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.

Mr. Chairman, we appreciate your leadership in this critical area and we share your concern with protecting consumers. That is why, beginning in 2002, Overture, which later became a wholly-owned subsidiary of Yahoo!, took its first preliminary steps to address this issue. At that time, Overture prohibited online pharmacies from advertising that prescription drugs could be purchased without a prescription. Then, in November of 2003, we took industry-leading actions 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 in order to get placement in search results. Only those listings relevant to a search term are permitted to enter or remain in the active database. These listings are clearly labeled "Sponsor Results" throughout the Yahoo! site.

In November of 2003, Yahoo! took the unprecedented action of removing all sponsored search pharmacy listings for prescription drugs as an interim step to developing 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. The 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 join the program and comply with its terms in order to participate in the sponsored search marketplace.

Second, the advertiser is directed to Square Trade, 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 Square Trade 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, Square Trade, in a program administered in conjunction with the NCPA, regularly monitors the licensure status of participating pharmacies as well as responds to any complaints it receives regarding these pharmacies.

Any negative action taken by the licensing entity or any complaints that are substantiated by Square Trade are reported to Yahoo and the advertiser will be removed as appropriate. Complaints will also be forwarded by Square Trade to the appropriate government licensing authority.

Finally, Yahoo prohibits online pharmacies from advertising the most dangerous and abused prescription drugs -- FDA Schedule II prescription drugs -- in the Yahoo marketplace.

Yahoo believes that this five-pronged Online Pharmacy Qualification Program complements our mission of aligning 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 the 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.

Our most recent statistics demonstrate that the program is working to make this marketplace a safer place for consumers by screening out online pharmacies that have not been approved by the appropriate governmental licensing entity. We have had approximately 209 applications, of which 66 have been approved. Of these, 6 were suspended after approval. The program has caused large numbers of prospective applicants not to apply at all. Of those who have actually applied, fewer than 30% have been accepted to advertise in our online marketplace.

You have also asked for our comments on pending applicable legislation. S. 2464 introduced by Senators Coleman and Feinstein precludes the sale of prescription drugs over the Internet absent disclosure by the site of the identities and licensing information of the seller, pharmacists, or medical consultants. It also prohibits the sale of prescription drugs over the Internet absent a valid prescription as that is described. This is a very thoughtful piece of legislation.

The bill would follow the lead of the Communications Decency Act by providing that an interactive computer service provider would not be liable

under this bill on account of another person's selling or dispensing prescription drugs, provided that the interactive computer service does not exercise corporate control over such person. Senator Coleman, we applaud you for including this critical provision. It recognizes that telephone companies, Internet service providers and Internet portals should not be liable for what others place on their sites or send over their lines.

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. We always reserve the right to get better.

Thank you for the opportunity to appear before you today.

Testimony of Google Inc.
Before the
Permanent Subcommittee on Investigations
Committee on Governmental Affairs
United States Senate
July 22, 2004

Sheryl Sandberg
Vice President, Global Online Sales and Operations
Google Inc.

The Internet enables consumers to make better health care decisions. It gives consumers access to more information and options when considering medical and pharmaceutical products and services. At the same time, the Internet has brought access to a range of unsafe products, such as those offered by rogue, unlicensed, online drug-merchants. Google shares this Subcommittee's concerns regarding the online availability of dangerous, illegal, or illegally obtained drugs. To do our part, Google has taken strong voluntarily measures—going beyond existing legal requirements – to ensure that our advertising services protect our users by providing access to safe and reliable information.

Google allows only licensed pharmacies and pharmacists, verified through a rigorous third-party process, to display advertisements in the United States. In the following testimony, we explain Google's advertising platform, and detail our third-party verification program for online pharmacy advertisers. In addition, we offer our views on pending legislation in this area.

About Google

Organize the world's information and make it universally accessible and useful. This is Google's mission statement and guiding principle. When you visit www.google.com or one of our 95 other domains, you are able to search in 90 different languages across more than 4 billion webpages and more than 880 million images. Google's utility and ease of use have made it one of the world's best known brands almost entirely through word of mouth from satisfied users.

Don't be evil. Focus on the user and all else will follow. These are the core values on which the Google culture is built. By placing the interests of the user—an individual performing a search on our site—first, Google has created useful services and built a loyal user base. We are dedicated to preserving and strengthening the trust our users have placed in us, even when it means sacrificing a current or future financial advantage for our company. Google's policies regarding pharmaceutical advertising flow from our commitment to our mission, our values, and our dedication to do our best to serve our users' interests.

Google's Advertising Products

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 entering the advertising market, Google tested our belief that highly relevant advertising can be as useful as search results or other forms of content. Our advertising has the same aim as our search results: give users information they will find useful.

Google first built an advertising system for search. 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 Google website.

We offer our advertising technologies to advertisers as part of 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 Duluth to an 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

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 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. Other policies are editorial in nature. For example, we do not accept AdWords ads containing potentially misleading content.

[1] AdWords Terms and Conditions are available at <https://adwords.google.com/select/tcsandcsfinder> AdWords Editorial Guidelines are available at <https://adwords.google.com/select/guidelines.html>. AdSense Terms and Conditions are available at <https://www.google.com/adsense/localized-terms>. AdSense Program Policies are available at <https://www.google.com/adsense/policies>.

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 Google staff, 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

Our users want information about pharmaceuticals, and we know that providing relevant information from trusted sources can be critically important. We have received numerous e-mails from users 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. Relevant, 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 relating to pharmaceuticals. Our belief is supported by research showing that pharmaceutical-related advertising is strongly positive for consumers. For example, a survey published in Prevention Magazine[2] indicates that pharmaceutical-related advertising allows patients to be more involved with and make better-informed decisions regarding, their treatments. The survey supports the general consensus that direct advertising can help empower consumers to participate actively in the assessment and treatment of their ailments. Likewise, a study by the Food and Drug Administration on pharmaceutical advertising and communications documented a prevalent view among physicians that the increased consumer awareness brought about by pharmaceutical-related advertising has a beneficial effect on patient diagnosis and treatment.[3]

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 strongly committed to providing its users with information about pharmaceuticals, pharmacies, and pharmacists.

Of course, pharmaceutical advertising carries some 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. We have been working hard to implement policies that will protect our users from encountering these dangerous rogue pharmacies 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 partners is as relevant, useful, and trustworthy as possible. In the context of pharmacies and pharmacists, Google has voluntarily embraced and implemented third-party verification.

In order for an online pharmacy to advertise with Google, it must establish, to the satisfaction of a 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.

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[2] *Prevention Magazine.* International Survey on Wellness and Consumer Reaction to DTC Advertising of Prescription Drugs, 2000/2001.
[3] Available at: http://www.fda.gov/cder/ddmac/globalsummit2003/

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.

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).[4]

How the Program Works

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.[5] A SquareTrade-certified pharmacy must also, at all times, employ a licensed 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

[4] More information about SquareTrade is available at <http://www.squaretrade.com>.

[5] 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 prescription drugs imported from a Canadian pharmacy by a U.S. consumer will violate the law."

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. Through these voluntary steps, Google is proud to be taking strong action to protect its users.

The Benefits of the Google / SquareTrade Partnership

Google makes every effort to provide an advertising service that is effective for advertisers and to supply information that is 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. Google prohibits the advertisement of certain non-FDA-approved drugs such as Ephedra, Lipostabil, and Sildenatil Citrate.

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.[6]

The Evolution of Google's Current Pharmacy 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

[6] Available at <http://www.deadiversion.usdoj.gov>.

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. In April Google and SquareTrade reached an agreement and signed the contract establishing the SquareTrade Seal Program for Google online pharmacy advertisers. Once the contract was signed, Google engineers immediately began work on an automated system to block pharmacy advertisers without a SquareTrade I.D. from running ads in the United States and its territories.

The implementation of the SquareTrade certification requirement has proceeded rapidly; however, for a system as large and complex as Google's, it has proven technically challenging. When, in early May, 2004, engineers working on the automated system encountered technical obstacles that would delay the implementation, Google deployed an interim solution to accelerate the launch of our revised online pharmacy policy. Leveraging some of the engineering work, we were able to begin identifying and then manually suspending existing advertising campaigns by online pharmacy advertisers that had not yet been certified by SquareTrade. The process of checking existing accounts was completed in June, and we then instituted a short-term manual process for identifying new advertisers as online pharmacies or pharmacy affiliates.

Google has worked diligently to implement the new Pharmacy Qualification Program, and has devoted considerable human resources to consistently identify and address all online pharmacy advertisers that are subject to the policy.

The Future of Google's Online Pharmacy Policy

Google's objective is to ensure that our customers, advertisers, and partners have a trusted marketplace for information about online pharmacies. The introduction of the AdWords Online Pharmacy Process has taken us a step closer to that goal. The next phase is to finish building and implementing our fully-automated pharmacy policy monitoring system.

The automated system will identify pharmaceutical-related advertisers before they even create their first ad. When the system identifies an advertiser as an online pharmacy attempting to run ads in the Untied States or its territories, the AdWords interface will immediately present the advertisers with several options, including the option to submit a valid SquareTrade I.D. Only if the advertiser has been SquareTrade-certified will the ads appear before human review.

Without a valid SquareTrade I.D., the advertiser will be 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.

Google strives to achieve consistency and accuracy in the implementation all of our policies. We will continue to work on improving our systems and processes in order to provide the optimal user experience with the greatest benefit to our users, our partners, and our advertisers.

Comments on Pending Legislation

In connection with today's hearing, I would like to offer some brief comments on two legislative proposals currently pending before the Senate: S. 2464 (the "Internet Pharmacy Consumer Protection Act"), offered by Senator Coleman and co-sponsored by Senator Feinstein; and S. 2493 (the "Safe IMPORT Act of 2004), offered by Senator Gregg and co-sponsored by Senators Smith, Collins, Coleman, Sessions, Lott, and Enzi.

Though these two bills are quite different in scope, objective, and approach, both contain provisions that relate to neutral Internet information services like Google. As a provider of Internet-based information tools, Google has no position on the broader merits of the drug importation debate, or on the optimal mechanisms for regulation of online pharmacies; rather, our interest is to preserve the ability of Internet users to find useful and relevant information, including information about licensed pharmacies.

Let me preface my specific comments by noting that Google has been working closely with the staffs of Senators Gregg, Coleman, and Feinstein to present our concerns and, in the case of S. 2493, to suggest some effective potential alternatives. We commend those Senators and all the members of this Subcommittee for proceeding in an open and

collaborative manner. We understand that there will likely be some changes in S. 2493 to address, at least in part, our concerns. The comments that follow are based on the last published versions of the bills available at the time my testimony was submitted; those versions may well be outdated by the time of today's hearing.

In the context of pharmacy advertising, we believe that society benefits when patients with valid prescriptions can look to Google's advertising service as a way to find properly licensed pharmacies that can legally fill their prescriptions in accordance with industry best practices. Measured against that objective, Google believes that S. 2464 (Coleman/Feinstein) embodies a sensible, thoughtful, and carefully-drafted approach to Internet information and advertising services. However, as currently published, Google believes that the provisions of S. 2493 (Gregg) are so burdensome that they could force Google to consider dropping all pharmacy-related advertising, including from licensed pharmacies— thereby depriving those with valid prescriptions of a useful tool to find legitimate, law-abiding pharmacies.

In particular, I'd like to highlight two provisions in S. 2464 that Google believes should be included in any online pharmacy legislation. The first is the explicit recognition that an "Internet information location tool" should not be treated as an online pharmacy. The second is the strong, common-sense liability protection for neutral Internet intermediaries, stating that providers of interactive computer services and advertising services should not be held liable for the illegal selling or dispensing of prescription drugs when they had no ownership or control over those that actually sold or dispensed the drugs.

In contrast, the currently published version of S. 2493 would make a provider of interactive computer services or advertising services directly liable for the illegal prescribing of drugs if it ever (1) "accepts advertising for a prescription drug from an unlicensed pharmacy," or (2) "accepts advertising stating that an individual does not need a physician's prescription to obtain a prescription drug." While Google's own policies provide, without ambiguity, that we do not accept either type of advertising, the risk to Google of making even a single mistake would be serious. The bill contains nothing to mitigate this liability threat. For example, there is no safe harbor for reasonable and reasonably-enforced policies, or for violations that might occur when rogue advertisers intentionally evade those policies.

In addition, S. 2493 would effectively prevent advertising services like Google from utilizing third-party verification services like SquareTrade. The bill would require Google to have "on file a copy of the license issued to the Internet pharmacy." Google would thus be forced to should the administrative burden of gathering, verifying, storing, and updating pharmacy licenses from its advertisers. These are precisely the tasks that Google has contracted with third-party verifier SquareTrade to provide.

If subjected to the burdens imposed in S. 2493 (mandatory in-house verification of advertisers' licenses, plus strict liability for any errors or circumvention of policies), Google would have to give strong consideration to simply blocking all online pharmacy- and pharmaceutical-related advertising – including ads by licensed pharmacies; addiction treatment, detoxification and rehab sites; and drug information sites. We think that would be bad public policy.

With our SquareTrade third-party verification protections in place, Google provides a valuable information service that allows those with valid prescriptions to find, compare, and select from among properly licensed online pharmacies that are legally authorized to fill the prescriptions. We think that making it easy for Internet users to find licensed pharmacies is a key part of the overall solution to the problem of rogue pharmacies, and we urge the United States Senate to avoid burdensome liability schemes and impractical requirements, and to give workable protections -- as has consistently been done in other federal laws relating to the Internet -- to neutral interactive service providers and advertising providers.

Conclusion

While there are many complicated issues relating to online pharmaceutical sales, Google has taken decisive steps to ensure that we protect our users. Though our SquareTrade program, we make sure that the only pharmacy ads we display in the United States are from properly licensed pharmacies that are legally authorized to fill prescriptions in the United States. Google believes strongly 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 are proud to have taken a leadership role in improving the quality and safety of online prescription drug advertising.

Thank you for the opportunity to share our views on the important issues addressed by this hearing. We appreciate the committee's attention to these issues and hope that this testimony has been helpful.

TESTIMONY ON BEHALF OF FEDEX CORPORATION REGARDING INTERNET PHARMACIES

July 22, 2004

Mr. Chairman, Members of the Committee:

My name is Robert A. Bryden and I appear here today in my role as Vice President of Corporate Security for FedEx Corporation. We appreciate the opportunity to testify today to add our voice to your efforts to control the illegal distribution of pharmaceutical drugs over the Internet. FedEx strongly supports U.S. efforts to control the importation of illegal drugs, including non-FDA approved pharmaceuticals from foreign markets.

FedEx specializes in fast, reliable transportation services for documents, packages and freight. FedEx employs more than 126,000 American workers. Worldwide, FedEx has a large global delivery network reaching 215 countries including every address in the U.S., moves more than 5 million packages each day, employs more than 240,000 employees and contractors, operates 643 aircraft and earns revenues of approximately $25 billion annually.

FedEx has a long and successful history of working cooperatively with law enforcement and other governmental agencies to prevent the illegal importation of drugs, including pharmaceuticals. 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 for at least two years and will continue to do so.

The recent GAO report on Internet Pharmacies (issued June 17, 2004) makes it clear that the proliferation of illegal Internet pharmacies is a serious and growing problem. FedEx has spent considerable time and effort trying to identify the scope of the problem as it relates to our business and believe that we now have a very good understanding of the issues and the magnitude. FedEx company 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 wee 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 email messages with various members of agencies represented at that original meeting. We have furnished information to law enforcement agencies when asked 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 House Energy and Commerce Committee 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.

From our perspective, enforcement is complicated by two primary factors. First, you must consider the nature of the Internet. These so called Internet pharmacy sites are "virtual entities" and cannot be linked by us to a shipping site unless law enforcement makes that association for us. We have in fact identified Internet sites that purported to be in one country and had multiple servers linked in several other countries, none of which proved to be an identifiable customer by our efforts.

We have made recommendations to both committees and to law enforcement regarding better control of Internet sites through the use of mandatory identification of points of contact, including a brick-and-mortar address prominently displayed on a pharmacy site, and the display of DEA or FDA license data on the website.

To validate our concerns about the tangled web of an Internet pharmacy's structure, we commissioned, NameProtect, Inc., a private company that is an expert on the issue, to define the scope of the problem. They analyzed approximately 400 million web pages and found 650,310 instances where the FedEx brand is used on the same page as a specified list of the top 22 drug names.[1] These initial search results contained multiple pages from the same root domain name thus they were 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.

In an effort to determine how many of these 12,200 websites were foreign, we asked NameProtect to also obtain whatever public information is available about the owners of these websites. 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. An electronic copy of all of this information, which runs some 18,000 pages, has been provided to the appropriate government agencies and this committee.

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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 webpages 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 among these number cannot be determined using the standard Google search engine. That is why we relied on the smaller NameProtect database.

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 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 may lack sufficient manpower to handle the suspected volume of illegal shipments now arriving at our ports.

We do not tolerate any attempted use of our global network or our brand for illegal purposes and take immediate steps to stop it when observed. 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 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. Often times, however, the website host is several layers removed from the actual shipper utilizing FedEx services or our logo may appear on the website but they may not even be a customer at all. In virtually all instances, the actual brick and mortar address of the Internet web site is not listed and not available to us. Clearly, individuals who sell illegal drugs do not list their real names and their real addresses on their web site. In fact, our experience is that Federal law enforcement agencies have difficulty in tracing the real address through their tracing of internet address protocols. To further complicate our efforts, we have discovered that the Internet pharmacy sites use multiple servers linked to each other, sometimes in different countries and that the actual drug shipments come from a location that is not linked to the Internet site. Hence, we have been unable on our own to establish a connection between the names or other information contained on foreign Internet pharmacy websites with any name or address listed in our internal FedEx customer account databases.

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 solution. We have package tracking technology that can be of significant assistance to law enforcement agencies and we can specifically target packages for inspection that they alert us to. However, we do not have law enforcement authority and do not have available the intelligence that would allow us to do more than assist law enforcement agencies as requested. We are happy to continue to work with law enforcement agencies and with the Congress to help find ways to solve this difficult law enforcement problem. But private industry cannot police these Internet pharmacy companies. We will cooperate fully with any investigation but must leave the police work up to the authorities.

Mr. Chairman, in conclusion, FedEx thanks the Committee for the opportunity to present this statement, and would be happy to respond to any inquiries on the part of Members.

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STATEMENT OF DAN SILVA
CORPORATE SECURITY MANAGER
UPS

THE DANGER OF PURCHASING PHARMACEUTICALS OVER THE INTERNET

BEFORE THE SENATE PERMANENT SUBCOMMITTEE ON INVESTIGATIONS
JULY 22, 2004

Chairman Coleman 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 morning to discuss the issue of internet pharmacies and the efforts of UPS to combat abuses involved with those pharmacies.

You have asked us to address three questions, which I will do in order. First, you have asked about efforts that we have undertaken to preclude the delivery by UPS of illegal controlled substances and other pharmaceuticals purchased over the internet. Let me state first of all that 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.

Additionally, 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 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 new 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. The applicability of this tool obviously goes well beyond the detection of illegal pharmaceuticals.

Your second question relates to current efforts with the DEA and FDA to address the issue of illegal purchases of controlled substances. On an ongoing basis, we respond to many subpoenas with information requested in support of ongoing investigations by these agencies. Additionally, we have met twice this year with officials of FDA and DEA here in Washington to discuss ways in which we might further our cooperation concerning illegal pharmaceutical shipments. 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. These meetings with FDA and DEA officials have been productive, and we will continue to meet as needed in the future.

The third question seeks our views on pending legislation regarding internet pharmacies. We support legislation that would establish clear requirements for internet pharmacies. In particular, we like provisions of the Coleman bill, S. 2464, that would require internet pharmacies to be licensed. To be licensed, the internet site would have 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, the bill 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.

These requirements are appropriate for ensuring 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 these requirements would provide 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. We support S. 2464 and similar bills, such as the Davis-Waxman bill in the House, that will address these problems.

We also support the goal of S. 2465 to insure that "a substantial majority of shipments of [illegally imported] controlled substances are identified, seized and destroyed" while efficiently using federal resources available to carry out this goal. The criminal use of the Postal Service and carriers like UPS to unwittingly deliver fraudulently declared prescription drugs into the United States is an enforcement problem for Customs, FDA and DEA. UPS alone ships more than 3 billion packages a year, about 15 million of which are imported into the U.S. We and other carriers have a limited ability to look behind declarations supplied by the shipper in the manifest. S. 2465 would direct the attention of federal agencies to this problem, and UPS would gladly work with them as we are already doing under current law.

Thank you for the opportunity to share the views of UPS and I look forward to any questions that you may have.

BUYER BEWARE: THE DANGER OF PURCHASING PHARMACEUTICALS OVER THE INTERNET

TESTIMONY OF JOSHUA L. PEIREZ
SENIOR VICE PRESIDENT AND ASSISTANT GENERAL COUNSEL
MASTERCARD INTERNATIONAL INCORPORATED

Before the
PERMANENT SUBCOMMITTEE ON INVESTIGATIONS
COMMITTEE ON GOVERNMENTAL AFFAIRS
UNITED STATES SENATE

July 22, 2004

Good morning, Chairman Coleman, Senator Levin, and Members of the Subcommittee. My name is Joshua Peirez, and I am Senior Vice President and Assistant General Counsel at MasterCard International Incorporated in Purchase, New York. It is my pleasure to appear before you today 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. 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 our customer financial institutions to shut off more than 370 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 our 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; (iii) exploring new ways to protect the MasterCard system against use for illegal activities; and (iv) working with the Drug Enforcement Administration ("DEA") and the Food and Drug Administration ("FDA") in a collaborative fashion. The efforts we have taken to date represent important steps in demonstrating MasterCard's commitment to play an appropriate role in addressing this issue. It is my belief that MasterCard could do more with the proper tools that can be provided legislatively.

An example of such a tool is included in S. 2493 introduced by Senator Judd Gregg (R-NH), the Safe IMPORT Act. The legislation clearly delineates those Internet pharmacies permitted to sell prescription drugs over the Internet from those that are not. Such an approach will be helpful to MasterCard in keeping prohibited transactions and entities out of our system. The Safe IMPORT Act also includes provisions intended to statutorily impose obligations on MasterCard and other financial institutions to stop payments related to illegal Internet pharmacy sales. As discussed below, we urge that changes be made to the legislation to ensure that the desired objectives can be implemented most effectively. It is MasterCard's view that the current

language of the bill could create operational difficulties and may actually diminish MasterCard's ability to meet the broader objectives intended by many policymakers. I discuss these and other issues in greater detail below.

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 our 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 core fundamental rule of our 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. We are sensitive to the fact that our 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 our rules, law enforcement's ability to gather evidence through our 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, we 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, we met with staff of this Subcommittee to discuss how MasterCard handles these issues, and what role MasterCard could play in the future. That meeting with your staff, Mr. Chairman, was 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. We 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 we 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, we have 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 we successfully established lines of communication that remain open in order to exchange information and do our part to assist in apprehending those violating the law. We have also provided information to the DEA on several occasions to help it with ongoing investigations.

Second, we sent a bulletin entitled "MasterCard Rules Prohibit MasterCard Transactions for Illegal Activities" to all of our customer financial institutions worldwide. (See Attachment 1). This bulletin reminded our 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, we 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 stop immediately 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. We 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. We are pleased to report that, to date, these efforts have been largely successful in shutting off the acceptance of MasterCard cards at more than 370 web sites. We note, however, that we have seen already some web sites that have been terminated through one Acquirer popping up elsewhere in our system. Unfortunately, this reflects one of the limitations of private enforcement efforts by industry. Although we can be successful in shutting off web sites engaged in illegal activity, we do not have the ability to uproot the bad actors the way state and federal law enforcement could. As a result, our security personnel sometimes feel that the problem resembles a game of "whack-a-mole," where they successfully terminate a merchant in one spot only to have it pop up in another spot.

MasterCard also is working on identifying ways in which we can strengthen our existing protections against the introduction of illegal transactions into our system. In particular, we are developing a plan to use one or more third-party firms to audit Acquirers for certain merchant categories to ensure that they are complying with their due diligence and other obligations to screen merchants before authorizing them to accept our cards. Under this plan, we would likely retain auditing firms to prepare audit reports for MasterCard regarding their findings. Those reports would then be used to work with Acquirers on any areas that need improvement and to help lay the groundwork for any disciplinary action that may be necessary. The feasibility of such a program is under review at this time.

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 our understanding from staff of the DEA and FDA that these standards are almost never achieved, and therefore that the activity is virtually never legal. However, the lack of a clear prohibition has made it more difficult to educate our Acquirers about the illegality of the sale of pharmaceuticals over the Internet to U.S. cardholders.

Legislation

MasterCard agrees that federal legislation on the issue of Internet sales of pharmaceuticals could be helpful in a number of areas. The Safe IMPORT Act, for example, contains provisions that would reduce the confusion regarding a number of legal issues surrounding the sale of pharmaceuticals via the Internet. In particular, pharmacies would need to be licensed to sell pharmaceuticals using the Internet, and a list of such licensees would be made public. Such a list could be helpful to MasterCard and its customers in having a clear understanding of whether particular pharmacy merchants are engaged in legal activities. And this knowledge will be useful in preventing illegal transactions from flowing through our system.

We also note that other provisions of the Safe IMPORT Act would statutorily impose obligations on MasterCard and other financial institutions to stop transactions involving the unlawful sale of pharmaceuticals over the Internet. As noted above, MasterCard is fully committed to doing its part to address this important issue. If Congress decides that it is necessary to impose statutory obligations on payments systems, MasterCard is prepared to

comply. MasterCard requests, however, that any such statutory obligations be carefully crafted to ensure that MasterCard can be an effective participant in the fight against the illegal sale of pharmaceuticals over the Internet. Accordingly, we have a number of suggested changes to the legislation that we believe would be necessary to ensure that MasterCard can play an appropriate and effective role. For example, with respect to MasterCard and other similar payments systems, we believe the bill should impose obligations on the systems themselves rather than on the financial institutions that participate in those systems. The bill currently would impose obligations on financial institution participants in the U.S., most of whom will have little if any direct control over the Internet pharmacies Congress seeks to address. For example, in the MasterCard system, the financial institutions that would be most affected by the bill would be card issuers that issue payment cards to consumers here in the U.S. but have no relationship with, or ability to control, Internet pharmacies that are signed up by Acquirers. To address this issue, MasterCard would suggest that the obligations be imposed on MasterCard itself, and MasterCard can adopt policies and procedures to prohibit Acquirers from permitting unlicensed Internet pharmacies from submitting restricted transactions into the MasterCard system.

We also urge that the Safe IMPORT Act be modified in other respects. Currently, the bill directs that certain federal agencies adopt rules to effectuate "coding and blocking" of restricted transactions. In other words, Acquirers would be required to "code" Internet pharmaceutical sales in a certain manner, and Card Issuers in the U.S. would be required to "block" the authorization of transactions having that code. The focus on coding and blocking in S. 2493 would inadvertently undermine efforts to achieve the broader goal of permitting some Internet pharmacy sales while prohibiting others. Our system is not designed in a way that would enable us to distinguish one type of Internet pharmacy sale from another. This is because the electronic message layouts used by our system do not enable coding to make distinctions at those levels in the two seconds or so in which the message is transmitted back and forth through our system. Instead, any sale made by a pharmacy, whether for an illegal sale of prescription drugs, a legal sale of prescription drugs, or the sale of household items, could be coded as a "pharmacy" transaction. If the sale is made via the Internet, a separate code is used to indicate that fact. If the coding and blocking approach included in the bill were implemented in our system, system participants would have little choice but to over-comply and block all transactions involving both the pharmacy code and the Internet code. This would mean that transactions would be blocked regardless of whether the Internet pharmacy involved was licensed and regardless of whether a pharmaceutical was sold. To avoid this result, MasterCard suggests that the legislation be modified to provide more flexibility to allow payments systems to choose the best method available to them to prevent restricted transactions. As indicated earlier, for the MasterCard system, we would likely use an approach aimed at the front end of the system, by working with our Acquirers to stop the restricted transactions from unlicensed pharmacies from being introduced into our system in the first place.

The Safe IMPORT Act also includes a helpful provision that would provide a safe harbor for stopping "restricted transactions" from successfully flowing through the payments systems. This is an important provision because efforts by the payments systems to stop transactions that may be legal in other countries create the potential for liability and litigation. We are concerned, however, that the current safe harbor is not broad enough. For example, it is unavoidable that MasterCard and others seeking to implement procedures to stop restricted transactions will inadvertently prevent some transactions that are permissible. Indeed, there is no perfect system

for distinguishing restricted from unrestricted transactions, and it may be prudent to err on the side of over-compliance with the statutory obligations rather than run the risk of a statutory violation.

We also believe that it is important to ensure that MasterCard and other payments systems are appropriately empowered to police their own rules. As discussed above, one of the current limitations in this area that has come to our attention as a result of our ongoing efforts to stop illegal transactions is that MasterCard itself cannot actually complete an Internet prescription drug purchase to confirm that the Internet pharmacy is engaged in illegal activity. We have been informed by DEA officials that making such a transaction would cause MasterCard to violate the law. To address this issue, we urge that any legislation imposing obligations on payments systems enable those payments systems to legally engage in transactions with licensed and unlicensed pharmacies as part of their efforts to ensure compliance with payments system rules.

Finally, we urge that any legislation requiring payments systems to stop illegal Internet pharmacy transactions include provisions establishing that legislation as the uniform national standard for Internet prescription sales. It would not be appropriate to require MasterCard and others to adopt dozens of different systems to prevent certain Internet pharmaceutical transactions to comply with a variety of state laws. Given the way our system operates, we would be forced to use only the highest standard, as we cannot distinguish based on what state a cardholder resides in. Indeed, such a patchwork approach would detract from dedicating resources to a proven approach embodied in federal law.

Chairman Coleman and Senator Levin, 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 we look forward to continuing our 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.

Attachment 1

MasterCard Rules Prohibit MasterCard Transactions for Illegal Activities

Joshua Peirez, Senior Vice President and Assistant General Counsel, Legal Department

Suggested routing: Compliance Contact, Legal Contact, Principal Contact, Risk Management Contact

Summary: This bulletin reminds members of the MasterCard Standards prohibiting the use of MasterCard systems for any illegal activities and the importance of adhering to the Standards.

Action Indicator: M Mandate

Effective Date: Immediately

This bulletin reminds members of the MasterCard Standards prohibiting the use of MasterCard systems for any illegal activities and the importance of adhering to the Standards.

Background

Strict adherence to the Standards has become increasingly important as the use of the Internet and e-commerce has grown and created new means by which people may attempt to use MasterCard® payment cards as a payment mechanism for activities that may not be legal in all jurisdiction(s).

Transactions that present heightened risks of potentially illegal activity include Internet payment for transactions involving gambling, pornography, and prescription medications.

Member obligations

Members should adhere to the following obligations to ensure compliance with MasterCard Standards.

Due diligence

Under MasterCard Standards, members must conduct due diligence on those merchants they elect to acquire from before permitting those merchants to accept MasterCard payment cards. This due diligence minimally must include ensuring that each such merchant is engaged in a bona fide business and not engaged in illegal activity.

If there is reasonable doubt with respect to the legality of the merchant's activities in any jurisdictions in which it intends to provide goods or services, the acquirer should not permit the merchant to accept MasterCard payment cards and must not acquire transactions from the merchant until the legality of the merchant's activities can be confirmed.

In addition, the acquirer periodically should check the merchant's Web site and business activities after conducting the initial due diligence screening to confirm that the merchant continues to sell the goods or services for which they entered into a contractual relationship with the acquirer, and is not engaging in illegal activity or activity that is contrary to MasterCard Standards.

Properly identified transactions

Another obligation incumbent on acquiring members is to ensure that transactions are properly identified within the MasterCard system. For example, an authorization request involving Internet gambling transactions must contain the proper codes indicating that the transaction is a gaming transaction and is being conducted by the cardholder via the Internet. For more information about coding, please refer to *Global Security Bulletin* No. 10, 17 October 2000.

Comply with all applicable laws

MasterCard Standards require all members to comply with all applicable laws and not to engage in illegal behavior, or in behavior that would cause MasterCard to violate any laws. Refer to Rule 3.1 in the *Bylaws and Rules* manual, which states: "Each member must conduct its programs and other activities that utilize or otherwise involve any of the [MasterCard] Marks in compliance with the Standards and with all applicable laws and requirements imposed by government or regulatory authority."

Also, MasterCard Standards obligate acquirers to ensure that merchants comply with the Standards as well. Refer to Rule 9.1.3 in the *Bylaws and Rules* manual, which states: "[Acquiring] member is responsible for ensuring that each of its merchants complies with the Standards."

MasterCard is working with law enforcement

MasterCard is working with law enforcement officials to address situations where the legality of activities related to payment card transactions is in question. For example, in the United States, MasterCard is working with a variety of federal and state law enforcement agencies on these issues, including:

- State attorneys general
- Drug Enforcement Administration

- Food and Drug Administration
- U.S. Secret Service
- Department of Justice
- Federal Bureau of Investigation

MasterCard also requires its members to act in such a way as to not cause MasterCard to violate any law applicable to MasterCard. Members that fail to comply may be required to absorb the cost of any illegal transactions, and may be assessed, suspended, or terminated at the sole discretion of MasterCard.

For more information

If you have any questions about the issues discussed above, or if your have any other concerns, please contact the following individuals in the Law Department:

Joshua Peirez
Senior Vice President and Assistant General Counsel

Phone: 1-914-249-5903
Fax: 1-914-249-xxxx
E-mail: joshua_pierez@mastercard.com

Jodi Golinsky
Vice President and Senior Regulatory Counsel

Phone: 1-914-249-5978
Fax: 1-914-249-xxxx
E-mail: jodi_golinsky@mastercard.com

To report an illegal transaction processed by your bank's merchants, contact the appropriate law enforcement agency and one of the following:

John J. Brady
Vice President, Merchant Fraud Control

Phone: 1-914-249-5492
Fax: 1-914-249-4256
E-mail: john_brady@mastercard.com

Paul Paolucci
Director, Merchant Fraud Control

Phone: 1-914-249-5447
Fax: 1-914-249-4256
E-mail: paul_paolucci@mastercard.com

WRITTEN STATEMENT
OF
STEVE RUWE
ON BEHALF OF
VISA U.S.A. INC.
BEFORE THE
PERMANENT SUBCOMMITTEE ON INVESTIGATIONS
OF THE
COMMITTEE ON GOVERNMENTAL AFFAIRS
UNITED STATES SENATE
JULY 22, 2004

Chairman Coleman, Ranking Member Levin and the Members of the Subcommittee, my name is Steve Ruwe. I am the Executive Vice President of Operations & Risk Management 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 Subcommittee's investigation into the dangers of purchasing pharmaceuticals over the Internet.

The Visa Payment System, of which Visa U.S.A.[1] is a part, is the largest consumer payment system, and the leading consumer e-commerce payment system, in the world, with more volume than all other major payment cards combined. The Visa Payment System consists of Visa, which performs communication and settlement services for its member banks, and Visa's member banks that issue Visa payment cards or that acquire transactions from merchants that have accepted Visa payment cards in payment for transactions. Accordingly, Visa, and Visa member banks 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 banks that acquire transactions from merchants do have a direct relationship with the merchants that accept Visa payment cards and the Visa rules require these acquiring banks to assume responsibility for certain aspects of their relationships with merchants. Because Visa payment cards are accepted worldwide, many of these banks, like the merchants that they service, are located in foreign countries.

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 and cross-border transactions. Visa fully supports the Subcommittee's efforts to prevent illicit sales of prescription pharmaceuticals over the Internet.

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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.

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, using the Visa card. 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 banks to the problem of illicit activities by Internet pharmacies.

In March of 2004, Visa reminded its member banks 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 advised its member banks 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 banks to investigate these pharmacies and to terminate the acceptance of Visa cards for illicit activity.

In June of 2004, Visa retained the services of an outside firm to search the Internet for websites selling controlled substances and accepting Visa payment cards. As a result of this monitoring effort, we have had discussions with some of our member banks regarding their merchants who appear to be involved in selling controlled substances. These member banks 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 understand that S. 2493, the "Safe Importation of Medical Products and Other Rx Therapies Act of 2004," or the "Safe IMPORT Act of 2004," would place additional responsibilities on operators of payment card systems to prevent the use of payment cards in illicit Internet pharmacy 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.

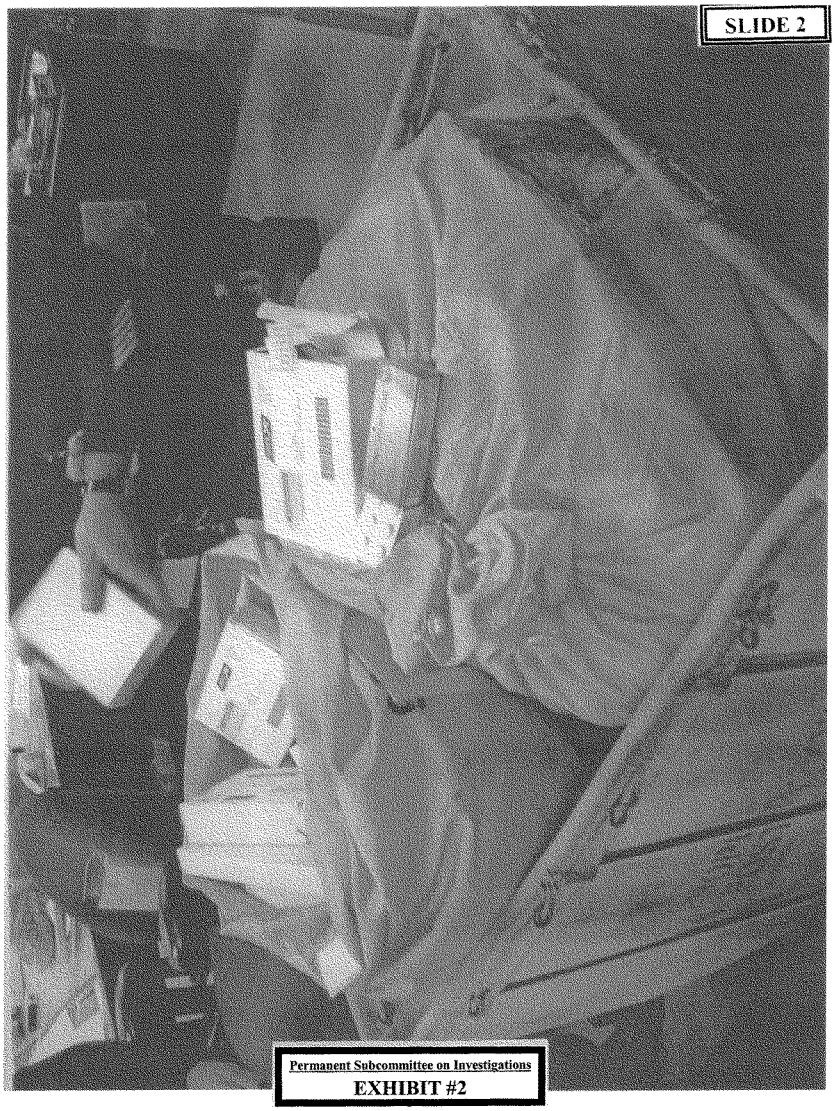
Accordingly, telephone companies, payment systems and delivery services typically are not required to know whether transactions that are effected using their facilities or services are legal. Historically, it has been only in those circumstances where the use is so unusual as to suggest illegality in its own right (such as transactions that trigger Suspicious Activity Report or Currency Transaction Report requirements) or where the illegality is overt and egregious (such as child pornography) 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. In the past, however, Congress also has recognized the costs and inefficiencies to legitimate transactions that result from compelling intermediaries to monitor the use of their facilities and services for illegal transactions, as well as the likelihood that the perpetrators will simply find other avenues to complete their illegal transactions once they become aware of such monitoring. Accordingly, this approach only has been used in limited circumstances. Further, to the extent that future technological developments to the communications industry make the task of policing illegal activity more difficult so that using intermediaries to police transactions is necessary, this approach should be used sparingly, in only the most egregious of circumstances, and after all other options have been explored before placing the burden on any particular type of communication, payment system or facility.

In this regard, I note that imposing the costs of acting as law enforcement on financial institutions, communication channels and other intermediaries for public policy purposes is effectively a tax on all of the members of the public who use those services. In choosing among alternatives, that tax, and the economic distortions that it will inevitably create, must be measured against alternative expenditures that might accomplish the same purpose—such as hiring more law enforcement personnel—even if those expenditures must be funded through more conventional taxes.

With respect to the "Safe IMPORT Act of 2004," we have reviewed this legislation and suggested technical changes to facilitate the operation of the provisions addressing the use of payment cards and other payment systems for transactions with illicit Internet pharmacies. If these provisions are adopted, Visa will move aggressively to see that the Visa Payment System complies with any applicable requirements. More broadly, however, pending adoption of additional requirements with respect to the use of payment cards in Internet pharmacy transactions, Visa will continue its history of cooperating with law enforcement efforts in the fight against illegal activity, including those involving Internet pharmaceutical sales. We will also continue to monitor the Internet for Internet pharmacies selling controlled substances.

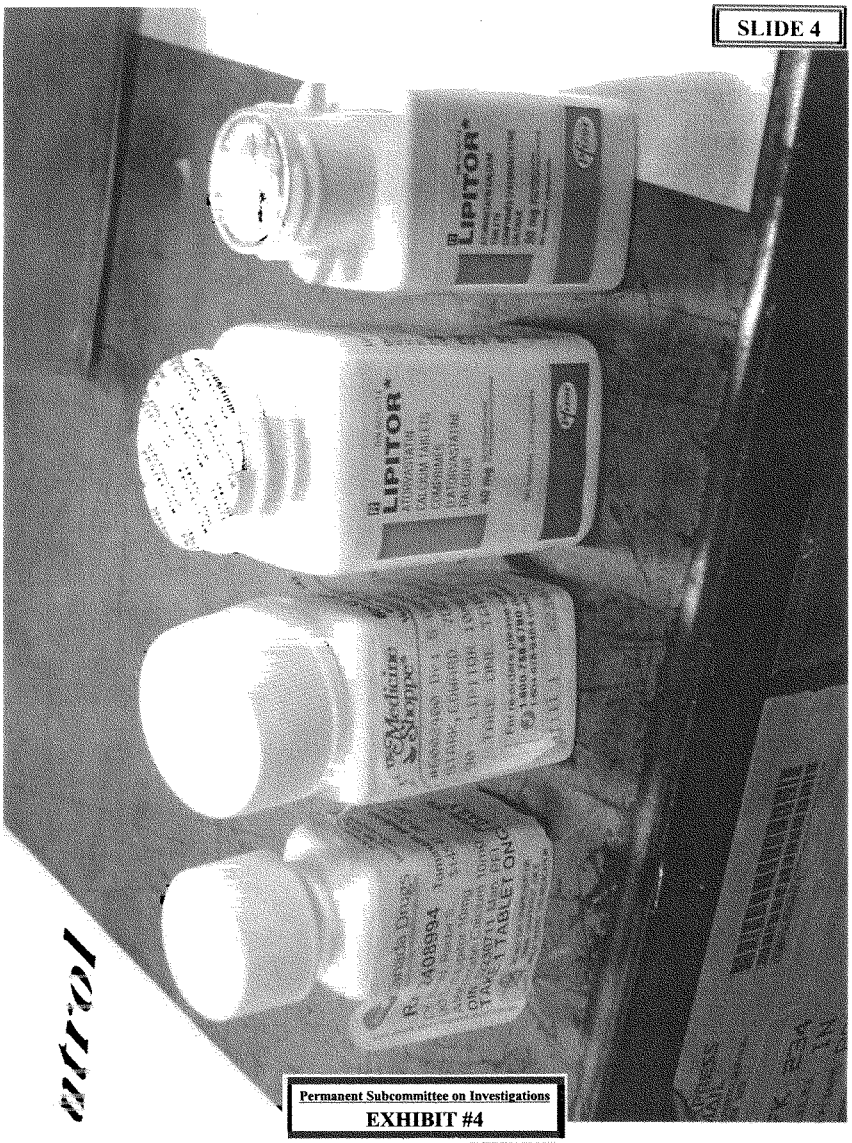
Visa appreciates the opportunity to appear before you today. I would be happy to answer any questions that you may have.

SLIDE 1
Permanent Subcommittee on Investigations
EXHIBIT #1



Permanent Subcommittee on Investigations
EXHIBIT #2

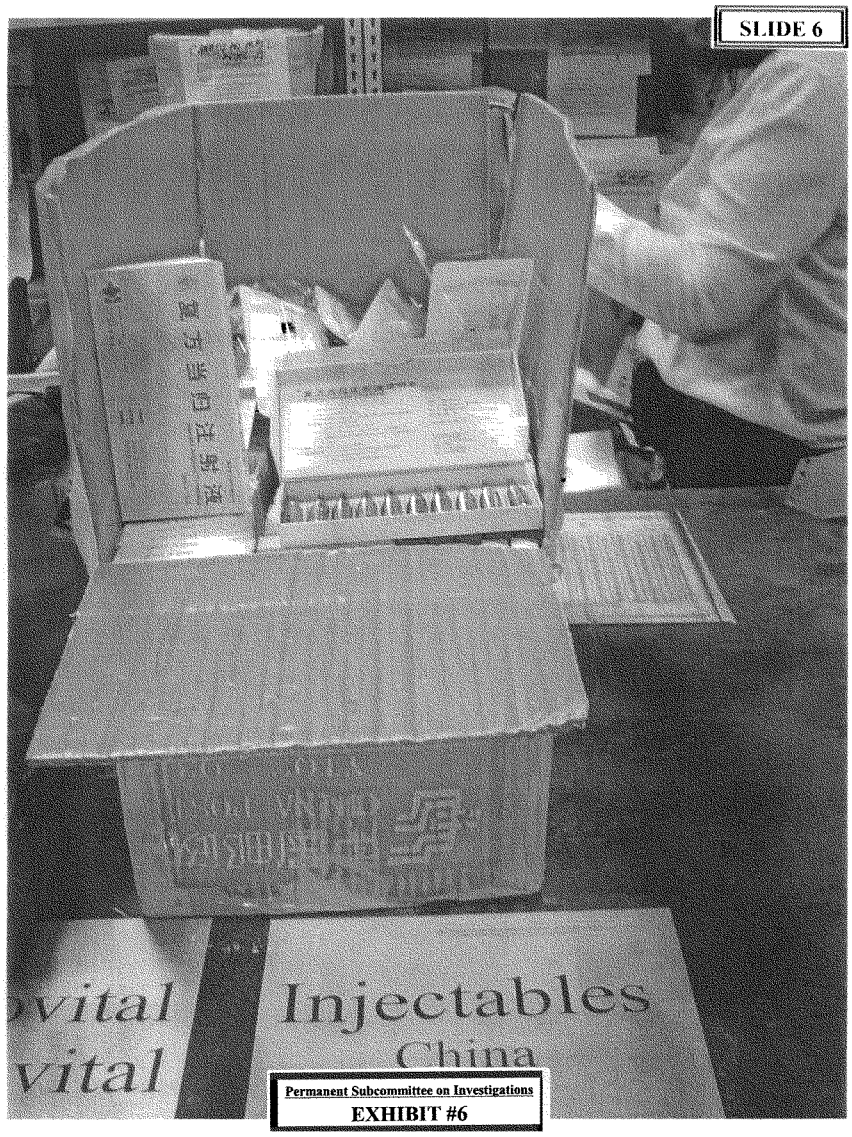
SLIDE 3
Permanent Subcommittee on Investigations
EXHIBIT #3



SLIDE 4

Permanent Subcommittee on Investigations
EXHIBIT #4

SLIDE 5
Sildenafil Citr
Silagra
Sildenafil
Citrate
Generic 'Viagra'
Permanent Subcommittee on Investigations
EXHIBIT #5


SLIDE 6
Injectables
China
Permanent Subcommittee on Investigations
EXHIBIT #6

SLIDE 7
Permanent Subcommittee on Investigations
EXHIBIT #7

SLIDE 8
LUPRON DEPOT
ACETATO DE LEUPROLIDA
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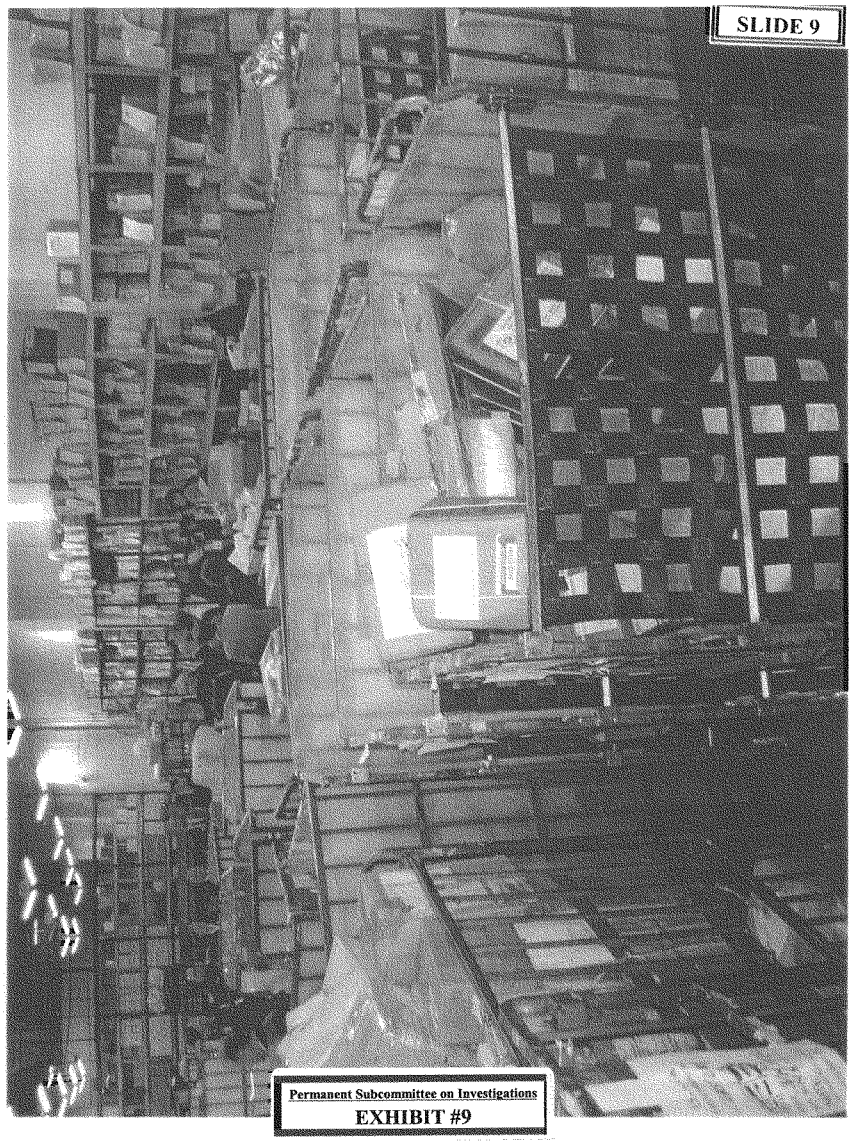
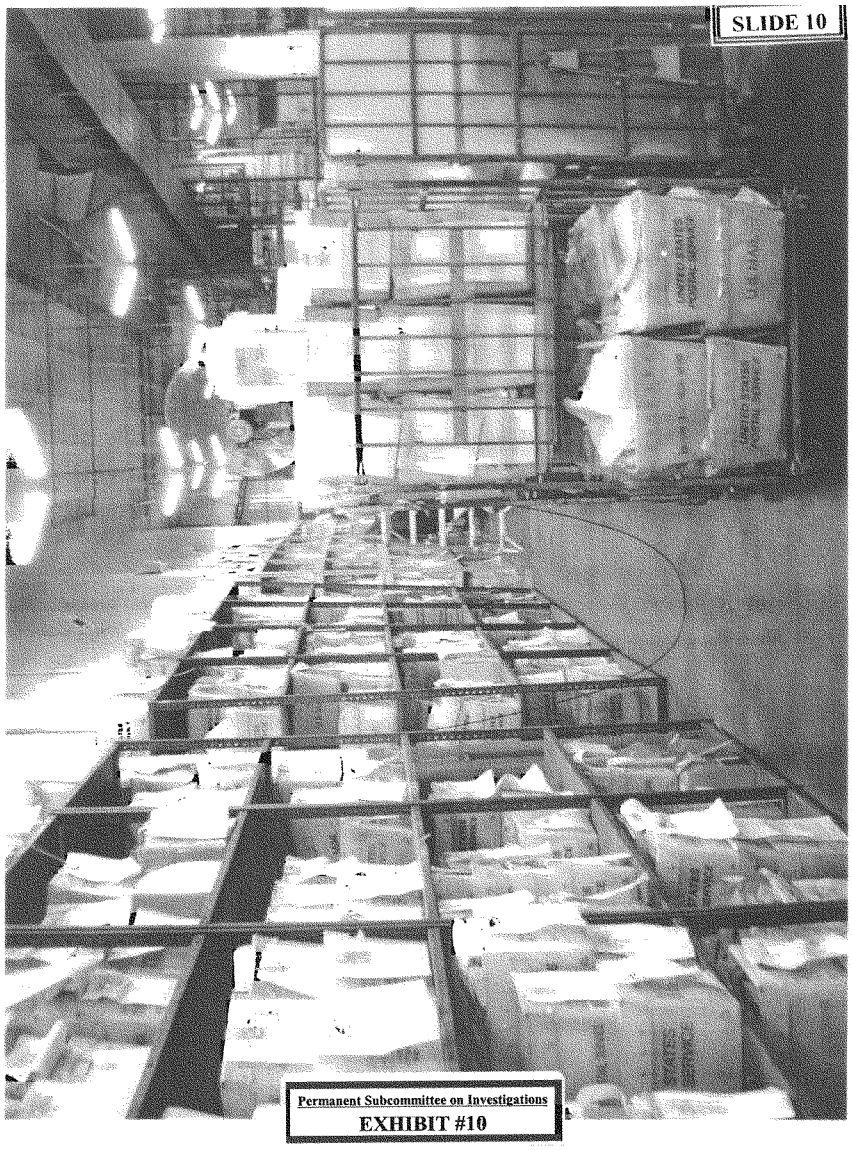
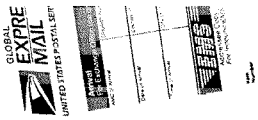
COLAR FITA ADESIVA
Permanent Subcommittee on Investigations
EXHIBIT #8


SLIDE 9
Permanent Subcommittee on Investigations
EXHIBIT #9


SLIDE 10
Permanent Subcommittee on Investigations
EXHIBIT #10

SLIDE 11

TO: CUSTO  CAGE

COUNTRIES OF INTEREST (COI)

1. AFGANISTAN
2. ALBANIA
3. ALGERIA
4. ANGOLA
5. ARGENTINA
6. ARMENIA
7. AZERBAIJAN
8. BAHRAIN
9. BANGLADESH
10. BHUTAN
11. BOSNIA & HERZEGOVINA
12. BRAZIL
13. BRUNEI
14. BURMA
15. COLOMBIA
16. CONGO
17. CYPRUS
18. DEMOCRATIC REPUBLIC OF CONGO
19. DJIBOUTI
20. EGYPT
21. ERITREA
22. EHTIOPIA
23. FRANCE
24. GAZA STRIP
25. GEORGIA
26. INDIA
27. INDONESIA
28. IRAN
29. IRAQ
30. ISRAEL
31. JORDAN
32. KAZAKSTAN
33. KENYA
34. KUWAIT
35. KYRGYSTAN
36. LEBANON
37. LIBERIA
38. LIBYA
39. MACEDONIA (SKOPJE)
40. MALAYSIA
41. MEXICO
42. MONGOLIA
43. MOROCCO
44. MYANMAR
45. NEPAL
46. OMAN
47. PAKISTAN
48. PALESTINE
49. PANAMA
50. PARAGUAY
51. PHILIPPINES
52. QATAR
53. REPUBLIC OF YEMEN (SANAA)
54. SAUDI ARABIA
55. SINGAPORE
56. SOMALIA
57. SRI LANKA
58. SUDAN
59. SYRIA
60. TAJIKISTAN
61. THAILAND
62. TUNISIA
63. TURKEY
64. TURKMENISTAN
65. UNITED ARAB EMIRATES
66. URUGUAY
67. UZBEKISTAN
68. VENEZUELA
69. WEST BANK
70. YEMEN (ADEN)
71. YEMEN (SANA REPUBLIC OF)
72. YUGOSLAVIA
73. BELGIUM
74. ECUADOR
75. GUYANA
76. HAITI
77. JAMAICA & REBUTS
78. PERU
79. DOMINICAN REPUBLIC

3/13

FROM: EXPRESS MAIL DATE: _____

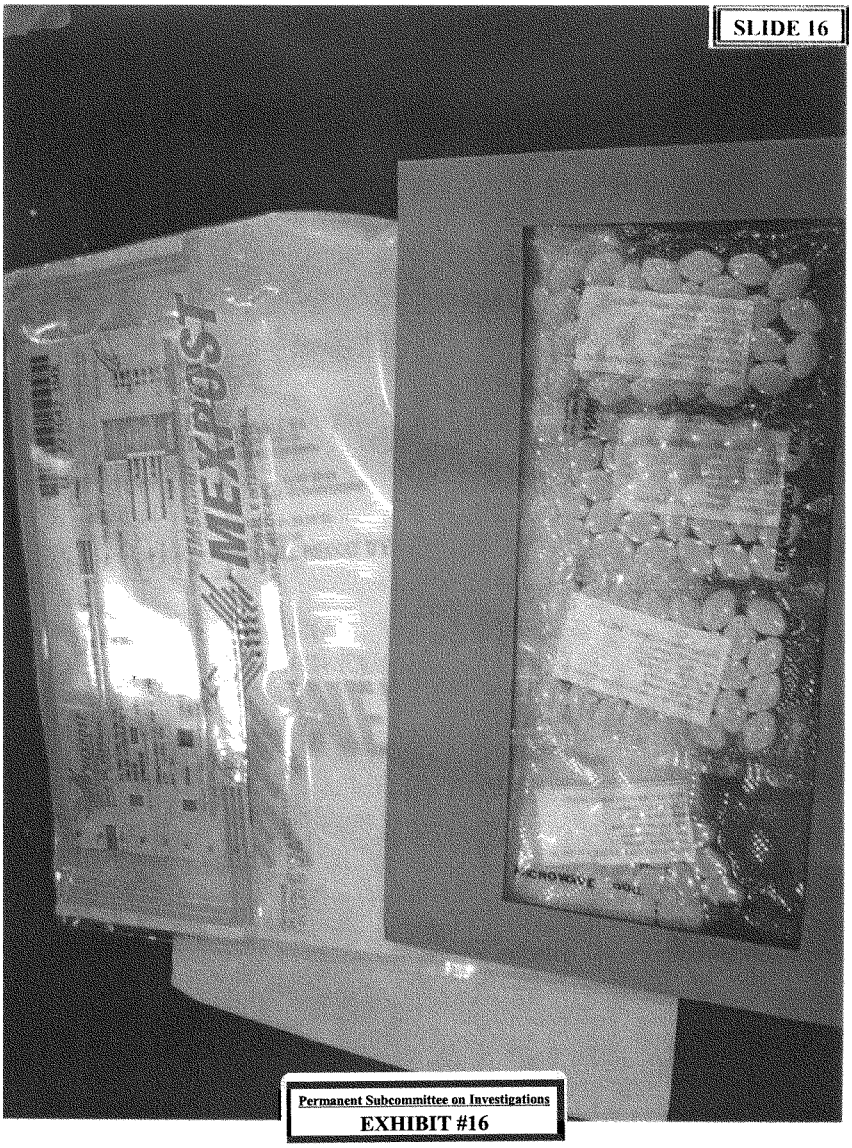
Permanent Subcommittee on Investigations
EXHIBIT #11

SLIDE 12
Permanent Subcommittee on Investigations
EXHIBIT #12

SLIDE 13
A&E MI
Permanent Subcommittee on Investigations
EXHIBIT #13

SLIDE 14
Permanent Subcommittee on Investigations
EXHIBIT #14

SLIDE 15
Permanent Subcommittee on Investigations
EXHIBIT #15



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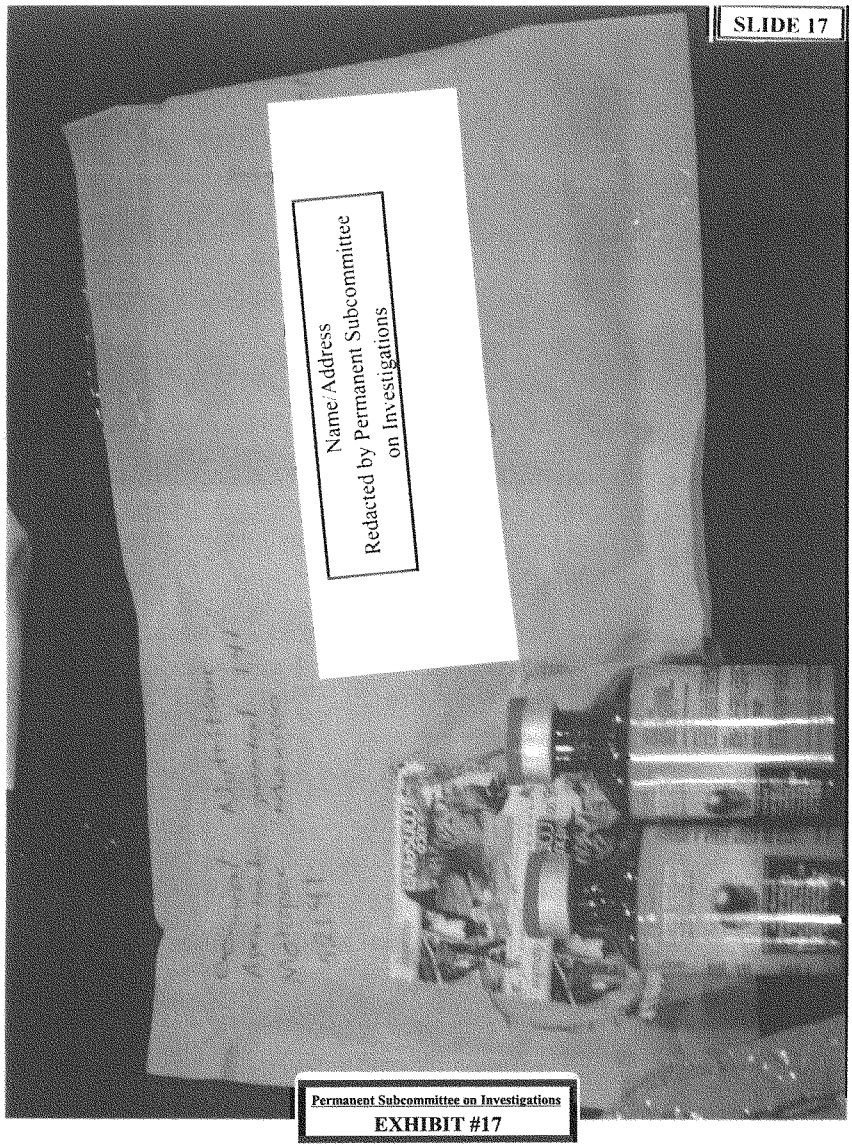
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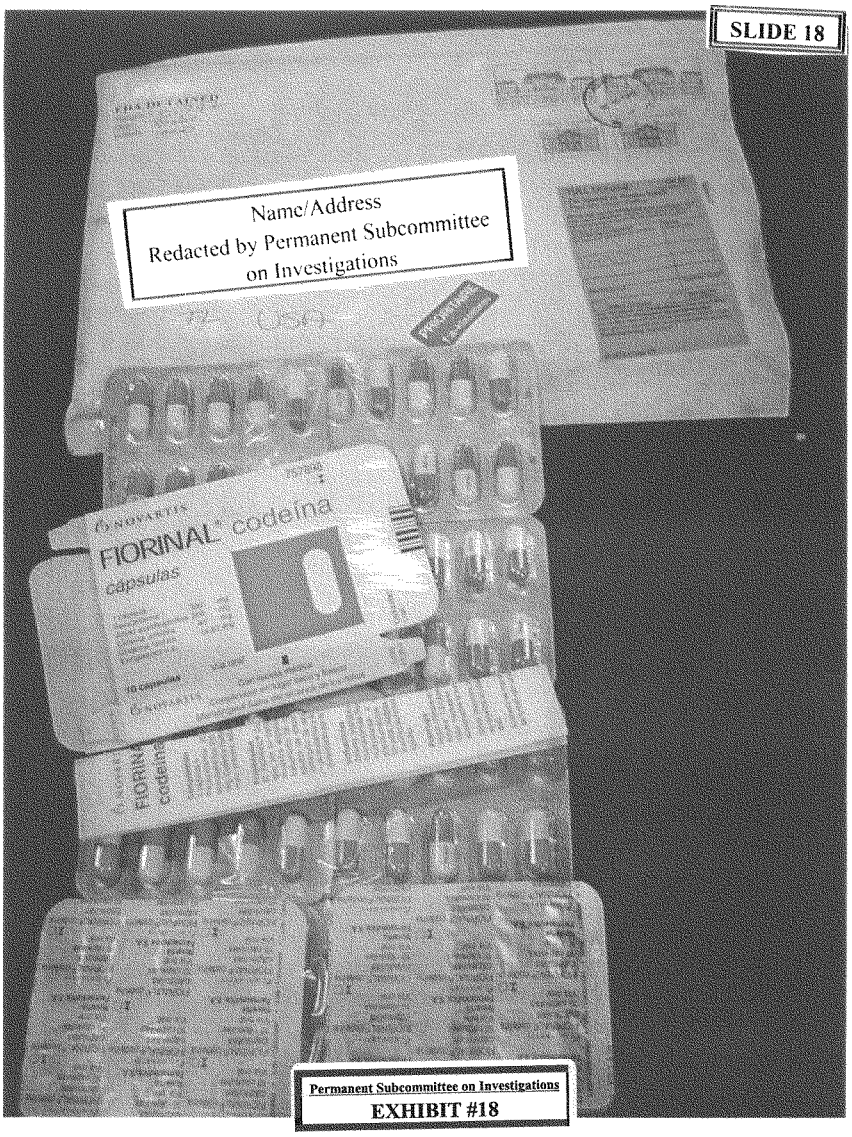
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SLIDE 19
PRIORITY MAIL
US
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FREEZER PACK
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TAKE WITH FOOD
Humulin
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SLIDE 21
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INTERNATIONAL PACKAGE ARRIVAL HOLDING AREA AT THE FEDEX HUB, MEMPHIS, TN

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INTERNATIONAL PACKAGES BEING HELD FOR FDA INSPECTION AT THE FEDEX HUB, MEMPHIS, TN

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EXHIBIT #25

Hydrocodone - Buy Hydrocodone/APAP Pain Medication, *Free Consult*, Hydrocodone.com-online.us -

Buy Hydrocodone/APAP (generic Lortab, Vicoden) pain medication online.

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Quick Pick List

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Meridia
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Propecia
Anti-Depressants
Prozac
Paxil
Zoloft
Effexor
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Fluoxetine
Wellbutrin
Serafem
Tramadol
Celexa
Anxiety
Buspar
Muscle Relaxers
Soma
Flexeril
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Flextra-DS
Skelaxin
Zanaflex
Pain Relief
Imitrex
Fioricet
Celebrex
Ultram
Tramadol
Vioxx
Vicodin ES
Hydrocodone
Women's Health
Vantiga
Ortho Tri-Cyclen
Diflucan
Ortho Evra Patch
Nordette
Estradiol
Ovral
Triphasil
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Upon approval, our US licensed Physicians will review your request and issue a Hydrocodone/APAP (generic Lortab or generic Vicodin), Vicodin, or other prescription for your Hydrocodone/APAP, Hydrocodone/APAP (generic Lortab or generic Vicodin), Vicodin, or other prescription medication. The Hydrocodone/APAP (generic Lortab or generic Vicodin), Vicodin, or other FDA-approved medication prescription will be reviewed and filled by a US Licensed Pharmacist and then shipped discreetly to your doorstep.

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Permanent Subcommittee on Investigations
EXHIBIT #26

Internet Prescription Drug Buys

HOW WAS IT PURCHASED?

MASTERCARD

ACCUTANE	6
CELEBREX	7
COMBIVIR	4
CRIXIVAN	4
HUMULIN N	4
HYDROCODONE	4
LIPITOR	5
VIAGRA	3
ZOLOFT	7

VISA

CELEBREX	2
COMBIVIR	1
CRIXIVAN	2
EPOGEN	1
HYDROCODONE	5
LIPITOR	4
OXYCOTIN	1
VIAGRA	6
ZOLOFT	2

HOW WAS IT SHIPPED?

POSTAL SERVICE

ACCUTANE	6
CELEBREX	5
COMBIVIR	4
CRIXIVAN	4
HUMULIN N	4
LIPITOR	6
OXYCOTIN	1
VIAGRA	3
ZOLOFT	6

FEDEX

CELEBREX	4
HYDROCRONE	9
LIPITOR	3
VIAGRA	5
ZOLOFT	3

UPS

CRIXIVAN	1
EPOGEN	1
VIAGRA	1

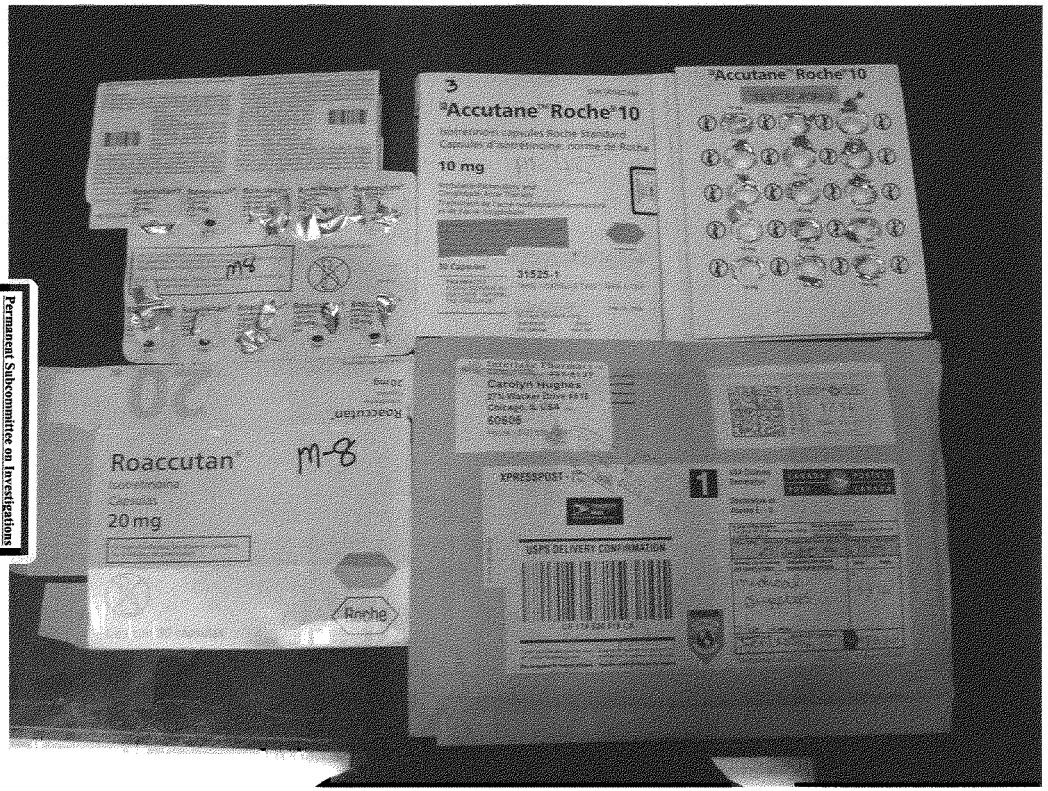
EMS COURIER

COMBIVIR	1
CRIXIVAN	1

Source: GAO data

Permanent Subcommittee on Investigations

EXHIBIT #27



Permanent Subcommittee on Investigations
EXHIBIT #28

ACCUTANE, A RESTRICTED DRUG THAT CAUSES BIRTH DEFECTS, ILLEGALLY IMPORTED FROM CANADA & MEXICO. THE LABELS & INSTRUCTIONS ARE IN FRENCH AND SPANISH.

Permanent Subcommittee on Investigations
EXHIBIT #29

HUMULIN N, A DRUG THAT SHOULD BE REFRIGERATED, SHIPPED FROM PAKISTAN WITHOUT INSULATION OR A COOLING PACK.

Permanent Subcommittee on Investigations
EXHIBIT #30

CRIXIVAN, A DRUG USED TO TREAT HIV, HIDDEN IN A SEALED CAN INSIDE A BOX LABELED AS GOLD DYE AND STAIN REMOVER WAX

Permanent Subcommittee on Investigations
EXHIBIT #31

COUNTERFEIT OXYCONTIN SMUGGLED IN A CD CASE FROM SPAIN.

United States General Accounting Office

GAO

Report to the Chairman, Permanent Subcommittee on Investigations, Committee on Governmental Affairs, U.S. Senate

June 2004

INTERNET PHARMACIES

Some Pose Safety Risks for Consumers

GAO-04-820

Permanent Subcommittee on Investigations
EXHIBIT #32

June 2004

GAO
Accountability·Integrity·Reliability

Highlights

Highlights of GAO-04-820, a report to the Chairman, Permanent Subcommittee on Investigations, Committee on Governmental Affairs, U.S. Senate

INTERNET PHARMACIES

Some Pose Safety Risks for Consumers

Why GAO Did This Study

As the demand for and the cost of prescription drugs rise, many consumers have turned to the Internet to purchase drugs. However, the global nature of the Internet can hinder state and federal efforts to identify and regulate Internet pharmacies to help assure the safety and efficacy of products sold. Recent reports of unapproved and counterfeit drugs sold over the Internet have raised further concerns.

GAO was asked to examine (1) the extent to which certain drugs can be purchased over the Internet without a prescription; (2) whether the drugs are handled properly, approved by the Food and Drug Administration (FDA), and authentic; and (3) the extent to which Internet pharmacies are reliable in their business practices. GAO attempted to purchase up to 10 samples of 13 different drugs, each from a different pharmacy Web site, including sites in the United States, Canada, and other foreign countries. GAO determined whether the samples contained a pharmacy label with patient instructions for use and warnings on the labels or the packaging and forwarded the samples to their manufacturers to determine whether they were approved by FDA and authentic. GAO also confirmed the locations of several Internet pharmacies and identified those under investigation by regulatory agencies.

www.gao.gov/cgi-bin/getrpt?GAO-04-820.

To view the full product, including the scope and methodology, click on the link above. For more information, contact Marcia Crosse at (202) 512-7119 or Robert J. Cramer at (202) 512-7455.

What GAO Found

GAO obtained most of the prescription drugs it targeted from a variety of Internet pharmacy Web sites without providing a prescription. GAO obtained 68 samples of 11 different drugs—each from a different pharmacy Web site in the United States, Canada, or other foreign countries, including Argentina, Costa Rica, Fiji, India, Mexico, Pakistan, Philippines, Spain, Thailand, and Turkey. Five U.S. and all 18 Canadian pharmacy sites from which GAO received samples required a patient-provided prescription, whereas the remaining 24 U.S. and all 21 foreign pharmacy sites outside of Canada provided a prescription based on their own medical questionnaire or had no prescription requirement. Among the drugs GAO obtained without a prescription were those with special safety restrictions and highly addictive narcotic painkillers.

GAO identified several problems associated with the handling, FDA approval status, and authenticity of the 21 samples received from Internet pharmacies located in foreign countries outside of Canada. Fewer problems were identified among pharmacies in Canada and the United States. None of the foreign pharmacies outside of Canada included required dispensing pharmacy labels that provided instructions for use, few included warning information, and 13 displayed other problems associated with the handling of the drugs. For example, 3 samples of a drug that should be shipped in a temperature- controlled environment arrived in envelopes without insulation. Manufacturer testing revealed that most of these drug samples were unapproved for the U.S. market; however, manufacturers found the chemical composition of all but 4 was comparable to the product GAO ordered. Four samples were determined to be counterfeit products or otherwise not comparable to the product GAO ordered. Similar to the samples received from other foreign pharmacies, manufacturers found most of those from Canada to be unapproved for the U.S. market; however, manufacturers determined that the chemical composition of all drug samples obtained from Canada were comparable to the product GAO ordered.

Some Internet pharmacies were not reliable in their business practices. Most instances identified involved pharmacies outside of the United States and Canada. GAO did not receive six orders for which it had paid. In addition, GAO found questionable entities located at the return addresses on the packaging of several samples, such as private residences. Finally, 14 of the 68 pharmacy Web sites from which GAO obtained samples were found to be under investigation by regulatory agencies for reasons including selling counterfeit drugs and providing prescription drugs where no valid doctor-patient relationship exists. Nine of these were U.S. sites, 1 a Canadian site, and 4 were other foreign Internet pharmacy sites.

In commenting on a draft of this report, FDA generally agreed with its findings and conclusions.

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Abbreviations

DEA	Drug Enforcement Administration
FDA	Food and Drug Administration
FDCA	Federal Food, Drug, and Cosmetic Act
NABP	National Association of Boards of Pharmacy
VIPPS	Verified Internet Pharmacy Practice Sites

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United States General Accounting Office
Washington, D.C. 20548

June 17, 2004

The Honorable Norm Coleman
Chairman
Permanent Subcommittee on Investigations
Committee on Governmental Affairs
United States Senate

Dear Mr. Chairman:

As both the demand for and the cost of prescription medications have increased, the Internet has emerged as a growing marketplace for the purchase of prescription drugs. Internet pharmacies offer benefits for consumers, such as the convenience of shopping from home 24 hours a day and the ability to compare prices offered by multiple vendors. Various types of pharmacies offer prescription drugs over the Internet, including pharmacies that sell a wide range of drugs, require a patient to provide a prescription, and are sometimes associated with traditional chain drug stores, and other pharmacies that issue a prescription based on an online medical history questionnaire or have no prescription requirement.[1]

Like traditional pharmacies, Internet pharmacies are subject to state and federal statutes and regulations designed to ensure the safety and efficacy of the medications they dispense. However, the global nature of the Internet poses challenges for regulators. States have identified Internet pharmacies that do not comply with state pharmacy laws, but have reported difficulty locating, investigating, and taking action against the pharmacies when they are located beyond state borders.[2] Federal agencies have also taken steps to stop illegal sales of prescription drugs through Internet pharmacies, including by prosecuting Internet pharmacies that dispense medications without a valid prescription. The Food and Drug Administration (FDA) recently reported instances of drugs sold over the Internet that were improperly handled, such as improperly packaged drugs, drugs that were unapproved, and drugs that were not the authentic products consumers intended to purchase. Consumer complaints

[1] Throughout this report, we refer to each Internet Web site selling prescription drugs as an Internet pharmacy.

[2] See U.S. General Accounting Office, *Internet Pharmacies: Adding Disclosure Requirements Would Aid State and Federal Oversight*, GAO-01-69 (Washington, D.C.: Oct. 19, 2000).

regarding the business practices of some Internet pharmacies have raised further concerns associated with the use of Internet pharmacies to obtain prescription drugs.

You asked us to assess:

1. the extent to which certain prescription drugs can be purchased over the Internet without a prescription;

2. whether drugs sold by Internet pharmacies are handled properly, are FDA-approved, and authentic; and

3. the extent to which Internet pharmacies are reliable in their business practices.

To determine the extent to which certain prescription drugs can be purchased over the Internet, we attempted to place up to 10 orders for each of 13 drugs, each from a different online pharmacy. The 13 targeted drugs included top selling drugs, drugs with special safety restrictions or handling requirements, drugs that have been counterfeited in the past, and narcotics.[3,4] (See table 1.) We generally attempted to purchase each of the 13 drugs with and without a prescription and produced our own prescriptions to enable us to do so.[5]

[3] One of the drugs, Humulin N, is prescribed by physicians and is also available without a prescription. We included it among the drugs we ordered because of its special handling requirements.

[4] The Controlled Substances Act established a classification structure for drugs and chemicals used in the manufacture of drugs that are designated as controlled substances. Controlled substances are classified into five schedules on the basis of their medicinal value, potential for abuse, and safety or dependence liability. Schedule I is reserved for the most dangerous drugs that have no recognized medicinal use, while Schedule V is the classification used for the least dangerous drugs. We attempted to purchase Schedule II and Schedule III narcotics. *See* 21 U.S.C. §§ 811 and 812.

[5] Due to the heightened regulation of controlled substances, we did not attempt to purchase narcotics from pharmacies that required patients to submit a prescription from their physicians.

Table 1: Prescription Drugs Selected for Purchase from Internet Pharmacies

Prescription drug	Condition treated	Remarks
Accutane®	Acne	Has special safety restrictions[a]
Celebrex®	Arthritis	--
Clozaril®	Schizophrenia	Has special safety restrictions[a]
Combivir®	HIV	--
Crixivan®	HIV	--
Epogen®	Anemia	Has special handling requirements
Humulin® N	Diabetes	Has special handling requirements
Lipitor®	High cholesterol	--
OxyContin®	Pain	Schedule II controlled substance, narcotic
Percocet®	Pain	Schedule II controlled substance, narcotic
Viagra®	Male sexual dysfunction	--
Vicodin®/hydrocodone	Pain	Schedule III controlled substance, narcotic
Zoloft®	Depression	--

Source: GAO analysis of information from drug manufacturers and the Drug Enforcement Administration.

[a]Due to health risks associated with using this drug, there are special safety restrictions imposed on its use and distribution in the United States, such as a requirement that patients undergo certain medical tests and restrictions on the distribution of this drug to physicians with special training or expertise. Because of the health risks, FDA advises consumers not to purchase this drug over the Internet.

We purchased drugs from Internet pharmacies that purported or appeared to be located in the United States, Canada, and other foreign countries.[6] We purchased drugs from Internet pharmacies with varying prescription requirements—some required purchasers to provide a prescription; some required purchasers to fill out an online medical history questionnaire, based on which a physician affiliated with the pharmacy issued a prescription; and some had no prescription requirement. We also purchased drugs from Internet pharmacies that are licensed online

[6] We determined the location of Internet pharmacies from which we received drug samples based on information contained in the pharmacy Web sites and the return addresses and postmarks on the packages we received. Throughout this report, we refer to Internet pharmacies from countries other than the United States or Canada as "other foreign Internet pharmacies."

providers of prescription drugs.[7] To identify the Internet pharmacies, we relied upon a list of Internet pharmacy Web sites compiled by a private consultant and provided to us by FDA; used Internet search engines, including Google, Yahoo, and Excite; and joined Internet pharmacy members-only Web sites, which provide enrolled members with lists of Web sites selling various prescription drugs. Because the universe of Internet pharmacies is not known, and because we obtained only one drug sample[8] from each pharmacy, our findings cannot be generalized.

To assess whether the drug samples we received were handled properly, we identified whether the samples contained a pharmacy label[9] with patient instructions for use and whether warnings were included on the labels or along with the packaging. We define handling as the manner in which Internet pharmacies labeled, packaged, and shipped the prescription drug samples we received. In addition, we made other observations about the manner in which the drugs were handled and the condition of the packaging.[10] To assess whether the drug samples we received were FDA-approved and authentic products, we forwarded the samples to manufacturers of the drugs that we ordered to make these determinations[11] and identify any other safety concerns associated with the drugs or their

[7] We selected these Internet pharmacies from among those associated with large drugstore chains and those certified as Verified Internet Pharmacy Practice Sites (VIPPS) by the National Association of Boards of Pharmacy (NABP). VIPPS certification is voluntary and indicates that the pharmacy meets applicable state licensure requirements and certain other criteria established by NABP.

[8] This report uses the word "samples" to refer to our purchases of drugs from Internet pharmacies rather than to those drugs provided to practitioners and others for the purpose of promoting drug sales. *See* 21 U.S.C. § 353(c)(1)(2000).

[9] The Federal Food, Drug, and Cosmetic Act defines "label" as the display of written, printed, or graphic matter upon the immediate container of any article and information required to be on the label must also be included on the outside container or wrapper, if any, of the retail package. *See* 21 U.S.C. § 321(k).

[10] We did not conduct a comprehensive review of the pharmacies' compliance with all applicable federal and state laws and regulations.

[11] FDA has noted that chemical analysis of prescription drug samples may not always detect slight changes in the manufacturing process or different types or amounts of inactive ingredients, which can affect the comparability and thus therapeutic equivalence of drug samples.

handling.[12] Where manufacturers commented on the adequacy of patient instructions for use or warnings, we relied upon their assessments rather than our own judgment. We did not disclose to the manufacturers information concerning the source of the drug samples we purchased, including whether the pharmacy purported to be located in the United States, Canada, or in another foreign country.

To examine the reliability of the business practices of Internet pharmacies, we contacted Internet pharmacy customer service staff and several of the processing centers or brokers that handled the transactions. We also compared the return addresses of some drug samples received against the business addresses provided by the processing centers or brokers and listed on the Internet Web sites. Where the packaging of the drug samples received from foreign Internet pharmacies raised questions, we coordinated with Drug Enforcement Administration (DEA) to obtain information about the physical entity located at the return address on the package and the tenants or owners of the property. Finally, we obtained information from DEA and FDA regarding their ongoing investigations of organizations associated with the Internet pharmacies from which we purchased drugs.

We conducted our work from January through June 2004 in accordance with generally accepted government auditing standards and in accordance with the standards of the President's Council on Integrity and Efficiency.

Results In Brief

We were able to obtain the majority of prescription drugs we targeted for purchase from a wide variety of domestic and foreign Internet pharmacies without providing a prescription. We obtained a total of 68 drug samples—each from a different pharmacy in the United States, Canada, or other foreign countries—representing 11 of the 13 drugs we targeted for purchase.[13] Drug samples received from other foreign pharmacies came from Argentina, Costa Rica, Fiji, India, Mexico, Pakistan, Philippines, Spain, Thailand, and Turkey. The samples included drugs with special

[12] We sent samples of the generic drug hydrocodone to the manufacturer of Vicodin for testing.

[13] We did not obtain samples of 2 of the 13 drugs we targeted for purchase. We placed nine orders for one of the drugs but received none, and we identified no source from which to purchase the other drug in a manner consistent with our methodology's protocols.

safety restrictions and addictive narcotic painkillers. Among the Internet pharmacies from which we obtained drugs, 5 U.S. and all 18 Canadian pharmacies required the patient to provide a prescription, whereas the remaining 24 U.S. and all 21 other foreign Internet pharmacies issued prescriptions based on their own medical questionnaires or had no prescription requirements. The availability and ease with which the drugs could be purchased varied by drug type. Top selling drugs such as Celebrex, Lipitor, Viagra, and Zoloft were readily available from multiple Internet pharmacies. Other drugs, such as those with special safety restrictions—Accutane and Clozaril—and narcotic painkillers—Percocet, OxyContin, and Vicodin—were offered for sale by fewer Internet pharmacies or were otherwise more difficult to obtain.

We identified several problems associated with the handling, FDA-approval status, and authenticity of the 21 drug samples received from other foreign Internet pharmacies, but fewer problems among the U.S. and Canadian Internet pharmacies. None of the 21 samples from other foreign pharmacies included dispensing pharmacy labels that provided instructions for use, and only about one-third included warning information. Thirteen of the 21 samples displayed other problems associated with the handling of the drugs. For example, 3 samples of a drug that should be shipped in a temperature-controlled environment arrived in envelopes without insulation, and 5 samples contained tablets enclosed in punctured blister packs, potentially exposing the tablets to damaging light or moisture. Finally, manufacturers reported that most of the drug samples from other foreign pharmacies (19 of 21 samples) were unapproved for the U.S. market because, for example, the labeling[14] or the facilities in which they were manufactured had not been approved by FDA; however, they reported that the chemical composition of all but 4 of the other foreign samples was comparable to the product we had ordered. Among the 4 exceptions, 2 samples were found to be counterfeit versions of the product we had ordered, containing a lesser amount of the active

[14] The term "labeling" is broader than the term "label" and includes all labels and other written, printed, or graphic matter upon an article or its container or wrapper, or that accompanies the article. *See* 21 U.S.C. § 321(m).

ingredient, and 2 samples had a significantly different chemical composition than that of the product we had ordered.[15] In contrast, all 47 of the drug samples we received from U.S. and Canadian Internet pharmacies included dispensing pharmacy labels that generally provided patient instructions for use, 41 included warning information, and none displayed evidence of mishandling. Like the samples received from other foreign pharmacies, most of those from Canada were also unapproved for the U.S. market; however, manufacturers determined that the chemical composition of all were comparable to the product we had ordered. Finally, manufacturer testing identified 1 sample from a U.S. pharmacy that was inappropriately removed from the sealed manufacturer container and dispensed in a pharmacy bottle.

Some Internet pharmacies—mostly other foreign pharmacies—were not reliable in their business practices. We did not receive six of the orders we placed and paid for, five of which were placed with other foreign Internet pharmacies and one of which was placed with a pharmacy whose location we could not determine. Also, we determined that several of the drug samples were sent from locations that raise questions, such as from private residences. We also observed Internet pharmacies that obscured details about the drugs sold, such as other foreign pharmacies from which we ordered brand name drugs, but then received a generic or foreign version of the drug. Finally, about 21 percent of the Internet pharmacies that sent us samples were found to be under investigation by DEA or FDA. Reasons for the investigations included allegations of selling adulterated, misbranded, or counterfeit drugs and providing prescription drugs where no valid doctor-patient relationship exists. Nine of these pharmacies were from the United States, one from Canada, and four from other foreign countries.

We provided a draft of this report to FDA, which generally agreed with our findings and conclusions. We provided a draft of this report to DEA for a technical review and it informed us it had no comments. We also provided each manufacturer with segments of this draft report that related to its product(s). They provided technical comments, which we incorporated where appropriate.

[15] Under federal law, counterfeit drugs include those sold under a product name without proper authorization, which falsely purport or are represented to be a particular product. *See* 21 U.S.C. § 321(g)(2). Counterfeit products may include products without the active ingredient, with an insufficient quantity of the active ingredient, or with the wrong active ingredient.

Background

Three general types of Internet pharmacies sell prescription drugs directly to consumers. First, some Internet pharmacies operate much like traditional drugstores, selling a wide range of prescription drugs and requiring consumers to submit a prescription from their physicians before their orders are filled. In some instances, these Internet pharmacies are affiliated with traditional chain drug stores. Second, other Internet pharmacies may sell a more limited range of drugs, often specializing in certain lifestyle medications, such as those that treat sexual dysfunction or assist in weight control. These Internet pharmacies typically require consumers to fill out an online medical history questionnaire in place of a traditional examination by a physician, and issue a prescription after a physician affiliated with the pharmacy reviews the questionnaire. Still other Internet pharmacies dispense drugs without a prescription.

In the United States, the practice of pharmacy is regulated by state boards of pharmacy, which establish and enforce standards intended to protect the public. State boards of pharmacy also license pharmacists and pharmacies.[16] 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.[17] The requirement that drugs be prescribed and dispensed by licensed professionals helps ensure patients receive the proper dose, take the medication correctly, and are informed about warnings, side effects, and other important information about the drug.

[16] Most states also license out-of-state pharmacies that dispense drugs to state residents, and some states regulate Internet pharmacies in a similar manner. See GAO-01-69.

[17] States also license health care professionals, grant them prescribing privileges, and outline standards of practice in state medical practice laws.

Under the Federal Food, Drug, and Cosmetic Act (FDCA), as amended, FDA is responsible for ensuring the safety, effectiveness, and quality of domestic and imported drugs. To do so, FDA establishes standards for the safety, effectiveness, and manufacture of drugs that must be met before they are approved for the U.S. market. To gain approval, a drug manufacturer must demonstrate that a drug is safe and effective, and that the manufacturing methods and controls that will be used in the specific facility where it will be manufactured meet FDA standards. The same drug manufactured in another facility not approved by FDA—such as a foreign-made version of an approved drug—may not be sold legally in the United States. Drugs are subject to other statutory and regulatory standards relating to purity, labeling, manufacturing, and packaging.[18] Failure to meet these standards could result in a drug being considered adulterated or misbranded and therefore illegal for sale, which could result in FDA enforcement action.[19]

The FDCA requires that drugs be dispensed with labels that include the name of the prescriber, directions for use, and cautionary statements, among other things. A drug is considered misbranded if its labeling or container is misleading, or if the label fails to include required information. Prescription drugs dispensed without a prescription are also considered misbranded. In addition, if a drug is susceptible to deterioration and must, for example, be maintained in a temperature-controlled environment, it must be packaged and labeled in accordance with regulations and manufacturer standards. Drugs must also be handled to prevent adulteration, which may occur, for example, if held under unsanitary conditions leading to possible contamination.

[18] *See, e.g.*, 21 U.S.C. §§ 351(b), 352(g), 352(h), 352(p), 355(d); 21 C.F.R. pts. 201 and 210 (2003). Additional requirements apply to controlled substances under the Controlled Substances Act and DEA's implementing regulations.

[19] Other federal agencies also play a role with respect to the regulation of prescription drugs under various circumstances. See GAO-01-69. GAO is currently reviewing available data on the volume of prescription drugs entering the United States through the Postal Service and private couriers and the policies and practices of federal agencies charged with preventing unapproved prescription drugs from entering the country.

FDA-approved drugs manufactured in foreign countries, including those sold over the Internet, are subject to the same requirements as domestic drugs.[20] Further, imported drugs may be denied entry into the United States if they "appear" to be unapproved, adulterated, or misbranded, among other things. While the importation of such drugs may be illegal, FDA has allowed individuals to bring small quantities of certain drugs into the United States for personal use under certain circumstances.[21]

Internet pharmacies pose challenges for regulators. State boards of pharmacy in many states have reported difficulty identifying Internet pharmacies located outside of their borders and have limited ability and authority to investigate and act against pharmacies that do not comply with state pharmacy laws when they are identified. In 2000, nearly half of the state boards had identified consumer complaints against Internet pharmacies or reported problems with Internet pharmacies not complying with state pharmacy laws. Additionally, state medical boards have reported receiving complaints about physicians prescribing drugs over the Internet without performing an examination of the patient.[22] Federal agencies have taken steps to stop the illegal sales of prescription drugs and other substances by Internet pharmacies. For example, FDA has taken enforcement actions against Internet pharmacies; the Department of Justice has prosecuted Internet pharmacies and physicians for dispensing medications without a valid prescription; and DEA has investigated Internet pharmacies for illegal distribution of controlled substances.

[20] The recently enacted Medicare Prescription Drug, Improvement, and Modernization Act of 2003 directed the Secretary of Health and Human Services to create a system for the importation of prescription drugs from Canada upon certification that the implementation of the program would (1) pose no additional risk to the public's health and safety and (2) result in a significant reduction in the cost of covered products to the American consumer. The act directed the Secretary to complete a study on drug importation from Canada within 1 year of enactment. *See* Pub. L. No. 108-173, §§ 1121, 1122, 117 Stat. 2066, 2464-69 (to be codified at 21 U.S.C. §§ 384, 384 note).

[21] FDA guidelines indicate that agency officials may use their discretion to allow importation if (1) the intended use is identified, is not for a serious condition, and the product is not known to represent a significant health risk; or (2) if the intended use is unapproved and for a serious condition for which effective treatment may not be available domestically, and other conditions are also met. See Chapter 9 of FDA's *Regulatory Procedures Manual.* http://www.fda.gov/ora/compliance_ref/rpm/default.htm. Downloaded June 10, 2004.

[22] In 2000, 39 of 45 state medical boards responding to our survey indicated that a physician who issued a prescription on the basis of an online questionnaire would not satisfy the standard of good medical practice required under their states' laws. See GAO-01-69.

Most of the Targeted Prescription Drugs Were Purchased from Multiple Internet Pharmacies Without Providing a Prescription

We were able to obtain the majority of prescription drugs we targeted for purchase from a wide variety of domestic and foreign Internet pharmacies without providing a prescription. Five U.S. and all 18 Canadian pharmacies from which we obtained drug samples required a patient-provided prescription, whereas the remaining 24 U.S. and all 21 other foreign pharmacies from which we obtained samples either provided a prescription based on an online medical questionnaire or had no prescription requirement. Although we obtained samples of most of the drugs we targeted for purchase, some drugs, such as those with special safety restrictions and narcotics, were available from fewer sources or were more difficult to obtain.

Samples of 11 of 13 Targeted Drugs Obtained from Internet Pharmacies

We obtained 1 or more samples of 11 of the 13 drugs we targeted, both with and without a patient-provided prescription. In total, we placed 90 orders—each with a different Internet pharmacy in the United States, Canada, and other foreign countries—and received 68 samples. Drug samples we received from other foreign pharmacies came from Argentina, Costa Rica, Fiji, India, Mexico, Pakistan, Philippines, Spain, Thailand, and Turkey. Most of the drugs—45 of 68—were obtained without a patient-provided prescription. These included drugs for which physician supervision is of particular importance due to the possibility of severe side effects, such as Accutane, or the high potential for abuse and addiction, such as the narcotic painkiller hydrocodone. (See table 2.)

Table 2: Prescription Drugs Ordered and Received from Internet Pharmacies

Drug ordered	Orders placed[a]	Drug samples received[b]	Drug samples obtained without a prescription provided by the patient
Accutane	10	6[c]	3
Celebrex	10	9	7
Clozaril	9	0	0
Combivir	6	5	1
Crixivan	6	6	2
Epogen	1	1	0
Humulin N	7	4	3
Lipitor	10	9	6
OxyContin	1	1	1

(Continued From Previous Page)

Drug ordered	Orders placed[a]	Drug samples received[b]	Drug samples obtained without a prescription provided by the patient
Percocet	0	0	0
Viagra	10	9	7
Vicodin/hydrocodone	10	9[c,d]	9
Zoloft	10	9	6
Total	**90**	**68**	**45**

Source: GAO.

Note: The samples were shipped by FedEx (24), UPS (3), the U.S. Postal Service (39), and other couriers (2).

[a]Does not include attempted orders that were not accepted. We did not reach our goal of placing 10 orders for each drug because we could not always locate 10 sources from which we could purchase the drugs in a manner consistent with our methodology's protocols.

[b]We did not receive a drug sample for every order placed. Reasons included the drug being out of stock, a requirement that physicians prescribing certain drugs be part of a registry, and pharmacy requests for follow-up information we could not provide. In several instances, we could not determine why an order placed was not received.

[c]Includes one sample we could not link to an order we placed.

[d]Although we placed orders for Vicodin, we did not receive any samples of the brand name version of the drug; all nine samples received were of the generic equivalent hydrocodone.

Although most of the samples we received were obtained without a patient-provided prescription, prescription requirements varied. Five U.S. and all 18 Canadian pharmacies from which we obtained drug samples required the patient to provide a prescription. The remaining 24 U.S. pharmacies generally provided a prescription based on a general medical questionnaire filled out online by the patient. Questionnaires requested information on the patient's physical characteristics, medical history, and condition for which drugs were being purchased. Several pharmacy Web sites indicated that a U.S.-licensed physician reviews the completed questionnaire and issues a prescription. The other foreign Internet pharmacies we ordered from generally had no prescription requirements, and many did not seek information regarding the patient's medical history or condition. The process for obtaining a drug from many of these pharmacies involved only selecting the desired medication and submitting the necessary billing and shipping information. (See table 3.)

Table 3: Prescription Requirements of Pharmacies from which We Obtained Samples

Prescription requirement	U.S. Internet pharmacies	Canadian Internet pharmacies	Other foreign Internet pharmacies
Prescription from patient's physician must be provided	5	18	0
Web site provides prescription based on questionnaire	24	0	3
No prescription required	0	0	18

Source: GAO.

The Availability and Ease of Purchase Varied by Drug

While we obtained samples of most of the drugs we targeted for purchase on the Internet, certain drugs were more widely available and easier to purchase than others. The top selling drugs Celebrex (a pain reliever), Lipitor (a cholesterol-lowering drug), Viagra (a medication for male sexual dysfunction), and Zoloft (an antidepressant) were available from multiple pharmacies. We placed 10 orders for each of these four drugs with little difficulty.

Other drugs were available from fewer sources or were more difficult to obtain. Some of our orders for drugs with special safety restrictions were more closely scrutinized. For example, one order we placed for Accutane was declined by a U.S. pharmacy. Accutane is an acne medication that may cause birth defects and serious mental disturbances leading to suicide among some users. The pharmacy indicated that it declined our order because the physician was not included on a national registry of qualified prescribers.[23] Similarly, one U.S. and one Canadian Internet pharmacy declined our order for Clozaril. According to its manufacturer, patients taking Clozaril, an antipsychotic medication, must have ongoing blood tests to monitor for the development of a fatal blood disorder that can occur during treatment. The U.S. pharmacy that declined our order indicated that Clozaril should not have been offered for sale on its Web site, and the Canadian pharmacy indicated that more stringent prescription

[23] Risk management protocols developed by the manufacturer in agreement with FDA prohibit U.S. pharmacies from accepting electronic prescriptions for this drug.

requirements prevented it from dispensing the drug to patients outside of Canada.

Narcotic pain medications—OxyContin, Percocet, and Vicodin—were also less readily available. Despite extensive searching of Internet pharmacy sites, we found few that sold these drugs without a prescription. Other factors also hindered our ability to purchase these drugs. For example, some pharmacies that advertised the narcotics did not actually sell them. Rather, they attempted to substitute a different, often less potent and nonnarcotic drug once the order was placed. In addition, several pharmacies that offered narcotics required payment by means that were beyond our scope, such as check, bank transfers, or "e-gold" exchanges.[24] We were able to place orders for the generic version of Vicodin at several U.S. pharmacies; however, some of these pharmacies required not only an online medical questionnaire, but also a telephone consultation with a pharmacy-designated physician in order to obtain a prescription. Finally, we were able to place only one order for a drug purporting to be OxyContin, and only after locating the source by paying a membership fee and joining an Internet pharmacy drug club, which referred us to the site.

Most Problems Identified among Drug Samples Received from Other Foreign Internet Pharmacies

We identified several problems associated with the handling, FDA-approval status, and authenticity of the 21 drug samples we received from other foreign Internet pharmacies. None included required pharmacy labels that provided patient instructions for use, and few provided warning information. Thirteen were shipped improperly, were packaged unconventionally, or arrived damaged. Manufacturers reported that most of the samples they reviewed at our request from other foreign pharmacies were not approved by FDA for the United States—although most had a comparable chemical composition to the product we ordered—and 4 were either counterfeit products or otherwise not comparable to the product we ordered. While most of the samples received from Canadian Internet pharmacies were unapproved for the U.S. market, they otherwise had a comparable chemical composition, and the samples from U.S. and Canadian pharmacies exhibited few problems otherwise. Table 4 summarizes the problems we identified among the 68 samples we received.

[24] "e-gold" is a system where sellers and buyers can establish accounts and electronically exchange values or amounts of gold in order to complete Internet transactions.

Table 4: Problems Observed Among Prescription Drug Samples Received

Pharmacy location	No pharmacy label with instructions for use (23 samples)	No warning information (21 samples)	Improperly shipped or dispensed (4 samples)	Unconventional packaging (6 samples)	Damaged packaging (5 samples)	Not approved for U.S. market (35 samples)	Counterfeit or otherwise not comparable to product ordered (4 samples)
Canadian		Celebrex (2) Zoloft (2)				Accutane (3) Combivir (3) Crixivan (3) Humulin N (1) Lipitor (2) Viagra (1) Zoloft (3)	
Other foreign	Accutane (3) Celebrex (3) Combivir (1) Crixivan (2) Humulin N (3) Lipitor (3) OxyContin (1) Viagra (2) Zoloft (3)	Accutane (2) Celebrex (3) Crixivan (2) Lipitor (3) OxyContin (1) Viagra (2) Zoloft (2)	Humulin N (3)	Accutane (1) Celebrex (1) Crixivan (2) OxyContin (1) Viagra (1)	Accutane (2) Celebrex (1) Crixivan (1) Lipitor (1)	Accutane (2) Celebrex (3) Combivir (1) Crixivan (1) Humulin N (3) Lipitor (3) OxyContin (1) Viagra (2) Zoloft (3)	Accutane (1) OxyContin (1) Viagra (2)
U.S.	Celebrex (1) Zoloft (1)	Lipitor (1) Zoloft (1)	Crixivan (1)				

Source: GAO and drug manufacturers.

Notes:

Drug names indicated are those that GAO ordered. The samples we received were not the brand name drugs we ordered in all instances.

Drug samples do not add to 68 because some samples exhibited more than one problem.

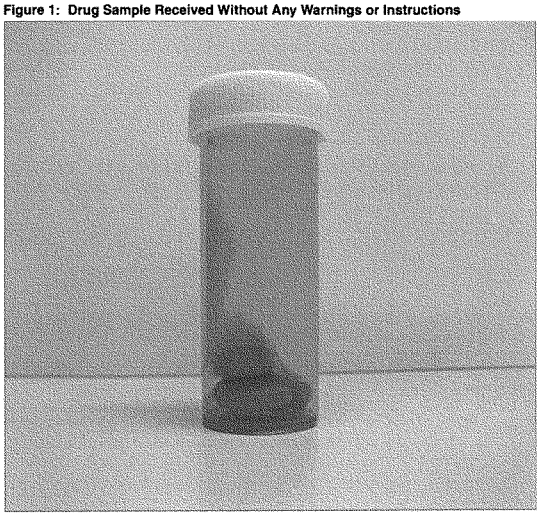
All Drug Samples Received from Other Foreign Pharmacies Exhibited Problems Associated with Their Handling

None of the 21 prescription drug samples we received from other foreign Internet pharmacies included a dispensing pharmacy label that provided patient instructions for use, and only 6 of the samples came with warning information.[25] Lack of instructions and warnings on these drugs leaves consumers who take them at risk for potentially dangerous drug interactions or side effects from incorrect or inappropriate use. For example, we received 2 samples purporting to be Viagra, a drug used to treat male sexual dysfunction, without any warnings or instructions for use. (See fig. 1.) According to its manufacturer, this drug should not be

[25] One of the samples we received from other foreign pharmacies included a dispensing pharmacy label; however, this label lacked patient instructions for use.

prescribed for individuals who are currently taking certain heart medications, as it can lower blood pressure to dangerous levels. Additionally, 2 samples of Roaccutan, a foreign version of Accutane, arrived without any instructions in English. (See fig. 2.) As noted, possible side effects of this drug include birth defects and severe mental disturbances. Compounding the concerns regarding the lack of warnings and patient instructions for use, none of the other foreign pharmacies ensured patients were under the care of a physician by requiring that a prescription be submitted before the order is filled.

Figure 1: Drug Sample Received Without Any Warnings or Instructions



Source: GAO.

Note: Sample purporting to be Viagra® arrived without any warning information or instructions for use.

Figure 2: Drug Sample Received Without Any Instructions in English

Source: GAO.

Note: Sample of Roaccutan®, a foreign version of Accutane®, arrived without instructions for use in English.

We observed other evidence of improper handling among 13 of the 21 drug samples we received from other foreign Internet pharmacies. For example, three samples of Humulin N were not shipped in accordance with manufacturer handling specifications. Despite the requirement that this drug be stored under temperature-controlled and insulated conditions, the samples we received were shipped in envelopes without insulation. (See fig. 3.) Similarly, 6 samples of other drugs were shipped in unconventional packaging, in some instances with the apparent intention of concealing the actual contents of the package. For example, the sample purporting to be OxyContin was shipped in a plastic compact disc case wrapped in brown packing tape—no other labels or instructions were included, and a sample of Crixivan was shipped inside a sealed aluminum can enclosed in a box labeled "Gold Dye and Stain Remover Wax." (See fig. 4.) Additionally, 5

samples we received were damaged and included tablets that arrived in punctured blister packs, potentially exposing pills to damaging light or moisture. (See fig. 5.) One drug manufacturer noted that damaged packaging may also compromise the validity of drug expiration dates.

Figure 3: Drug Sample Shipped Improperly

Source: GAO.

Note: Despite the requirement that Humulin®N be stored under temperature-controlled and insulated conditions, samples we received were shipped in an envelope without insulation.

Figure 4: Drug Samples Shipped in Unconventional Packaging

Source: GAO.

Note: Sample purporting to be OxyContin® was shipped in a plastic compact disc case wrapped in brown packing tape—no other labels or instructions were included.

Source: GAO.

Note: Sample of Crixivan® was shipped inside a sealed aluminum can enclosed in a box labeled "Gold Dye and Stain Remover Wax."

Figure 5: Drug Sample Received in Damaged Packaging

Source: GAO.

Note: Sample of Crixivan®, a moisture sensitive drug, arrived in punctured blister packs.

Most Drug Samples Received from Other Foreign Pharmacies Were Unapproved, Four Were Not Authentic

Among the 21 drug samples from other foreign pharmacies, manufacturers determined that 19 were not approved for the U.S. market for various reasons, including that the labeling or the facilities in which they were manufactured had not been approved by FDA.[26] For example, the manufacturer of one drug noted that 2 samples we received of that drug were packaged under an alternate name used for the Mexican market. The manufacturer of another drug found that 3 samples we received of that drug were manufactured at a facility unapproved to produce drugs for the U.S. market. In all but 4 instances, however, manufacturers determined that the chemical composition of the samples we received from other foreign Internet pharmacies was comparable to the chemical composition

[26] The manufacturer of one of the remaining two samples determined it was approved for the U.S. market and the manufacturer of the other sample could not make a determination.

of the drugs we had ordered. Two samples of one drug were found by the manufacturer to be counterfeit and contained a different chemical composition than the drug we had ordered. In both instances the manufacturer reported that samples had less quantity of the active ingredient, and the safety and efficacy of the samples could not be determined. Manufacturers also found 2 additional samples to have a significantly different chemical composition than that of the product we had ordered.

Drugs Received from Canadian and U.S. Internet Pharmacies Exhibited Fewer Problems

All 47 of the prescription drug samples we received from Canadian and U.S. Internet pharmacies included labels from the dispensing pharmacy that generally provided patient instructions for use and 87 percent of these samples (41 of 47) included warning information. Furthermore, all samples were shipped in accordance with special handling requirements, where applicable, and arrived undamaged. Manufacturers reported that 16 of the 18 samples from Canadian Internet pharmacies were unapproved for sale in the United States, citing for example unapproved labeling and packaging. However, the samples were all found to be comparable in chemical composition to the products we ordered. Finally, the manufacturer found that 1 sample of a moisture-sensitive medication from a U.S. pharmacy was inappropriately removed from the sealed manufacturer container and dispensed in a pharmacy bottle.

Some Internet Pharmacies Were Not Reliable in Their Business Practices

We observed questionable characteristics and business practices of some of the Internet pharmacies from which we received drugs. Most, but not all, involved other foreign pharmacies. These included pharmacies that accepted payment but did not provide the drugs ordered, shipments of drugs with questionable return addresses, pharmacies that obscured details about the drugs sold, and pharmacies that were under investigation by regulatory agencies.

We ultimately did not receive six of the orders we placed and paid for, suggesting the potential fraudulent nature of some Internet pharmacies or entities representing themselves as such.[27] The six orders were for Clozaril, Humulin N, and Vicodin, and cost over $700 in total. Five of these orders were placed with non-Canadian foreign pharmacies and one was placed with a pharmacy whose location we could not determine. We followed up with each pharmacy in late April and early May of 2004 to determine the status. Three indicated they would reship the product, but as of June 10, 2004, we had not received the shipments. Three others did not respond to our inquiry.[28]

We determined that at least eight of the return addresses included on samples we received from other foreign Internet pharmacies were shipped from locations that raise questions about the entities that provided the samples. For example, we found a shopping mall in Buenos Aires, Argentina, at the return address provided on a sample of Lipitor. Authorities assisting us in locating this address found it impossible to identify which, if any, of the many retail stores mailed the package. The return address for a sample of Celebrex was found to be a business in Cozumel, Mexico, but representatives of that business informed authorities that it had no connection to an Internet pharmacy operation. Finally, the return addresses on samples of Humulin N and Zoloft were found to be private residences in Lahore, Pakistan.

Certain practices of Internet pharmacies may render it difficult for consumers to know exactly what they are buying. Some non-Canadian foreign Internet pharmacies appeared to offer U.S. versions of brand name drugs on their Web sites, but attempted to substitute an alternative drug during the order process. In some cases, other foreign pharmacies substituted alternative drugs after the order was placed. For example, one Internet pharmacy advertised brand name Accutane, which we ordered. The sample we received was actually a generic version of the drug made by an overseas manufacturer.

[27] NABP has reported receiving complaints from consumers who state they have provided payment to various Internet pharmacies, but have not received the products ordered.

[28] We received no notice from federal agencies indicating that our drug samples had been seized, nor did the Internet pharmacies we contacted about unreceived shipments indicate they had received such notification.

About 21 percent of the Internet pharmacies from which we received drugs (14 of 68) were under investigation by regulatory agencies. The reasons for the investigations by DEA and FDA include allegations of selling controlled substances without a prescription; selling adulterated, misbranded, or counterfeit drugs; selling prescription drugs where no doctor-patient relationship exists; smuggling; and mail fraud. The pharmacies under investigation were concentrated among the U.S. pharmacies that did not require a patient-provided prescription (9) and other foreign (4) pharmacies. One Canadian pharmacy was also included among those under investigation.

Concluding Observations

Consumers can readily obtain many prescription drugs over the Internet without providing a prescription—particularly from certain U.S. and foreign Internet pharmacies outside of Canada. Drugs available include those for which patients should be monitored for side effects or where the potential for abuse is high. For these types of drugs in particular, a prescription and physician supervision can help ensure patient safety. In addition to the lack of prescription requirements, some Internet pharmacies can pose other safety risks for consumers. Many foreign Internet pharmacies outside of Canada dispensed drugs without instructions for patient use, rarely provided warning information, and in four instances provided drugs that were not the authentic products we ordered. Consumers who purchase drugs from foreign Internet pharmacies that are outside of the U.S. regulatory framework may also receive drugs that are unapproved by FDA and manufactured in facilities that the agency has not inspected. Other risks consumers may face were highlighted by the other foreign Internet pharmacies that fraudulently billed us, provided drugs we did not order, and provided false or questionable return addresses. It is notable that we identified these numerous problems despite the relatively small number of drugs we purchased, consistent with problems recently identified by state and federal regulatory agencies.

Agency and External Comments

In commenting on a draft of this report, FDA generally agreed with our findings and conclusions and made suggestions to clarify or expand upon its contents (see app. II). FDA commented that, while the draft report noted Internet pharmacy Web sites purported or appeared to be from various countries, the draft did not demonstrate that the drug samples we received were actually sent from those countries, such as by discussing

return addresses and postmarks on the samples. FDA suggested we indicate the methods we used to determine the samples' origins. We modified the report to indicate that we determined the location of the Internet pharmacy Web sites from which we received drug samples based on information contained in the pharmacy Web sites and the return addresses and postmarks on the packages we received. FDA also commented that our finding that certain unapproved drugs were chemically equivalent to the brand name products we ordered was misleading. FDA noted that chemical equivalence testing may not always determine whether a drug is comparable in all respects to the FDA-approved drug and therefore fully therapeutically equivalent. We relied on manufacturers to determine whether the drug samples we received were comparable to their own FDA-approved brand name version of the drug, and manufacturers conducted a range of tests to make this determination. Nevertheless we modified the final report to note the potential limitations to chemical equivalence testing. FDA also made several observations about the practices of Internet pharmacies and provided technical comments, which we incorporated where appropriate.

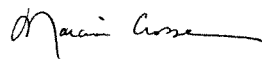
We also provided a draft of this report to DEA for technical comments and to ensure information we reported did not compromise its ongoing investigations. The agency responded that it had no comments.

Finally, we provided segments of the draft report to the manufacturer of each drug sample we received. Each manufacturer reviewed the segments of the draft report relating to its own product(s), and provided technical comments, which we incorporated as appropriate.

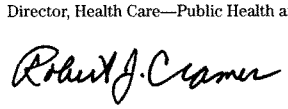
As agreed with your office, unless you publicly announce this report's contents, we plan no further distribution until 30 days after its issue date. At that time, we will send copies to the Acting Commissioner of FDA, the Administrator of DEA, and others upon request. In addition, this report will be available at no charge at the GAO Web site at http://www.gao.gov.

Please call Marcia Crosse at (202) 512-7119 or Robert Cramer at (202) 512-7455 if you have any questions. Another contact and other major contributors are listed in appendix I.

Sincerely yours,



Marcia Crosse
Director, Health Care—Public Health and Military Health Care Issues



Robert J. Cramer
Managing Director, Office of Special Investigations

Appendix I

Comments from the Food And Drug Administration

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

June 4, 2004

Marcia Crosse
Director, Health Care-Public Health
and Military Health Care Issues
United States General Accounting Office
441 G Street, N.W.
Washington, D.C. 20548

Dear Ms. Crosse:

Please find the enclosed comments from the Food and Drug Administration on the GAO draft report entitled *INTERNET PHARMACIES: Some Pose Safety Risks for Consumers (GAO-04-820)*. The Agency provided technical comments directly to your staff.

We appreciate the opportunity to review and comment on this draft report before its publication as well as the opportunity to work with your staff in finalizing this report.

Sincerely,

Lester M. Crawford, D.V.M., Ph.D. Acting
Acting Commissioner of Food and Drugs

Enclosure

General Comments by the Department of Health and Human Services' Food and Drug Administration on GAO's Draft Report, *INTERNET PHARMACIES: Some Pose Safety Risks for Consumers* (GAO-04-820)

The FDA appreciates the opportunity to review and comment on GAO's draft report. FDA concurs with the overall conclusions contained in this report that many imported prescription drugs appear to be of poor quality, are mishandled, have questionable authenticity and approval status, and that these drugs are readily available and can be easily purchased by consumers via Internet pharmacies. Our general comments follow:

1. The report repeatedly states that the Internet sites "purported" or "appeared" to be from Canada, the U.S., or other foreign countries. The study does not demonstrate with any certainty, particularly for the U.S. or Canadian websites, that the products were sent from or manufactured for use in those countries. It also does not discuss return address labels, post marks or other indicators of the origin of the packages. If Congress were to legalize importation of prescription drugs, we anticipate a proliferation of websites claiming to be Canadian pharmacies and entry of unscrupulous individuals into the marketplace. It is easy to design a fraudulent Canadian website that looks completely legitimate. We request that GAO make clear in its report how they determined the origin of the products they purchased. Further, when GAO refers to a "Canadian Internet pharmacy," how is that defined? Even if Canadian drugs are absolutely reliable, American consumers would still need a way to make sure that the medicines they order are actually coming from Canada and not simply transshipped through the country.

2. Many Canadian Internet Pharmacies market specifically to U.S. citizens seeking lower drug prices. The numerous storefront Canadian pharmacy operations in the U.S. are a direct offshoot of these business initiatives.

3. In several places throughout the report, GAO comments that, while "unapproved", the drugs obtained from abroad were chemically equivalent to FDA-approved drugs. We think this claim is misleading. Whether a foreign product contains the same active ingredient is no guarantee that it is identical to the FDA-approved product. For example, the foreign drug may contain different inactive ingredients (to which some persons may be allergic), and there is no guarantee that the foreign and FDA-approved drugs are bioequivalent.

   Because two drug products are "chemically equivalent" does not make them therapeutically equivalent. Most of a generic drug's application review is directed to demonstrating its bioequivalence to the innovator drug.

   Drug products are considered to be therapeutic equivalent only if they are pharmaceutical equivalents and if they can be expected to have the same clinical effect and safety profile when administered to patients under the conditions specified in the labeling.

4. The report does not mention the fact that criminal enforcement of the FD&C Act as it relates to the "online questionnaire" used in most domestic sites selling non-controlled prescription pharmaceuticals depends on individual States interpretation of what constitutes a valid prescription. This, in turn depends on their interpretation of what constitutes an adequate "doctor/patient relationship". Some states do not require a "face to face" medical evaluation. Where this is the case, FDA is deprived of the "misbranding" charge that results from the allegation that a prescription based solely on review of an online questionnaire is not valid.

5. Many U.S. Internet pharmacy sites selling drugs through the use of an online questionnaire do not offer lower prices, but cater to persons seeking so called "lifestyle" drugs, or to others wanting to avoid a doctor's visit or those intent on self-prescribing. These sites sell such drugs as Viagra, Zenical, Propecia and minor tranquilizers usually at a higher price than in a traditional brick and mortar or Internet pharmacy.

6. Sites that sell controlled substances do so usually at substantial mark up. For example, the AWP for generic Percocet is $11 but it sells for $265 per hundred on the Internet. These Internet sites are often sought out by drug abusers. Sites that are identified in the report as operating legally, like traditional drug stores, do not sell controlled substances because of DEA restrictions. FDA has found an increased number of controlled substances in the two "port blitzes" it did in 2003. In 2004 the large volume of controlled substances coming into the U.S. continues.

7. The sampling GAO conducted is extremely small when viewed in the context of the vast number of Internet sites offering prescription drugs for sale. Although the size of the study demonstrates the gravity of the situation regarding "other foreign" Internet sites, a much larger study that has statistical significance should be considered.

Appendix II

GAO Contact and Staff Acknowledgments

GAO Contact

Randy M. DiRosa, (312) 220-7671

Acknowledgments

Major contributors to this report were Margaret Smith, Corey Houchins-Witt, Andrew O'Connell, Ramon Rodriguez, Julian Klazkin, Helen Desaulniers, Robert Copeland, and Harold Lewis.

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Jeff Nelligan, Managing Director, NelliganJ@gao.gov (202) 512-4800
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Senate Governmental
Affairs Committee Hearing
July 22, 2004
FDA Exhibits
Permanent Subcommittee on Investigations
EXHIBIT #33

2

3

4

Internet Pharmacy Data

- Survey of 1,009 sites that appeared to be Canadian
- Analyzed random sample of 106 sites:
  - 47 sold Controlled Substances
  - 77 sold Restricted Distribution Drugs
  - 42 contained “FDA-approved” language
  - 94 had Liability Disclaimers

Canada-Drugstore

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$12.99
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Canada drugstore is Canada's premiere supplier of Canadian drugs. Our online Canadian pharmacy provides access to high quality Health Canada approved Canadian drugs at an average savings of up to 80%. Our state of the art Canadian pharmacy provides fast, safe, friendly service to 1000's of international consumers just like you. To begin shopping at Canada drugstore simply search our Canadian Drug Prices. You will be amazed at the savings offered at our Canada drugstore.

order tracking

Now Available - UK meds! ***Click for more info!***
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Start Saving at our Canada drugstore now!

TOP SELLING DRUGS

Albuterol	Dilaudid	Lipitor	Prevacid
Alendronate	Divalproex	Lipitor	Prevacid
Allopurinol	Doxazosin	Lisinopril	Prevacid
Amitriptyline	Doxepin	Lovastatin	Prilosec
Atenolol	Elavil	Mevacor	Procardia
Bactrim	Eskalith	Metoclopramide	Procaine
Bactrim	Celexa	Metoprolol	Procrit
Bactrim	Flexeril	Mexiletine	Propranolol
Captopril	Fluoxetine	Miacalcin	Reminyl
Cardizem	Fosamax	Minipress	Salbutamol
Cardura	Furosemide	Minipress	Sertraline
Celebrex	Gabapentin	Mycelex	Serzone
Chlorpropamide	Glucophage	Mycelex	Sinemet
Cimetidine	Glyburide	Naprosyn	Synthroid
Clavulin	Humalog	Nasalide	Tamoxifen
Clindamycin	Hydralazine	Nefazodone	Tetracycline
Cozaar	Hydroxyzine	Neurontin	Tranxene
Cozaar	Hyzaar	Nitroglycerin	Vasotec
Cozaar	Imipramine	Nortriptyline	Viagra
Cytotec	Inderal	Oxycontin	Vioxx
Diflucan	Isoptin	Paxil	Voltaren
Digoxin	K-Dur	Paxil	Xalatan
Detrol	Lasix	Pepcid	Zantac
Dexedrine	Lasix	Percocet	Zestril
Diclofenac	Levaquin	Plavix	Zocor
Diltiazem	Levaquin	Provachol	Zoloft
Dipyramidate	Lexapro	Provastatin	Zyban

Where is DiscountDrugsofCanada.Org?

Where do they say they are?	Winnipeg, Manitoba
Who is the registrant?	Truong Thi Thu Thuy
Where is Truong Thi Thu Thuy?	88 Dong Khoi Street Ho Chi Minh City, VN +84.8488247544

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Enter the name or the first few letters of the drug you are looking for

lipitor Submit

SEARCH BY LETTER

A B C D E F G H I J K L M N O P Q R S T U V W X Y Z

LEGEND

Canadian Med | G Canadian Generic | UK Med | G UK Generic

3 Prescription Drugs Results for 'lipitor'

(1 of 1) | JUMP TO PAGE: GO

LIPITOR
Generic name: ATORVASTATIN CALCIUM
Package size: 10MG-90 TABLET
Quantity: 1
search for more
$155.33
Add To Cart

LIPITOR
Generic name: ATORVASTATIN CALCIUM
Package size: 10MG-90 TABLET
Quantity: 1
search for more
$145.99
Add To Cart

LIPITOR
Generic name: ATORVASTATIN CALCIUM
Package size: 10MG-45 TABLET
Quantity: 1
search for more
$88.02
Add To Cart

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Search Results

Create/Edit Account

SEARCH BY NAME

Enter the name or the first few letters of the drug you are looking for

meridia Submit

SEARCH BY LETTER

A B C D E F G H I J K L M N O P Q R S T U V W X Y Z

LEGEND

Canadian Med | G Canadian Generic | UK Med | G UK Generic

1 Prescription Drugs Results for 'meridia'

(1 of 1) | JUMP TO PAGE: GO

MERIDIA	search for more
Generic name: SIBUTRAMINE Package size: Quantity:	N/A

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Create/Edit Account

SEARCH BY NAME

Enter the name or the first few letters of the drug you are looking for

saizen Submit

SEARCH BY LETTER

A B C D E F G H I J K L M N O P Q R S T U V W X Y Z

LEGEND

Canadian Med | G Canadian Generic | UK Med | G UK Generic

1 Prescription Drugs Results for 'saizen'

(1 of 1) | JUMP TO PAGE: GO

SAIZEN

Generic name: SOMATROPIN

Package size: 5MG-1 POWDER FOR SUSPENSION FOR INJECTION

Quantity: 1

search for more

$196.64

Add To Cart

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2. Canada Drugstore's or its contractor's manner or timeliness of completing any actions I have authorized above, including, without limitation, in prescribing the appropriate strength, dosage, or dispensing generic drugs and non-child-protective packaging;
3. My breach of any terms, conditions or representations or warranties in this agreement

$12.99

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Flat Rate Shipping

order tracking

"any and all suits"

"losses and damages of any kind"

Dear Sir,

We have pleasure to advice you that we are in a position to supply the drugs and medicine attached herewith of well known branded complanies like ABBOT,ELY LILLY. AVENTIS, BARRET HODGSON, BRISTOL MYERS , GLAXO
SMITH KLINE, CHIESI, ICI, JOHNSON & JOHNSON, KNOLL, LUNDBECK, MERCK
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SCHERING, SEARLE, SERVIER, STIEFEL, UPJOHN ETC.

Our prices are very attractive and competetive and we can become a source for your customers on back to back order basis. We can ship directly to your customer, on reciept of your advice.

We anxiously await for your response and enquiry and on reciept of which we shall be too pleased to quote our best possible prices for your kind consideration.

We trust we will be able to build long term business relations with you and anxiously await to hear from you by return.

Thanks and Regards.

R.A. Taquie

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	Ambien™	10 mg	30 tablets	$159	$99.95	38%	BUY NOW
	Lipitor™	20 mg	30 tablets	$159	$99.95	38%	BUY NOW
	Nexium™	40 mg	30 tablets	$189	$119.95	37%	BUY NOW
	Paxil™	20 mg	30 tablets	$189	$119.95	37%	BUY NOW
	Phentermine	37.5 mg	30 tablets	$139	$79.95	43%	BUY NOW
	Viagra™	100 mg	30 tablets	$399	$179.95	56%	BUY NOW
	Vioxx™	25 mg	30 tablets	$159	$99.95	38%	BUY NOW
	Xanax™	2 mg	30 tablets	$189	$119.95	37%	BUY NOW

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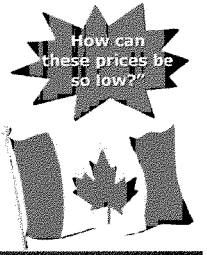


The Path of the Canadian Generics Drugs

Where are they registered?	Dandong, China
Where was the post-mark address?	Dallas, TX
Where was the return address?	Miami, FL
Where was the credit card billed?	St. Kitts
Where was the listed phone number?	Belize

Laboratory Analysis of " Canadian Generics"

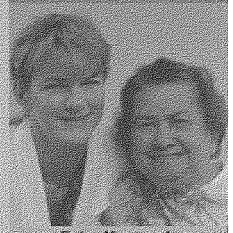
	"Lipitor"	"Viagra"	"Ambien"
Potency	Fail	Fail	Fail
Dissolution	Fail	Fail	Pass
Impurities	Fail	Fail	Pass

State of Wisconsin

Prescription Drug Resource Center

March 17, 2004

Welcome
In the News
Safety First
Your Savings Options
Ordering Information
Canada Internet Drug Prices
Recent Medicare Changes
Other Resources
Stay Informed
E-Petition
Helpline



Enter Keyword:

Search

Print Version

Order Drugs From Canada

Click to Order Drugs from Canada

Just across the border, citizens in Canada can walk into their corner drugstore and buy the same safe prescriptions we have here, but at a fraction of the price. But too many citizens of this country are forced to make unbearable choices between food and medicine. If the federal government isn't willing to take on the drug companies and fight for more affordable prices, states like Wisconsin will have to lead the way.

This website gives our citizens the ability to buy certain prescriptions at significantly lower prices directly from Canadian pharmacies that our state has visited and found to be safe, reputable, and reliable. It also provides information about SeniorCare, the new Medicare drug benefit, and other programs that may be an option for you.

The goal is to let consumers make an informed choice among all of the available options - including local pharmacies, lower price generics available domestically, and safe Canadian pharmacies.

Thanks for visiting this website. I hope you find it useful.

-- Governor Jim Doyle

—Highlights—

Governor Doyle's Radio Address on High Cost of Prescription Drugs

Governor Doyle's Letter to Attorney General Ashcroft

SENIORCARE Rx

Prescription Drugs for Wisconsin Seniors

SeniorCare

Wisconsin's Rx drug assistance program for low-income seniors

In The News

E-Petition Form

State of Wisconsin

Prescription Drug Resource Center

July 21, 2004

- Welcome
- In the News
- Safety First
- Your Savings Options
- Ordering Information
- Canada Internet Drug Prices
- Recent Medicare Changes
- Other Resources
- Stay Informed
- E-Petition
- Helpline
- FAQs

Enter Keyword:

Search

Print Version

Prescription Medicine List

Click Here For Important Information About the Legality of Purchasing Medications from Canada

Find your medicine(s) in the A-to-Z prescription medicine list below. **Click on the the appropriate letter** your prescription medicine starts with to view your specific prescription medicine. Once the prescription medicine list appears, **click on your medicine**. You will then be taken to the prescription medicine summary information page, which will show the cost for each pharmacy. Once on the medicine summary page, you will be able to **choose the pharmacy from which you want to order**. You may also view the Full A-Z List which is available in PDF Format.

A B C D E F G H I J K L M N O P Q R S T U V W X Y Z

Choose the appropriate form below. If you are ordering for the first time, you MUST USE the FIRST TIME CUSTOMER ORDER form and the ORDER SUMMARY form.

Click here for the Shipping Information

***** Please note: All prices are listed in U.S. dollars *****

Price List for LIPITOR

Canada Drugs • 1st-Time Customer Order Form — Order Form Summary

Strength	Qty	Form	Cost
80 MG	30	TABLET	$79.94
10 MG	90	TABLET	$155.59
20 MG	90	TABLET	$201.28
40 MG	90	TABLET	$219.21

Granville Pharmacy • 1st-Time Customer Order Form — Order Form Summary

Strength	Qty	Form	Cost
80 MG	30	TABLET	$79.61
10 MG	90	TABLET	$164.17
20 MG	90	TABLET	$202.46
40 MG	90	TABLET	$216.81

Total Care Pharmacy • 1st-Time Customer Order Form — Order Form Summary

Strength	Qty	Form	Cost
80 MG	30	TABLET	$75.56
10 MG	90	TABLET	$156.22
20 MG	90	TABLET	$186.38
40 MG	90	TABLET	$203.40

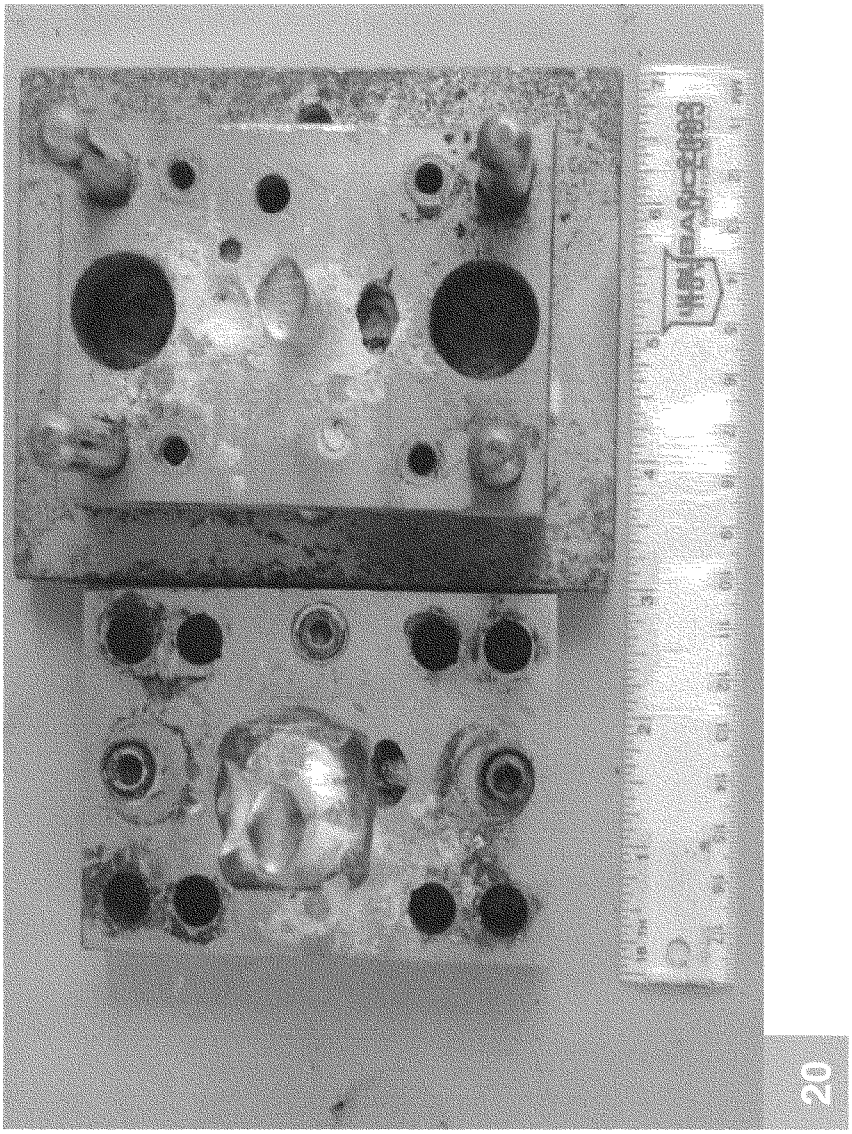
Violations of Agreement by Participating Pharmacies in Wisconsin's Website Program

- PSW Findings:
  - 1/3 of total prescriptions violated state agreement
  - 237 impermissible drugs dispensed
  - 134 non-FDA approved
  - 6 drugs requiring refrigeration
- FDA Findings:
  - 2/3 of total prescriptions violated state agreement
  - Mostly generic drugs

18

Authentic
Serostim® mg
(somatropin (rDNA origin) for injection)
Serono
Fake
Serostim® mg
(somatropin (rDNA origin) for injection)
Serono

19



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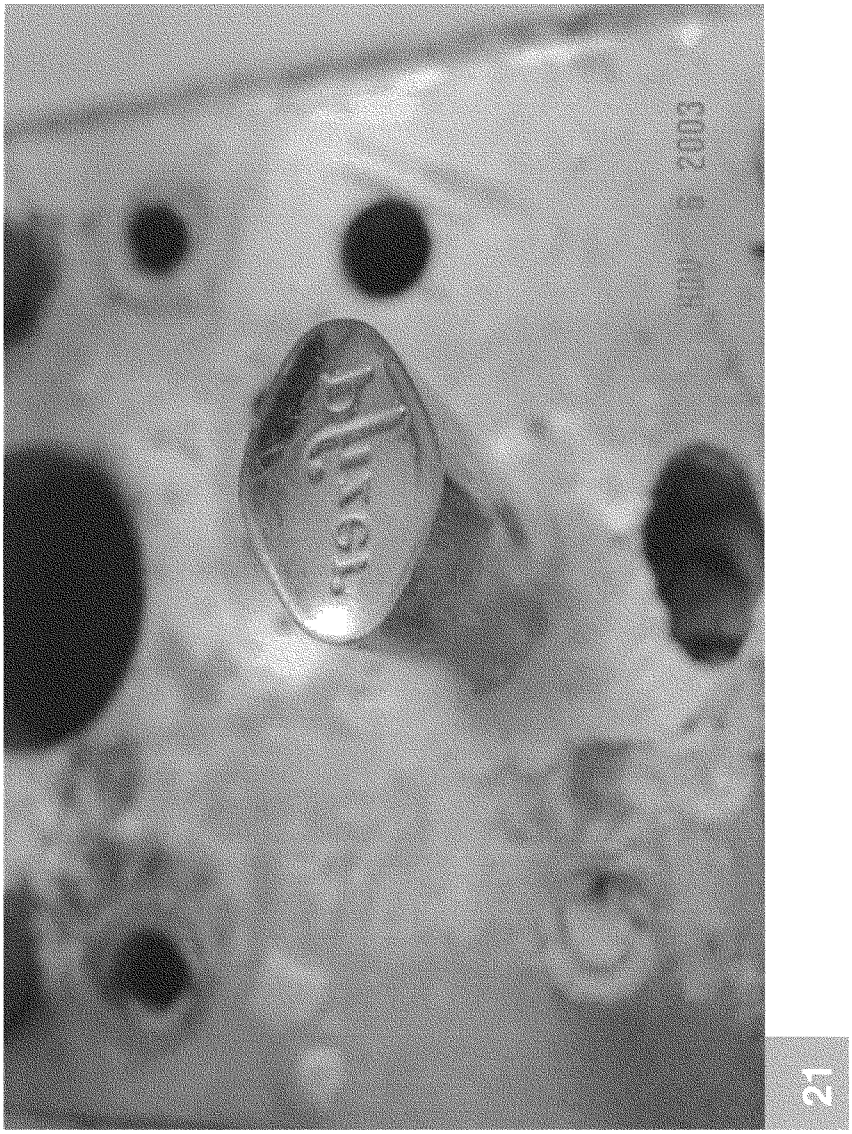

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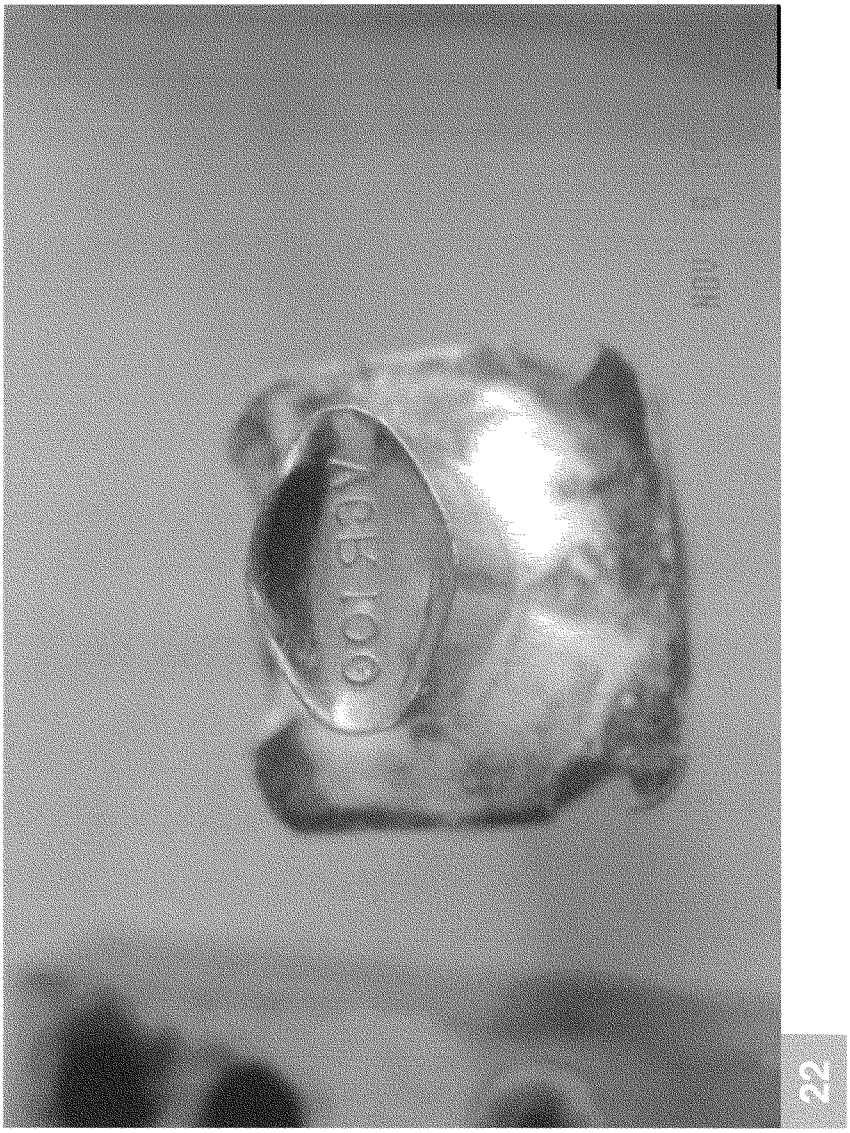

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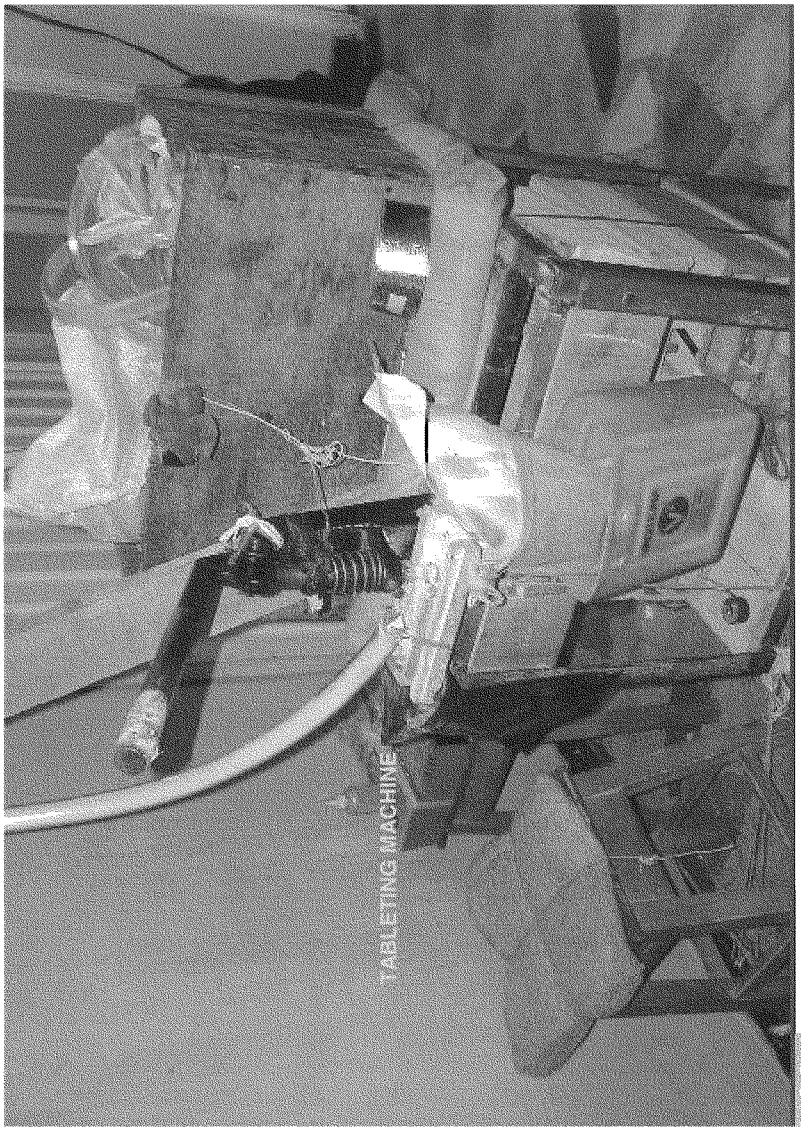

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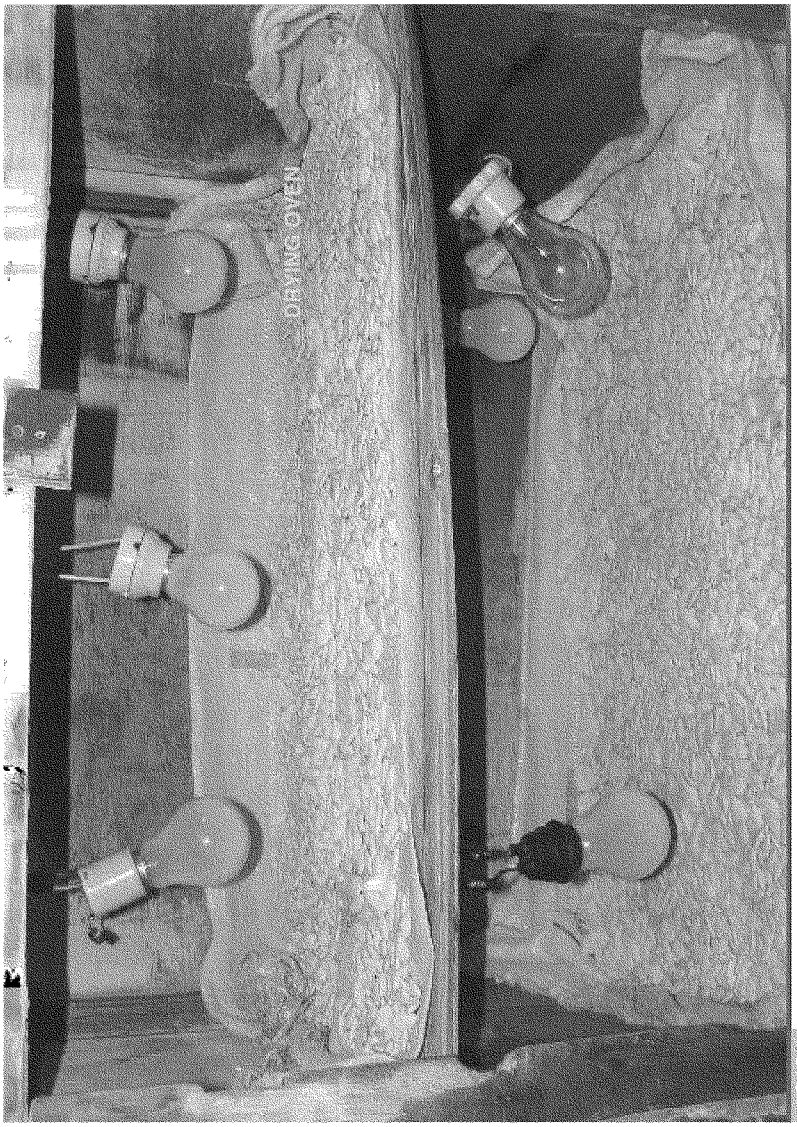

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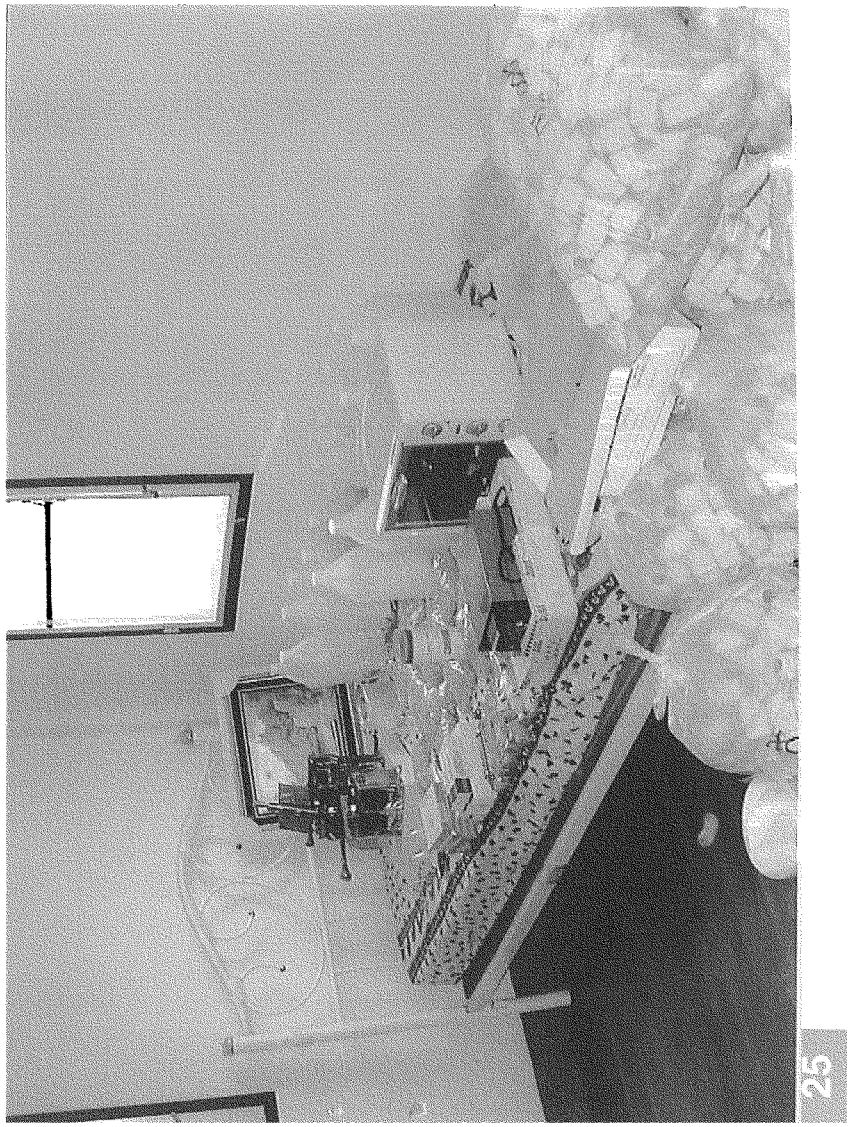
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U.S. House of Representatives

Committee on Energy and Commerce

Washington, DC 20515–6115

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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.

Permanent Subcommittee on Investigations
EXHIBIT #34a

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

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.

Permanent Subcommittee on Investigations
EXHIBIT #34b

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?

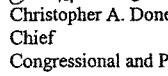
One of the key elements of Administrator Tandy's vision for the DEA is to renew a significant emphasis on taking away the proceeds of all illicit drug trade. Accordingly, DEA officials have met with both Visa and Master Card. Both companies are aware that their businesses are being exploited for illicit 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.

W.J. "BILLY" TAUZIN, LOUISIANA
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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.

Permanent Subcommittee on Investigations
EXHIBIT #34c

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

Statement of the
Federation of State Medical Boards of the United States
Committee on Governmental Affairs
Permanent Subcommittee on Investigations
United States Senate
Internet Pharmacy Safety

June 17, 2004

The Federation of State Medical Boards of the United States is a national non-profit association established in 1912, which serves as a collective voice for 70-member state medical licensing and disciplinary boards. The Federation's primary mission is to improve the quality, safety, and integrity of health care by promoting high standards for physician licensure and practice, as well as supporting and assisting state medical boards in the protection of the public.

Early Interest in Use of Internet for Practice of Medicine

The Federation has been actively involved as a national leader on the use of telecommunications and the Internet in the practice of medicine for a number of years. In 1996, the Federation published *A Model Act to Regulate the Practice of Medicine Across State Lines.* In 2000, it published guidelines for Internet prescribing. In 2002, it published *Model Guidelines for the Appropriate Use of the Internet in Medical Practice*, one of the first national standards established for Internet medical practice.
Those guidelines, which the Federation recommends be adopted by state medical boards, include a key provision:

> "A documented patient evaluation, including history and physical evaluation adequate to establish diagnoses and identify underlying conditions and/or contraindications to the treatment recommended/provided, must be obtained prior to providing treatment, including issuing prescriptions, electronically or otherwise."

This has been the key interest of the Federation with respect to Internet pharmacies. There must be an appropriate relationship between the patient and the physician before a prescription is written and dispensed.

Internet Clearinghouse

In addition to issuing these guidelines, the Federation has aggressively sought to identify Internet pharmacies that are dispensing drugs on the basis of prescriptions written by health care providers whose relationship with the patient does not appear to meet minimal standards. In September 2000, the Federation of State Medical Boards established The National Clearinghouse on Internet Prescribing, to collect and disseminate information on "rogue" Internet sites offering prescribing and dispensing services for prescription drugs to consumers.

The Clearinghouse is uniquely qualified to coordinate information between regulatory and enforcement entities because of its formal relationship with all state medical boards in the U.S. and its territories and its well-established lines of communication with state and federal

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regulatory agencies, including the Department of Justice, the Drug Enforcement Agency, the Food and Drug Administration, and the Federal Trade Commission, as well as the National Association of Boards of Pharmacies, the National Association of Drug Diversion Investigators , and the National Association of Attorney Generals, representatives of the pharmaceutical industry, and the media.

Results of Clearinghouse Activities

To date, approximately twelve physicians have been the subject of disciplinary sanctions based on Clearinghouse supplied information. The Clearinghouse has supplied information for more than 127 cases on the federal level and more than 200 cases on the state level. Additionally, information regarding Internet prescribing has been shared with the Medical Council of New Zealand and the Ministry of Health in Germany.

Enforcing the Law

The Federation strongly supports state-based regulation of the practice of medicine. With regard to Internet prescribing, state medical boards have the authority to discipline licensed physicians prescribing and dispensing medications inappropriately. Several boards have already taken actions against licensees, adopted rules/policies or introduced legislation to clarify this authority. In addition, state medical boards are communicating among themselves regarding physicians licensed in more than one state. These cooperative efforts have been effective in closing several Internet sites and causing a number of physicians to cease their affiliation with questionable operations.

Need for Federal Legislation

The Federation believes that S. 2464, the Ryan Haight Act, should be enacted for the following reasons.

First, patients should know with whom they are dealing. They should know the name and location of the pharmacy that is dispensing the drug and the name of the physician who will be providing a medical consultation that will be the basis of a prescription. Almost without exception, a state would find that such physician had violated licensure standards if he or she wrote a prescription on the basis of an online questionnaire without having any preexisting relationship with the patient. Therefore, disclosure will not only be beneficial to patients, but will allow medical licensing boards to identify individuals against whom they can take disciplinary action. S. 2464 specifically addresses the issue of disclosure by amending the Food Drug and Cosmetic Act with the addition of a new Section 503B(a).

Second, currently state attorneys general are not able to enjoin the operations of an Internet pharmacy that affect citizens in their particular states if that pharmacy is operated out of another state. Many of our member boards have indicated that they believe that a number of Internet sites that dispense drugs in an inappropriate manner could be shut down if the attorneys general had nationwide injunctive powers as well as the ability to pursue other civil remedies including damages, restitution or other compensation across state lines. S. 2464 addresses this issue by amending the statute mentioned above with the addition of a new Section 503B(c)

Third, while state licensing boards have the authority to discipline physicians who are prescribing and dispensing drugs over the Internet inappropriately, and many boards have taken such action, medical licensing boards cannot take actions against operators of Internet sites that dispense drugs. While state licensing boards believe that the law and regulations governing the physicians in their state are clear as to what constitutes an appropriate physician-patient relationship for purposes of writing a prescription, some courts and prosecutors have indicated that they believed that certain state laws and regulations are ambiguous in this regard. Because of that ambiguity, prosecutors have not pursued certain legal actions.

The Federation worked with Congress to try to craft language that would define an appropriate physician-patient relationship for purposes of regulating Internet pharmacies, while preserving the rights and responsibilities of state medical licensing boards. The language in S. 2464, adding a new Section 503B(b) to the Food, Drug and Cosmetic Act, strikes a reasonable balance in requiring and defining an appropriate physician-patient relationship for the narrow purpose of regulating Internet pharmacies, while recognizing the exclusive role of state medical boards in defining that relationship under other circumstances.

In conclusion, the Federation of State Medical Boards believes that enactment of S. 2464 into law will provide significant protection for consumers who use the Internet to obtain pharmaceuticals.

Statement on

Internet Pharmacy

Prepared for

Senate Governmental Affairs Committee,
Permanent Subcommittee on Investigations

Presented by

National Association of Chain Drug Stores, Inc.

Thursday, July 1, 2004

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Mr. Chairman and members of the Committee. The National Association of Chain Drug Stores (NACDS) is pleased to submit a statement for the record on the important issue of Internet pharmacy.

NACDS represents more than 210 chain pharmacy companies operating about 35,000 community retail pharmacies. Our members are the primary providers of outpatient prescription services in the United States, filling more than 70 percent of the 3.4 billion prescriptions dispensed in 2003. A growing number of our members provide services through the Internet.

Internet Access to Pharmacy Provides Convenience for Patients: In this age of immediate information and consumer convenience, most retail businesses have Internet sites available to consumers. In particular, retail pharmacies maintain Internet sites that provide consumers with convenient access to their products and services. The vast majority of legitimate pharmacy-based Internet sites are operated by traditional state-licensed "brick-and-mortar" pharmacies that maintain those sites for the convenience of their patients. These sites allow patients to order prescription refills and non-prescription items. Most of the legitimate sites do not allow ordering of new prescriptions, other than perhaps to allow a patient to ask a pharmacist to call the patient's physician, where a legitimate medical relationship has already been established. Legitimate retail pharmacy Internet sites are not affiliated with, and do not provide, a prescriber for the patient.

While there are a handful of legitimate, state-licensed pharmacies whose only connection to consumers is via an Internet site, we are well aware of the existence of rogue Internet sites, both domestic and foreign, that are engaged in a pattern of illegal activity regarding the prescribing and dispensing of prescription medications. We deplore these activities. Policymakers have legitimate concerns about the patient safety implications of prescription medications sold through these rogue Internet-based entities. These entities sell prescription medications, usually without a legitimate medical relationship with the consumer, and even without a valid prescription. Many of these so-called "pharmacies" are not licensed by any state or other jurisdiction, and are shipping unapproved, counterfeit, mislabeled, or adulterated products within or into the United States.

NACDS wants to work with Members of Congress and regulators to eliminate these illegal Internet suppliers from the market. Foreign-based pharmacies that attempt to falsely represent themselves as U.S.-based or, in some instances, as presumably safe Canadian-based Internet sites are a major source of the dangerous, unapproved, and adulterated pharmaceuticals being shipped into the United States.

Consequently, patients assume an incredible risk when they go shopping internationally for health care products. In the case of international Internet pharmacies, there is virtually no way for consumers to discern a "legitimate" source from a dangerous source. If the drug is sub potent or adulterated or otherwise ineffective, any savings realized is lost. Moreover, many of these international businesses, purportedly doing

business in Canada, are not what they advertise to consumers and their drug supply may be from questionable sources.[1]

Elimination of these sites and their sources of supply could significantly reduce the flow of illegal products into this country. Federal Internet pharmacy legislation must target the elimination of these sites, without adversely impacting legitimate traditional "brick-and-mortar" pharmacies that merely operate an Internet site.

The impact of any new Federal regulation of the Internet could also have unintended consequences. For example, we know that the recently-enacted Medicare legislation requires the Secretary to create standards for the electronic transmission of prescriptions from physicians to pharmacies. Sending prescriptions electronically offers great promise both in terms of enhancing patient safety and assuring cost-effective drug therapy. However, we are concerned that attempts to regulate the transmission of legitimate prescriptions – both new and refill – over the Internet from physicians to pharmacies could stifle the many benefits that are available through electronic

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[1] *See* Testimony of William Hubbard, Associate Commissioner of Policy and Planning and Legislation, FDA, before the Committee on Government Reform, U.S. House of Representatives (June 24, 2003) (discussing purported Canadian pharmacy service website run by three-time convicted felon which delivered drugs made in India to an American who ordered from website); *see also*, Global Options, Inc., "The Analysis of Terrorist Threats to American Medicine Supply," (2003) at 145-48. *See* Testimony of William Hubbard, Associate Commissioner of Policy and Planning and Legislation, FDA, before the Committee on Government Reform, U.S. House of Representatives (June 24, 2003) (discussing purported Canadian pharmacy service website run by three-time convicted felon which delivered drugs made in India to an American who ordered from website); *see also*, Global Options, Inc., "The Analysis of Terrorist Threats to American Medicine Supply," (2003) at 145-48. Also, the Coalition for Manitoba Pharmacy reported on April 2, 2004 that a Vancouver internet pharmacy company is openly selling Americans prescription medicines from Mexico, approved by neither HealthCanada nor the U.S. Food and Drug Administration. *See* Manitoba Coaltion of Pharmacy, "Vancouver Internet Pharmacy Selling Mexican Drugs to Americans," Press Release (April 2, 2004) ("Press Release"). The company, www.canadianpharmacytrust.com , which dispenses drugs through its "affiliate" Southland Pharmacy of Vancouver, announces on its website "Generic Viagra now available at 80% off," and "Generic Cialis & Levitra also available from our pharmacy. Why pay more?!?"
"They are shipping Americans drugs from Mexico," said Michele Fontaine, Vice President of the Coalition for Manitoba Pharmacy in the Press Release. "Who knows what's in those pills? These drugs have not been validated by Health Canada or the FDA. And it seems that they're violating U.S. and Canadian patent laws, too. From our perspective it looks like internet pharmacy companies will stop at nothing in putting profits before the interests of patients. To me, this isn't pharmacy, its piracy."
"And now they're openly selling Americans medicines not just from Canada's supply, but from any other country where they can get their hands on more drugs," said Fontaine in the Press Release. Fontaine went on to say that "[t]he trans-shipment of medicines originating in distant countries has been a major concern for pharmacy and medical organizations in Canada and the U.S., as well as for the FDA. Research from Prudential Financial and the FDA has indicated a major increase in drug imports to Canada from countries including Bulgaria, Pakistan, India and Argentina. If, as the Coalition believes, these drugs are being trans-shipped to the U.S., the concern is that neither the FDA nor Health Canada verifies whether these medicines are safe and effective, or if they even contain the proper active ingredient."

prescribing. The point is that legitimate pharmacies should not inadvertently be included in legislation targeting illegal entities.

Legitimate Pharmacies are Already Highly Regulated by the States: State boards have effectively regulated the practices of medicine and pharmacy for more than 100 years. We are concerned that Federal regulation of Internet pharmacies will ultimately lead to Federal regulation of pharmacy practice. That is, we are concerned that Federal regulation of Internet pharmacies would result in de facto Federal regulation of all pharmacies – including traditional brick-and-mortar pharmacies that have Internet sites. That will occur unless Federal legislation distinguishes between traditional brick-and-mortar pharmacies with Internet connections that are already licensed by state boards of pharmacy, versus pharmacies whose primary method of access by consumers is via the Internet, where there is no state board licensure.

Currently, all pharmacies must be licensed by the state in which the pharmacy resides, including pharmacies that have Internet websites. Many states also require licenses for out-of-state pharmacies that ship or mail pharmaceuticals into the state to residents; in other words, many states require non-resident pharmacy licenses. To secure and maintain their state licenses, all legitimate pharmacies must comply with voluminous regulations, which are continuously updated. Illegal "pharmacies" are those without state licenses. State pharmacy boards do not have the authority to license foreign pharmacies. Any Federal legislation should not subject state-licensed pharmacies to further regulation, simply because they provide consumers the option of ordering via an Internet site.

Our perspectives on Federal initiatives to regulate Internet pharmacies are based on several criteria and their impact on our patients and our industry.

Entities Subject to Legislation: First, the entities that any Internet pharmacy bill will seek to regulate must be carefully defined, since the broader the definition, the more likely that traditional brick-and-mortar pharmacies with Internet sites will be swept into the regulations.

For example, proposals that broadly regulate pharmacies if any part of the prescription ordering or sales transaction is conducted through an Internet site are problematic. Legitimate state-licensed pharmacies that merely operate Internet sites for the purposes of allowing patients to order refill prescriptions could be subject to this bill. This would be duplicative of the existing state-based retail pharmacy regulatory scheme.

Congress should also avoid legislative language that could prohibit legitimate pharmacies from contacting physicians for prescription refills through the Internet. If Congress were to indicate that a pharmacy may not dispense a prescription if the patient did not have a prescription for the drug when the communication began, a prescription with no more refills, for example, would no longer be a valid prescription. This raises several questions about whether a pharmacist can use the Internet, or an

electronic prescribing technology that is Internet-based, to contact a prescriber to obtain permission to obtain permission to create a new prescription for that drug.

We believe that any legislation must be narrowly tailored to affect only the offending entities that are not licensed as a pharmacy in the United States. For these reasons, we believe that an Internet pharmacy should be defined as a pharmacy that: (1) uses the Internet as the primary method to facilitate the ordering of a prescription and the receipt of prescriptions for filling; (2) uses mail or commercial carriers as the primary method to deliver the prescriptions to patients; and (3) is not licensed by the board of pharmacy in the states to which they are sending prescription drugs.

Internet Disclosure Requirements: Second, some Congressional proposals would require Internet pharmacies to disclose certain information, similar to the information that traditional pharmacies have already posted in their stores about licenses, pharmacists, and certain other information as required by state boards of pharmacy. The goal of any Internet pharmacy legislation would be to provide consumers with sufficient information to assess the legitimacy of the Internet pharmacy and assure that consumers can make an informed decision about whether they want to obtain a prescription drug from an Internet site. NACDS believes that such information can be helpful to consumers in assessing the quality of the Internet site.

However, such disclosure requirements could be interpreted to require every community pharmacy that has an Internet site to post on the site information relating to the names and licensure status of its pharmacists for each pharmacy that it operates. Duplicative and burdensome "posting" requirements should not be imposed on legitimate retail pharmacies simply because they operate an Internet site.

For example, a pharmacy chain of 400 stores that has an Internet ordering connection might be required to post on its website licensure information about each and every one of its pharmacists at each and every one of its stores. Many pharmacists are licensed in multiple states, which requires the pharmacy operator to know significant licensure information about the pharmacist beyond that which is already require to practice in their own state. Finally, pharmacists often change pharmacy practice locations, making it impossible to accurately maintain this type of information on an Internet site. The burden of this requirement is obviously greater for chains with thousands of operating units. This would create significant burdens for pharmacies to continually update their Internet sites.

These burdens are duplicative, because pharmacy stores are already required by state boards of pharmacy to visibly post this information in each pharmacy outlet. Therefore, brick-and-mortar pharmacies with Internet sites should not have to aggregate and post this information on their sites if the information is already posted in their individual stores.

Certification of Internet Pharmacies: Third, many legitimate pharmacies have already invested substantial resources in obtaining certification of their Internet site under the

National Association of Boards of Pharmacy (NABP) Verified Internet Pharmacy Practice Sites (VIPPS) certification program. NABP is the professional association that represents the state boards of pharmacy in all U.S. jurisdictions. In response to public concerns regarding the safety of pharmacy practices on the Internet, NABP developed the VIPPS program in 1999. A coalition of state and federal regulatory associations, professional associations, and consumer advocacy groups provided their expertise in developing the criteria that VIPPS-certified pharmacies follow. To be VIPPS certified, a pharmacy must comply with the licensing and inspection requirements of their state and each state to which they dispense pharmaceuticals. In addition, pharmacies displaying the VIPPS seal have demonstrated compliance with VIPPS criteria including patient rights to privacy, authentication and security of prescription orders, adherence to a recognized quality assurance policy, and provision of meaningful consultation between patients and pharmacists. The VIPPS program can be considered the gold standard for Internet pharmacy certification programs. The VIPPS program requires rigorous certification and recertification of pharmacies that have Internet sites. Fourteen pharmacies have VIPPS certification, and many other are currently engaged in the VIPPS certification process.

This VIPPS "seal of approval" should be sufficient for consumers and policymakers to be sure that the Internet site is legitimate and will provide quality pharmacy services to consumers. This recognition of VIPPS certification should be incorporated into any legislative proposal. It would be redundant for pharmacies with Internet sites that are certified by VIPPS to also have to meet Federal requirements. Additionally, we are concerned that multiple Internet pharmacy certification programs may cause public confusion, and may require conflicting and substandard certification requirements.

State Causes of Action and Penalties: Fourth, there are legislative proposals that would give state attorneys general the authority to enforce certain provisions of Federal Food, Drug, and Cosmetic Act by seeking nationwide injunctions against Internet pharmacies. A nationwide injunction would prohibit the Internet pharmacy from doing business in all states, rather than just the state in which the state attorney general is located.

We recognize that the state attorneys general may want this authority to help shut down illegal entities on a nationwide basis, so that each state attorney general does not have to bring separate actions in their own states. However, we are concerned that this proposal represents an overly broad grant of authority that would give state attorneys general nationwide jurisdiction to take action against legitimate brick-and-mortar pharmacies that happen to have Internet sites.

With billions of prescriptions being filled each year, pharmacies could inadvertently and unknowingly violate the Food, Drug and Cosmetics Act. Thus, it is possible that this new authority could result in aggressive action by a state attorney general against a nationwide or regional chain for unintended violations of the Food, Drug and Cosmetics Act, simply because they provide consumers with an Internet connection.

Rather than grant nationwide federal powers to states attorneys general, Congress should grant the U.S. Department of Justice discretion to intervene in actions filed by state attorneys general to enforce the Federal Food, Drug and Cosmetics Act. The Department of Justice could then seek a nationwide injunction against an illegal Internet pharmacy. That would respect the principles of federalism while shutting down illegal Internet pharmacies.

Beyond leveling fines against Internet pharmacies that violate the law, penalties should also be assessed against prescribers that order prescriptions for consumers outside a valid physician-patient relationship. Success in eliminating the dispensing of prescriptions from illegal entities will only be reached if all contributing entities are targeted for violations.

Another concern is exclusion of the advertisers of illegal Internet pharmacies from liability. Advertisers should not be exempt from liability when they publicize illegal drug sales over the Internet. Any bill should state that advertisers may be held liable when they know or reasonably should have known that they are aiding and abetting illegal drug sales.

Workable Solutions: Despite our reservations, NACDS has seen favorable provisions in proposals we believe would help eliminate illegal Internet entities that sell prescription drugs. NACDS encourages the following:

- Narrowly limit the definition of Internet pharmacy to exclude legitimate, state-licensed brick-and-mortar pharmacies in this new regulatory structure, and specifically target rogue Internet pharmacies.
- Encourage and empower federal and state agencies to work together to enforce existing laws against illegal Internet pharmacies in federal and state courts.
- Clearly identify legitimate pharmacy Internet sites through a credible and thorough certification program.
- Educate consumers about the dangers of dealing with illegal Internet pharmacies, and provide a convenient method for consumers to report suspected illegal entities to state boards of medicine and pharmacy, and to the state attorneys general, for investigation.
- Require a pharmacy that maintains an interactive consumer Internet site to list on the site the states in which it maintains valid pharmacy licenses.

Conclusion

NACDS agrees that illegal Internet "pharmacies" present patient health and safety concerns. However, existing laws and regulations have not been adequately enforced that could rectify many of the problems that already exist.

We have concerns that many proposals create an unprecedented beachhead for FDA to regulate the practices of medicine and pharmacy, which traditionally have been the authority of the states. While illegal Internet entities must be shut down by Congress

and the states, consumer access to prescription medications through legitimate pharmacies must be protected. We look forward to working with this Committee and the Congress in defining that appropriate balance and achieving the overarching goal of eliminating rogue Internet operations that threaten our drug supply and patient safety.

Statement of
James Christian
Vice President and Head of Global Corporate Security
Novartis International AG

before the
Senate Government Affairs Committee
Permanent Subcommittee on Investigations
July 22, 2004

My name is James Christian and I am Vice President and Head of Global Corporate Security for Novartis International AG. My primary responsibility is to protect the assets and reputation of Novartis group of companies in the 140 countries in which they market products or in which the products or their raw ingredients are manufactured, packaged, stored, or shipped. Over the past 15 years, I have witnessed firsthand the considerable ingenuity and resourcefulness that unlawful enterprises in foreign countries utilize to manufacture and distribute ineffective and frequently unsafe counterfeit prescription drugs. It is beyond peradventure that foreign drug counterfeiters take full advantage of offshore mail-order pharmacies, the Internet, and distribution channels in other countries to market their illicit goods. The financial rewards for drug counterfeiters compel them to make every effort to penetrate the lucrative U.S. marketplace, causing considerable harm to the health and safety of American citizens. Proposals to permit importation of drugs into the United States from foreign countries will play into the hands of counterfeiters and black marketers whose illegal enterprises will be greatly facilitated by such legislation.

NOVARTIS' INTERESTS

Novartis is a group of multinational research-based health care businesses. The corporate parent is headquartered in Basel, Switzerland, and the U.S. pharmaceuticals company is located in New Jersey. The group of companies has more than 67,000 employees worldwide with over 15,000 located in the United States. In 2004, Novartis will spend approximately four billion dollars on research and development of new pharmaceutical therapies. The companies' product lines includes 126 prescription drugs to treat or prevent conditions as varied as leukemia, rheumatoid arthritis, schizophrenia, hypertension, Alzheimer's disease, high cholesterol, migraine headaches, epilepsy, cancer, and organ rejection in kidney, liver, and heart transplants.

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It is absolutely essential that patients using Novartis products, and the physicians who prescribe them, have complete confidence that the drugs are safe and effective. For this reason, Novartis has dedicated considerable manpower and financial resources to combating drug counterfeiting on a global scale. Novartis works closely with law enforcement and health authorities in numerous countries to investigate and suppress the counterfeiting of its products. Equally important are Novartis' efforts to ensure that drugs purchased from Internet pharmacies are authentic, safe, and effective.

COUNTERFEITING

Counterfeit drugs are "fake" products, produced and packaged to look like the genuine article. They may include products containing correct ingredients, incorrect ingredients, no active ingredient, an insufficient quantity of active ingredient, and have phony packaging and labeling. Illicit operations may combine counterfeit product with adulterated or expired product, or on occasion, with genuine product to make detection more difficult. Counterfeiters employ state-of-the-art technologies such as desktop publishing to produce counterfeit labels that are indistinguishable from the true original labels. These labels put false "new" expiration dates on expired products and make adulterated or ineffective drugs look like the real thing. Counterfeiters have the ability to make and stamp tablets with company logos and even to package them in blister packs.

The threat of drug counterfeiting is not fanciful conjecture – it is a real and present danger. Novartis has first-hand knowledge of numerous examples of counterfeiting activities. Consider the following:

(1) A raid on a counterfeiter's facility uncovered tens of thousands of vials of a drug whose expiration date had long-since passed. The vials were soaked in hot water to remove old labels, and counterfeit labels bearing a new expiration date were affixed. Not only were the drugs past their expiration date but they likely lost any remaining efficacy when their temperatures were raised to unacceptable levels during the label-removing process.

(2) Novartis helped interdict millions of counterfeit yellow tablets of a popular pain killer that were virtually indistinguishable from the genuine product – including the company logo stamped onto the pill. These tablets were made from boric acid, floor wax, and lead-based yellow paint used for road markings. There was no active ingredient in the pills.

These are not isolated examples. Over the last five years, Novartis has assisted or otherwise been involved in over 100 investigations of counterfeiting operations, in over 33 countries, involving more than 11 Novartis products and more than 200 products manufactured by other companies.

Drug counterfeiting is a prevalent and pernicious problem throughout the world.

Mexico and Central America. Counterfeit products are a major concern in Mexico, Central America, and the Dominican Republic. Counterfeiting in Mexico is particularly dangerous for American consumers because of the shared border between Mexico and the United States. U.S. consumers traveling to Mexico to buy products off pharmacy shelves are often purchasing dangerous counterfeit or adulterated products. American law enforcement officials have opined that the amount of counterfeit and substandard medications in Mexico could be as high as 25 percent. Based on Novartis' knowledge, the problem could, in fact, be much larger.

Argentina. From May 1999 until June 2000, Novartis cooperated with authorities in Argentina to combat the counterfeiting of four Novartis products – Voltaren (an anti-inflammatory), Tegretol (an anti-epileptic), Hydegine (dementia), and Reliveran (arthritis). As a result of that investigation, 72 individuals were arrested, 7 tons of counterfeit pharmaceuticals were seized, 49 different pharmaceuticals were identified, 13 clandestine laboratories were dismantled, and 5 print shops were seized.

Brazil. In 1999, 132 counterfeit drugs – involving products from most of the major pharmaceutical companies – were being distributed in Brazil. The Pharmaceutical Security Institute (an industry organization formed to support anti-counterfeiting efforts) worked with the Brazilian Minister of Health to train a team of 25 investigators to attack the counterfeit medicine

problem. Approximately 20 clandestine labs were seized and numerous arrests were made as a result of these efforts.

Columbia. Counterfeit drugs are manufactured in Columbia for international distribution. In 2000 alone, more than 400 products from 80 companies, either expired, adulterated, diverted or counterfeit, were seized by INVIMA (the Columbian food and drug authority) in collaboration with Novartis and other pharmaceutical companies. Some of the seizures have been huge – e.g. in one instance, approximately 6 million ampules of counterfeit Voltaren were seized. In another case, tens of millions of counterfeit tablets of a non-steroidal anti-inflammatory drug were seized.

Asia. The counterfeiting of pharmaceuticals is a burgeoning problem in China. For example, in March 2001, Novartis and other pharmaceutical companies participated in a raid with authorities in Shantou that resulted in the seizure of over 1800 cartons of counterfeit pharmaceutical products from 14 multinational companies.

India. Another threat to U.S. consumers relates to the distribution of bulk pharmaceutical products from India. Health authorities in a number of Latin American countries believe that India and Cuba use the region as a dumping ground for batches of substandard pharmaceuticals, ultimately providing for easy entry into the US marketplace. Health authorities there have discovered products without sufficient active ingredient and some even contaminated with foreign materials including pieces of glass.

Russia. Russia is a drug counterfeiter's paradise. Politically connected counterfeiters in that country face little resistance from the government, and the laws and penalties for counterfeiting pharmaceuticals are weak or non-existent. With the recent expansion of the European Union, the EU border in the east is no longer the well-controlled German border but instead is the much more porous Polish border. Once counterfeit drugs have crossed Poland's relatively unprotected border, they have virtually unobstructed access to the markets in France, Germany, Spain, and the rest of the European Union countries. Under several of the drug importation proposals currently under consideration in Congress, counterfeit drugs from Russia, which have passed through nations in the European Union could easily find their way to

pharmacy shelves in the United States. Indeed, some counterfeit Russian pharmaceuticals have already been discovered in this country.

INTERNET PHARMACY

The Internet pharmacy marketplace is expanding at an enormous rate. Unfortunately, counterfeit and substandard drugs are finding their way into this market with astounding ease. There is a general perception that Internet pharmacies located in Canada are reliable sources of safe and effective drugs. Such an assumption is unfounded and dangerous. Many of the websites that make reference to Canada in their names and sport the Canadian flag or Maple Leafs on their WebPages are not in Canada at all. Some the Internet operations are in Asia and India while others are in South America and even the United States. The Internet pharmacies create the impression that they are selling Canadian drugs; many are not. They are peddling drugs made in Bangkok, not New Jersey.

Drug purchasers from Internet sites are also in the dark about another critical factor: were the products stored and shipped in a manner that ensures that they are safe and effective. Even a bona fide pharmaceutical purchased from a website (or imported commercially) can become ineffective or even harmful if it is not stored and shipped correctly. Important questions abound when attempting to ascertain the safety and efficacy of drugs purchased over the Internet: Where were the drugs stored prior to shipment to the end-purchaser? Were the storage facilities temperature and climate controlled? Were the drugs transported in a manner that protects them from spoilage? If a shipment of drugs were exposed to harsh conditions—e.g. the extreme cold of a Canadian winter—would that exposure be known to the person to needs the drugs? Did the failure to properly store and ship the drugs compromise their efficacy and/or safety? How would a patient or physician ever know?

Novartis has taken an active role in monitoring on-line offerings of its ethical pharmaceuticals and, periodically ordering product in order to examine the quality, authenticity, and condition of its prescription products received from these suppliers. The market sweeps in this ongoing exercise are not focused solely on so called "Canadian Internet" suppliers but covered a broad range of off-shore suppliers. Several noteworthy purchases which highlight the risk associated with the ease of obtaining these drugs via the internet are outlined below.

Several orders of Lotrel 10mg. tablets were placed and three orders received. (Lotrel is a branded, fixed-dose combination product with two active ingredients, amlodipine and benazepril.) Two of the Internet suppliers substituted Benace (foreign version of benazepril) and Amdepin (foregin version of amlodipine) for genuine Lotrel. However, the orders did not contain the same proportion of Benace and Andepin needed to reproduce the effects of Lotrel 10 mg. and no directions were included in the shipments. The shipments were received from Fiji and Thailand.

Three orders of Diovan 80mg tablets were obtained from three separate Internet suppliers. One package was received from Thailand which contained an English label. This product was not intended for distribution in the United States. The second package was from Mexico and had only a Spanish label and Spanish package insert. The third package of Diovan was shipped from Fiji and contained a generic substitution for Diovan which is not approved for use in the United States.

One order of Lamisil 250mg tablets was shipped from Mexico and arrived without a package insert or carton and the tablets were shrink wrapped in a "food saver" bag.

Finally, and perhaps most troubling, two separate orders for Clozaril were received from Canadian suppliers. (Clozaril is specially regulated and patients must be listed on an approved registry before dispensing of this product.) In two cases the vendor accepted a faxed copy of a prescription and conducted no follow up to verify the script's authenticity. The patients were not added to the required registry.

Novartis also examined its adverse events reports to ascertain whether any such events could be traced to imported drugs. The search revealed that there may indeed be such a link.

Over the past two years, a number of patients have called Novartis' drug information center to express concern about medications received from Canada. On four documented occasions, the patient's symptoms worsened while taking drugs from Canada and improved once he or she resumed taking medication manufactured and sold in the United States. One woman taking Diovan tablets bought Diovan capsules from Canada; she experienced blurred vision,

dizziness, and higher blood pressure while on the Canadian capsules. Once she returned to taking Diovan tablets purchased in the U.S., her symptoms improved.

A woman who was taking Estraderm 50 mcg began using patches from Canada. While using the Canadian patch, she experienced breast pain but once she stopped using the Canadian patches, the breast pain disappeared. Another patient who was prescribed Lamisil tablets reported that he was not getting the same results from products purchased at a Canadian pharmacy that he was with the products purchased from a U.S. pharmacy. He reported that the printing on the tablets was not the same on the Canadian and U.S.-purchased products. Finally, a patient had had a prescription for Tegretol CR reported experiencing severe nausea and disorientation the day he switched from Tegretol-SR to Tegretol CR and had received the new prescription through the mail from Canada. He switched back to Tegretol-XR therapy and his condition improved.

Other patients reported adverse events following the purchase of prescription drugs from Canada. One patient purchased Diovan on the Internet. The drug had passed its expiration date, and the patient developed pulmonary infiltrates on x-ray. While the patient had a history of hypertension there was no sign of heart failure.

In August 2003, a patient who had been prescribed Lotensin 20 mg tablets for ten years began taking Lotensin that had been purchased from a pharmacy in Canada. She stated that the tablets looked different than the ones she had taken in the past. Three months later, she was admitted to the hospital after experiencing heaviness in her chest. She received nitroglycerin, a heart catheterization, and a blood thinner.

COMBATING COUNTERFEIT DRUGS

Many counterfeit pharmaceuticals are manufactured so cleverly that it is virtually impossible for consumers, government officials, and law enforcement agencies to identify them as counterfeit. Counterfeiters do not care about the quality and safety of the product. They concentrate their resources on the appearance of the product and its packaging. The goal is to sell a cheap, fake product to an unsuspecting consumer, not to provide a safe and effective

medicine to a patient. This simple fact makes it extremely difficult to control drug counterfeiting.

Novartis, like other drug companies, and, unfortunately, law enforcement authorities, are hampered in the effort to control international counterfeiting practices by several factors including the: (1) difficulty of detecting counterfeits; (2) lack of dedicated resources in local jurisdictions and the failure to give appropriate priority to anti-counterfeiting activity; (3) ingenuity of counterfeiters and the ease with which criminal elements can resume operations at new sites; and (4) lack of applicable criminal statutes and the prevalence traditionally light sentences.

Proponents of legislation to permit drugs to be imported into the United States from foreign countries have placed great faith in the ability of new security technologies to curtail drug counterfeiting. Unfortunately, such reliance is misplaced in the real world.

While certain overt and covert technologies may improve the distribution system and increase the manufacturers' ability to manage the supply chain and to track and trace products, no one has yet demonstrated the ability of such technology to protect against counterfeiting. A survey of pharmaceutical companies last year by the Pharmaceutical Security Institute revealed that, while the vast majority of manufacturers are examining, implementing, or planning to implement new secure packaging technology, only 15% of them believed that such steps would prevent the types of counterfeit cases they have previously encountered.

New anti-counterfeiting technologies have numerous shortcomings including, inter alia:

- In almost every case, the technology, be it a hologram, tamper proof labels, embossing, thermo-reactive ink, RFID tags, DNA markers, and the like, enable companies to track cardboard not product. It is not unusual to find genuine product in counterfeit packaging and counterfeit product in genuine packaging.

- In the United States and in the European Union, the two largest pharmaceutical markets in the world, repackaging is legal; thus, without violation of any law,

packaging with all types of expensive, state of the art secure devices can end up in the trash or worse, in the hands of a counterfeiter, while genuine product is legally distributed in packaging with no security features.

- RFID technology which was featured in a recent FDA task force report has multiple deficiencies.

  - RFID has no accepted standards.

  - A counterfeiter or diverter could purchase RFID tags and mimic manufacturers' RFID codes.

  - Industries which have and are using RFID products have noted that when their products enter the "grey market", their RFID tags are often "zapped" rendering them unreadable. It is in this "grey market" where the RFID tags must perform. One cosmetic company tried to use RFID technology, but found that the chips were too vulnerable to disruption because they could be easily altered, damaged, or destroyed by cutting, scratching, brewing, or microwaving them. In situations where the manufacturer attempted to conceal the RFID chip inside the packaging or label, the counterfeiter/diverter examined the label to the point of destruction to locate the chip. Once found it was rendered useless.

  - One research study revealed that RFID tag failure rates are as high as 30% and upon failure often act as a blank or unprogrammed tag would react. In order words, when passed near the tag reader they simply do not respond. A counterfeiter or diverter, by applying tags and that are physically the same as the tags the drug industry might use, would lead the examiner to the assume that the tag had failed not that there was a problem with the product. Proponents of RFID claim that when a reader does not get a response, the product will be isolated. In reality, no distributor will isolate up to a third of its shipments. If they did, the distribution system would break down. If a counterfeiter mixed a case or two of counterfeit product with empty/blank RFID tags on them into a pallet of genuine

product with legitimate tags, it would simply appear to the distributor that several tags failed -- a common occurrence with the technology.

- As noted earlier, counterfeiters generally deal not only with counterfeit product but with diverted, expired, and stolen product as well. Envision the scenario where a counterfeiter stole product, took the legitimate tags off of the product and then applied these legitimate tags to counterfeit product and then reinserted the counterfeit product back into the system. The counterfeit product would pass through all the readers successfully. Meanwhile the counterfeiter could apply blank tags to legitimate product and ship that. When the shipment arrived, none of the tags would be capable of being read possibly resulting in the quarantine of the product and testing. But upon testing, the product would be found to be genuine.

- There exists no certain mechanism for ensuring that an RFID device is defeated or destroyed after the product reaches its final destination. As a result, authentic, legitimately coded RFID tags can potentially be used over and over again by counterfeiters.

The bottom line with RFID, at this time, is that programming errors, human errors, system failures, network issues, the masking of signals, magnetic and/or electronic interference, the absorption by liquids of signals, the reflection of signals by metals, and the interference of criminal counterfeiters, diverters, and thieves can potentially render the technology useless.

CONCLUSION

It cannot be gainsaid that drug counterfeiters, blackmarketeers, and other organized criminal elements are ready, willing, and able to exploit legislation that would permit drug importation into the United States. Their considerable profits will come at the expense of the health and safety of those who unwittingly purchase their ineffective or unsafe products. Internet pharmacy operations headquartered throughout the world present similar perils to the American public. The belief that technology can control the flow of counterfeit drugs is misplaced. The only way to protect United States citizens from the ingenious artifices of counterfeiters is to strengthen, not weaken, the laws that prevent the importation of drugs into this country.

Corporate Affairs
Pfizer Inc
Liberty Place, Suite 1200
325 7th Street, NW
Washington, DC 20004
Tel 202 783 7070 Fax 202 347 2044

M. Kenneth Bowler
Vice President
Federal Government Relations

October 12, 2004

The Honorable Norm Coleman
United States Senate
Washington, D.C. 20510

Re: Hearing Record on the Dangers of Internet Drug Sales

Dear Senator Coleman:

This letter is a follow-up to a hearing you chaired in your capacity as Chairman of the Permanent Subcommittee on Investigations, Senate Governmental Affairs Committee, on June 17 and July 22 on the dangers of purchasing prescription drugs via the internet. Pfizer has since found information that corroborates many of the findings presented at the hearings and requests that you include this information in the hearing record.

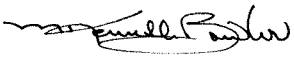
Pfizer was honored to participate substantially in the first of these hearings by testing for authenticity the products purchased by the Government Accounting Office from internet pharmacies. As you know, GAO purchased samples of 36 prescriptions for Pfizer products. Among the findings, it was determined that two product samples were outright counterfeits, only three were confirmed to be genuine Pfizer products approved for US distribution, and 14 were from non-US markets and not approved for US distribution (these diverted samples originated from Canada, Mexico, Australia and Pakistan).

Pfizer Global Security has engaged its own investigation of the reliability of internet pharmacy sales by purchasing prescription orders of its own products. The results have been disturbing. We have found that many internet pharmacy websites purport to be Canadian pharmacies and offer products as approved by FDA but are in fact located elsewhere overseas and sell unauthorized copies of Pfizer products that are not approved by FDA, frequently contain no active ingredient, and generally have visible quality problems.

Permanent Subcommittee on Investigations
EXHIBIT #38

Examples of our findings are contained in the enclosed presentation. We ask that you include it in the hearing record.

Sincerely,

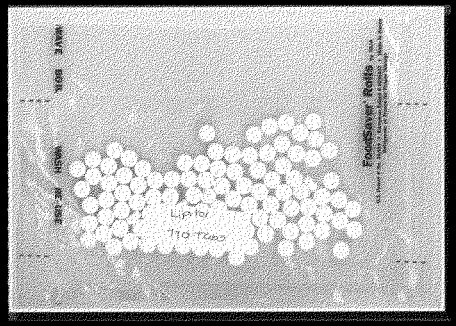


M. Kenneth Bowler

Enclosure

Imported Medicines

A Snapshot Sample of Pfizer's Purchases on the Internet



October 2004

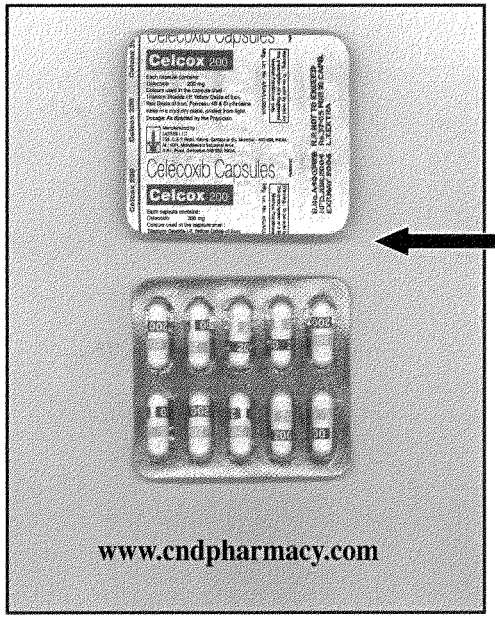
Part I
"Hiding under the Maple Leaf"

"Shoppers need to be aware of a deceptive tactic known as 'hiding under the maple leaf': Web sites that advertise themselves as Canadian or prominently display the familiar maple leaf flag but are actually registered elsewhere. -- Prevention Magazine

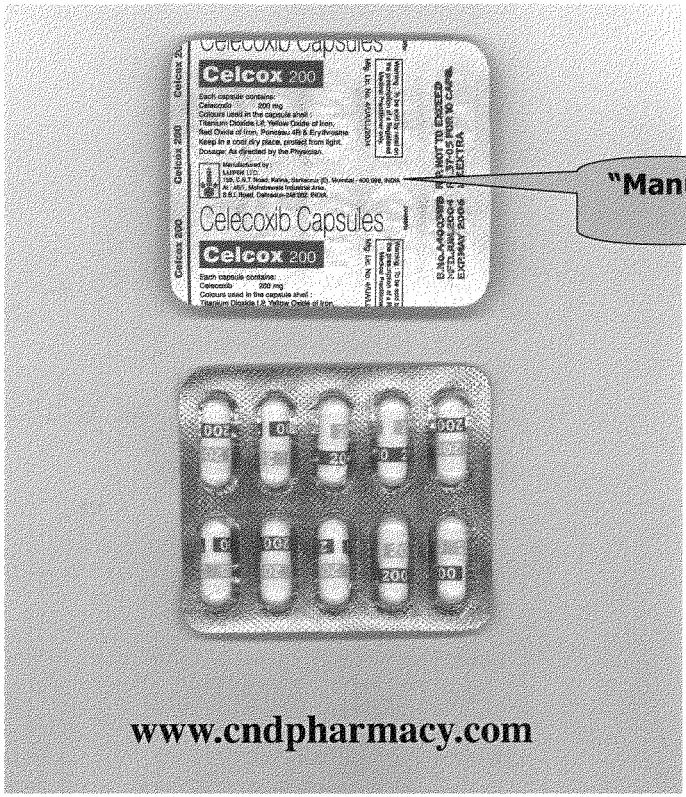
Examples

- www.cndpharmacy.com
- "Canadian Generics" (www.medsstar.com)
- www.rxvaluecanada.com
- www.directprescriptions.org

www.cndpharmacy.com



- "cndpharmacy" looks and sounds Canadian.
- But the site sent an unapproved, unauthorized version of celecoxib from Mumbai, India.
- No prescription was required!



"Manufactured by Lupin Ltd. . . . Mumbai" (India)

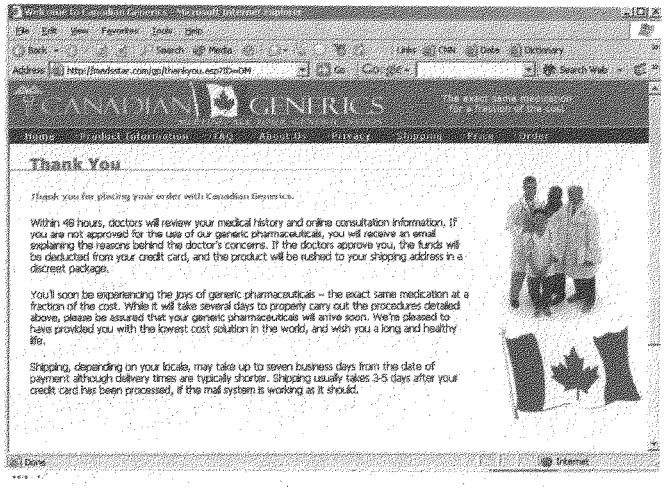
Pfizer is the approved manufacturer of Celebrex® (celecoxib).

This product from India is not authorized and has never been approved by the FDA.

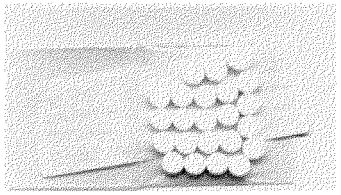
www.cndpharmacy.com

The packaging disclosed nothing about the true location of the exporter.

"Canadian Generics"
(www.medsstar.com)



- This website looks Canadian.
- But the owner is in China.
- And the site sent us unapproved, unauthorized atorvastatin with labeling from Belize.

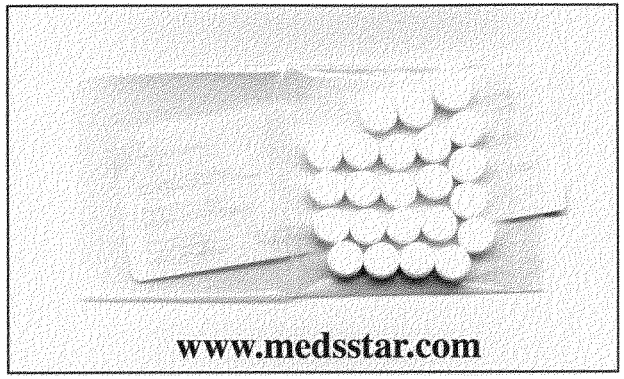


www.medsstar.com

"Canadian Generics"
(www.medsstar.com)

- The product was sent through a PO Box in Florida to hide the export location and the distribution route.

"Canadian Generics" site



- Unapproved pills -- loose in a baggy.
- No patient leaflet.
- No prescription required.

"Canadian Generics" site

The only reference to a manufacturer or distributor whatsoever is www.genericpharmacy.bz – a Belize internet designation

www.rxvaluecanada.com

Customer Care Toll-Free 1-800-957-9979

RxValueCanada.com
304-5795 SW SCOTT CODE 078
Montreal, Quebec, H4W 2T7, Canada

424

- This site delivers medicines from Russia and Hungary to American consumers.

www.RxValueCanada.com

www.RxValueCanada.com

unapproved, unauthorized and misbranded imports from Russia

Кардилопин®

таблетки по **2,5** мг, **5** мг или **10** мг для приема внутрь

ОДОБРЕНО
Фармакологическим Комитетом МЗ РФ

ИНСТРУКЦИЯ
(информация для пациентов)
по медицинскому применению препарата
Кардилопин® (Cardilopin®)

Регистрационный номер
П №014354/01-2002

Торговое название: Кардилопин®

Международное непатентованное название: Амлодипин

Лекарственная форма:
таблетки по 2,5 мг, 5 мг или 10 мг для приема внутрь

Состав:
В каждой таблетке содержится по 2,5 мг, 5 мг или 10 мг активного вещества - амлодипина (в виде амлодипина бесилата по 3,475 мг, 6,95 мг или 13,90 мг соответственно). А так же вспомогательные вещества: микрокристаллическая

- нестабильная стенокардия
- острый инфаркт миокарда и период в один месяц после него
- клинически значимый стеноз аорты

ОСОБЫЕ УКАЗАНИЯ

Из-за отсутствия достаточных клинических данных препарат не рекомендуется принимать детям до 18 лет.

Беременность и период лактации

Учитывая недостаток клинического опыта применения Кардилопина при беременности и в период лактации, назначение Кардилопина беременным женщинам, а также женщинам планирующим беременность и которые не принимают эффективные противозачаточные средства, требует тщательной оценки польза/риск.

Если кормящая мать принимает Кардилопин, то кормление грудью необходимо прекратить.

Влияние на способность управлять автомобилем и специальной техникой

www.RxValueCanada.com

unapproved, unauthorized and misbranded imports from Russia

428

www.RxValueCanada.com

ИНСТРУКЦИЯ (информация для потребителей) **по медицинскому применению препарата**

ОДОБРЕНО ФАРМАКОЛОГИЧЕСКИМ Комитетом Минздрава России

Регистрационный номер: П № 012274/01-2000

НОРМОДИПИН®

NORMODIPINE®

Общие сведения для идентификации препарата

Лекарственная форма: таблетки

Состав

Действующее вещество:

амлодипин

Вспомогательные вещества:

микрокристаллическая целлюлоза 101, микрокристаллическая целлю-

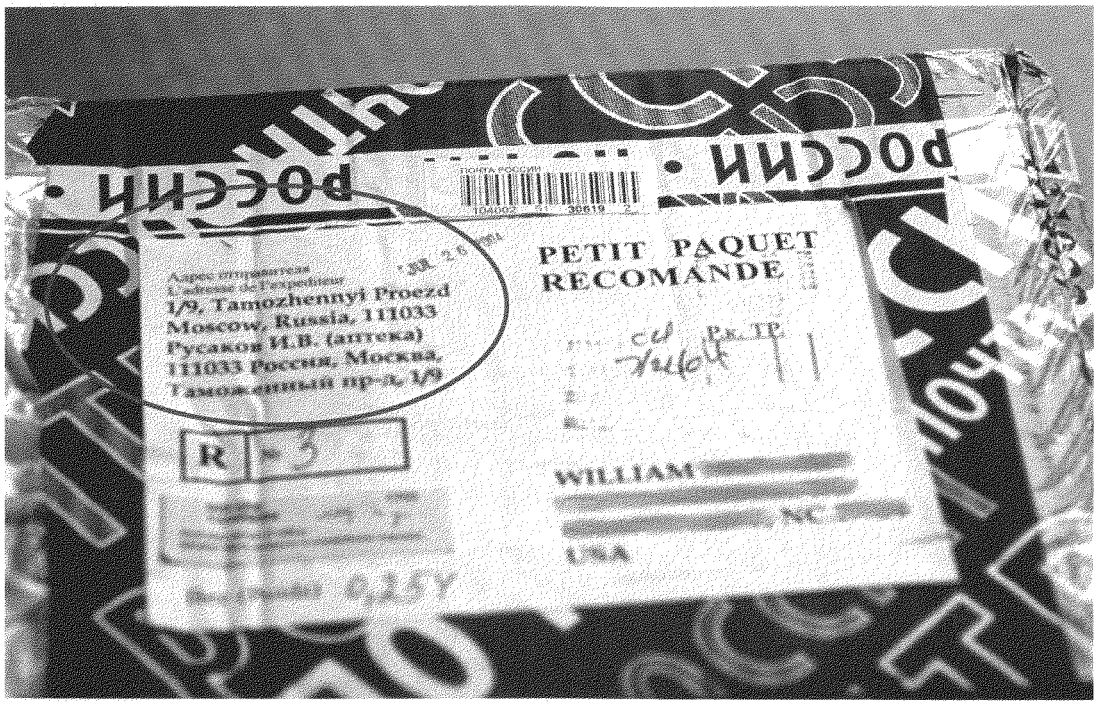
коронарной (ишемической) болезни сердца (стенокардии).

Во избежание осложнений применять строго по назначению врача.

Противопоказания

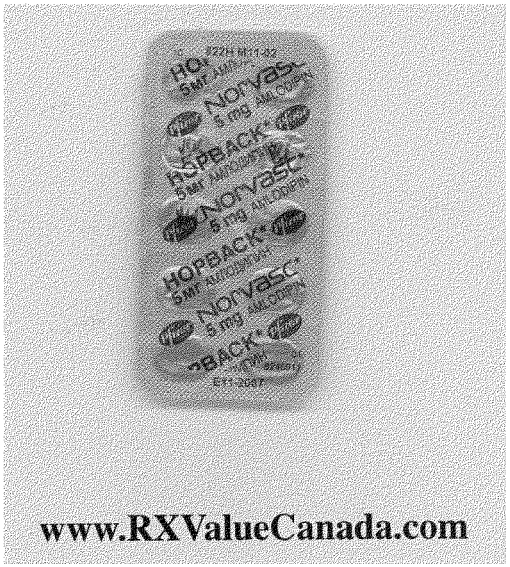
Повышенная чувствительность к производным дигидропиридина или к любому вспомогательному компоненту препарата. В связи с этим применение Нормодипина не реко-

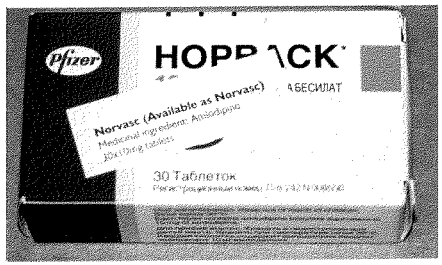
www.rxvaluecanada.com

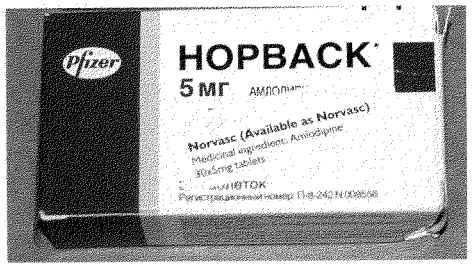


www.rxvaluecanada.com

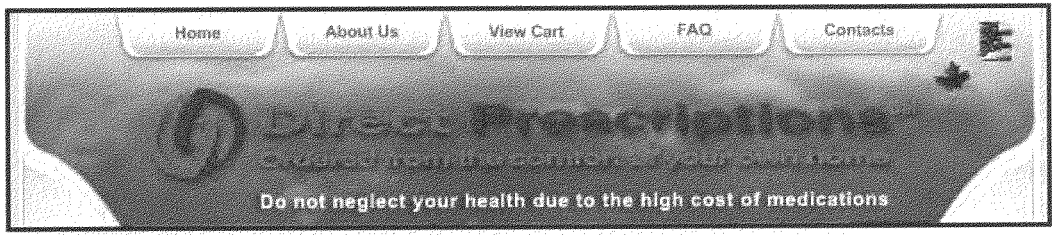
Norvasc® sent from Russia (tests pending)







www.directprescriptions.org



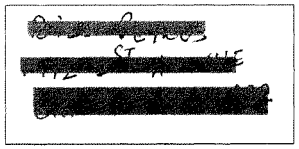
- The Direct Prescriptions site wants users to think they are Canadian.
- But the owner hides behind a domain registration service.
- Pfizer has information suggesting that the owner is in Russia and that the site is hosted on a server in China.

www.directprescriptions.org

- The products shipped in a baggy are not real Pfizer product.

www.directprescriptions.org

- Pfizer's investigation showed that the return address on the shipping envelope was actually a prior customer.
  - Again, we see the lengths foreign internet pharmacies will go to in order to hide their true location.



To
DAVID [redacted]
131 [redacted]
[redacted], NY [redacted]

11757#5020

Pricing

- **The directprescriptions order itself came out to more than <u>double</u> the advertised price:**

  - **Item# VG1101**
    Direct Viagra® 50mg 20 pills $65.00
  - **Doctor Consultation $35.00**
    No doctor contacted us. No doctor was identified.
  - **Shipping $49.95**
    Product arrived in envelope with 74¢ postage !!
  - **Order Total =<u>$149.95</u>**

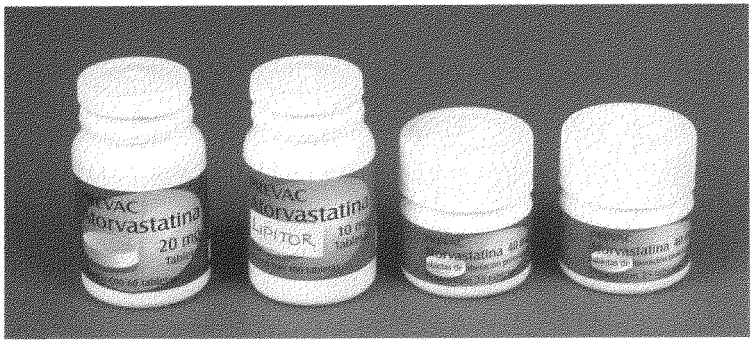
Part II

Unapproved, Unauthorized Products Offered Illegally as "generic Lipitor"

WITH NO ATORVASTATIN

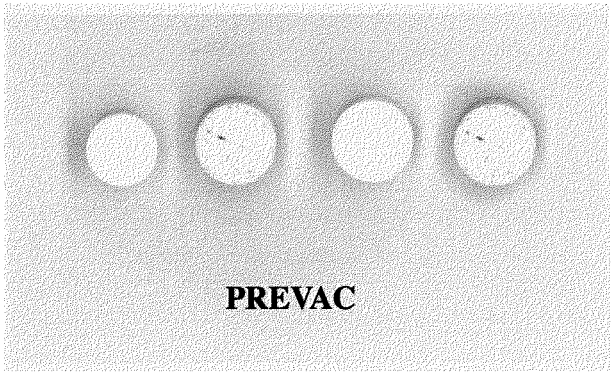
PREVAC – unapproved, unauthorized "generic Lipitor"

- Four similar looking products purchased from four different websites.
  - All of these products are unapproved.
  - Two of the samples contained tablets with NO ATORVASTATIN whatsoever.



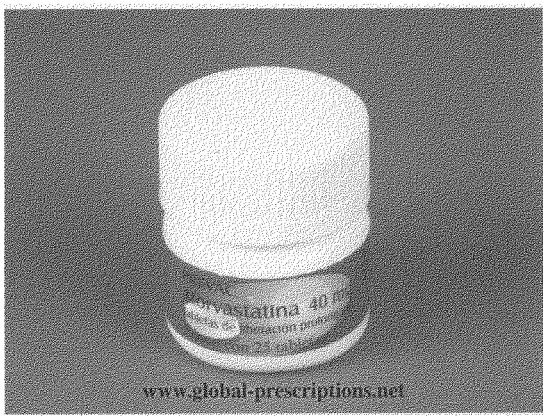
PREVAC – unapproved, unauthorized "generic Lipitor"

- In some cases, the poor quality of the pills was readily apparent.



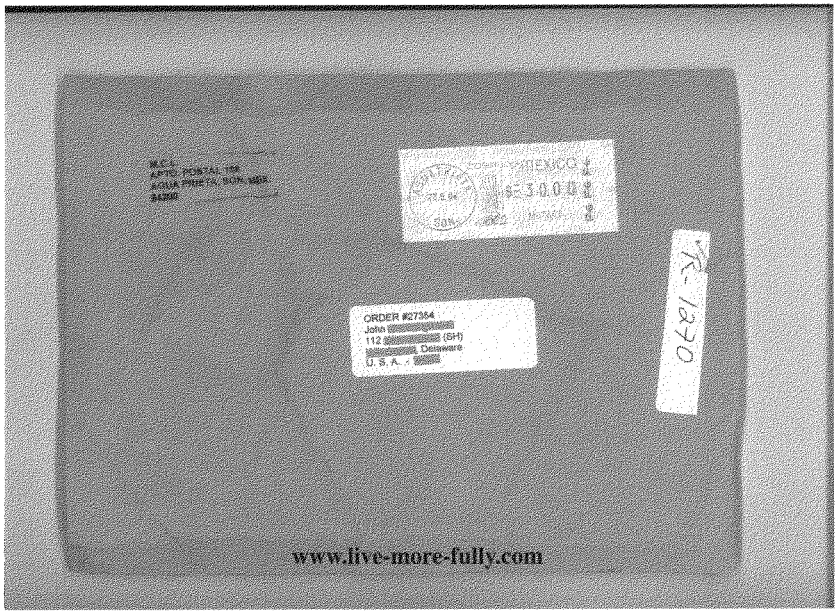
www.global-prescriptions.net

www.global-prescriptions.net

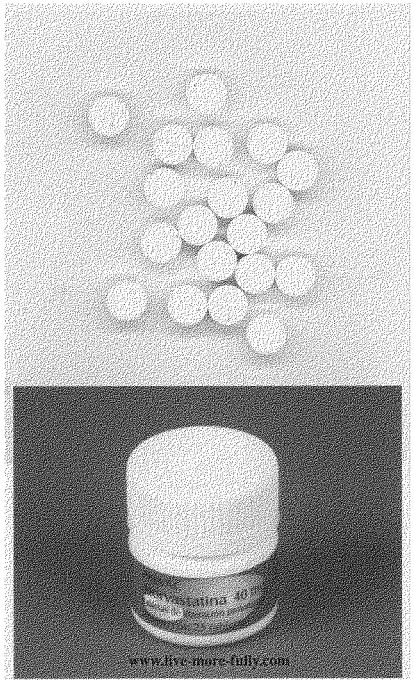


- Samples were tested by Pfizer.
- They contained NO Atorvastatin.

www.live-more-fully.com



www.live-more-fully.com



- Samples were tested by Pfizer.
- They contained NO Atorvastatin.

Part III

European Product Takes an Interesting Route

www.pharmadrugstore.com

- This site says it is your "online pharmacy for FDA approved medications"

- But it sent amlodipine
  - From the Netherlands
  - With labeling and patient information in Dutch
  - Using a physician in Cape Town, South Africa
  - From a Swiss address using Swiss post

www.pharmadrugstore.com

Online pharmacy, Anxiety drugs, Depression prescription medication - pharmadrugstore.com

Customer Login

Login

Register here!

Your shopping cart

Contains no items

Search our store

Search

Top Products

ALPRAZOLAM

ALZAM

AMBIEN

ATIVAN

BUSPAR

CARISOPRODOL

CELEBREX

Home | About Us | FAQ's

pharmadrugstore.com

Customer Service

Customer service

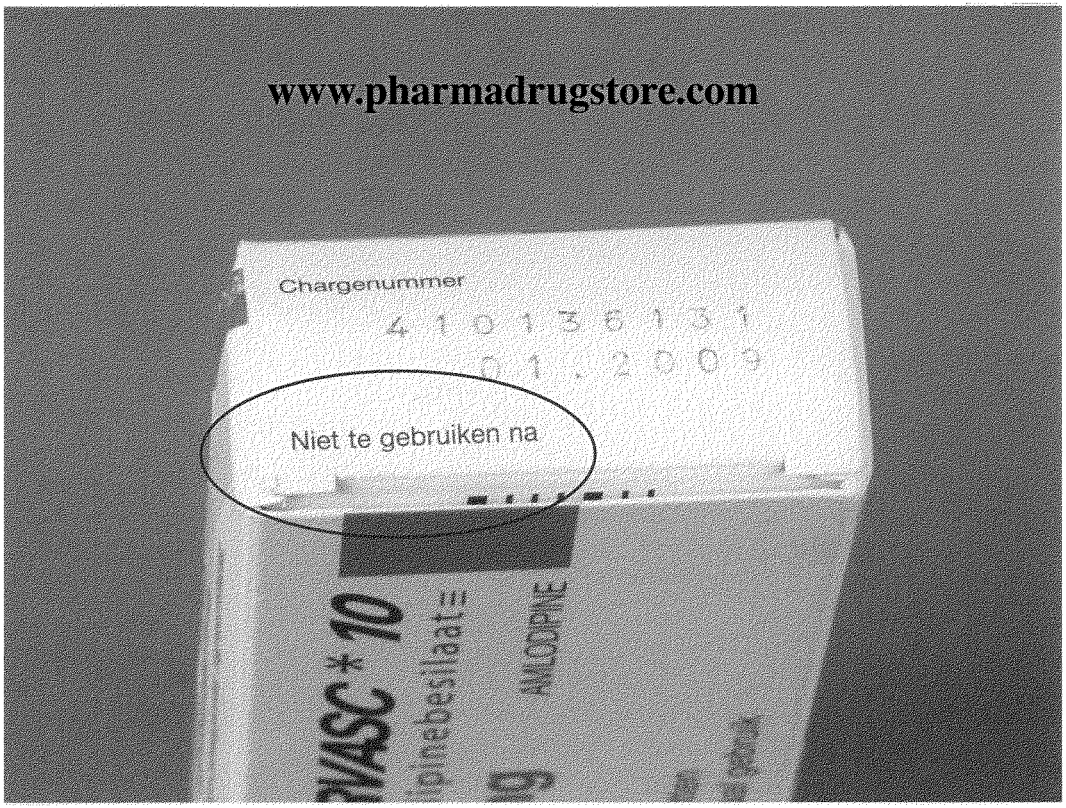
About us

Pharmadrugstore.com is your **USA online pharmacy** for **FDA approved medication** through FREE online consultations . We offer a wide range of drugs available through **secure and easy online ordering** with **delivery within 7-12 working days**.

Licensed physicians
With our trusted health care professionals, dedicated **customer service** representatives and simple ordering system, it has never been easier to get the drugs you need - **confidentially and discreet!**

No physical exam needed
If you have had a physical exam recently and consider yourself healthy, you do not necessarily require another physical exam in order for you to obtain the medications we offer. Thousands of psychiatrists and general practitioners throughout the USA are prescribing certain medications after only reviewing the patient's medical history, without a physical exam.

The medical factors that would prohibit a physician from prescribing these medications are discoverable through a review of the patient's medical history. There is no reason to suggest that an in-person review of this history is any more relevant than an online consultation.


www.pharmadrugstore.com
Chargenummer
4 1 0 1 3 6 1 3 1
0 1 . 2 0 0 9
Niet te gebruiken na
AMLODIPINE
10

www.pharmadrug

Informatie voor de patiënt

8685614
HOL
December 2001

Lees deze bijsluiter zorgvuldig door voordat u start met het gebruik van dit geneesmiddel. Bewaar deze bijsluiter, het kan nodig zijn om deze nogmaals door te lezen. Heeft u nog vragen, raadpleeg dan uw arts of apotheker. Dit geneesmiddel is aan u persoonlijk voorgeschreven, geef dit geneesmiddel niet door aan anderen. Dit geneesmiddel kan schadelijk voor hen zijn, zelfs als de verschijnselen dezelfde zijn als waarvoor u het geneesmiddel heeft gekregen.

Inhoud van deze bijsluiter

1. Wat is Norvasc en waarvoor wordt het gebruikt?
2. Wat u moet weten voordat u Norvasc inneemt.
3. Hoe wordt Norvasc ingenomen?
4. Mogelijke bijwerkingen.
5. Hoe bewaart u Norvasc?

Norvasc 5
Norvasc 10

- Het werkzame bestanddeel is amlodipinebesilaat overeenkomend met resp. 5 mg en 10 mg amlodipine.
- Andere bestanddelen (hulpstoffen) zijn microkristalijne cellulose, watervrij calciumbifosfaat, natriumzetmeelglycollaat en magnesiumstearaat.

Registratiehouder

Pfizer bv, Rivium Westlaan 142, 2909 LD Capelle aan den IJssel

Voor vragen over dit geneesmiddel, bel 0800-MEDINFO (63 34 636).

In het register ingeschreven onder RVG 13348 (Norvasc 5) en RVG 13349 (Norvasc 10).

Informatie voor de patiënt

1. Wat is Norvasc en waarvoor wordt het gebruikt?

Een tablet Norvasc bevat amlodipinebesilaat overeenkomend met resp. 5 mg en 10 mg amlodipine.
Norvasc 5, tabletten à 5 mg amlodipine: smaragd-vormige witte tabletten aan één zijde gemerkt met het Pfizer-logo, aan de andere zijde met AML-5.
Norvasc 10, tabletten à 10 mg amlodipine: smaragd-vormige witte tabletten aan één zijde gemerkt met het Pfizer-logo, aan de andere zijde met AML-10.
Amlodipine behoort tot de groep van de calciumantagonisten. Het heeft een bloeddrukverlagende werking door een ontspannend effect op de wand van de bloedvaten. Ook wordt het hart ontlast waardoor amlodipine gebruikt kan worden bij hartkramp (angina pectoris).

Norvasc 5 en Norvasc 10 worden geleverd in verpakkingen van 30 tabletten in doordrukstrips van 10 tabletten en in potten met 200 tabletten. Tevens worden speciale ziekenhuisverpakkingen van 50 stuks in doordrukstrips geleverd.

Norvasc kan bij de volgende aandoeningen worden toegepast:
- **Verhoogde bloeddruk:** Norvasc verlaagt, indien nauwkeurig volgens voorschrift ingenomen, de bloeddruk. Of deze behandeling bij u aanslaat, is alleen met behulp van een bloeddrukmeter te bepalen.
- **Hartkramp (angina pectoris):** Norvasc wordt ook toegepast bij de behandeling van hartkramp. Het effect van de behandeling is merkbaar aan een vermindering van het aantal malen dat u last hebt van pijn op de borst, of aan het feit dat u meer kunt doen (bv. verder lopen) voordat u last krijgt.

2. Wat u moet weten voordat u Norvasc inneemt.

Gebruik Norvasc niet:
- indien u overgevoelig bent voor één van de stoffen uit de groep van calciumantagonisten waartoe ook amlodipine behoort, namelijk de dihydropyridines. Indien u niet zeker bent of dit op u van toepassing is, raadpleeg dan uw apotheker of arts.

Dr. A. Collison

Welgemoed - X CAPE TOWN - Zuid Afrika
E-mail:
BIG.nr.: 19059995001

PRESCRIPTION

Invoice/Prescription No: @18671
V34462601

Date : 24-08-2004

Patient details:
Ray [redacted]

Apt 243-L
20410 [redacted] E
[redacted] S[redacted]
WA
United States

Item	Description	Quantity
NORV10PF30	norvasc 10mg 30 tabletten	1

Dosage: According doctor's instructions, see also patient information leaflet

This prescription was issued after consulting your online questionaire.
The data provided by you will be considered legally binding.

PRIORITY
Please return to:
P.P.
Swiss Post Int.
SPI 16, 040
CH-4002 Basel
Swiss Post
4002 Basel
98387
SER1062421349
Ray
20410
98387
United States
SWISS POST
Zoll / Douane
CN22
Pers. Import
$68
www.pharmadrugstore.com

www.247-pharmacy.com

- This exporter sent amlodipine from Spain

247-pharmacy.com

- No prescription required.
- Damaged packaging.
- Spanish patient labeling.

NORVAS® 5 mg Comprimidos

AMLODIPINO

COMPOSICIÓN

Cada comprimido contiene:
Amlodipino (D.C.I.) (Besilato) ..... 5 mg
Excipientes: celulosa microcristalina, fosfato cálcico dibásico anhidro, almidón glicolato sódico y estearato magnésico ..... c.s.

FORMA FARMACÉUTICA Y CONTENIDO DEL ENVASE

Forma Farmacéutica: Comprimidos
Contenido del envase: Envase con 30 comprimidos
Envase clínico con 500 comprimidos

ACTIVIDAD

NORVAS® (Amlodipino) es un fármaco con acción vasodilatadora desarrollado por Pfizer para el tratamiento de diferentes enfermedades cardiovasculares (véase el apartado de indicaciones).

TITULAR Y FABRICANTE

TITULAR: Laboratorios PFIZER S.A. Avda. de Europa 20-B, Parque Empresarial La Moraleja. 28108 ALCOBENDAS (Madrid).
FABRICANTE: FARMASIERRA, S.A., Ctra. N-I Km. 26,200; 28700-San Sebastián de los Reyes (Madrid).

INDICACIONES

NORVAS® (Amlodipino) está indicado en el tratamiento de los siguientes procesos:
1. Hipertensión arterial.
2. Isquemia miocárdica producida por obstrucción vascular coronaria (angina estable) y/o por vasoespasmo / vasoconstricción (angina variante).

CONTRAINDICACIONES

NORVAS® (Amlodipino) está contraindicado en pacientes con hipersensibilidad conocida a las dihidropiridinas, al Amlodipino y a cualquiera de los excipientes.

PRECAUCIONES

El tratamiento con NORVAS® (Amlodipino) requiere el control periódico por el médico.

INTERACCIONES

Siempre es importante que su médico conozca otros tratamientos que usted está tomando actualmente.
NORVAS® (Amlodipino) se ha administrado junto con otros antihipertensivos, antianginosos u otros fármacos como antiinflamatorios no esteroideos, antibióticos, hipoglucemiantes orales, warfarina, digoxina o ciclosporina, sin que se produjeran consecuencias negativas. La administración simultánea de cimetidina tampoco alteró la farmacocinética de Amlodipino. En caso de estar tomando medicamentos que contengan teofilina o ergotamina, consulte a su médico.

ADVERTENCIAS

Uso durante el embarazo y la lactancia

La seguridad de NORVAS® (Amlodipino) durante el embarazo o la lactancia no ha sido establecida. La administración de NORVAS® (Amlodipino) durante el embarazo o la lactancia sólo se aconseja cuando, a juicio del médico, no exista otra alternativa terapéutica más segura y cuando la propia patología plantee un riesgo mayor para la madre o para el feto.

Uso en niños

La seguridad y eficacia de NORVAS® (Amlodipino) en niños no han sido establecidas.

Uso en ancianos

A dosis iguales, NORVAS® (Amlodipino) se tolera igualmente bien en los pacientes jóvenes y en los ancianos, por lo que en ambos casos se aconsejan las pautas terapéuticas normales.

Uso en pacientes con insuficiencia renal

En los pacientes con insuficiencia renal, NORVAS® (Amlodipino) se puede administrar siguiendo las pautas posológicas habituales.

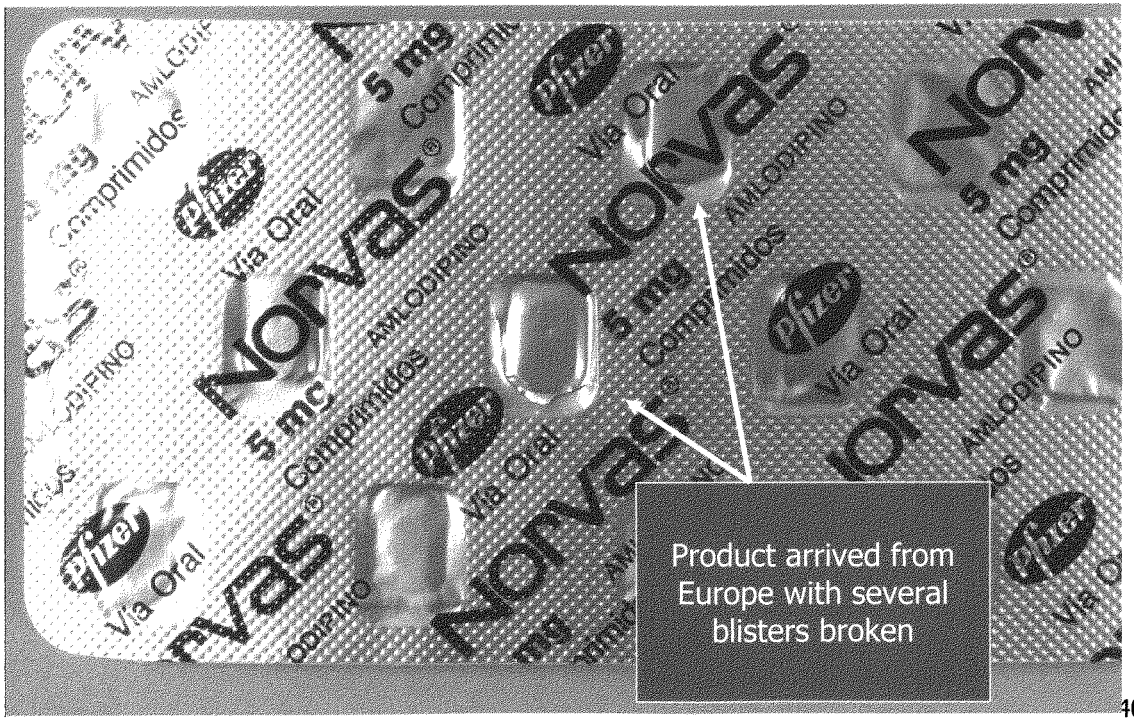
Uso en pacientes con alteración de la función hepática

NORVAS® (Amlodipino) debe ser utilizado con precaución y bajo control médico en pacientes con función hepática alterada. No se han establecido recomendaciones para su dosificación.

Pfizer

www.247-pharmacy.com

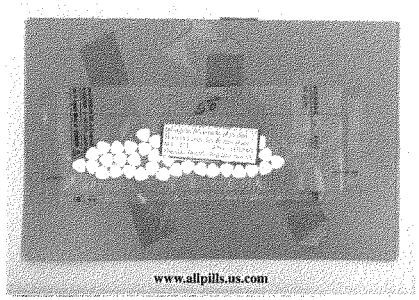
www.247-pharmacy.com

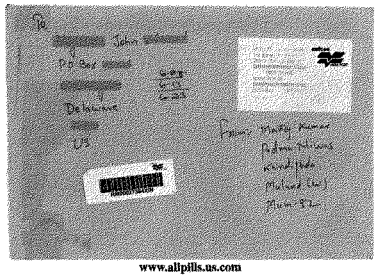


Part IV

A Direct Pipeline for Unauthorized Unapproved Product from India and Pakistan

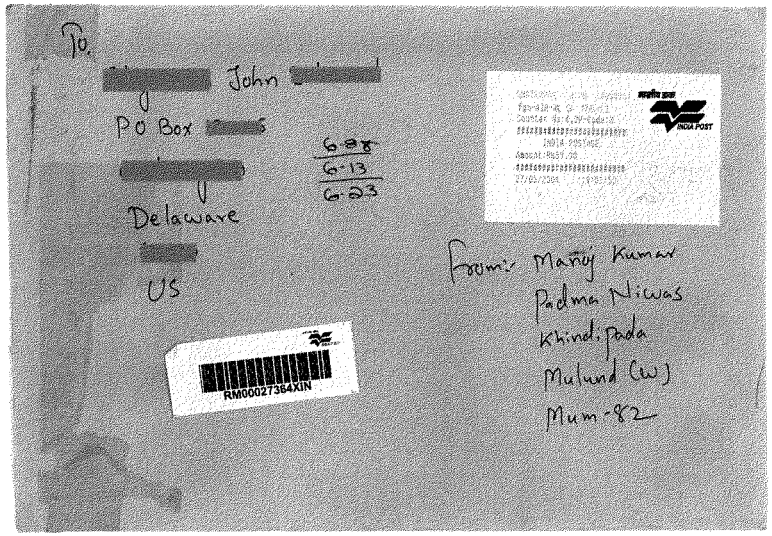
www.allpills.us.com





- This site looks American: "allpills.us.com".
- But they sent unapproved pills from India.
- The medicines were taped to a piece of cardboard!

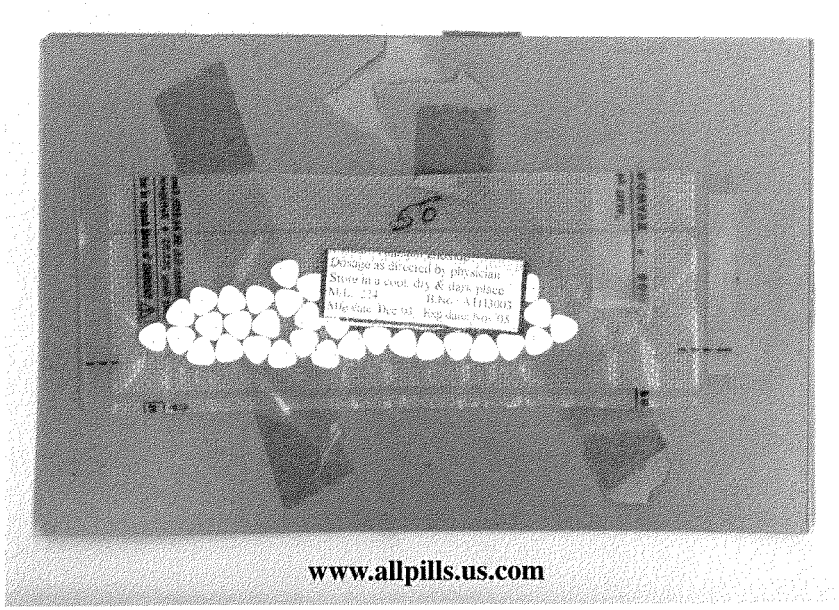
www.allpills.us.com

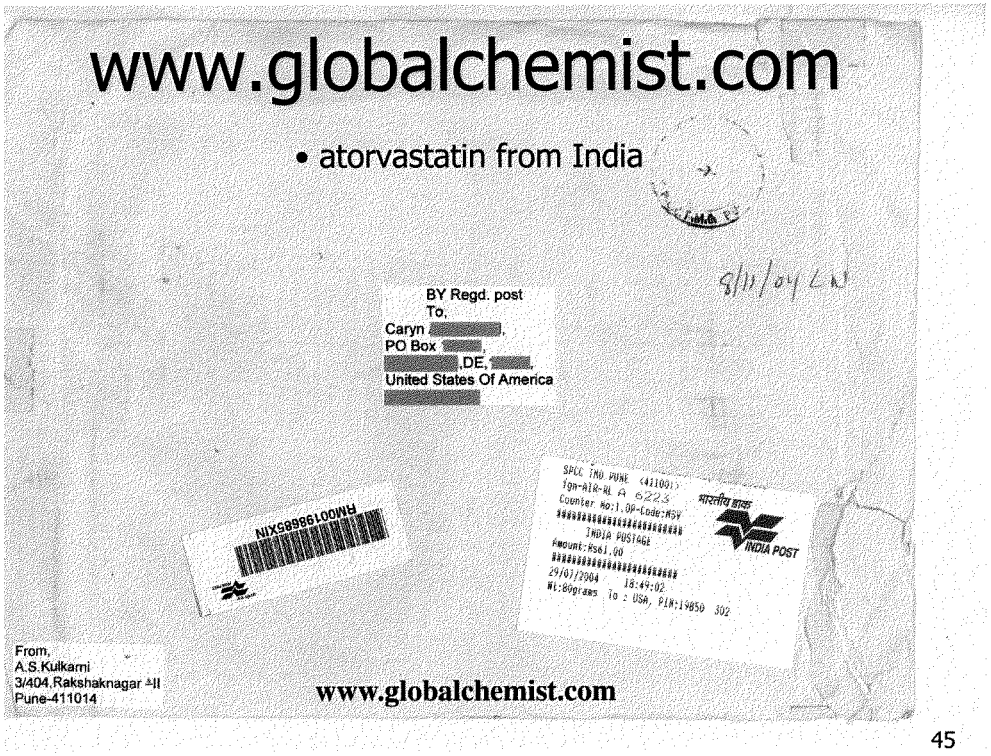


www.allpills.us.com

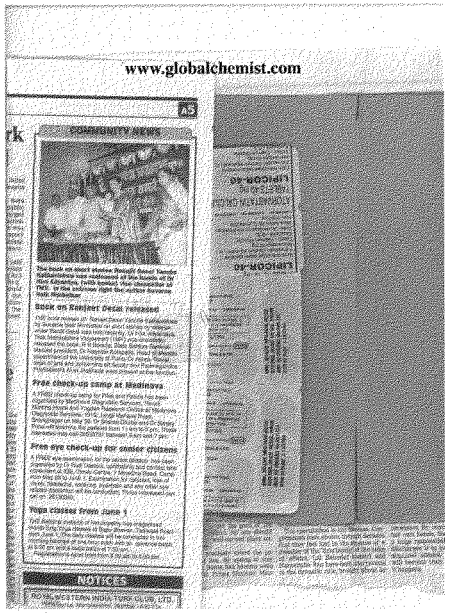
www.allpills.us.com

Unapproved, unauthorized product from India, taped to cardboard

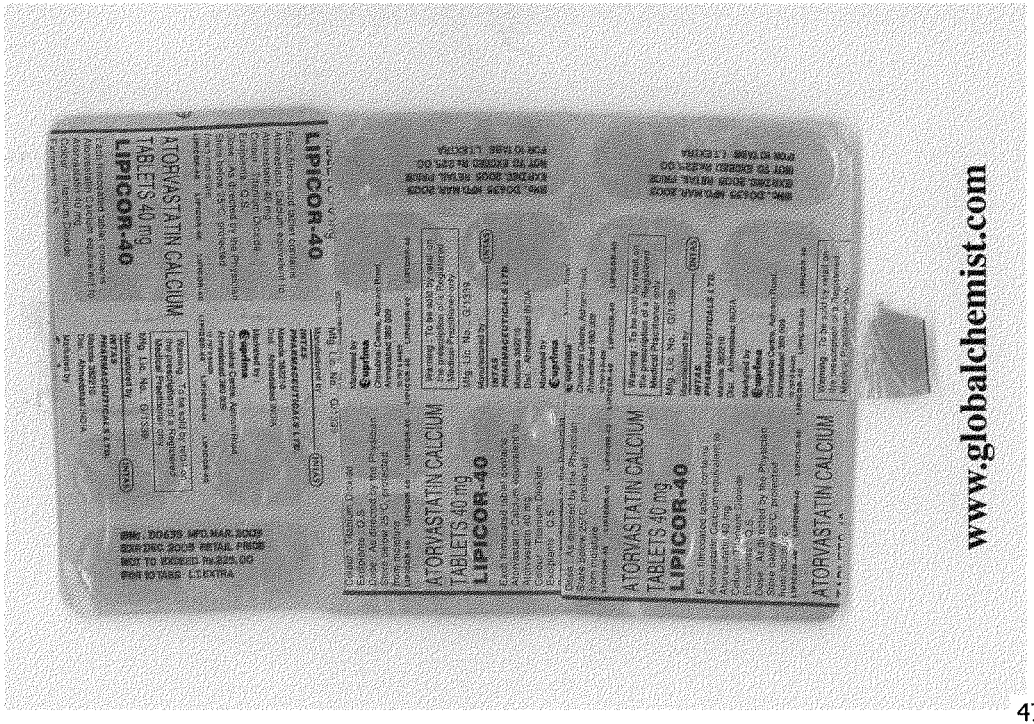



www.globalchemist.com
• atorvastatin from India
BY Regd. post
To,
Caryn [redacted],
PO Box [redacted],
[redacted],DE,[redacted],
United States Of America
[redacted]
RN001986BSXIN
SPCL IMO PUNE (411001)
Ign-AIR-NL A 6223
Counter No:1,OP-Code:MSV
INDIA POSTAGE
Amount:Rs61.00
29/07/2004 18:49:02
Wt:80grams To : USA, PIN:19850 302
भारतीय डाक
INDIA POST
From,
A.S.Kulkarni
3/404,Rakshaknagar -II
Pune-411014
www.globalchemist.com

Product wrapped in newspaper



Unauthorized Unapproved Product

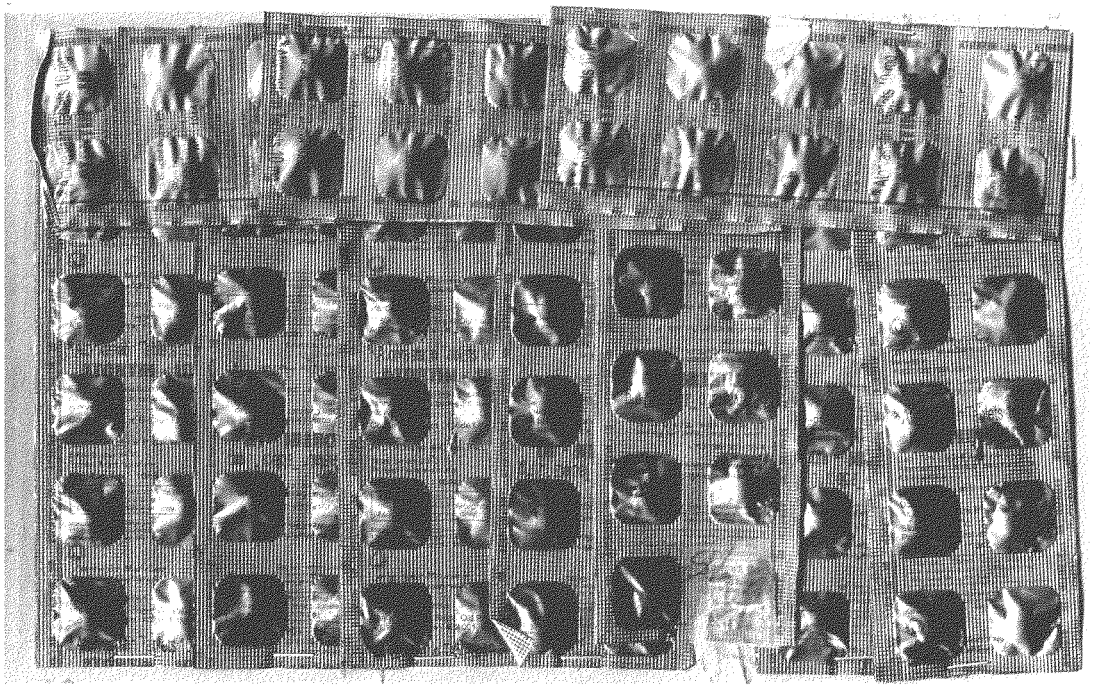


www.globalchemist.com

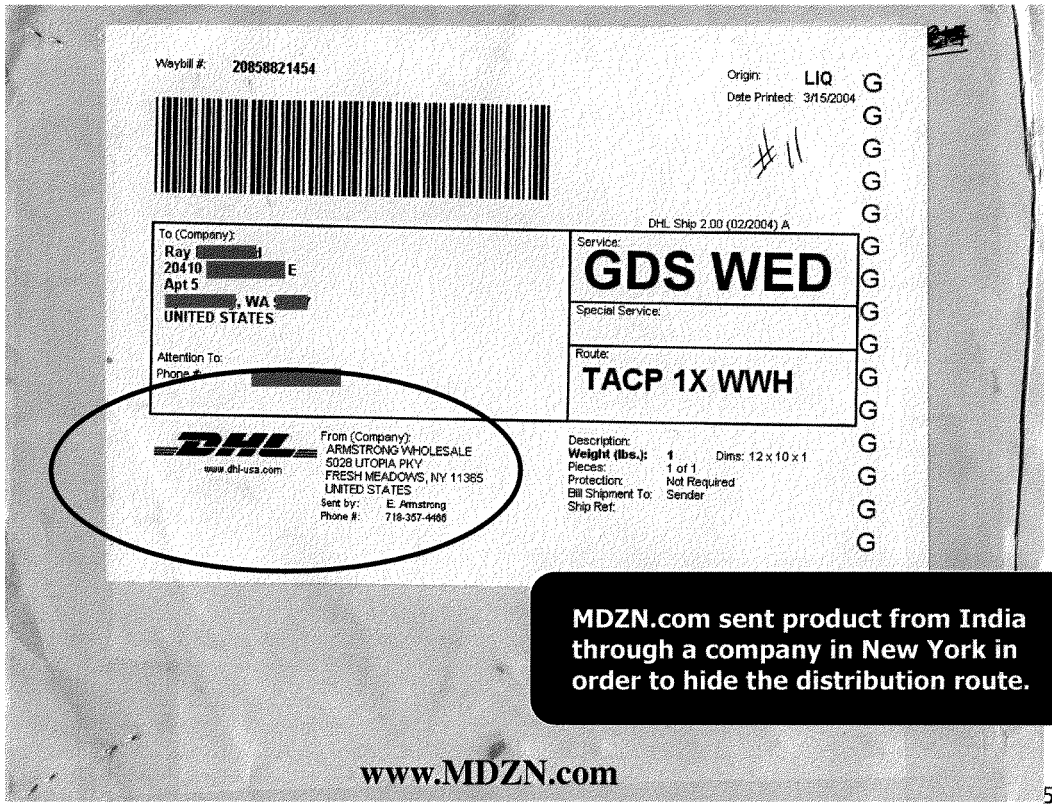
www.MDZN.com

- Unauthorized, unapproved atorvastatin from India
- Stapled to a piece of cardboard !
- Sent through a location in NY in order to hide the true export location.

www.MDZN.com



49



Waybill #: 20858821454

Origin: LIQ
Date Printed: 3/15/2004

#11

DHL Ship 2.00 (02/2004) A

To (Company):
Ray [redacted]
20410 [redacted] E
Apt 5
[redacted], WA [redacted]
UNITED STATES

Attention To:
Phone #: [redacted]

Service:
GDS WED

Special Service:

Route:
TACP 1X WWH

DHL
www.dhl-usa.com

From (Company):
ARMSTRONG WHOLESALE
5028 UTOPIA PKY
FRESH MEADOWS, NY 11365
UNITED STATES
Sent by: E. Armstrong
Phone #: 718-357-4466

Description:
Weight (lbs.): 1 Dims: 12 x 10 x 1
Pieces: 1 of 1
Protection: Not Required
Bill Shipment To: Sender
Ship Ref:

G G G G G G G G G G G G G G G G

MDZN.com sent product from India through a company in New York in order to hide the distribution route.

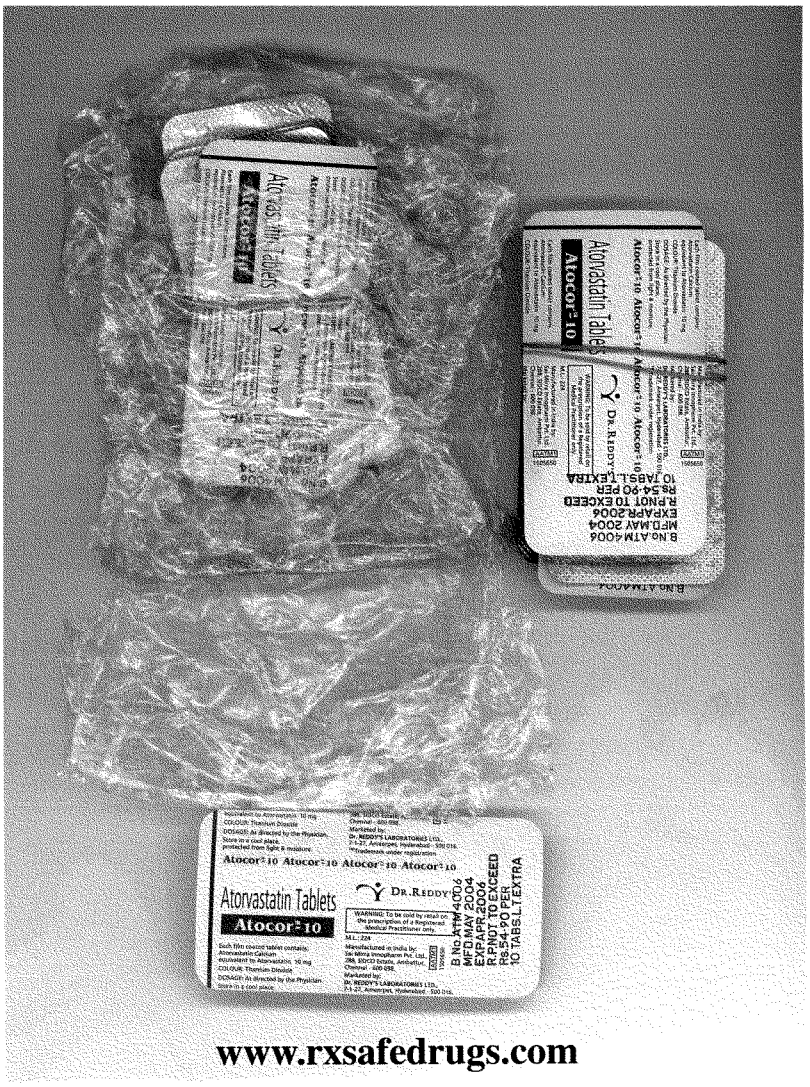
www.MDZN.com

www.MDZN.com

- The disappearing website:
  - www.MDZN.com has apparently disappeared
  - the address now links to www.onlinepharmacyservices.com
  - which in turn sends you to www.GoMedicine.com

www.rxsafedrugs.com

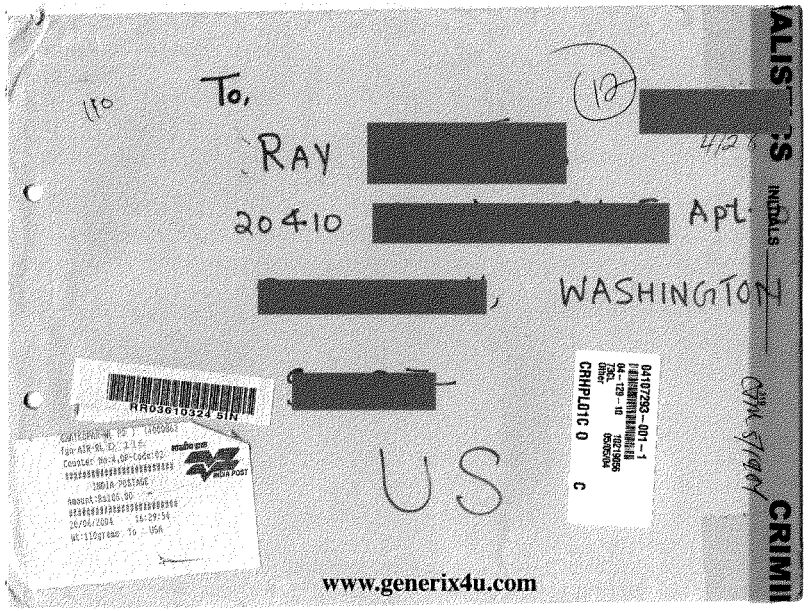
- This site suggests that they sell Lipitor® – a Pfizer product approved by the FDA.
- But they sent product from India -- never reviewed or approved by the FDA.



www.rxsafedrugs.com

www.generix4u.com

- Unauthorized unapproved atorvastatin from India



www.generix4u.com

www.gopharmacy.com

- Lipitor® exported from Pakistan

38569631387
Ray [redacted]
20410 [redacted] Apt 8
[redacted] WA
[redacted] USA
(12)
513 C,Johar Town,Lahore-Pakistan

Dr Bashir Ahmed
M.B.B.S.

Name: Ray [redacted] 20410 [redacted] Apt 8[redacted] WA [redacted] USA Date: 24-02-04

Address:

38569631387

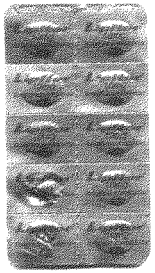
Lipitor 10mg x 30 tabs. (1) - 88

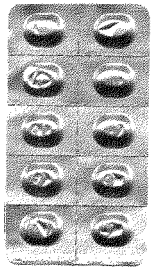
Raiwind Road, Tohkar Niaz Baig Ph: 5420280
www.gopharmacy.com

www.gopharmacy.com

- This export pharmacy sent Lipitor® from Pakistan
- This exporter did not require any American script but apparently used a Dr Bashir Ahmed in Pakistan.

www.gopharmacy.com

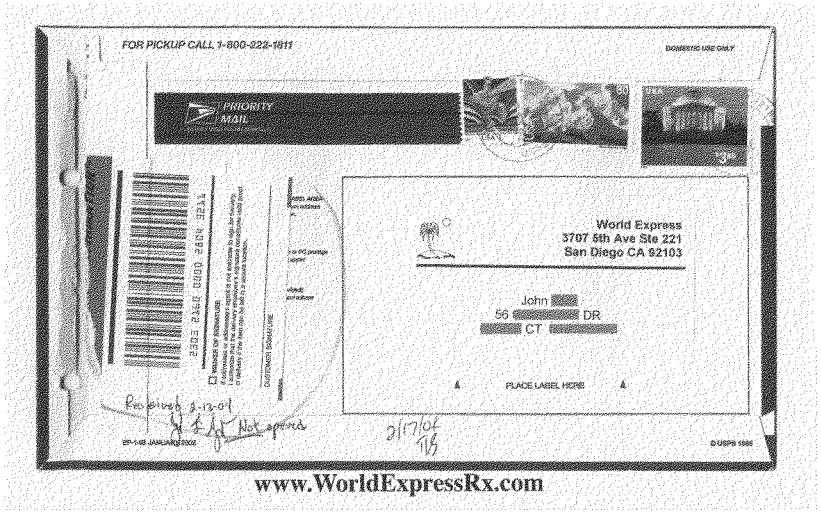




- This Lipitor sent from Pakistan is still being tested.

www.WorldExpressRx.com

- This internet pharmacy sent unauthorized, unapproved atorvastatin from an unknown source

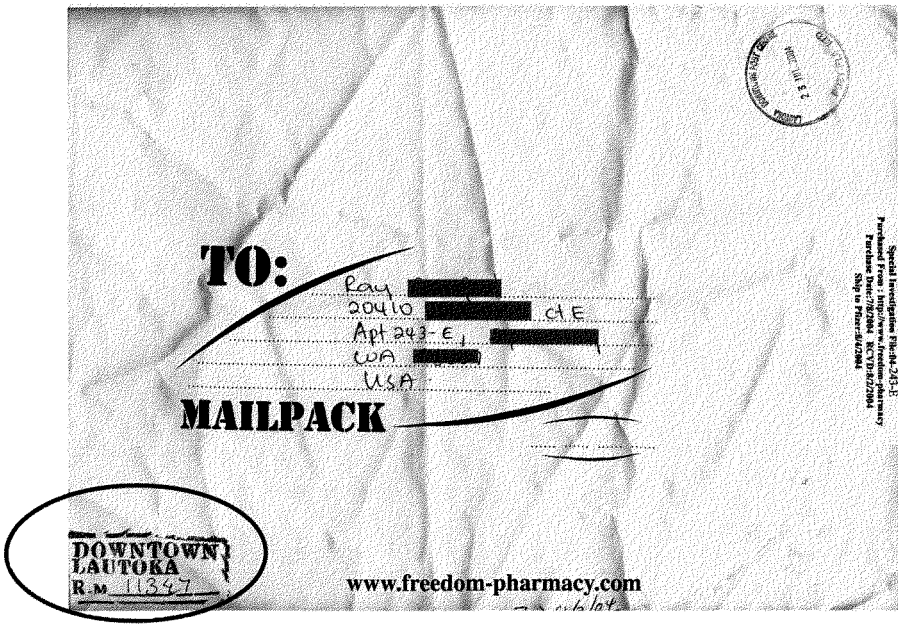


Even a cursory examination of these pills suggests serious quality concerns.
www.WorldExpressRx.com

61

www.freedom-pharmacy.com

- unauthorized unapproved atorvastatin
- manufactured in India and sent from FIJI



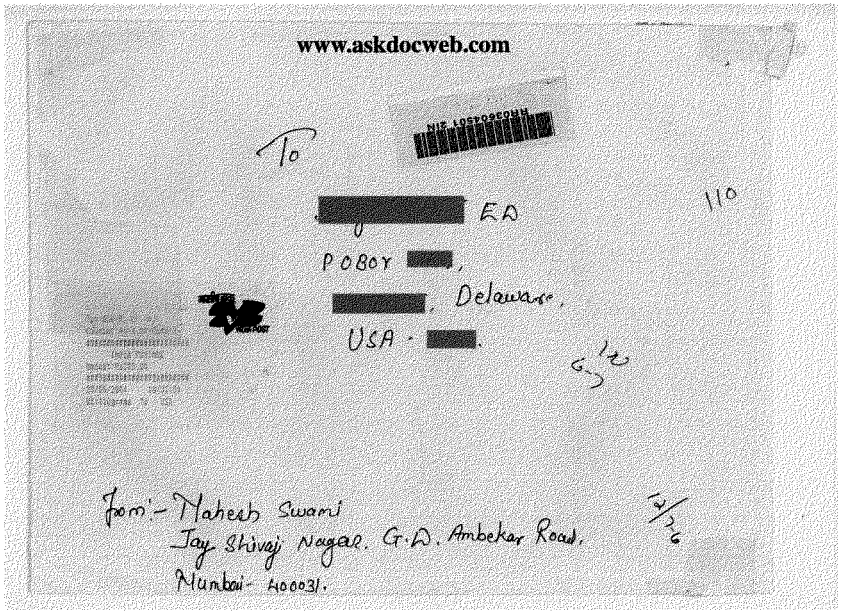
Unauthorized Unapproved Product

Manufactured in India, sent from Fiji

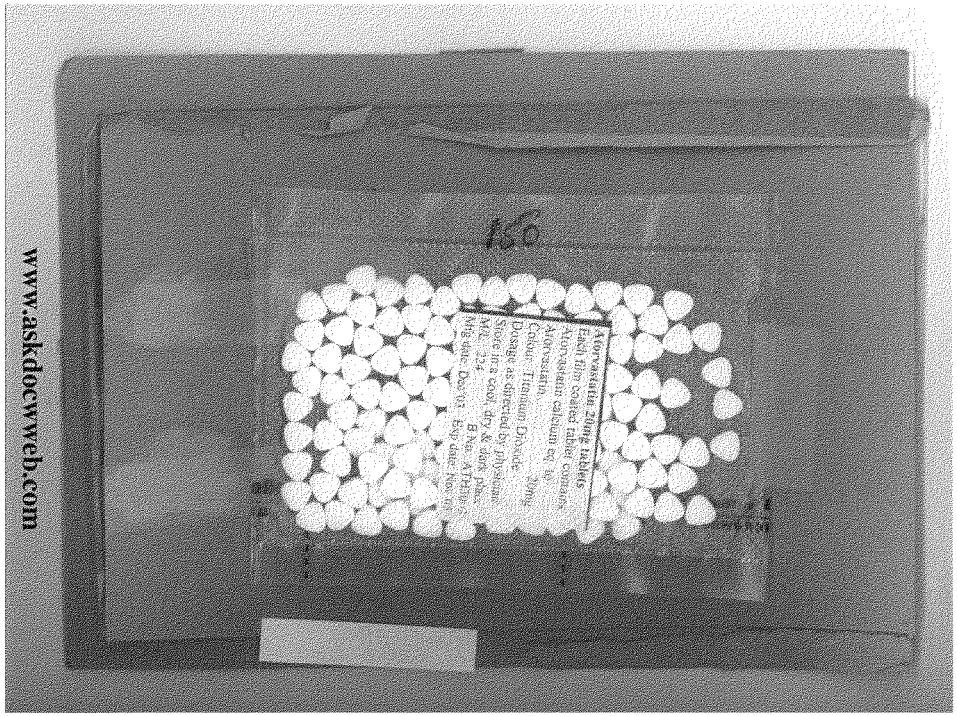
Product information crossed out

www.askdocweb.com

- Unauthorized, unapproved atorvastatin from India

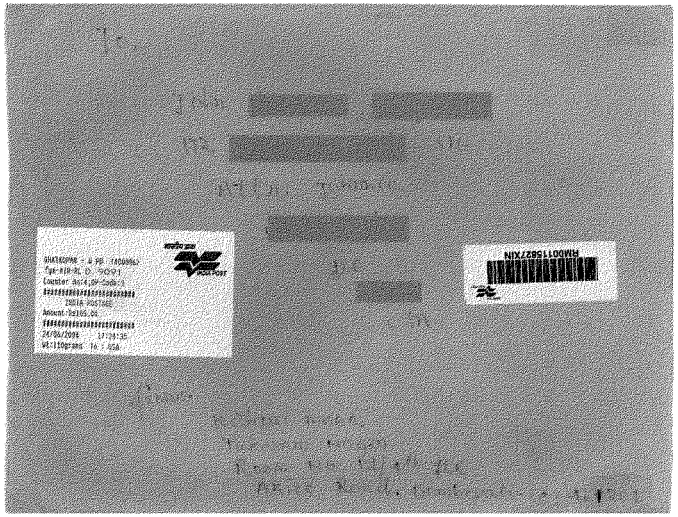


Unapproved, unauthorized atorvastatin



www.generic-lipitor.com

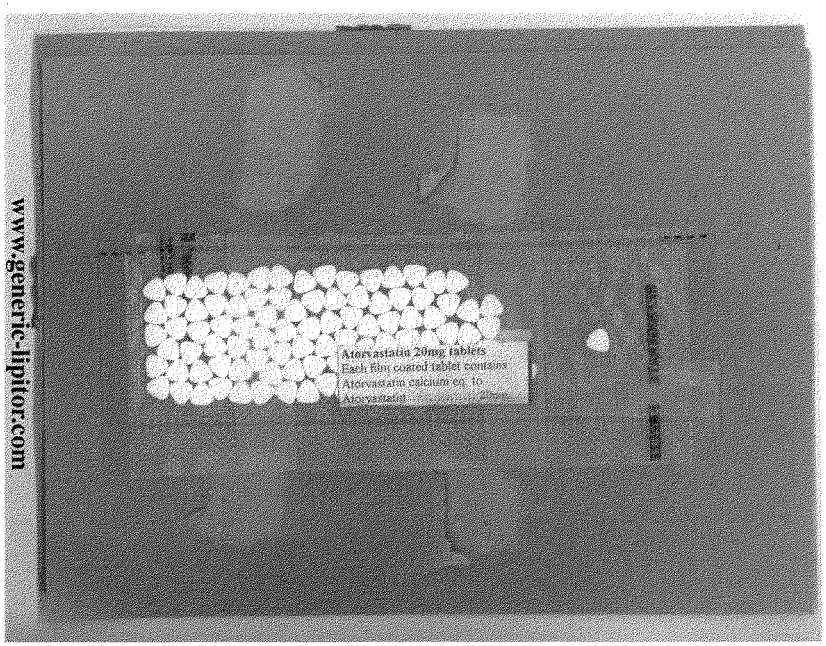
- Unauthorized, unapproved, illegal "generic Lipitor" from India



www.generic-lipitor.com

unapproved illegal "generic Lipitor"

Sent taped to a piece of cardboard



U.S. Food and Drug Administration

U.S./Canadian Price Comparisons
October 2004

U.S. Customs and Border Protection (CBP) recently detained more than 400 packages containing prescription drug products at the Miami mail facility. FDA reviewed a list of the drugs contained in these packages and observed that about half of the drugs were foreign generic drugs or drugs for which there were generic versions available in the United States.

The detained packages were apparently being sent to U.S. addresses from a source in the Bahamas by a Canadian pharmacy, Kohler's Drugstore of Hamilton, Ontario, which recently set up an internet operation (www.canadarx.net) to do business with American consumers.

FDA analyzed the prices actually charged on customer invoices for a sample of the detained foreign generic medications encountered in the shipments. FDA converted the price paid to U.S. dollars and checked the prices at four U.S. pharmacies. In every instance, a U.S pharmacy price for the FDA-approved generic drug was less than what consumers had paid for the foreign generic drug ordered from Kohler's Drugstore in Canada. The following chart shows these findings.

U.S./Canadian Price Comparisons

Drug (strength and amount)	Medical Use	Price paid by patient from CanadaRX in USD*	CanaRX*	U.S. Pharmacy Price**
Amiodarone 200mg (100)	Rapid Heart Beat	$116.97	$134.90	$41.89
Verapamil SR 240mg (100)	High Blood Pressure	$83.90	$93.95	$43.97
Lisinopril 20mg (100)	High Blood Pressure	$83.59	$97.90	$16.19
Lisinopril 5mg (100)	High Blood Pressure	$47.96	$67.90	$13.99
Terazosin 2mg (100)	High Blood Pressure, Prostate	$43.98	$52.90	$17.09
Digitek 0.25mg (250)	Heart Medication	$51.30	N/A	$29.47
Diltiazem CD 240mg (100)	High Blood Pressure	$139.75	$145.00	$127.99
Hydrochlorothiazide 25mg (100)	High Blood Pressure	$12.73	N/A	$6.29
Warfarin 5mg (100)	Prevention of Blood Clotting	$18.60	$24.90	$20.69
Aricept 10mg (30)	Alzheimer's treatment	$128.65	$147.96	$140.69

*Shipping charges by Canadian pharmacies not included, but range from $15-$30.
**Based on prices available on Oct. 4 and 5, 2004.

http://www.fda.gov/oc/opacom/hottopics/importdrugs/canadarx.html

Permanent Subcommittee on Investigations
EXHIBIT #39