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BUYER BEWARE: PUBLIC HEALTH CONCERNS OF COUNTERFEIT MEDICINE

HEARING

BEFORE THE

SPECIAL COMMITTEE ON AGING
UNITED STATES SENATE

ONE HUNDRED SEVENTH CONGRESS

SECOND SESSION

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BUYER BEWARD: PUBLIC HEALTH CONCERNS OF COUNTERFEIT MEDICINE

TUESDAY, JULY 9, 2002

U.S. SENATE,
SPECIAL COMMITTEE ON AGING,
Washington, DC.

The committee met, pursuant to notice, at 2:35 p.m., in room SD–562, Dirksen Senate Office Building, Hon. John Breaux (chairman of the committee) presiding.

Present: Senator Breaux, Wyden, and Carper.

OPENING STATEMENT OF SENATOR JOHN BREAUX

The CHAIRMAN. The Aging Committee will please be in order.

I want to welcome all of our witnesses who are with us this afternoon and all of our guests and thank them for being with us.

I want to especially welcome Mr. Rick Roberts who has traveled all the way from Colorado to share his story with us, and we thank him for being with us this afternoon.

Last September, this committee held a hearing to examine the marketing practices of some of our dietary supplement companies. What we found at that time was that unscrupulous con men were making unsubstantiated health claims about products which undergo practically no Food and Drug Administration approval process. As unsavory as these characters were, none of their products claimed to have FDA approval. They were simply gaming the system.

Today's hearing, "Buyer Beware: Public Health Concerns of Counterfeit Medicine," is being called to examine an even worse practice; that is, the counterfeiting of FDA-approved prescription pharmaceuticals.

The term "counterfeit" will be used today to discuss pharmaceutical products which fall under three very broad headings. The first consists of products which contain the correct active ingredients, but have either incorrect dosages or have expired or have been re-labeled. These drugs could trigger allergic reactions or simply be ineffectual in treating the problems for which they were intended.

The next group consists of products with no active ingredients. These products may sound safe, but, in fact, they prevent patients from receiving the proper medical treatment and could effectively lead to a patient's untimely death.

Finally, the third group consists of products containing the wrong ingredients. These drugs may actually contain other medicines or toxic substances which can lead to immediate health care problems.

It was reported last year that nearly 8 percent of drugs imported into the United States are fake. The World Health Organization has estimated that about 8 percent of the medicines available worldwide are also counterfeit. These statistics are, of course, very troubling.

The United States maintains the most rigorous pharmaceutical regulatory system in the world, but high prescription drug costs and the growing Internet marketplace make the United States an increasingly attractive market for these who engage in these unscrupulous activities.

Additionally, we will hear today that counterfeits are entering our country not only through personal importation and the Internet, but also on the shelves of trusted retail pharmacies.

The Congress has held dozens of hearings on the rising costs of prescription drugs, and we have heard countless stories of individuals and families who have been devastated by the financial burdens of treating chronic illnesses. Today's hearing will illustrate that we cannot look abroad for the solution to the prescription drug dilemma. We in the Congress must do all that we can to provide a meaningful, affordable prescription drug plan for our Nation's seniors, and we must do it before more of our vulnerable citizens jeopardize their lives looking for a solution.

I look forward to hearing from our panel members and their testimony and also the participation of our colleagues. I would first recognize our colleague on the committee who contributes so much, Senator Wyden.

STATEMENT OF SENATOR RON WYDEN

Senator WYDEN. Thank you, Chairman Breaux, and thank you very much for your continued interest in this problem. My sense is that this problem has grown in the United States since the World Health Organization concluded in 1992 that, in some countries, as much as 60 percent of all drugs may be counterfeit.

I will tell you, Chairman Breaux, I think your hearing is particularly timely because, at a time when the Congress is working to add a prescription drug benefit to Medicare, it is absolutely critical that the senior citizens of this country get the real thing. Counterfeit medicine is certainly a financial ripoff, but I think what we have seen in your investigations and others is that it can be life-threatening as well.

I would wrap up with just a couple of points, Mr. Chairman, that I am interested in working with you on. First, with respect to the Internet sites, it is going to be very important to examine them carefully because I think there can be some serious questions with respect to documenting the chain of custody for drugs that are sold over the Internet, and the challenge will be to make sure that there is the adequate documentation without creating a whole barrage of new red tape and bureaucracy. I am going to be asking our witnesses about that issue in particular.

The other point that I would want to mention, Mr. Chairman, is that I think there are some great opportunities technologically to root out the fake drugs, the counterfeit drugs. As you know, I chair the Commerce Committee's Subcommittee on Technology. I work very closely with you on the Commerce Committee.

For example, there are some exciting new handheld devices that, in effect, work almost like X-rays. They are almost X-ray gadgets that can, I think, be an ideal tool for rooting out the counterfeits. I would hope that we could work together both on this committee and in our work on the Senate Commerce Committee to look at some of the new technologies that can help us root out the fakes and counterfeits that threaten the people of our country.

I thank you again for your leadership.

The CHAIRMAN. Thank you, Senator Wyden.

Senator Carper.

STATEMENT OF SENATOR TOM CARPER

Senator CARPER. Thank you, Mr. Chairman.

To our witnesses, we welcome you. We are delighted that you are here and look forward to your testimony.

I am scheduled to preside at 3. So, if I get up and walk out during the middle of somebody's testimony, I have gone to do my day job, and I ask for your forgiveness.

During this past week, we have been in recess. I live only in Delaware. I go home virtually every night, but recess for me is just a chance to not only reconnect with my family a little bit, but also to reconnect big time with my State.

We held a series of housing summits throughout the State on affordable housing, home ownership, and I held a number of meetings, almost like focus groups, with senior citizens. The issue, not surprisingly, was prescription medicines under Medicare.

I don't know if your ears were burning, Mr. Chairman, but your name was invoked kindly in the number of stops, Bob Graham for his legislation. The House Republican bill was discussed at some length, and we talked about the different proposals, what the copays were, what the deductibles were, what the monthly premiums were, what the caps were of which Medicare picked up the entire tab. There was a fair amount of discussion on that, but in every one of those meetings, we also talked about the issue of medicines that can be obtained across the border, maybe across the border in Canada or in Mexico or in other places around the world.

I wish that those people who were good enough to participate in those focus groups back in Delaware with me over the last week were able to be here today to hear this testimony, and my hope is that some of them are watching on television. This is a good hearing, and it is a timely hearing.

I just want to say to you for all the time and effort that you have put into the issue of how do we make prescription drugs available to senior citizens, to our Medicare population, and doing so in a way that is consistent with a balanced budget and that harnesses market force, my special thanks.

The CHAIRMAN. I thank both of my colleagues for their generous comments, and we are very pleased to have our panel.

First would be Mr. Rick Roberts. He is a professor in the Department of Communications Studies at the University of San Francisco, spends his summers working with at-risk high school students at the Eagle Rock School in Colorado, and will tell us about his firsthand experience about using a prescription drug that turned out to be counterfeit.

Mr. Roberts, we welcome you to the committee.

STATEMENT OF RICK C. ROBERTS, SAN FRANCISCO, CA

Mr. ROBERTS. Thank you. I appreciate this opportunity to share my story.

The CHAIRMAN. Pull the mike up a little bit closer, Mr. Roberts. Thank you.

Mr. ROBERTS. Thank you for this opportunity to share my story.

Yes. I teach at the University of San Francisco and work with at-risk youth. I am on the board of the Andrew Ziegler Foundation committed to HIV care and standard of care and access to that care, but today I am really here to talk to you as an individual, not from those perspectives, but as someone who has experienced counterfeit medicine.

I think my story is important because it is truly, in the end, the individual who suffers from this crime either by way of not receiving medication required or potentially getting something dangerous and the anxiety that is associated with taking a counterfeit medication.

My story starts in the early 1980's. I was a student in college and was infected with HIV before we even knew about HIV. In 1988, I became ill and was diagnosed with AIDS-related complex, I immediately began taking AZT, which was the only antiretroviral approved by the FDA at that point, and that began my journey of doctors and procedures and pharmacies and insurance companies and medications and side effects. I think it has been quite a journey.

Twelve years later, in the year 2000, I was facing HIV Wasting Syndrome. I was on a number of medications to help prevent that. They were failing, and so what I needed was Serostim, which is human growth hormone produced by Serono. I was fortunate enough that my insurance company approved a 12-month supply of Serostim, and I began taking it. I injected it every day and with very positive results.

But, about halfway through this process of Serostim, I noticed burning at the injection sites and what I think were some subtle differences in packaging.

January 2001, I asked my pharmacist. He was at the counter and I said, "Do you know why this is burning?" He said it shouldn't, but that I should go home because maybe I had some fake Serostim. I asked him what he meant by that. He said he didn't know much more except that he knew that there was some fake Serostim.

So I went home and looked very closely at what I had, the empty vials and boxes with the remaining doses I had, plus what I had just received from the pharmacy, and noticed that there were three groups, the group that matched exactly what I had just picked up, and then two other groups, one with some subtle differences and one which it turned out to be big differences in their packaging and quality of drugs.

At that point, it was pretty clear that for at least for a month, I had injected daily something other than growth hormone. The question that immediately came to my mind was, "what had I injected?"

I went online, went to the Serono website where they did have a warning and a lot number listed. I checked. I had that lot, but I was sure that I had something in addition to that lot, and they said they were cooperating with the FDA's criminal investigation.

I went to the FDA site and read their warning that this counterfeit had been found in seven States and that they had a criminal investigation that was ongoing.

I contacted both of those groups, and it would be 3 months of sleepless nights and doctor appointments and anxiety attacks before I found out what I had injected. At the end of those 3 months of waiting, I was told that there would be no long-term consequences for what I had injected. It would be another 3 months before I found out what was in the second batch, and that it was still true that I would be OK in the long run. Luckily, I was stable enough that I hadn't suffered from not getting the medication I needed during that month. So I feel like I was pretty lucky.

I still have a number of questions. I am looking forward to the conclusion of the FDA investigation for some answers.

I think, most importantly to me, that I feel fortunate that I found out about it and that I was stable, but I only knew about it because I happened to ask my pharmacist and he told me. There was never an attempt to inform me or warn me of the dangers of counterfeit Serostim, even though I was one of just 6,000 people in the country on the drug at the time.

These were really high-quality counterfeits. You can see here some, just subtle, differences between them.

The CHAIRMAN. Go ahead and show them what you have.

Mr. ROBERTS. These two here are the real thing. This box is the real thing.

These are both counterfeits and came with these boxes here.

Obviously, they were counterfeited well enough to fool the pharmacist. As I said, I noticed small changes, a rubber stopper in one bottle that wasn't in the other, the tabs on the top were slightly different colors.

These are counterfeit. These are real. Counterfeit. Real.

I think I know these in detail now. I am very careful. Every time I get a prescription, I examine everything very carefully. After this experience, I became very, very aware of the fact that I needed to be diligent about checking the prescriptions I was receiving.

These are not run-of-the-mill drugs. Most HIV medication and related medications are very, very expensive, especially growth hormone.

So, in the end, after I found out I was safe, I became frustrated and angry that no one had tried to contact me. I wasn't aware of the danger, and just as I began, I think this story is important because, in the end, it is the individual who really does suffer from this crime.

Thank you.

[The prepared statement of Mr. Roberts follows:]

I would like to start by thanking the committee for the opportunity to share my story- my personal experience with counterfeit medicine. My name is Rick Roberts and my story can be told through a series of questions I faced a year and a half ago followed by my attempts to find the answers to those questions.

I am currently a professor at the University of San Francisco and spend my summers working with at-risk high school students at the Eagle Rock School in Colorado. I serve on the Board of the Andrew Ziegler Foundation – an organization committed to access to state-of-the-art HIV care. I have been interviewed regarding my experience with counterfeit medicine by SF Frontiers Magazine, the Boston Globe, ABC Nightly News, Canadian Television (CTV), and Time Magazine (not yet in print).

My story begins about 20 years ago. I graduated from a small town high school in the Sierra Nevada Mountains of California. That summer I turned 18 and moved away to start my college career. I was a college freshman, gay, living in San Francisco, and it was 1981. HIV was isolated and determined by many to be the cause of AIDS a few years later. In 1986 I graduated from the University of San Francisco. In 1988, while in graduate school at San Francisco State University, I became ill and was diagnosed with AIDS Related Complex. I was most likely infected before anyone knew about HIV.

I started AZT, the only retroviral approved at the time by the FDA. This was the beginning of my experience with HIV medications and today I take a combination of 25 to 50 pills a day. I have become quite familiar with pharmacies, formularies, and side effects.

It has been quite a journey and along the way I was diagnosed with AIDS. There have been many critical junctures on the journey in terms of my health. One of them was my fight against AIDS Wasting Syndrome. This particular fight caused me to ask myself the first question of this story.

Would I make it through yet another health crisis? It had been a 12-year battle at that point and I knew the reality of the situation. I was already using the most accessible drugs to combat wasting. They were not working, but there was some hope. I was notified that my insurance company had approved 12 months of

Serostim (Human Growth Hormone). I had used Serostim before, with good results, when I participated in an experimental study. I started the daily injections and they stabilized my condition. It looked like I would make it.

Toward the end of my year on Serostim I noticed some subtle changes in the packaging of the drug and the actual quantity of the drug itself. This was in November and December of 2000. **Where the changes I had noticed significant?** I was not alarmed, but when I started having burning at the injection site I made a note to ask the pharmacist about it the next time I went to pick up my medications.

I asked the pharmacist during my next visit at the end of January 2001 and he simply stated that I might want to go home and check what I had because it could be fake. Fake? He said that he had heard that some people had received counterfeit Serostim. **Did I actually have counterfeit drug?** After meticulously and systematically inspecting and comparing the empty vials, boxes, and full doses of Serostim that remained, I concluded that there were differences between them. In fact, they seem to fall into one of three groups: those that were identical to the prescription Serostim I had just picked up, those that were only subtly different, and those that upon consideration had some very obvious differences.

If I had received counterfeit drug from the pharmacy, who else knew about it? I went on-line and went to the website of Serono, the manufacturer of Serostim. They indeed did know that Serostim had been counterfeited. Serono identified one particular lot number and stated that they had issued a recall of that lot. They also stated that, along with providing some contact information, they were cooperating with the FDA's criminal investigation. So, I went to the FDA website and found a warning statement.

The FDA announced that they were conducting a criminal investigation into counterfeit Serostim found in seven states. It also identified the same lot number as Serono. Naomi Aoki of the Boston Globe had also written a brief article describing what I had just found on the Serono and FDA sites. **If the pharmacy, Serono, and the FDA knew about this counterfeit, why didn't anyone tell me?**

The "Serostim" that had the obvious differences matched the lot number reported to be counterfeit. I had a couple of empty boxes- it turns out I had injected a few weeks worth of the counterfeit. I called both Serono and the FDA. After a week of trying I was never able to get in touch with the contact person at the FDA. Serono did return my call.

The person from Serono told me they would make good on anything I suspected was counterfeit and if I returned everything suspicious to the pharmacy, they would replace it with "real" Serostim. He insisted that there was only one lot of counterfeit, but I was convinced that there were two. No one said why patients had not been notified. **How could they guarantee that what they gave me would be "real" when they didn't believe there was another lot of counterfeit?** I didn't return what I had. In fact, because I seemed to be stable in terms of my weight, I stopped taking growth hormone all together. I couldn't believe that this was happening and became suspicious of all my medicine.

Then came the most critical question, after realizing I had everyday injected, for at least a month, something other than growth hormone. **If it wasn't Serostim, what had I injected and what were the consequences?** No one seemed to either know the answer or to want to answer the question.

Eventually, Serono did identify a second counterfeit. But it would be three months of fear, sleepless nights, Doctor visits and anxiety attacks before I would learn that one of the drugs I injected would have no negative long-term effects. It would be another few months before I found the same was true of the second counterfeit lot. Other than my initial ARC diagnoses in 1988, this was one of the most difficult periods of my life.

While I had been through difficult crises before, I always knew what I was up against. In this case, I was never warned (even though it was a known danger), I was told I was mistaken about a second counterfeit, and I didn't feel I could trust Serono and the pharmacy to replace the counterfeit with real drug. The most devastating period for me was the six-month wait.

How did this happen?

Who was responsible?

When the FDA finishes the investigation they started a year and a half ago I hope to have the answers to these and other remaining questions. The questions that I may never understand the answers to are:

Why were the approximately 6,000 US citizens using Serostim not warned?

Why didn't Serono use pictures and identify specific differences on their website to help us better identify counterfeit Serostim?

Why was I forced to wait so long before any one could help me know that I was going to be okay after injecting these counterfeit drugs?

Thank you for listening to my story.

The CHAIRMAN. Thank you, Mr. Roberts. We have a number of questions we want to get into, but we will hear from our other witnesses.

Next, we have, please, Mr. Bill Hubbard, who is Senior Associate Commissioner for Policy, Planning and Legislation at the Food and Drug Administration.

Mr. Hubbard, we welcome your testimony.

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

Mr. HUBBARD. Thank you, Mr. Chairman.

We are all familiar with counterfeiting. We hear about it in handbags and watches and clothing and other sorts of things, and it is a problem throughout the country and, in fact, throughout the world. But pharmaceuticals, we believe, represent a special problem in that consumers not only can have their pocketbook placed at risk, but their life as well, and consumers cannot discern for a pharmaceutical what they have.

This is a counterfeit watch from the streets of Washington. It cost $9, but I could take this to a jeweler who would readily know that it is counterfeit. Even a consumer can see from the second hand that it is probably not a fine Swiss timepiece.

This is a counterfeit drug made by the same company that Mr. Roberts was talking about, that is indistinguishable from the real thing, and if I showed this to a patient, he couldn't tell the difference. If I showed it to a pharmacist, he couldn't tell the difference. If I showed it to a doctor, he couldn't tell the difference. As a matter of fact, if I took it to the company, they would likely be unable to show initially the difference until they spent some time looking at that. So this is a real problem, and the sophistication of the counterfeiters, we believe, is a problem. So it is very timely that you are having this discussion with us.

Counterfeiting has been a very limited problem in the past, but we are concerned that it is getting to be more of a problem. Since 1998, we have had about 55 counterfeit drug cases that have resulted in 26 arrests and convictions, If you look at the pyramid of those cases, they are increasing.

In 1999, we had six cases opened. In 2000, we had 10 cases opened. In 2001, the FDA opened 23 cases, and so far this year, we have opened 16 counterfeit cases, which would mean we are going on a rate for the year of 30 or more.

We are also seeing something we haven't seen before that my colleagues at Customs are very used to, and that is the concept of smuggling. We all hear about smuggling of narcotic drugs, which is a very old story, but now we are seeing smuggling of prescription drugs.

This is a toy from China that came in, and in the back was a pocket that contained Viagra. There has been a case on that.

We have a little toy car that has a little metal motor in it to make it go around, but they took the motor out put a drug called Tramadol in there, and that has been a problem.

American consumers are seeking out these products more because, as you pointed out, the high cost of drugs drives people to look for cheaper medications.

We have also seen an increase in the use of the mail and the Internet to purchase drugs, as you know, and that is also a challenge because neither we nor the Customs Service can deal with these thousands and thousands of packages that come in.

As a matter of fact, we and Customs did a sample look a couple of years ago at international mail facilities, and if you extrapolate from what we saw just in a few days, there may be 1- to 2 million of these little individual packages coming in that people order over the Internet. The system really can't deal with trying to assess the quality of each one of these and try to assure the public that they are safe.

Our criminal investigators are also seeing counterfeit or otherwise suspect drugs from just any possible country. We have an example from Spain, England, China, France, Germany, Bahamas, Mexico. It is everywhere, as you pointed out in your opening remarks, Mr. Chairman. So it is clearly an issue that we are very concerned about.

Also, there is this emergence of what we see as an illicit wholesale drug system out there that, because of the tiered pricing in the industry. There are profits to be made. If you can find a way to get drugs at a discount over here more than you need, you can sell them over there, and then that gives the counterfeiters a potential entree.

The system in this country has traditionally been closed. It is hard to get into the drug distribution system in this country unless you are a manufacturer or established wholesaler. The counterfeiters want a way to get in, and we are concerned that some of these things that are going on open that up.

The latest we see is Canada. That is the trend of the day. The Canadian drugs are clearly cheaper. The numbers are there, and we see ads in newspapers, particularly in areas with large numbers of senior citizens. Come on down or buy our drugs from this site, 86-percent savings, Congress says this is legal, this is a good thing, and just fill out the form and send in your check and your drugs will be on the way.

So that tendency of the promotion of these products as well as the consumers looking for the cheaper drugs——

The CHAIRMAN. Excuse me, Mr. Hubbard. Is that ad a mail order ad for mail order?

Mr. HUBBARD. This particular ad is a newspaper ad, but then it says you can fill out this form and order the drugs or you can go on their website and order the drugs. It says that they are Canadian drugs that would offer 86-percent savings. Our data shows the savings from Canada is probably more like 40 to 60 percent, somewhere in that range, but there probably are some that go as high as 86 percent because, in fact, there is a range of price savings if you go to Canada.

The CHAIRMAN. OK.

Mr. HUBBARD. Of course, these ads imply that it is legal, it is acceptable, and the drugs are safe.

So thank you for this hearing, and we stand ready to provide whatever assistance we can to the committee.

[The prepared statement of Mr. Hubbard follows:]

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

STATEMENT OF

WILLIAM K. HUBBARD

SENIOR ASSOCIATE COMMISSIONER FOR POLICY, PLANNING AND LEGISLATION

FOOD AN DRUG ADMINISTRATION

BEFORE THE

SPECIAL COMMITTEE ON AGING

UNITED STATES SENATE

JULY 9, 2002

RELEASE ONLY UPON DELIVERY

INTRODUCTION

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

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

PERSONAL IMPORTATION OF DRUGS THROUGH THE MAIL

Under the Federal Food, Drug, and Cosmetic (FD&C) Act, unapproved, misbranded, and adulterated drugs are prohibited from importation into the United States. In general, all drugs

imported by individuals fall into one of these prohibited categories. This includes drugs that are foreign versions of FDA-approved medications, and drugs that are dispensed without a prescription. In addition, under the Act, FDA-approved drugs that are manufactured in the U.S. and exported may not be reimported by anyone other than the manufacturer.

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

At mail facilities, Customs officials identify parcels that may violate the FD&C Act for FDA examination. FDA inspectors then determine if these products should or should not be permitted to enter the country. If detained, FDA must issue a notice to the addressee describing the potential Federal violation and provide the individual with an opportunity to respond and provide reasons why the drug parcel should be allowed entry. If the addressee does not respond or provides an inadequate response, FDA will give the parcel back to Customs to have it returned to the exporter. Due to the requirements for notice and an opportunity to respond, the detention and

further processing of mail parcels consumes large amounts of FDA resources. In addition, considerable storage space is needed to hold the large number of detained parcels until replies are received from the addressees.

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

From a public health standpoint, importing prescription drugs for personal use is a potentially dangerous practice. FDA and the public have no assurance that unapproved products are effective or safe, or have been produced under U.S. good manufacturing practices. FDA cannot assure the public that re-imported drugs made in the U.S. have been stored under proper conditions or that they are even the real product, because the Agency does not regulate foreign distributors or pharmacies. Therefore, unapproved drugs and re-imported approved medications may be contaminated, subpotent, superpotent, or counterfeit. In addition, some websites based outside the U.S. offer to dispense prescription drugs without a prescription by a licensed practitioner or a physical examination, bypassing the traditional doctor-patient relationship. As a result, patients may receive inappropriate medications due to misdiagnoses, they may fail to

receive appropriate medications or other medical care, or they may take a product that could be harmful, or fatal, if taken in combination with other medicines they might be taking.

Personal Importation Policy

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

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

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

The current personal importation policy permits the exercise of enforcement discretion to allow entry of an unapproved prescription drug only if the intended use is for a serious condition for

which effective treatment may not be available domestically; the product is considered not to represent an unreasonable risk; the product is for personal use; there is no known commercialization or promotion to U.S. residents by those involved in the distribution of the product; and the individual seeking to import the product affirms in writing that it is for the patient's own use and provides the name and address of the U.S. licensed doctor responsible for his or her treatment with the product or provides evidence that the product is for the continuation of a treatment begun in a foreign country.

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

Due to the huge volume of drug parcels entering the U.S. through the international mail and courier services, the requirements for notice and hearing, and our limited resources, it is difficult for FDA to detain and refuse mail imports for personal use. As a consequence, tens of thousands of parcels that FDA does not review are eventually released by Customs and sent on to their

addressees, even though the products contained in these parcels may violate the FD&C Act and pose a health risk to consumers. We do not believe this is an acceptable public health outcome.

CARSON MAIL FACILITY PILOT

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

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

Analysis of the Carson Pilot Drug Parcels

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

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

Several drugs do not appear to correspond with any FDA-approved drugs and the risks are therefore difficult to assess. One drug had been reviewed for FDA approval but was denied approval due to cardiac abnormalities and because its efficacy could not be demonstrated.

Several shipments contained three drugs that were once approved by FDA but have been withdrawn from the market based on serious safety concerns.

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

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

Many of the drugs identified in the Carson pilot are intended to treat conditions that only physicians can properly diagnose. Consumers who bypass physician diagnosis and prescribing

may be exposing themselves to risks and toxicities that cannot be justified by offsetting benefits. For example, almost ten percent of the shipments were for antibiotics, despite the fact that consumers are generally not able to diagnose whether their symptoms are caused by bacterial or viral infections. Several drugs listed are potent steroids, which are generally prescribed for conditions that are not self-diagnosable.

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

INTERNET DRUG SALES

Based on a survey conducted in early 2000 by FDA's Office of Criminal Investigations (OCI) and a subsequent study by the General Accounting Office, there appears to be roughly 300 to 400 Internet sites selling prescription drugs to consumers, with approximately half located domestically and half located outside the U.S. FDA has long taken the position that consumers are exposed to a number of risks when they purchase drugs from Internet sites that are not operated by pharmacies licensed and operating within state pharmacy law or sites that dispense foreign drugs. These outlets may dispense expired, subpotent, contaminated or counterfeit product, the wrong or a contraindicated product, an incorrect dose, or medication unaccompanied by adequate directions for use. FDA cannot provide consumers with any assurance that these products were manufactured under current good manufacturing practice standards. Taking an

unsafe or inappropriate medication puts consumers at risk for dangerous drug interactions and other serious health consequences.

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

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

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

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

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

Norfolk Men's Clinic

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

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

Medications Express

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

Canadian Drug Store, Inc.

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

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

Total Remedy / Prescription Center II

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

Pillbox Pharmacy

In March of this year, a Texas pharmacist, three doctors, two corporations and an individual were charged in a federal indictment alleging that they conspired to illegally dispense drugs in connection with an Internet pharmacy operation. The indictment charged one pharmacist, three physicians and two corporations, the S&H Script Shop and the Pillbox Medical Center, with conspiring to illegally dispense controlled substances and commit money laundering. According to the indictment, between January 1, 2000, and June 12, 2001, the defendants grossed more than $7.7 million from the Internet sales of just two drugs alone. The indictment alleges the doctors

would issue prescriptions without establishing a patient history, performing a mental or physical exam, using appropriate diagnostic or laboratory testing, or providing any means to monitor medication response. The charges were the result of an 18-month investigation by FDA, the DEA and the Internal Revenue Service, working with the U.S. attorney's office. In April, the pharmacist and two corporations pled guilty to illegally dispensing controlled substances, and agreed to forfeit $1 million.

Other Enforcement Activity

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

Currently, FDA has 90 sites under active review for possible regulatory or civil action. Warning letters have been sent to 55 domestic online sellers. Additionally, FDA has sent 137 "cyber letters" to operators of Internet sites in many countries, including Canada, that offer to sell online prescription drugs or unapproved drugs. These sites may be engaged in illegal activity such as offering to sell prescription drugs to U.S. citizens without valid (or in some cases without any) prescriptions. Cyber letters are sent over the Internet to the suspect websites to warn the operators that they may be engaged in illegal activities, and inform them of the laws that govern prescription drug sales in the U.S. Cyber letters have a deterrent effect and FDA has seen

positive results from using them. FDA also sends copies of its cyber letters to the home governments of targeted websites when the locations can be identified. Follow-up depends on the ability and willingness of the foreign regulatory bodies to investigate and take actions against website operators who are illegally shipping drugs to other countries.

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

IMPORTATION AT LAND BORDERS

FDA is aware that a number of U.S. citizens travel to other countries to purchase medications at a lower cost. However, many prescription drugs available from foreign sources are either unapproved foreign versions of FDA-approved drugs or products for which there is no U.S. approved counterpart. In either case, these products are unapproved drugs prohibited from importation by section 505 of the FD&C Act. In FDA's experience, many drugs obtained from

foreign sources that purport to be the same as U.S. approved prescription drugs are of unknown quality. FDA cannot provide adequate assurance to the American public that the drug products they purchase in other countries are the same products approved by FDA.

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

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

Southwest Border Survey (August 2000)

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

from the U.S., bringing back primarily antibiotics or pain relievers for their own use. Prescriptions were held by 63 percent of the persons interviewed (59 percent U.S. prescriptions and 41 percent Mexican). The most common drugs and their indications that were purchased in Mexico during the survey were as follows: Amoxicillin (antibiotic), Glucophage (diabetes), Premarin (estrogen), Dolo Neurobion (vitamin supplement), Vioxx (inflamation), Retin-A (acne), Tafil (anxiety), Celebrex (arthritis), Penicillin (antibiotic), Viagra (impotence), and Carisoprodol (analgesic). While many of these products are already available as FDA-approved drugs in the U.S., some are unapproved for sale in this country.

Canadian Border Survey

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

surgery); Claritin and Allegra (allergies) purchased OTC in Canada; Sibelium capsules (calcium channel blocker); and a variety of OTC products sold in Canada and not available in the U.S. Some of these drugs are unapproved foreign versions of FDA-approved drugs, although some approved for sale as prescription drugs in the U.S. are sold as over-the-counter medications in Canada.

Southwest Border Survey (April 2001)

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

Controlled Substances

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

COUNTERFEIT DRUGS

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

The manner in which FDA handles these types of counterfeit and tampering incidents are driven by two primary goals that are often, but not always, complementary. First and foremost, FDA works with consumers, manufacturers, wholesalers, distributors, state agencies and others in order to determine the composition of the unsuitable product and the extent to which it has been

introduced into the distribution chain, and we use this information do whatever is necessary to protect the public health. Second, OCI, with the support and cooperation of other FDA components and other law enforcement agencies, attempts to bring the perpetrators of criminal acts to justice. It must be noted, however, that the need to publicize the existence of a counterfeit or adulterated product in order to alert professionals and the public to potential dangers may compromise the successful conduct of criminal investigations.

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

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

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

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

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

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

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

In May 2002, Serono became aware that counterfeit Serostim displaying a fake lot number had been distributed. Preliminary information indicates that the counterfeit product may have been distributed via the Internet. Laboratory analysis by FDA shows that the product contains no active ingredient, and it has been determined that the product did not originate from Serono. On May 16, Serono issued a letter advising Serostim handlers to be aware of the counterfeit lot even though it has not shown up in normal distribution channels.

Neupogen (filgrastim), Amgen, Inc.

In the spring of 2001, based on observations by a distributor about product appearance, Amgen analyzed a suspect lot and determined that the vials contained only saline solution. Investigation by the company and FDA revealed that the lot did not display a legitimate Neupogen lot number, but one that had been assigned to a lot of Epogen, another Amgen product. The FCC performed additional analysis. In May 2001, Amgen issued 17,000 Dear Health Care Professional letters

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

Epogen (epoetin alfa), Amgen, Inc.

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

Combivir (lamivudine plus zidovudine), GlaxoSmithKline

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

Zyprexa (olanzapine), Eli Lilly & Co.

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

Procrit (epoetin alfa), Amgen/Ortho Biotech

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

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

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

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

related to the misbranding and distribution of human growth hormone and steroids. Gansen assisted Nicholas Hanson in the counterfeiting of Serostim.

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

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

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

unscrupulous individuals to place counterfeit, substandard or otherwise dangerous drug products into U.S. commerce and into citizens' medicine cabinets, as discussed below.

DRUG IMPORTATION LEGISLATION

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

In particular, S. 2244, recently introduced by Senator Dorgan and others, would create two new pathways for drugs to enter the U.S. outside of the current drug regulation system that, while not perfect, has a remarkable record of protecting the public from contaminated, ineffective, or counterfeit drugs. Of particular concern are the provisions for allowing individuals to import drugs directly from Canadian pharmacies. This would greatly exacerbate the growing problem of the hundreds of websites purporting to sell legitimate medications that are in fact selling unapproved or otherwise dangerous drugs to Americans. These personal importation provisions

are so broad that they will over-ride existing statutes that allow FDA to refuse entry to prescription drugs from Canada if they are believed to be unsafe, ineffective, adulterated, contaminated or counterfeit.

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

S. 2244 would create a second route for transporting drugs into the U.S. outside of the existing regulatory system. The bill would allow pharmacists and wholesalers to purchase drugs from Canadian sellers over which U.S. authorities (FDA or others) have no jurisdiction or control. Because the bill requires that the drugs comply with sections 501, 502 and 505 of the Act, it may be found, in practice, that for the bill to have its intended effect, U.S. manufacturers would have to sell drug products manufactured, labeled and intended solely for the U.S. market to Canadian distributors, specifically for re-sale to the U.S. As a practical matter, meeting these requirements would be very difficult, and it is unlikely that Canadian sellers and U.S. importers would be willing to endure them. Additionally, it is not clear as to how FDA could ensure that drugs reimported under this proposal would in fact comply with those sections of the Act, because the Agency has no practical ability to regulate or inspect Canadian facilities.

The bill attempts to ensure the safety of the drugs under 804(b) by requiring testing for authenticity. Unfortunately, authenticity can rarely be established solely through chemical analysis. That can only be assured by the multiple layers of safeguards that are built into the FDA's oversight system in which drug approval, regulation, inspections and surveillance tracks drugs over their entire life cycle. The testing required by S. 2244 would not protect against the threat of counterfeit drugs because no random sampling plan can protect against such criminal conduct. The threat of counterfeits does not depend on the integrity of the product itself, but on the integrity of those handling it. Since counterfeits can easily be commingled with authentic product, either by the case, by the bottle, or by the pill, there is no sampling or testing protocol sufficient to protect against the grave public harm they pose.

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

We would also like to recognize that the Administration is continuing to review this legislation and may have further comments. Finally, FDA notes that we will continue to offer our expertise

and advice to the Congress, as we have in the past, in exploring any additional proposals which may be offered to address the drug pricing issue, including those involving reimportation.

CONCLUSION

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

The CHAIRMAN. Thank you very much. We have some questions, I know, for you as well.

We are delighted to have Elizabeth Durant, who is Executive Director of Trade Programs at the U.S. Customs Service.

Ms. Durant, welcome to the committee.

STATEMENT OF ELIZABETH G. DURANT, EXECUTIVE DIRECTOR, TRADE PROGRAMS, U.S. CUSTOMS SERVICE, WASHINGTON, DC

Ms. DURANT. Thank you, Mr. Chairman.

I would like to, today, talk to you about U.S. Customs' efforts to address this ever-increasing trend of personal and bulk importation of pharmaceutical products into the United States.

The main focus of the Customs Service has shifted to protecting the United States from terrorist attacks. There is no doubt about it, but we have many other missions in Customs and we do perform services under the direction of over 40 other Federal agencies. One of our closest partners is the Food and Drug Administration.

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

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

A disturbing trend is the increase in bulk shipments through the mail indicating that these products could be making their way to pharmacy shelves. Detecting prohibited pharmaceuticals among the tens of millions of parcels passing through our facilities each year presents a massive challenge. Our limited resources require a risk management approach with which we utilize advanced intelligence, records of past seizures, and other factors to locate packages that present the most significant threats.

Customs' laboratories help us find discrepancies in shipments of bulk and finished pharmaceuticals, but we do require the assistance from the FDA to establish effective national standards for the interdiction of pharmaceuticals subject to FDA laws.

Based on an operation nicknamed Operation Safeguard that we have carried out over the past couple of years, we have 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 an active pharmaceutical ingredient, but merely substances such as starch or sugar. Other problems include expired materials, unapproved products, improper use instructions, and products made in facilities not under proper regulation.

The vast majority of pharmaceuticals that enter the U.S. via the mail do so in a manner that violates present FDA requirements.

Additionally, we have found many parcels contain 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 the products would be used properly.

It is important to note that after 3 weeks of one phase of Operation Safeguard, the quantity of illegal and defective pharmaceutical shipments slowed significantly. So they are watching us, and they are watching what we get, and they move on or wait a while until we can get back to them.

During a recent phase of Operation Safeguard that took place at two international mail branches, 31 parcels containing 52 different types of questionable pharmaceuticals underwent intensive chemical analysis. The analysis of these products showed that eight of the so-called pharmaceuticals, or 15 percent, contained no identifiable active ingredient, and 18 contained a substance that is regulated under Federal Controlled Substance Act.

Additionally, during this phase of the operation, it was found that large parcels of fake or gray-market pharmaceuticals are being split into different mail shipments, but arrive at the same address. This is a relatively new trend.

Accordingly, there is a possibility that stateside pharmaceutical distributors are using these products as a source of supply. It is clear that this remains an overwhelming problem.

Travelers who attempt to import pharmaceuticals upon their return to the United States are also a source of concern. Customs is seeking and working with the FDA to more sharply define the current broad discretion given to Customs inspectors to decide whether or not an importation is for a legitimate personal medical use.

From an overall perspective, the spiraling volume of goods at our borders has put immense pressure on our ability to enforce the Nation's laws and protect 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 Customs.

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

[The prepared statement of Ms. Durant follows:]

TESTIMONY OF ELIZABETH G. DURANT
EXECUTIVE DIRECTOR, TRADE PROGRAMS
U.S. CUSTOMS SERVICE
BEFORE THE
SPECIAL COMMITTEE ON AGING
UNITED STATES SENATE
HEARING ON THE IMPORTATION OF PHARMACEUTICAL PRODUCTS
JULY 9, 2002

Mr. Chairman, Members of the Committee, thank you for this opportunity to testify. I am Elizabeth Durant, Executive Director of Trade Programs at the U.S. Customs Service. Today I would like to discuss with you U.S. Customs efforts to address the ever-increasing trend of personal and bulk importation of pharmaceutical products into the United States.

As you know, the top priority of the Customs Service following the events of September 11 is to help protect the United States from terrorist attacks. This is a formidable task given the number of passengers, vehicles, and goods that pass through our nation's borders each year. Customs is responsible for processing 470 million people, 129 million cars, and nearly 20 million trucks, railcars, and sea containers that arrive into the United States every year.

In our role as America's frontline, the Customs Service also enforces over 400 requirements for more than 40 other federal agencies at U.S. borders. These include the laws that prohibit the importation of illegal or unapproved pharmaceuticals that fall under the jurisdiction of the Food and Drug Administration, or FDA.

The challenge facing Customs today on this front is enormous. Although our main focus has shifted to anti-terrorism, we are committed to fulfilling all aspects of our mission. This includes enforcing FDA requirements on imported pharmaceuticals to help ensure the safety and well being of the American public. We are concerned about three particular ways that pharmaceuticals are imported: those that are purchased over the Internet and shipped through our international mail or express courier facilities; those carried into the United States by individuals transiting our land borders; and bulk shipments of adulterated or counterfeit pharmaceuticals.

Millions of packages come through mail and express courier facilities every year. Thousands of packages, particularly in the mail, are found to contain illegal and unapproved pharmaceuticals. We also estimate that 10 million people cross the land border annually carrying the same unapproved products. A disturbing trend is the increase in bulk shipments through the mail indicating that these products could be making their way to pharmacy shelves.

The growth of the Internet has spawned a wave of pharmaceutical purchases on-line. These purchases are commonly sent through international mail. We have Customs Inspectors stationed at fourteen international mail facilities across the United States to contend with these shipments. Customs is also located in or near twenty-nine strategically located express courier facilities throughout the country.

Detecting prohibited pharmaceuticals among the tens of millions of parcels passing through Customs 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.

A key difference between the mail and express environments is the level of automation. Customs receives virtually no advance information on mail shipments, making it impossible to target shipments for closer inspection or referral to another agency. Express couriers are required to provide advance manifests, making targeting easier. We have found, however, that many express packages containing pharmaceuticals are manifested as documents.

Customs laboratories also play a critical part in our investigations. Their expertise in analyzing everything from textiles, to foreign oil, to food products to determine point of origin and composition is world-renowned. We maintain fully equipped labs at seven locations around the country and we have three mobile labs to deploy as needed.

We are confident in the forensic capability of our labs to find discrepancies in shipments of bulk and finished pharmaceuticals. But where we do require assistance, specifically from the FDA, is in the establishment of effective national standards for the interdiction of pharmaceuticals subject to FDA laws.

The development of such standards is critical to Customs. To that end, we have been working closely with the FDA to develop the needed guidelines. We began by forming a task force to examine pharmaceutical purchases shipped by U.S. mail. The task force set up a thirty-day pilot program at the Los Angeles mail facility in 2001. During the program, FDA detailed four full-time employees who observed first-hand the daunting volume of packages screened by Customs every day.

Over a period of twenty-four workdays, the FDA detained a total of 721 parcels. 677 parcels, or just over 93 percent of this amount, were denied entry and 44, or six percent, were released for delivery by the Postal Service. It is important to note that without the presence of FDA inspectors, U.S. Customs would have had to detain some 3,000 packages per week, or about 15,000 packages over an equal time span, under the existing guidelines provided to our personnel.

At that time, 102 parcels underwent detailed laboratory analysis to determine whether the pills and capsules contained the claimed active ingredient and/or contained a scheduled substance. The results of these analyses found 9 instances in which the imported pharmaceutical did not contain an active pharmaceutical ingredient, but were merely found to contain substances such as starch or sugar.

Customs also initiated a multi-faceted counterfeit pharmaceutical interdiction program called "Operation Safeguard." The first phase of Operation Safeguard was carried out between September and October of 2000 at the International Mail Branches at Dulles Airport and Oakland, California. This operation was intended to give Customs a snapshot of the types of pharmaceutical products entering the United States. That snapshot revealed that a vast percentage - - perhaps as much as eighty to ninety percent - - of the pharmaceuticals that enter the U.S. via the mail do so in a manner that violates present FDA or other requirements.

Counterfeit pharmaceuticals enter in both wholesale and retail quantities. Additional problems include expired materials, products that have not been approved by the FDA for usage, products made in facilities not under proper regulation and products not having the proper usage instructions. To offer an example, one seizure included a three thousand-tablet shipment of a counterfeit drug with an expiration date of 1980 on it.

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

During a recent phase of Operation Safeguard that took place at two International Mail Branches, 31 parcels containing 52 different types of questionable pharmaceuticals underwent intensive chemical analysis. The analyses of these products showed that 8 of the so-called pharmaceuticals or 15% contained no identifiable active ingredient and 18 contained a substance

that is regulated under the Federal Controlled Substance Act. Additionally, during this phase of the operation it was found that large parcels of questionable or illegal pharmaceuticals are being split into different mail shipments but arrive at the same address. Accordingly, there is a possibility that state side pharmaceutical distributors could be using these products as a source of supply.

In light of these results and the volume of imports, it is clear that this remains an overwhelming problem and Customs is seeking guidance from the FDA to develop a more practical and workable approach.

Travelers who attempt to import pharmaceuticals upon their return to the U.S. are also a source of concern. Customs is seeking the guidance of the FDA on this front. We are seeking direction that more sharply defines the current broad discretion given to Customs inspectors to decide whether or not an importation is for a "legitimate personal medical use."

In addition to Operation Safeguard, our Office of Investigations is continuing to work with the FDA to combat the sale of prohibited pharmaceuticals via the Internet. Customs Cybersmuggling Center is playing a leading role in these cases. Our efforts to date have included a successful investigation with authorities in Thailand that closed down seven on-line pharmacy sites operating in that country. As a result, we saw a marked decrease in subsequent pharmaceutical seizures from Thailand.

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. We have taken many steps to address anticipated challenges, including refinement of our targeting approach and development of a resource allocation model to project future staffing needs across the country. But we still face a daunting workload, which has been exacerbated by the need to secure the borders against the threat of terrorism.

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

This concludes my statement. Thank you again for this opportunity to testify on this important issue. I will be happy to answer any questions you may have.

The CHAIRMAN. Thank you, Ms. Durant.

Next, we will hear from Mr. John Theriault, who is Vice President for Corporate Security at Pfizer Corporation.

Mr. Theriault.

STATEMENT OF JOHN THERIAULT, VICE PRESIDENT, CORPORATE SECURITY, PFIZER, INC., NEW YORK, NY

Mr. THERIAULT. Thank you, Mr. Chairman, Senator Wyden. It is a pleasure for me to appear before you today to discuss the critically important issue of counterfeit medicine.

I am the Vice President of Corporate Security at Pfizer, and in that position, I am responsible for implementing policies and procedures to protect Pfizer's personnel, its products, its facilities, and its intellectual property. That responsibility is global in scope.

Prior to joining Pfizer, I was a special agent of the FBI for 25 years and served in a variety of investigative, management, and executive positions. I spent seven of those years outside of the United States serving as Legal Attaché in Ottawa, Canada, and in London, England. During the London assignment, I was also diplomatically accredited to our embassies in Ireland and all of the Scandinavian countries. I have substantial experience in international law enforcement, and when I retired from the FBI in 1995, I was a member of the Bureau's of Senior Executive Service.

Mr. Chairman, while my testimony today focuses on my own experience and that of my company, Pfizer, I want also to convey to you the very significant message that the problems of counterfeiting, copying, adulterating, and misbranding prescription drugs are faced by many companies.

A significant aspect of my job is to protect the health and safety of consumers by identifying counterfeit, diverted, adulterated, or unsafe Pfizer products in the marketplace, and to ensure that prompt and decisive action is taken to eliminate them.

Pfizer takes this responsibility very seriously and has taken some of the most innovative and aggressive steps in the industry to deal with an emerging global counterfeiting problem that could have disastrous consequences for consumers.

My testimony and the pictures that accompany it describe some of the actions that we have taken in China, Taiwan, and Thailand, using well-documented cases involving Viagra.

Right now, I want to move on to describe two cases in the United States to illustrate what I think is a much larger problem facing the entire pharmaceutical industry with respect to counterfeit medicines.

First, in September 2001, a self-employed carpet cleaner doing business as Mr. Spotless and Dr. Schwab was arrested for selling counterfeit Viagra on the basis of information that we developed and local authorities in Ohio corroborated.

During the investigation, authorities intercepted 36,000 counterfeit Viagra tablets consigned to Mr. Spotless from a fictitious toy company in China. As you can see from this photograph of the evidence that was seized, the counterfeit medicine, pill bottles, foil bottle seals, and labels were all concealed in stuffed animals. Information indicated that Mr. Spotless had a fairly extensive distribu-

tion network. An investigation is currently ongoing to determine the extent of it.

Next, on May 17, 2002, seven individuals and five companies were indicted by a New York grand jury and charged with manufacturing counterfeit Viagra and selling it over the Internet. The investigation, which we initiated, covered a 17-month period during which investigators purchased 28,000 bogus Viagra tablets from China and India. The scope of that conspiracy is demonstrated in this exhibit that shows the linkage between counterfeit wholesalers in Hong Kong and resellers in Florida, Nevada, and Colorado. The wholesalers were also linked with counterfeit product that was found in three cities in China.

Another aspect of this same case involved an individual named Girith Vishwanath of Benzo Chemical Industries in India who actually sold undercover operators a tablet-punching machine that weighed 1,500 pounds, which you can see in this photograph, and offered a constant supply of tablet blend so that his customer could manufacture his own Viagra. During the investigation, those indicted bragged that they could deliver 2.5 million counterfeit Viagra tablets to New York each month.

Mr. Chairman, it is significant to note that in both the Ohio and New York cases I have cited, ingenious criminals were able to import counterfeit medicine notwithstanding our current regulations and border controls. It is my opinion that any lessening of those regulations and controls will expose American consumers to an unacceptable level of risk.

Our experience with Viagra has been illuminating. It has lifted the curtain and allowed us to see into a world of clandestine drug manufacturing that we might not have otherwise discovered. It is a world that couldn't care less about regulatory and legal standards, good manufacturing practices, consumer health and safety, or the affordability of prescription drugs. It is a world of sophisticated and some not so sophisticated, organized criminal enterprises accountable to no one.

Other drugs are being counterfeited extensively, as some of my testimony indicates. What we have learned from Viagra, though, should be taken as a warning about what can happen and what is happening with other products.

These stories demonstrate that notwithstanding current stringent border controls and importation requirements, counterfeit medicines are a constant threat. There is no doubt in my mind that as we sit here today and discuss the issue, criminals are attempting to figure out ways to get counterfeit medicine into the United States.

This is organized crime in a real sense, and organized crime will always seek out the weakest entry point in any distribution system. Any public policy measure that eases the current border controls simply makes it easier for criminals to target and exploit American patients.

Mr. Chairman, thank you for the opportunity to testify before this important committee. I look forward to answering any questions.

[The prepared statement of Mr. Theriault follows:]

Testimony of John Theriault
Vice President, Corporate Security, Pfizer Inc.
Before the Senate Special Committee on Aging

July 9, 2002

Chairman Breaux, Ranking Member Craig, distinguished Members of the Committee, it is indeed a pleasure to appear before you today to discuss the critically important issue of counterfeit medicine.

My name is John Theriault and I am Vice President of Corporate Security at Pfizer Inc. In this position, I am responsible for implementing policies and procedures to protect Pfizer's personnel, products, facilities, and intellectual property. This responsibility is global in scope.

Prior to joining Pfizer, I was a Special Agent of the FBI for 25 years and served in a variety of investigative, management, and executive positions. I spent 7 years outside of the United States serving as Legal Attaché in Ottawa, Canada, and in London, England. During the London assignment I was also diplomatically accredited to our Embassies in Ireland and all of the Scandinavian countries. I have substantial experience in international law enforcement. When I retired from the FBI in 1995 I was a member of the Bureau's Senior Executive Service.

Pfizer is a diversified, global health care company and the world's largest pharmaceutical company with annual sales of over 30 billion dollars and approximately 90,000 employees around the world. Our core business is the discovery, development, and marketing of innovative pharmaceuticals for human and animal health, and we are committed to ensuring the integrity of those products when they reach the market.

Mr. Chairman, while my testimony today focuses on my own experience, and that of my company, Pfizer, I want also to convey to you the very significant message that the problems of counterfeiting, copying, adulterating, and misbranding prescription drugs are faced by many companies and are not the exclusive purview of Pfizer.

You will hear FDA mention today, as they have in the past, their experiences with numerous product problems, that range from out-and-out counterfeiting to dangerous re-packaging and re-labeling of outdated, subpotent, or otherwise ineffective and unsafe drug products made by many U.S. pharmaceutical companies.

Therefore, I hope as you listen to Pfizer's experiences with one of our very significant products -- and thus one that has been a popular target for criminals -- that you will extrapolate those experiences to many products manufactured by many companies other than Pfizer. This is indeed a problem that faces the entire research-based pharmaceutical industry.

I have attached to my testimony a number of commentaries on products other than the one I will discuss here today. I hope this information will be as helpful to you as will my testimony regarding my direct experiences with the Pfizer product, Viagra.

A significant aspect of my job is to protect the health and safety of consumers by identifying counterfeit, diverted, adulterated, or unsafe Pfizer products in the marketplace and ensuring that prompt and decisive action is taken to eliminate them. Pfizer takes this responsibility seriously, and has taken some of the most innovative and aggressive steps in the industry to deal with an emerging global counterfeiting problem that could have disastrous consequences for consumers. I would like to share with you some of the actions we have taken, using well-documented cases involving Viagra to illustrate what I think is a much larger problem facing the entire pharmaceutical industry.

Soon after we launched Viagra, we began receiving reports that it was available in markets where it had not yet been approved. We made purchases of the product in those markets and tested for authenticity. In most cases we found authentic product that had been diverted from approved markets. But in one instance, a man in New Delhi complained that the product was not effective. We tested it and found our first counterfeit. You can see that the packaging is similar to ours, as is the tablet.

Later that year (1999) we became aware of an organized crime investigation being conducted by the National Crime Squad in the United Kingdom. One of the targets, Ken Bloom, was charged with conspiring to import counterfeit Viagra from Caplin Point Pharmaceuticals in India. The managing Director of Caplin Point, P. C. Parthabaan, was also charged in that case. I think this case has serious implications for a number of reasons, most importantly because it shows the interest of organized crime in the counterfeit drug business and the willingness of an officer of a publicly traded Indian company to become involved in providing counterfeit product.

China

As Pfizer's efforts expanded we became increasingly aware that China was evolving into a major manufacturing source for counterfeit medicine. In response to this Pfizer established an anti-counterfeiting program that focused on three key elements: identifying the extent of the counterfeiting problem in a given country through various methods including limited market surveys; encouraging law enforcement and administrative action against those identified; and raising the issue to a political level in cases where public policy review is warranted.

In 2001 we conducted a limited market survey in seven major population centers in China. We purchased Viagra (and other products), tested for authenticity, and established a chemical fingerprint library to identify common sources of manufacture where possible. As a result of our survey, we enlisted the help of Chinese officials who conducted 122 raids, arrested 58 individuals, and seized 146,336 counterfeit Viagra tablets.

Between January and April 2002, at our urging, Chinese officials have seized almost 1 million counterfeit Viagra tablets and 86 kilograms of sildenafil citrate (the active pharmaceutical ingredient in Viagra). They have made several arrests and shut down some manufacturing operations. Much more needs to be done in tracking down the major manufacturers and shutting down the factories.

Elsewhere in Asia

Taiwan

Historically, police in Taiwan have been more aggressive in addressing product counterfeiting issues than other countries in the region. Between November 1999 and May 2001 Taiwan law enforcement officials conducted 9 raids, arrested 18 individuals, and seized 533,000 counterfeit Viagra tablets and 147,000 counterfeit Norvasc tablets. Norvasc is the world's best-selling medicine for high blood pressure. They also seized counterfeit packaging, including holograms.

Thailand

Working on the internet, we identified a Turkish national living in Thailand who was offering Viagra for sale. We made several covert purchases and then made arrangements to meet with him personally to close a major deal. Working with the Royal Thai Police Crime Suppression Division, we met with the individual, later identified as Gokhan Ozek, in March 2002. He delivered 150 bottles of counterfeit Viagra and stated that for the last 18 months he had been selling approximately 1,500 30-count bottles per week, primarily to the US and the Middle East. The Thai police, who also raided two operating factories and a warehouse, arrested Ozek. They seized 2,038,000 counterfeit Valium tablets and 80,150 counterfeit Viagra tablets, all believed to be under the control of Ozek. The following photographs reveal the conditions at one of the manufacturing sites.

We have experienced problems with counterfeit Viagra in other countries in the region and through chemical fingerprint analysis have identified most of the counterfeit product as Chinese in origin.

The facts I have cited give a view of just the tip of the counterfeit iceberg – one product in a few countries. The problem is much bigger than that, and I would like to cite cases that illustrate the potential risk to the US drug supply.

United States (Ohio)

In September 2001, Hassib R. Selbak, a self-employed carpet cleaner doing business as "Mr. Spotless" and "Dr. Shwab," was arrested for selling counterfeit Viagra on the basis of information that we developed and local authorities in Ohio corroborated. During the investigation, authorities intercepted 36,000 counterfeit Viagra tablets consigned to "Mr. Spotless" from a fictitious toy company in China. The Viagra, along with pill bottles, foil bottle seals, and labels were concealed in stuffed animals.

Information indicated that Mr. Selbak had a fairly extensive distribution network and he Food and Drug Administration's Office of Criminal Investigations is conducting follow-up investigation to determine the extent of that network.

United States (New York)

On May 17, 2002, seven individuals and five companies were indicted by a New York grand Jury and charged with manufacturing and selling counterfeit Viagra over the internet. The investigation, which we initiated, covered a 17-month period during which investigators purchased 28,000 bogus Viagra tablets from India and China.

One of those indicted and arrested, Girish Vishwanath of Benzo Chemical Industries in India, actually sold undercover operators a tablet-punching machine and offered a constant supply of tablet blend so that his customer could manufacture his own Viagra.

Another individual indicted and arrested, Winhway Lee of Tienjin, China, claimed to be the supplier of Jane Ye and Raymond Chan. The following slide shows the linkage between Ye and Chan and the other people charged in this matter.

During the investigation, those indicted bragged that they could deliver 2.5 million Viagra tablets to New York each month. It is important to note that 100% of the counterfeit Viagra seized in the US has been of Chinese origin. Illegal prescription product sales via the Internet are of great concern for a number of reasons, not the least of which is the consumers' complete lack of knowledge about the source of the products. Today, many products are imports from countries where controls are far less scrupulous than in the U.S. But if the drug product importation border between the U.S. and Canada were lifted, for example, Canada will almost certainly become the counterfeiters' warehouse of choice.

One might think that these cases involving Viagra are interesting, but should not be taken too seriously on the grounds that Viagra is "just a life style medicine." It would be foolish and dangerous to dismiss these cases for a number of reasons. The main points I hope the Special Committee would take away from my presentation today are the following:

Our experience with Viagra has been illuminating. It has lifted the curtain and allowed us to see into a world of clandestine drug manufacturing that we might not have discovered otherwise. It is a world that could not care less about regulatory and legal standards of medical quality, good manufacturing practices, consumer health and safety, or the affordability of prescription drugs. It is a world of sophisticated (and some not so sophisticated) organized criminal enterprises accountable to no one. Other drugs are being counterfeited extensively, as some of my testimony indicated. What we have learned from Viagra should be taken as a warning about what can happen and is happening with other products.

Indeed, news reports and press releases in recent weeks confirm that Pfizer's experience with Viagra is far from unique. The stories below demonstrate that counterfeiting of medicines is a growing problem in the U.S. and that dangerous counterfeit drugs can find their way onto pharmacy shelves and into medicine cabinets even under current law.

On May 4, Eli Lilly notified pharmacy professionals of several incidents of product tampering involving Zyprexa (olanzapine). The drug is indicated for the treatment of schizophrenia and acute bipolar mania. Pharmacists found that genuine 60-count Zyprexa bottles (for the 10 mg and 15 mg dosages) had been emptied and filled with white tablets marked "aspirin." The counterfeits were found in Minnesota and Wisconsin. See attached May 4 "Dear Pharmacy Professional" letter.

On May 8, Amgen notified healthcare professionals about the existence in the U.S. of a counterfeit drug product labeled as Epogen (epoetin alfa). Epogen is primarily used for the treatment of anemia associated with chronic renal failure for in patients on dialysis. The counterfeit vials were filled with a clear liquid that contained the active ingredient of Epogen, but at a diluted level. See attached May 8 "Dear Health Care Professional" letter, found at www.fda.gov/medwatch/SAFWTY/2002/epogen.html.

On May 10, GlaxoSmithKline issued a letter to pharmacy professionals announcing that it had received reports of bottles of Ziagen (abacavir sulfate) that were incorrectly labeled as Combivir (lamivudine plus zidovudine), due to third party tampering. Both drugs are approved for treatment of HIV infection. The counterfeit products were found in California, Connecticut, Florida, and Maryland. The company reported it believes two patients took improper medication. According to an FDA press release, the risk to patients is primarily due to the fact that approximately 5 percent of individuals who receive abacavir sulfate develop a potentially life-threatening hypersensitivity reaction. See attached FDA press release, at www.fda.gov/medwatch/SAFETY/2002/ combivir.htm, and Wall Street Journal article dated 5/14/02.

On May 16, 2002, Serono issued a press release announcing that it had become aware of a counterfeit lot of Serostim (somatropin (rDNA origin) for injection. Serostim is indicated for treatment of wasting due to AIDS. Preliminary information indicated that the counterfeits had been distributed via the Internet. See attached FDA press release, www.fda.gov/oc/po/firmrecalls/serono05_02.html.

On June 6, Johnson & Johnson issued a letter to healthcare professionals about counterfeit drugs labeled as Procrit (epoetin alfa). The counterfeit vials, which were found in Texas, contained only one-twentieth of the drug's active ingredient. The drug is used to treat anemia associated with chemotherapy, chronic renal failure (pre-dialysis), zidovudine treatment in HIV patients, and patients undergoing elective, noncardiac, nonvascular surgery. See attached letter from FDA website, available in PDF form at www.fda.gov/medwatch/SAFETY/2002/safety02.htm.

These are only the counterfeiting incidents during the last nine weeks. Many other equally dangerous incidents have occurred over the past few years, and they are increasing in frequency. The problem is widespread and poses a serious risk to public health in the U.S. Every pharmaceutical company has a corporate security officer and security personnel focused on the detection, investigation, and prosecution of counterfeiting.

These stories demonstrate that notwithstanding current, stringent border controls and importation requirements, counterfeit medicines are a constant threat. There is no doubt in my mind, that as we sit here today and discuss this issue, criminals are attempting to figure out ways to get counterfeit medicine into the United States. This is organized crime and organized crime will always seek out the weakest entry point. Any public policy measure that eases the current border controls simply makes it easier for the criminals to target American patients.

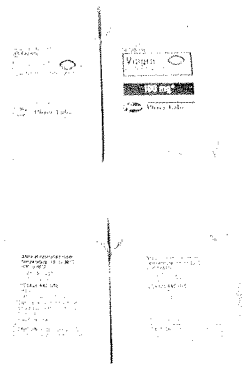
Mr. Chairman, thank you for the opportunity to testify before this important committee. I look forward to answering questions from you and your distinguished colleagues.

India
(1999)

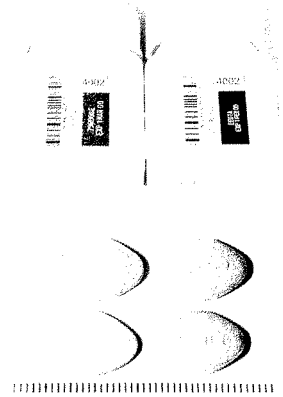
New Delhi Counterfeits

- Fair likeness to genuine Viagra tablets
- No active ingredient
- Fair quality packaging in US trade dress

Counterfeit Genuine



Counterfeit Genuine



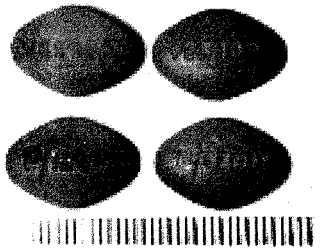
India
(1999)

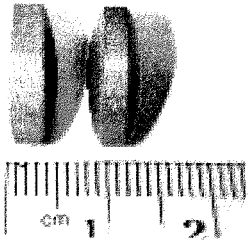
Caplin Point Pharmaceuticals

Good likeness to genuine Viagra

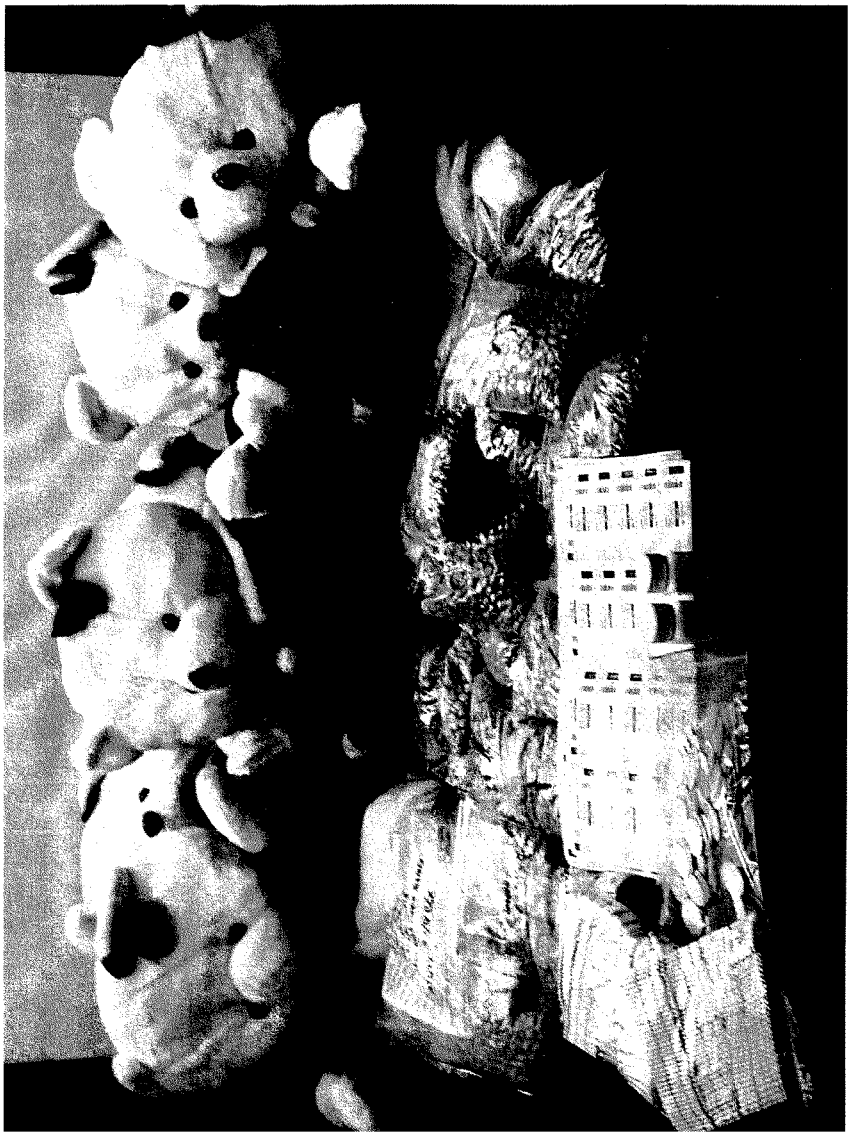
Active ingredient

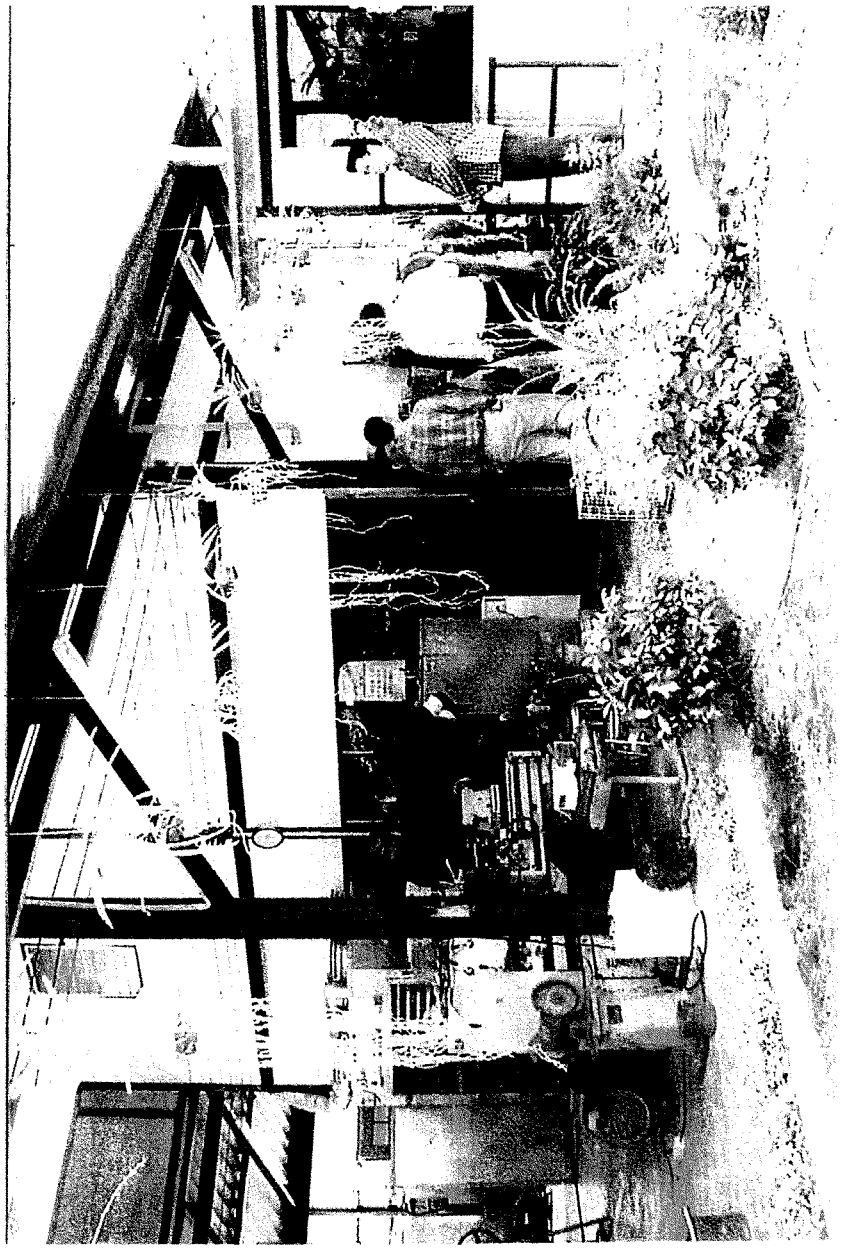
No packaging obtained

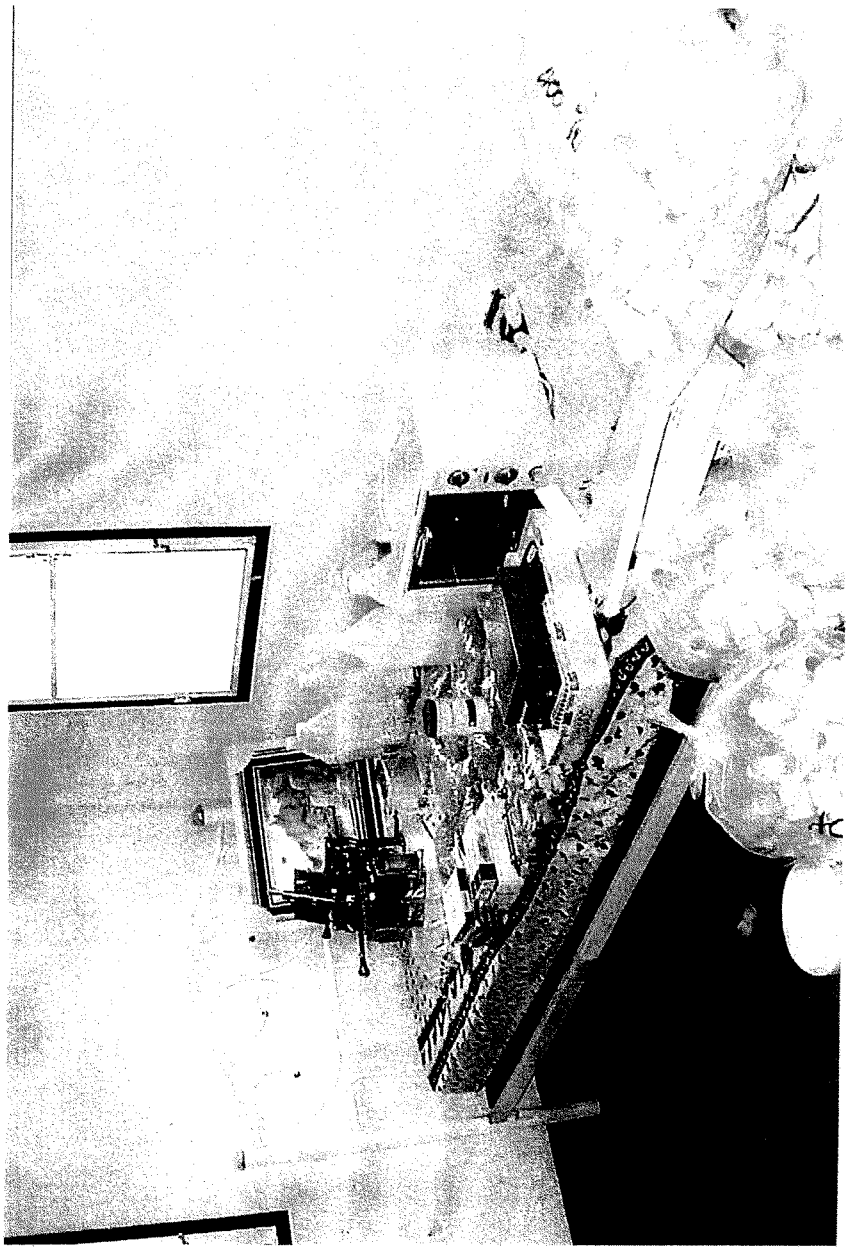


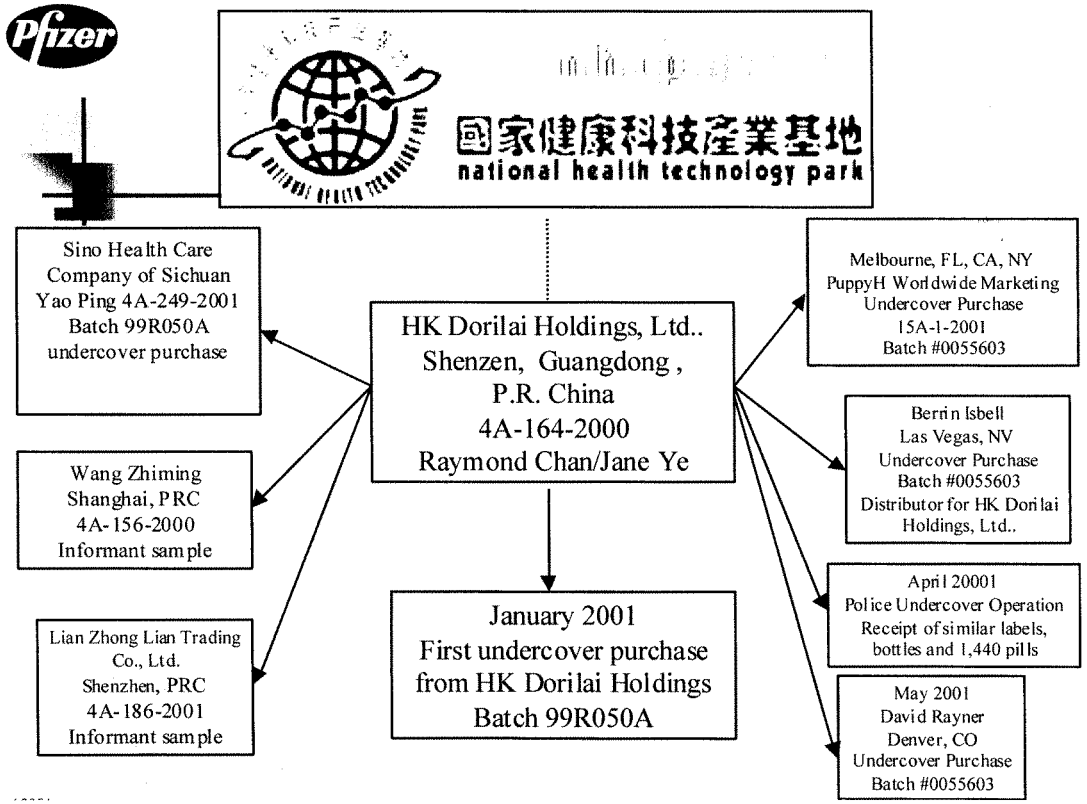


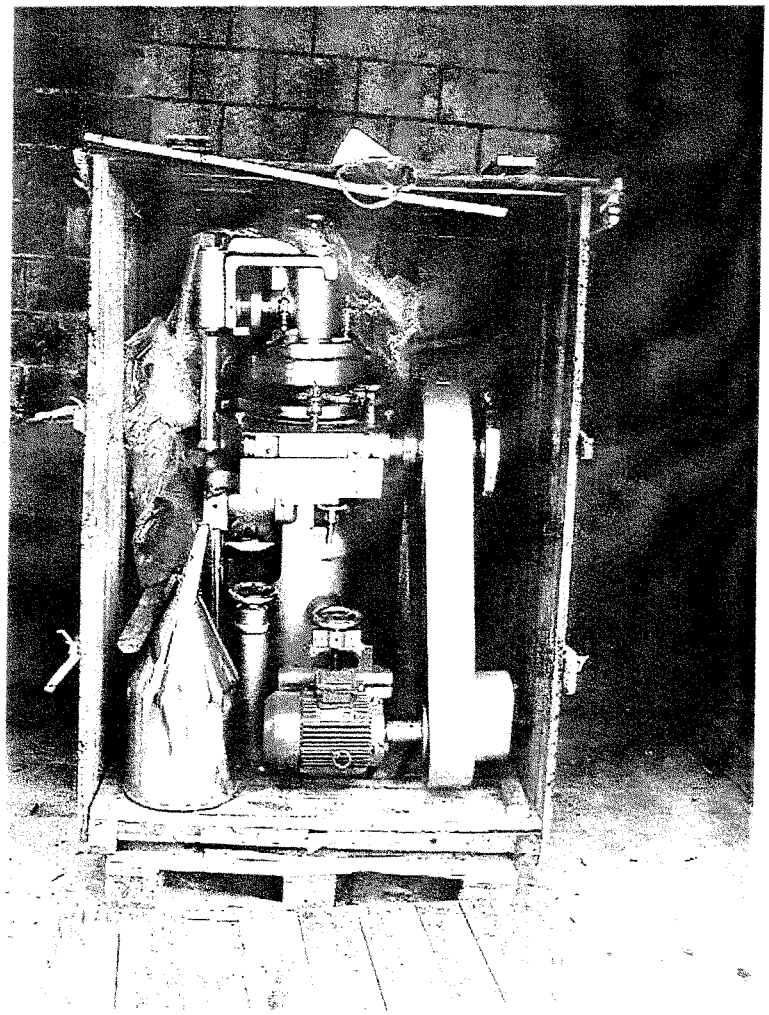
Managing Director indicted in U.K. Organized crime investigation








Pfizer
國家健康科技產業基地
national health technology park
Sino Health Care Company of Sichuan Yao Ping 4A-249-2001 Batch 99R050A undercover purchase
Wang Zhiming Shanghai, PRC 4A-156-2000 Informant sample
Lian Zhong Lian Trading Co., Ltd. Shenzhen, PRC 4A-186-2001 Informant sample
HK Dorilai Holdings, Ltd.. Shenzen, Guangdong , P.R. China 4A-164-2000 Raymond Chan/Jane Ye
January 2001 First undercover purchase from HK Dorilai Holdings Batch 99R050A
Melbourne, FL, CA, NY PuppyH Worldwide Marketing Undercover Purchase 15A-1-2001 Batch #0055603
Berrin Isbell Las Vegas, NV Undercover Purchase Batch #0055603 Distributor for HK Dorilai Holdings, Ltd..
April 20001 Police Undercover Operation Receipt of similar labels, bottles and 1,440 pills
May 2001 David Rayner Denver, CO Undercover Purchase Batch #0055603



Lilly
Answers That Matter.

NOTIFICATION OF PRODUCT TAMPERING

May 4, 2002

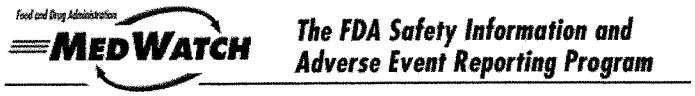
Dear Pharmacy Professional,

We would like to bring to your attention a situation involving tampering with Zyprexa® (olanzapine), indicated for the treatment of schizophrenia and acute bipolar mania. Lilly has been made aware of a small number of tampering incidents in which pharmacists in the United States have found Zyprexa 10 and 15 mg bottles which have had all of the Zyprexa tablets removed and replaced with white tablets marked, "aspirin." The reports, thus far, have been confined to 60 count 10 mg and 15 mg bottles of Zyprexa. We have been in contact with the United States Food and Drug Administration and are continuing to gather additional information through a diligent investigation of this situation.

From what we know at this time, these incidents appear to be isolated and limited in scope and no injuries or adverse effects related to the tampering have been reported to date.

Zyprexa 10 mg tablets are round and white, similar to aspirin; however, they are clearly marked in blue with the word, "Lilly" and the number, "4117" on one side, and no markings on the other side. Zyprexa 15 mg tablets are oval-shaped and blue and are embossed with the word, "Lilly" and the number, "4415." If you discover a bottle of Zyprexa that contains white tablets marked "aspirin," or any markings other than "Lilly" and the four-digit Lilly identification number, please notify NNC Group at 1-800-668-4391.

At Lilly, patient safety is our first priority. We appreciate your assistance in helping us to resolve this matter as quickly as possible. Lilly and the United States Food and Drug Administration are investigating this matter. Lilly is taking all possible steps to protect the quality and integrity of its products. If you have any additional questions, please contact us at 1-800- LILLY-RX.



2002 Safety Alert - Epogen (Epoetin alfa)

This is the retyped text of a letter from Amgen. Contact the company for a copy of any referenced enclosures.

IMPORTANT DRUG WARNING
COUNTERFEITING OF EPOGEN

May 8, 2002

Dear Health Care Professional:

Amgen Inc. recently became aware of the existence in the U.S. of a counterfeit drug product labeled as EPOGEN (Epoetin alfa) 40,000 U/ml vials in ten-pack boxes, lot number P002970 and expiration 7/03. In cooperation with the U.S. Food and Drug Administration (FDA), Amgen is informing patients, physicians, pharmacies, and wholesalers about this potentially serious health risk. EPOGEN is primarily used for the treatment of anemia associated with chronic renal failure for patients on dialysis.

The counterfeit vials examined by Amgen to date contain a clear liquid that contains active ingredient. However, the concentration of active ingredient is approximately 20 times lower than expected for EPOGEN 40,000 U/ml vials.

Pharmacists and all other health care professionals should carefully examine the EPOGEN before use. The following information may help in determining if the product you have is counterfeit.

In order to view pictures illustrating these differences, please log onto Amgen's web site at www.amgen.com/corporate/AmgenNews.html.

Features of authentic EPOGEN	Features of counterfeit product
Amgen logo on carton closure label on exterior of box will shift colors from blue to purple when viewed at different heights Photo	Amgen logo on carton closure label on exterior of the box lacks color shifting properties (remains blue when viewed at different heights)

Degree sign present for storage temperature on vial label. Photo "Store at 2° to 8° C"	Degree sign missing from storage temperature on vial label. "Store at 2 to 8 C"

If you receive any product that you suspect is counterfeit, quarantine it and store it under labeled conditions. Please promptly contact FDA for further instructions at 1-800-835-4709.

If you have questions about EPOGEN, please contact Amgen Medical Information at 1-800-772-6436. Please convey this information to your staff and any others who administer EPOGEN. You should instruct them on what to look for and what to do in the event they find a suspect counterfeit vial.

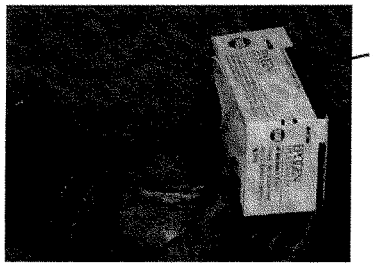
Amgen does not recommend the purchase of Amgen products from wholesalers that do not currently purchase EPOGEN directly from Amgen. A list of wholesalers that currently purchase EPOGEN directly from Amgen can be found on its website at www.amgen.com/product/productCenter.html. The parties on this list are the only wholesalers whom Amgen currently sells to for distribution of its products. If you have purchased Amgen product from another source, you should verify the origin of that product by contacting the distributor.

Amgen is cooperating fully with the FDA to investigate this matter and prevent the further distribution of counterfeit product. To Amgen's knowledge, the counterfeit product has only been found in distribution in the U.S.

Full product information and any updates on this situation are available on the web at www.amgen.com.

William Sheridan, MB, BS, FRACP
Vice President, Medical Affairs
Amgen Inc.

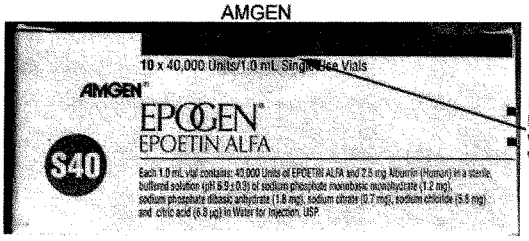
Other Contact Information:
U.S. Food and Drug Administration (for press inquiries: 301-827-6242



Carton closure label

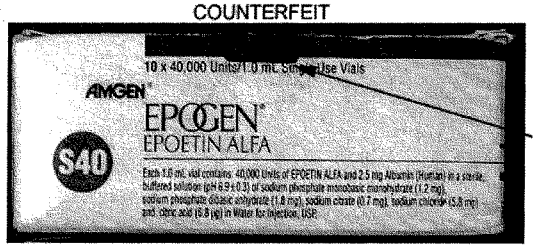
Hold box with carton closure label facing upward. View the color shift on the carton closure label in a well lit environment with the light source in front of you.

AMGEN



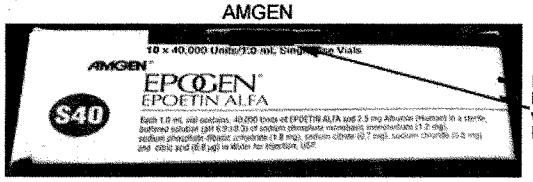
Blue Amgen logo is seen when held at waist height.

COUNTERFEIT



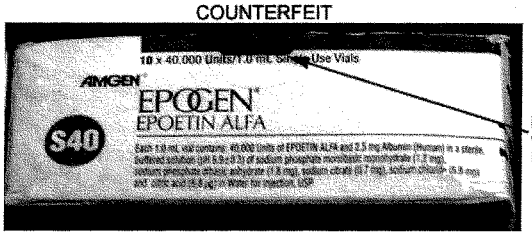
Blue Amgen logo is seen when held at waist height.

AMGEN



Purple Amgen logo seen when held just below eye level.

COUNTERFEIT



Blue Amgen logo remains when held just below eye level.

Location of storage temperature

AMGEN

Degree sign present

COUNTERFEIT

Degree sign not present

May 14, 2002

Dear Pharmacy Professional,

We would like to call to your attention a situation involving counterfeit labeling of Combivir® (lamivudine plus zidovudine) Tablets. GlaxoSmithKline has received four reports of bottles labeled as Combivir Tablets that actually contained another medicine, Ziagen® (abacavir sulfate) Tablets. The company has determined that counterfeit labels for Combivir were placed on two bottles of Ziagen and labels on another two bottles are suspect. Both medicines are used as part of combination regimens to treat HIV infection.

These incidents appear to be isolated and limited in scope. No injuries or adverse reactions have been reported. Company tests have shown no problems with the medicine itself. GlaxoSmithKline is working with the U.S. Food and Drug Administration to investigate.

Involved in the counterfeit labeling cases were 60-count bottles of Combivir® Tablets, which contain 150-milligrams of lamivudine and 300 milligrams of zidovudine, and 60-count bottles of 300-milligram tablets of Ziagen.

Pharmacists, physicians, and patients should immediately examine the contents of each Combivir bottle to confirm it does not contain Ziagen tablets. The two kinds of tablets are easily distinguishable. Combivir is a white capsule-shaped tablet engraved with "GX FC3" on one side; the other side of the tablet is plain. Ziagen is a yellow capsule-shaped tablet engraved with "GX 623" on one face; the other side is plain. The Combivir label shows a color photo of the tablet.

If you discover a bottle of Combivir that contains Ziagen, please notify **GSK** at **888-825-5249** (toll free). We are urging patients who have questions about the medicine in their Combivir bottle to return it to you or they may also call GSK at 888-825-5249. Full product information is available on the GlaxoSmithKline website, **www.gsk.com**.

The risk to patients is primarily due to the fact that approximately 5% of individuals who receive abacavir sulfate in Ziagen® or Trizivir® (abacavir sulfate, lamivudine and zidovudine) Tablets have developed a potentially life-threatening hypersensitivity reaction. Symptoms generally resolve after discontinuing the medication, however, patients who have had a hypersensitivity reaction to Ziagen® are advised to never take the medication again. Patients taking Combivir® would not have been advised about the hypersensitivity reaction and how to take Ziagen® safely because Combivir® does not contain abacavir sulfate. Patients who have had a hypersensitivity reaction to abacavir yet take Ziagen® or Trizivir® again experience more severe symptoms within hours that may include life-threatening hypotension (lowering of the blood pressure) and death. In addition, the replacement of Combivir® which contains two antiviral drugs with Ziagen®, a single antiviral, may decrease the effectiveness of a patient's treatment regimen.

At GlaxoSmithKline, patient safety is our first priority. We appreciate your help as we try to resolve this matter as quickly as possible. GSK is taking all possible steps to protect the quality and integrity of our products. If you have any additional questions, please contact us at 1-888-825-5249.

? $ Article Dow Jones Publications Library

THE WALL STREET JOURNAL.

Article 1 of 6
Health

GlaxoSmithKline
Warns About Switch
In Drugs for AIDS

05/13/2002
The Wall Street Journal
Page B4
(Copyright (c) 2002, Dow Jones & Company, Inc.)

WASHINGTON (AP) -- Patients given prescriptions for the AIDS drug Combivir should immediately make sure they got the right pills, the manufacturer says, after people in four states bought Combivir bottles that actually contained another AIDS drug called **Ziagen** .

The tampering could be dangerous, manufacturer GlaxoSmithKline PLC of London warned Friday. About 5% of people who take **Ziagen** can suffer potentially life-threatening allergic reactions. Combivir doesn't carry the same risk, the company said. Another problem: Combivir provides HIV patients with two antiviral medications in one pill, while **Ziagen** is one completely different antiviral drug. An unintentional switch could lower the effectiveness of a patient's therapy.

Glaxo makes both drugs, shipping them in presealed bottles. The company said its own investigation had ruled out a manufacturing glitch and that the **Ziagen** in the mislabeled bottles is real and not tainted -- meaning someone sold **Ziagen** with a counterfeit Combivir label. A 60-tablet bottle of Combivir costs about $200 more than the same amount of **Ziagen** .

The Food and Drug Administration's criminal-investigations unit is probing the problem. No illnesses have been reported.

So far, four bottles -- in Connecticut, Maryland, Florida and California -- have been discovered, Glaxo said.

Combivir is a white capsule-shaped tablet engraved with "GX FC3" on one side. **Ziagen** is a yellow capsule-shaped tablet engraved with

"GX 623" on one side.

Patients should check that their Combivir bottles contain the right drug, and pharmacists should open new bottles in front of the customer so both can see if it's really Combivir, Glaxo said.

Return to Headlines

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FDA posts press releases and other notices of recalls from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

Serono Issues Notification of Counterfeit Serostim®

NEWS RELEASE

Contact: Carolyn Castel
781-681-2340

For Immediate Release

Serono Issues Notification of Counterfeit Serostim®

Rockland, MA - May 16, 2002 -- Serono, Inc. has recently become aware of a counterfeit lot of Serono's Serostim® [somatropin (rDNA origin) for injection]. The counterfeit material has been packaged to appear as drug product lot number S810-1A1. This is not a legitimate Serostim® lot number. Serono has notified the appropriate regulatory and law enforcement authorities of this matter.

Preliminary information appears to indicate that the counterfeit material may have been distributed via the Internet. However, Serono is also alerting pharmacists to the counterfeit material and recommending that they examine Serostim® prior to dispensing to ensure that the package does not bear lot number S810-1A1.

The counterfeit material was neither manufactured nor distributed by Serono. Therefore, it cannot be assumed that the counterfeit material is either safe or effective.

Serono continues to cooperate with regulatory and law enforcement authorities to identify and prosecute individuals involved in drug counterfeiting.

Serostim® is approved in the U.S. for the treatment of AIDS wasting. Patients seeking information regarding Serostim® may call Serono at 1-888-275-7376.

###

Past MedWatch Alerts

IMPORTANT DRUG WARNING
COUNTERFEITING OF PROCRIT®

June 6, 2002

Dear Healthcare Professional:

Ortho Biotech Products, L.P. (OBPLP) recently became aware of the existence of counterfeit drug product labeled as PROCRIT®(epoetin alfa)* 40,000 U/mL vials in four-pack boxes, **lot number P002641** and expiration **September 2003**. OBPLP is informing physicians, pharmacies, and wholesalers/distributors about this potentially serious health risk. PROCRIT is used primarily for the treatment of anemia associated with chemotherapy, chronic renal failure (pre-dialysis), zidovudine treatment in HIV patients, and patients undergoing elective, noncardiac, nonvascular surgery.

> **Based upon the evidence we have reviewed to date, we have determined that these vials are indeed counterfeit. Analysis shows that they contain a clear liquid with active ingredient. The examined vials appear to be intact. However, the concentration of active ingredient is approximately 20 times lower than expected for PROCRIT 40,000 U/mL vials. Based upon evidence available to date, it appears that counterfeiters may be acquiring PROCRIT 2,000 U/mL vials and relabeling the product with counterfeit 40,000 U/mL labels. Because of the lower than labeled strength of the counterfeit vials, it is possible that patients could be under-dosed. In addition, other potential health risks cannot be ruled out at this time.**

Authentic PROCRIT, lot number P002641, expiration September 2003 was last shipped from the OBPLP Distribution Center on February 20, 2002. Based on historical usage patterns and inventory practices, it is likely that virtually all authentic PROCRIT with lot number P002641, already has been used. Thus, any product bearing this lot number in particular, should be considered suspect and be closely examined.

Physicians, pharmacists, nurses and all other healthcare professionals should carefully examine all PROCRIT vials before use. The following information may help in determining if the product you have is counterfeit.

This counterfeit product deviates from authentic PROCRIT in that the counterfeit product may:

- Have a visible "strike-through" on number 6 in the lot number on the vial.
- Have text alignment on the bottom of the folding carton (box) that is shifted to the extreme right side of the panel.
- Have a varnished (shine/gloss) fluted tray, which holds the vials in place. The authentic product has an unvarnished fluted tray that has no shine/gloss.

In order to view pictures illustrating these differences, please log onto www.procrit.com or www.orthobiotech.com.

Features of Authentic PROCRIT	Features of this Counterfeit Product
VIAL: No "strike-through" on number **"6"** as it appears in the lot number. Photo #1	**VIAL:** "Strike through" on number **"6"** as it appears in the lot number. Photo #2
FOLDING CARTON (BOX): Text alignment on bottom of folding carton appears with a right hand margin between end of text and edge of carton. Photo #3	**FOLDING CARTON (BOX):** Text alignment on bottom of folding carton may be shifted to extreme right side of panel without a right hand margin. Photo #3

Please convey this information to your staff and any others who administer PROCRIT so that they will be able to identify the characteristics of a suspect counterfeit vial.

If you receive any product that you suspect is counterfeit, do not use the product. Please quarantine and store the product under labeled conditions. Promptly contact the FDA at 1 (800) 835-4709, prompt #5 for further instructions. If you suspect that you may be in possession of counterfeit PROCRIT, you should immediately contact your wholesaler/supplier regarding refund for the product.

If you have medical questions regarding suspected counterfeit PROCRIT, please contact Ortho Biotech Medical Information at 1 (800) 325-7504, prompt #2.

OBPLP is cooperating fully with the FDA to investigate this matter and prevent the further distribution of counterfeit product. As of June 6, 2002, OBPLP is aware of the distribution of counterfeit product in the U.S. only.

Full product information and updates on this situation will be available at www.procrit.com or www.orthobiotech.com. For those who do not have Internet access, please contact Ortho Biotech Medical Information at 1 800 325-7504, prompt #2

Martine George, M.D.
Vice President
Clinical Affairs - North America, Ortho Biotech Products, L.P.

Other Contact Information: U.S. Food and Drug Administration (for press inquiries): (301) 827-6242

*PROCRIT is the brand name of epoetin alfa manufactured by Amgen Inc., and marketed by Ortho Biotech Products, L.P.

The CHAIRMAN. Well, thank you, Mr. Theriault, and let me thank all of our witnesses for what I think is very, very valuable and very important information for all of us and to Congress to have before us as we consider what to do with prescription drugs and how do we go about handling this.

Mr. Theriault, your statement is a very strong indication of what is happening out there in the real world. You know, taking counterfeit Viagra might embarrass you, but it is not going to kill you.

Mr. Roberts, your situation and taking counterfeit drugs instead of the real product could have killed you, and for most pharmaceutical products, if you are taking a counterfeit product or a product that has ingredients in it that you may be allergic to or cause additional health problems could, in fact, kill you.

Where were you getting the medicine? I mean, were you going down to your local drug store and getting this? Are you getting it over the Internet or mail order, or how?

Mr. ROBERTS. I receive quite a few prescriptions. I average about 14 to 15 prescriptions a month, and I was going to CVS Pro Care Pharmacy in the Castro District of San Francisco.

The CHAIRMAN. So you were going to a regular drug store, a retail drug store, and giving your prescription to be filled, and what you were getting was not the real thing.

Mr. ROBERTS. Right. The Pro Care Pharmacy is a system for people taking multiple medications and really need special attention. So these are pharmacists who I do think spend a lot of time looking at these particular drugs.

The CHAIRMAN. Do you know what happened to that drug store? Are they still in business?

Mr. ROBERTS. Oh, yes. They are very much in business. It is a large pharmacy. There are two main pharmacies, if you are getting HIV drugs, that we tend to go to in that area or part of town, and that is one of them.

I went back and asked them, about the counterfeit and they said they had received a letter to recall anything they had on the shelf. They had sent back the counterfeit that they had on the shelf, identified by one lot number, although I do know that there were at least two lot numbers of counterfeit.

The CHAIRMAN. Well, your testimony is very helpful. A lot of this, my interest, is sort of from a legal standpoint. Was the drug store getting it, do you know, from importing it from another country, or where were they getting the supplies that were not real?

Mr. ROBERTS. That is a really good question. I don't know, and no one seems to be able to tell me.

The CHAIRMAN. Either Mr. Hubbard or Mr. Theriault, they may not know this particular thing, but if a person is going to the drug store and he is getting fake, counterfeit medicine from a retail outlet, where is it likely to be coming from? I mean, is that druggist likely to be making up a batch of counterfeit stuff in the back room, or is he buying it, in most cases, innocently from a supplier, or is he trying to do it on the cheap by importing it? Is there a pattern here?

Mr. HUBBARD. I would say this. There is not in the sense that we see all permutations.

This product was brought in, in bulk from a foreign source, and then made in a back room of a pharmacy on Long Island. However, there are other cases, I think the Viagra cases or others, in which the pills are actually made in the foreign country and arrive here either ready to go or unpackaged, but ready to be put in a bottle with a label put on it. So we are seeing——

The CHAIRMAN. OK. Who is a likely contact or person that would be importing the fake stuff? I mean, is there someone or a group in the United States that knows that there is a contact in China or some other foreign country that can get all of this fake stuff and then they actually just buy it and import it?

Mr. HUBBARD. I think, again, our experience has been centered that it varies. In some cases, a pharmacy may be the so-called bad guy and he is going out and then seeking out this stuff, or in other cases, it may be a wholesaler and a pharmacist is an innocent victim, as is the patient.

So I would not want to say there is any strong pattern in any of these cases because we see every possible permutation.

The CHAIRMAN. Let me ask, I guess, Mr. Hubbard with regard to the current state.

Congress in 1987 passed a Prescription Drug Marketing Act, and that makes it illegal for anyone other than the original manufacturer to import a drug back into the United States. It is illegal to import unapproved drugs, but FDA has a policy, apparently, and I would like you to talk about that, that allows people to either go to a foreign country and bring back a 90-day supply of prescription drugs for their personal use.

Now, does the Act allow that, or is that just something that someone created to say, "Look, the Act says it is illegal to do this, but we are going to have a policy that allows you to do it"?

Mr. HUBBARD. The 90-day issue, Mr. Chairman, goes back many years. Imagine that Congress enacted what we think of as prescription drugs in the 1950's, Senator Humphrey, and at that point, any drug anyone got in a foreign country brought back was technically illegal, but think about a couple vacationing in France and one of them gets sick and goes to the local doctor and gets an antibiotic and he is told to finish the 10-day supply. He arrives back in New York with 5 days left, and he would say "I've got this drug," and, technically, FDA should take it away or say you can't bring it in, but, of course, the right medical decision is to let the person finish the medication. For 40 or 50 years, that was really no problem. That is all we ever saw.

Then, when the AIDS——

The CHAIRMAN. The situation is different today, isn't it?

Mr. HUBBARD. It is very different, Mr. Chairman. It really started to happen when the AIDS epidemic happened in the 1980's in which there were no approved FDA-approved drugs. So people would go to other countries to seek drugs, and the FDA at that time attempted to carve out an exception to allow patients to bring in a 90-day supply of a drug that is unapproved for which there is no therapy in this country.

Now, again, I emphasize no therapy in this country. So, if you had a treatment for a given disease already available here, you couldn't bring it in, but if you had a disease like a cancer or AIDS

that had no treatment, FDA would use its discretion to allow that in. It is not in the law. It is just enforcement discretion on the agency's part, and that compassionate exception has been misinterpreted by many of the sellers of these drugs and say, "Well, FDA will let you bring in 90-days worth. So feel free to go do that." That is really not true.

The bigger problem we have is so much of this is coming in, we have so few people at the borders, that neither we nor Customs can deal with them effectively, and so what tends to happen is it all just comes in.

The CHAIRMAN. What would your concerns be to what we have seen so much in the press where seniors who are desperate to get drugs at an affordable price take these bus trips to Canada or to Mexico and buy drugs on the street or in stores in these countries and then bring them in? What would your concerns be, or advice, to these type of bus trips?

Mr. HUBBARD. What we tell people when they ask, and sometimes at the border when they declare, is "You are taking great risk here." We do not, however, board those busses and attempt to take drugs away from patients.

The CHAIRMAN. Why is it a great risk?

Mr. HUBBARD. Because we believe that they are much more likely to get a drug in a foreign country that is unapproved, unsafe, ineffective, contaminated, subpotent, superpotent, or some other way not the real drug.

The CHAIRMAN. Thank you, Mr. Hubbard.

Ms. Durant, I take it that if I am a senior citizen in this country and I want to get drugs from overseas, I mean, there is a number of ways. I can take the bus trip to Mexico. I can do a mail order, I take it, from one of these advertisements that Mr. Hubbard had, I guess, coming from Canada and just send them a check or a credit card and they will mail me the drugs.

I guess the third way, obviously, would be through an Internet transaction where I can just order it over the Internet.

Would you discuss maybe the problems associated with monitoring each one of those? I mean, is one more prevalent now than the others? Where is the biggest concern of the volumes coming in of drugs that FDA has not approved coming in from overseas? Is it Internet? Is it mail order? Is it bus trip-type operations?

Ms. DURANT. It is all of the above. Those are the three biggest as opposed to other modes of transportation, sea cargo or air shipments, through normal air cargo.

If I had to venture the most overwhelming vehicle for Customs and FDA, it would be the international mail, although it is all pretty daunting because there is just so much of it. There is a lot of smuggling. There is a lot of misdescription. So, regardless of how much advanced information we had, if it is smuggled, it would be difficult to find, just because of the numbers.

But in the mail, which would result often from an Internet or mail order transaction, we have so many millions of parcels. It is so easy to smuggle small dosages, and we have the least amount of targeting and automated targeting ability in the mail. We don't have advanced manifest information from the carriers, and it is just overwhelming.

The CHAIRMAN. I appreciate your fact that it is overwhelming. I mean, that is an important, important statement, and I agree with it.

I would imagine that once that counterfeit product reaches the drug store shelf or the supermarket that sells over-the-counter drugs that it is almost impossible for Customs or for FDA to really determine that that product is a fake, a counterfeit, unless someone gets sick, like Mr. Roberts, or doesn't get better. I mean, because once it is on the shelf, Customs doesn't run around drug stores in America doing random testing on the products they sell. I mean, you probably can't do that.

Ms. DURANT. We actually don't have that authority after it is released.

The CHAIRMAN. So, if you got a bad-actor drug store down there on the corner in San Francisco or New Orleans or anywhere else, once that person unscrupulously decides to order those products from overseas and it hits the shelf and he starts selling it, unless someone really gets sick, like Mr. Roberts did, it is going to get into commerce.

Ms. DURANT. We have to get it at the border, that is true, when it comes in, or it is in the commerce, and I guess with the FDA, it is the same situation, except that if you have an investigation or some evidence where we would open an investigation so that we could——

The CHAIRMAN. Thank you, Ms. Durant.

We have to get to Mr. Wyden and let him have whatever time he needs.

But we had debate on the floor of the Senate about the importation of drugs, and both the previous Secretary of HHS, Secretary Shalala, and this Secretary Thompson of HHS—members have said, "Look, we only want to let drugs come in that FDA can approve or guarantee are safe like we guarantee drugs in this country."

But as I understand it, both Secretary Shalala and this Secretary Thompson have said that, look, FDA can't do that because we can't go into the factories and the plants in foreign countries and watch how they manufacture it, what their standards are, what the ingredients are, and follow that from the time it is put into that capsule through the whole process of reaching this country. Is that the reason why you say we cannot certify that those drugs coming in from foreign countries are not what they are supposed to be?

Mr. HUBBARD. That is correct, Mr. Chairman. Because we could not go certify and look in the other countries, the bill that they refuse to implement or decline to implement would have replaced the normal quality control system with a testing process and with a paper or so-called pedigree process that attempted to follow the trail of the drugs, but both Secretaries found that the paper process could be forwarded by faking documents and that you really couldn't adequately test these products, either economically or feasibly.

The CHAIRMAN. Well, some of our colleagues say Canada is our friends, our neighbors, our colleagues and close associates, and we have the highest amount of trade with Canada. Is that the same concern with a country like Canada?

Mr. HUBBARD. Well, yes and no. I mean, if I were in Canada today and got sick and got a prescription and went to a Canadian pharmacy, I would feel fairly comfortable that I was getting the real drug, but if you legitimized that and say to Americans, "Go to Canada," then the counterfeiters know that and they will say that is where the money is.

We talked to the Canadians just yesterday. I talked to a dozen Health Canada officials, and I said if this would have happened, would you take responsibility for the safety of these drugs coming to America, and they said absolutely not. Why would they? They are not going to their citizens.

In fact, our own law has a provision called "import for export"; that if a drug comes here from another country that is unapproved, just to put it in the tablet or the bottle or otherwise finish it and then send it to another country, FDA doesn't look at that because it is not going to American citizens. So the same thing would apply in Canada.

The CHAIRMAN. Ms. Durant, do you agree with that?

Ms. DURANT. Yes, I do.

The CHAIRMAN. Mr. Theriault, my last question is you talked about the massive counterfeiting of Viagra, but, I mean, it is also not just Viagra. It is also drugs that are very important to a person as a cure of major illnesses and major diseases and also attempting to be counterfeit as well. Can you give us some examples of other type of products that the pharmaceutical industry has experienced in the area of trying to be counterfeited?

Mr. THERIAULT. Yes, sir. In fact, the Viagra example, I think, is a good one because it has really opened up some doors to let us see what is going on in an illegal industry that we didn't have insight into before, and by that, I mean we have been able to find Viagra in alternate distribution channels. By that, I mean we have found it in black markets, and we have been able to test it easily to determine whether it was authentic or counterfeit. When we found it in those black-market areas, we have also found other products packaged and ready for distribution in the U.S. system.

We had a case a couple of months ago in Thailand that originated with the purchase of Viagra over the Internet. We worked with the Thai police officials, and they ultimately seized 80,000 counterfeit Viagra tablets at a factory in Thailand, but they also seized over 2 million Valium tablets.

The police in Taiwan have been very aggressive in raiding illegal drug-manufacturing sites, and they found counterfeit drugs from a number of companies, ours and Glaxo and Bristol-Myers, a number of companies.

To your point a moment ago about the product getting into the country and then being indistinguishable to the consumer or anybody else, one of these bottles is counterfeit Viagra, the other is authentic Viagra, that was involved in the case I mentioned involving Hong Kong. You can't tell the difference between them. No one can tell the difference.

We found counterfeit product in Russia recently that our laboratory in Groton had to test three times before they could distinguish it from authentic product. That is how good these people are.

The point about Viagra is—and to Mr. Roberts' situation—we see Viagra because it is kind of out there in the open, but it is an indicator of how much activity is going on in this pharmaceutical counterfeiting world, and it is all a matter of money. They will counterfeit Viagra because there is money involved. They will counterfeit the anti-AIDS drugs because there is big money involved. They will counterfeit anything.

The CHAIRMAN. Thank you. I thank all the members of the panel.

Senator WYDEN.

Senator WYDEN. Thank you, Mr. Chairman.

Mr. Hubbard, what are the penalties for counterfeiting now?

Mr. HUBBARD. We don't actually bring a counterfeiting charge when we and the FBI arrest people because there is usually a better and more effective fraud charge, but we and the Justice Department bring a series of charges against these individuals, mail fraud, economic fraud, adulteration, and other charges, usually a long list of things because we want to make sure we get the goods on them properly.

Senator WYDEN. Are these people back on the streets selling again fairly shortly?

Mr. HUBBARD. One of the most recent arrests and convictions, I think, put the lady involved in jail for 6½ years and a gentleman for 25. So they won't be back very quickly, but it is very resource-intensive, of course, to do these cases, and I certainly can't say that we catch every case. If, in fact, the counterfeiting is increasing, that could be a problem.

Senator WYDEN. Mr. Hubbard, any way for a person to know the website that they are ordering from today is a reputable one?

Mr. HUBBARD. No, there is not. There is one program——

Senator WYDEN. Would you say that that is a serious problem? To me, you have got two problems with the web. First, there is clearly some ripoff sites out there, and second, you have got this problem with respect to documenting the chain of custody that I touched on. Aren't both of those very serious concerns with respect to websites?

Mr. HUBBARD. I think that is right, Mr. Wyden.

I mean, a savvy patient might be able to track back to a website to determine its legitimacy, but most consumers would not know how to do that.

Senator WYDEN. Well, that's the point.

Chairman Breaux and I took a look at these, Mr. Hubbard. The chairman is one of the most influential people in the country now in terms of health policy. I guess I am a humble soul, but I also have been specializing in health for years, and the two of us can't tell the difference in these kinds of bottles. So I think it is fair to say that the typical senior is not going to be able to crack a website——

Mr. HUBBARD. That is correct, Mr. Wyden.

Senator WYDEN [continuing]. In terms of rooting out the ripoff artists, are they?

Mr. HUBBARD. That is correct.

The CHAIRMAN. I can't even read the words. They are too small.

Senator WYDEN. Mr. Hubbard, is there a correlation in your view between low prices and counterfeiting? What I am trying to drive

at is whether if the price is so low, so low, should a senior be on the alert that there is a higher possibility of a counterfeit.

Mr. HUBBARD. I certainly think if someone offered any of us something that we knew the value of for an incredibly low price, a car for a thousand dollars, a new car for a thousand dollars or something, we would, hopefully, be alert.

I am not sure with drugs, people are as savvy, and senior citizens can be particularly vulnerable.

Senator WYDEN. The chairman and I teamed up on a port issues hearing last week, and we were looking—and the Customs Office has been very helpful at this—at trying to do more in terms of point-of-origin efforts, to try to keep these products from coming into the country. Is Customs trying, for example, to negotiate some agreements with other countries to keep them from allowing these ripoff products to come to our shores, Ms. Durant?

Ms. DURANT. Customs doesn't have an active pharmaceutical program like that. We take our direction generally from the FDA. We can seize counterfeit drugs under our own law, and we have had some success with our attaches' offices working with foreign countries and foreign enforcement agencies, particularly in Thailand, to help us in special operations, but we do not have a program of negotiating with other countries for foreign——

Senator WYDEN. Ms. Durant and Mr. Hubbard, do you think it would be a good idea for our trade authorities to go after, in a very aggressive way, these agreements with other countries to try to do more to control these products at the point of origin?

We are doing that in virtually every other area. What is striking is we don't seem to be doing it in the pharmaceutical area, and it would seem to me that our trading leaders ought to be pushing for that.

Ms. Durant.

Ms. DURANT. Well, as I—the Customs——

Senator WYDEN. I am talking about from a policy standpoint.

Ms. DURANT. The Customs Service does not make trade policy, but I will tell you that we support not——

Senator WYDEN. Right.

Ms. DURANT.—ever letting it get to our borders in the first place in every arena, what we can do foreign——

Senator WYDEN. Mr. Hubbard, from——

Mr. HUBBARD. Certainly.

Senator WYDEN.—a policy standpoint?

Mr. HUBBARD. Yeah. I am afraid I am not qualified to really answer your question.

Certainly, we have worked as an agency with governments of other countries that deal with these problems and ask them to help us, and in many cases, they have, but I can't really ask answer your policy question.

Senator WYDEN. Ms. Durant, I was told that the Customs Office had to reduce some of the other functions that it had been performing since September 11, to deal with what all of us regard as the urgent priority with respect to the war on terrorism. Have you had to reduce what you all are doing in terms of the work on counterfeit drugs since you had to put more resources into the war on terrorism?

Ms. DURANT. No. In fact, I think it is safe to say that because we are looking at more things, we are finding more things in every arena, including our mail divisions and couriers. It is the needle-in-the-haystack theory, but we are doing more examinations, more X-rays.

We reduced some of our more discretionary trade functions, some potentials in tariff evasion that were not high-risk trade issues, some technical violations. We did do some reductions in that area to devote our resources to more of the up-front examinations, but I would not say that we diverted resources from this problem.

Senator WYDEN. I hope not because my concern is, under the Homeland Security Proposal, I don't see how Customs is going to be able to do all of these other issues that are so important, such as addressing counterfeit medicine, with the budget that is being proposed. Obviously, you are a very dedicated professional, and you have figured out a way to keep this effort on track.

But I will tell you, as I look at the Homeland Security Proposal, I don't see how it is going to be possible to devote the kind of resources that are needed to this effort and still perform all of those other functions.

The last area I want to get at is the question of some technologies that can help us root out these ripoffs, and let me ask you, Mr. Hubbard, about this in particular. Clearly, the ripoff artists are not technology simpletons. These are very savvy people.

What, if anything, are you all doing in terms of trying to find technological breakthroughs? I mentioned some of the handheld devices and others that could be cost effective here. What are you all doing, and does this avenue show any real promise?

Mr. HUBBARD. It certainly does, I think, show promise, Mr. Wyden.

We have, first and foremost, been attempting to upgrade our data systems, our computer systems, so that we actually know what is coming in and where it is coming from and those sorts of things. That is a basic thing.

We have also been looking at new technology to identify things like tag-ins and other things. I can't say any of those technologies are ready to go into use, but I do believe there is a lot of interest in the agency in trying to look to the future for that sort of technology. There will likely be some funding issues for that, but I believe you are right that we ought to be looking to those sorts of new technologies.

Senator WYDEN. The last question I wanted to ask the FDA is you have got a chance now to speak to American consumers, you have got a chance to speak to the public. What ought they be looking for? What should they know?

Mr. HUBBARD. Well, for those who buy drugs overseas, we have been consistently saying you are really taking a great risk. You certainly risk your pocketbook, but you may be risking your health and you may be even risking your life. So we urge people not to buy these drugs or, if they do, to take whatever steps they can to consult with a doctor or their pharmacist to make sure that they are getting the real thing.

Senator WYDEN. Senator Breaux and I hear constantly from our constituents. They will say, "Look, I went out to pay $20 in this

country from something I got in Mexico for $4 or in Canada for $2," and we need to know what to tell them because these are people who are hurting and these are people who are having to make tough choices every single day, people who take three pills when they ought to be taking four and then they go to two and then they go to one. What should they know when they are trying to make these choices?

Mr. HUBBARD. Well, I think, as I said, they have got to know about the risk. Clearly, the cost savings are there. The cheaper drugs are there.

We just have no way to say to a given consumer, "You have gotten a good product that will help, will save your life," and we fear that many people will get a bad product that will hurt them.

Senator WYDEN. How do you get that message out to consumers now? What is the FDA doing to get that out to the public now?

Mr. HUBBARD. We have significant warnings on our website, as Mr. Roberts mentioned. We are preparing brochures to put at the border for those who travel to Canada or Mexico, and we do public service announcements and other things to try to alert people to these problems, but it is a tough sale because the lure of cheaper drugs tends to get past the safety message at times.

Senator WYDEN. All right. Mr. Chairman, my sense is that this is an area that we should be looking at in a comprehensive way. Clearly, as we deal with the homeland security question, there is going to be a real issue with respect to whether enough resources are going to be devoted to this.

I think that the savvy consumer clearly can use some of the tools that were mentioned today, but if you are an elderly person who is hurting financially, you don't have the technology at home, that person is going to be a magnet for these kind of ripoff artists. I just appreciate all of our witnesses really playing the role of Paul Revere here and trying to make sure that people understand what is ahead.

I think the problem is going to get worse, given the difficulties so many have in terms of affording these medicines, and I look forward to working with you to get colleagues on both sides of the aisle to support a response that deals with the seriousness of the problem.

The CHAIRMAN. I thank you very much, Senator Wyden, for your questions and your comments. They are well taken.

I think the potential for a terrorist to see this as an avenue to do grave damage to U.S. citizens, particularly the elderly, is certainly very, very real. This is a pipeline to American citizens that, if they wanted to use it to do damage, this would be an easy way to do it.

Mr. Roberts, I just have one question. Had you not found out that what you were taking for your illness was counterfeit, what could have been the consequences had you continued to take the counterfeit drug?

Mr. ROBERTS. Because of the expense of Serostim, it really is a last line of defense against HIV Wasting. So, if I hadn't been stable and I started to waste again or continued wasting and felt like I had failed in the last drug, there would have been few options after that. I probably would have continued to waste.

The CHAIRMAN. You could have died.

Mr. ROBERTS. Certainly, the HIV wasting is a major cause of death in HIV cases.

The CHAIRMAN. Is there a greater awareness now in the community of the potential for counterfeiting these type of products?

Mr. ROBERTS. Some of the stories in San Francisco, they have been in the local papers and magazines. The Boston Globe has run a good series on counterfeit medicines, but I don't think in general the public that I am associated with, the HIV community, is even aware of it. Anyone I get a chance to tell the story to, I certainly do.

It is different than when a car part gets recalled. They seem to track down the car owner and tell them, and there seem to be procedures or policies that allow people to be made aware of the recall.

In my case, there was no warning. There was no attempt to contact me. I just happened to ask my pharmacist.

The CHAIRMAN. That is a very good point.

I just had a product that had a recall that required me to bring the vehicle in to do some minor maintenance work, and I didn't do it. I got another notice 6 months later saying, "We noticed that you haven't brought the vehicle in to fix this relatively minor problem," but they kept tracking it because they knew there was something wrong. But with a life-saving medicine that was counterfeit, you never got that.

Mr. ROBERTS. No.

The CHAIRMAN. Well, thank you very much for traveling. You have told the story, and I think that it has been very, very helpful, hopefully to a lot of people, and I thank our Government witnesses and Mr. Theriault for the private sector.

I think what we have learned today, hopefully, will be looked upon by all Members of Congress as to the risk of counterfeit drugs in this country, and I thank the witnesses for being with us.

Mr. HUBBARD. Thank you, Mr. Chairman.

[Whereupon, at 3:38 p.m., the committee was adjourned.]

APPENDIX

Robert Schwartz, Chairman of the Board
Ronald J. Streck, President & CEO

July 17, 2002

The Honorable John Breaux
Chairman
Special Committee on Aging
G31 Dirksen Office Building
Washington, DC 20510-6400

Dear Senator Breaux:

I am writing to request that the statement of Ronald J. Streck, President and CEO of the Healthcare Distribution Management Association, be included in the official record for the July 9, 2002 Special Committee on Aging hearing "Buyer Beware: Public Health Concerns of Counterfeit Medicine." A hard copy as well as a computer disk copy of the statement is enclosed.

HDMA is the national trade association representing pharmaceutical and healthcare product distribution. HDMA's active member companies operate over 240 distribution centers throughout the country that serve every state, the District of Columbia and U.S. territories. HDMA's distributor members provide services to approximately 129,100 pharmacy settings, including: 19,400 independent pharmacies; 18,500 chain pharmacies; 9,300 food stores; 10,600 hospital pharmacies; 6,400 mass merchandisers; 5,200 long-term care and home health facilities; 58,300 clinics; 1,100 HMOs; and 300 mail-order pharmacies.

If there are any questions, please have your staff contact me at rfalb@hdmanet.org or 703-787-0020, ext. 235. Thank you.

Sincerely,

Robert J. Falb
Director of Congressional Affairs

Enclosures

Healthcare Distribution Management Association
Formerly National Wholesale Druggists' Association (NWDA)
1275 K Street N.W., Suite 1212 • Washington, D.C. 20005-4006 • 703/787-0000 • fax: 202/312-5005 • www.HealthcareDistribution.org

Robert Schwartz, Chairman of the Board
Ronald J. Streck, President & CEO

Statement of Ronald J. Streck
President and CEO
Healthcare Distribution Management Association
For the Senate Special Committee on Aging
July 9, 2002 Hearing
"Buyer Beware: Public Health Concerns of Counterfeit Medicine"

My name is Ronald J. Streck and I am President and CEO of the Healthcare Distribution Management Association (HDMA). I want to commend the chairman and the members of the committee for holding this important hearing, "Buyer Beware: Public Health Concerns of Counterfeit Medicine."

HDMA is the national trade association representing pharmaceutical and healthcare product distribution. HDMA's active member companies operate over 240 distribution centers throughout the country that serve every state, the District of Columbia and U.S. territories. HDMA's distributor members provide services to approximately 129,100 pharmacy settings, including: 19,400 independent pharmacies; 18,500 chain pharmacies; 9,300 food stores; 10,600 hospital pharmacies; 6,400 mass merchandisers; 5,200 long-term care and home health facilities; 58,300 clinics; 1,100 HMOs; and 300 mail-order pharmacies.

In the United States today, the great majority of all pharmaceuticals are distributed through healthcare distributors. The marketplace in which they do business is an extremely competitive one as evidenced by the industry's net profit margin of less than one percent since the mid-1990s.

Pharmaceutical distributors are a vital part of the system that is charged with ensuring product integrity. This is a responsibility that HDMA members take very seriously. The products they store and distribute help to ease pain, improve the quality of life and cure diseases. If these drugs are not properly stored or adequate systems are not in place to safeguard against improper handling, the results can be troublesome at best, devastating at worst.

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HDMA members are continually reviewing their procedures and systems in an effort to ensure that the drugs they receive and distribute are the genuine product. HDMA and our member companies have a long history of working closely with the Food and Drug Administration, Drug Enforcement Administration and other federal and state enforcement agencies in their counterfeiting and related investigations. For example, we are currently involved in discussions with state enforcement agencies as they attempt to enhance their ability to address their growing concerns about counterfeit product. Additionally, HDMA is in the process of meeting with various stakeholders to better understand the issue with the goal of establishing a multi-disciplinary task force that can develop voluntary industry guidelines for better screening purchases.

Pharmaceutical distributors in our country are highly regulated with strong oversight from both federal and state government agencies. The Prescription Drug Marketing Act (PDMA), enacted by Congress and signed into law in 1988, established the national standards for the storage and distribution of pharmaceutical products in the United States. As anyone familiar with our industry will attest, PDMA requirements are understandably quite extensive.

Under PDMA, all distributors are required to meet numerous federal and state regulations to ensure the integrity and security of pharmaceutical products that reach the American public. Every distributor must be licensed in every state in which they have a warehouse facility. Additionally, 42 states have further licensure requirements for distributors doing business in their state, even if their warehouse(s) is located in another state. Every distribution center is subject to inspection by the Food and Drug Administration, Drug Enforcement Administration, Environmental Protection Agency, Department of Transportation, Occupational Safety and Health Administration and the state agency counterparts.

Under PDMA, all licensed distributors must have in place detailed storage and handling procedures that address:

- Temperature and humidity control and documentation
- Inspection of incoming and outgoing product shipments
- Rotation of product to prevent expiration
- Employee training in storage and handling of pharmaceuticals
- Extensive background checks on employees
- Facility and product security
- Procedures for handling recalls and returned goods
- Sanitation of facility
- Disaster plans for both inside and outside the facility
- Comprehensive written policies

PDMA has worked. The extensive handling and storage standards, backed up with strong oversight, have resulted in the "gold standard" when it comes to ensuring product integrity. Overall, the closed method of distribution from manufacturer to distributor to pharmacy to patient has resulted in a system in which Americans do not question the authenticity of the prescription drug they are about to take. However, we cannot rest on our laurels.

Reliable data measuring the level of fake or adulterated pharmaceuticals entering our marketplace are very hard to come by. As the committee is aware, the World Health Organization estimated several years ago that between five and eight percent of the worldwide trade in pharmaceuticals is counterfeit. However, most experts believe this number to be low and that it is increasing.

I would be remiss if I also did not take this opportunity to discuss the dangers of prescription drug reimportation as it relates to counterfeit drugs.

Legislation has been introduced in this Congress (S. 2244/H.R.4614) that would allow pharmacists and pharmaceutical wholesale-distributors to reimport prescription drugs from Canada into the United States. Limiting it to Canada does not preclude the likelihood of counterfeit or adulterated drugs from entering the United States.

If reimportation becomes the law of our land, Americans would expect unlimited access to cheaper drugs. However, in an environment of over-demand and under-supply, criminals will be given a new opportunity to make a quick buck by infiltrating the U.S. market with counterfeit, subpotent, diverted or adulterated drugs through Canada.

As the committee may recall, prescription drug reimportation legislation was passed in the previous Congress. That legislation required the Secretary of Health and Human Services to certify that reimportation would not result in an increased threat to the health and safety of Americans and that there would be cost savings for the patient before it could be implemented. After an extensive review, then-Secretary Shalala announced that she could not certify these two factors. Her successor, Secretary Thompson, undertook his own investigation and reached the same conclusion.

Limiting reimportation to Canada would not change these findings. Indeed, Canada would become the gateway for those looking to introduce counterfeit drugs into our country. Therefore, the pending measures should be vigorously opposed.

In conclusion, I want to again thank the committee for bringing more attention to the emerging issue of counterfeit drugs and assure you that HDMA stands ready to work with you and other interested parties to ensure that our pharmaceutical supply system remains the best and safest in the world.

Statement of
Mary R. Grealy
President, Healthcare Leadership Council

Hearing on
"Buyer Beware: Public Health Concerns of Counterfeit Medicine"

United States Senate Special Committee on Aging
Tuesday, July 9, 2002
2:30 p.m.
562 Dirksen Senate Office Building

The Healthcare Leadership Council (HLC) commends Chairman Breaux for holding today's Special Committee on Aging hearing on the public health concerns of allowing the purchasing of pharmaceuticals from outside the nation's borders. It is critically important that Congress examine and understand the threats that reimportation of medicines poses for patients, including threats from counterfeit, adulterated, or substandard medicines coming into the United States. Patients could be harmed by these medicines without any guarantee of lower prices.

Until now, U.S. food and drug law has been steadily strengthened (not weakened) to protect consumer safety, culminating in the landmark 1988 Prescription Drug Marketing Act (PDMA). Recent proposals to reverse this course to allow drug reimportation led ten former FDA commissioners to write letters expressing their views that this would be dangerous for patients.

In 2001, the FDA testified before Congress that drugs being imported from outside the United States "pose considerable risks to consumers because they may be counterfeit, expired, superpotent, subpotent, simply tainted or mislabeled." Similar concerns led HHS Secretary Thompson to conclude that he could not certify that legislation allowing importation or reimportation was safe for consumers and patients. Recent examples of attempts to bring unsafe prescription drugs into the United States illustrate these safety concerns.

It is also unlikely that reimportation would be cost effective or save consumers money overall. The costs of repackaging, testing, and certifying the safety of reimported drugs make the scheme uneconomical. In December 2000, former HHS Secretary Shalala agreed, saying that it is "impossible...to demonstrate that it [reimportation or importation] is safe and cost effective."

HLC continues to urge that Congress reject reimportation legislation and, instead, focus on what seniors truly need, coverage for prescription drugs.

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