Testimony of

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DEPARTMENT OF HEALTH & HUMAN SERVICES
Food and Drug Administration
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STATEMENT OF

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INTRODUCTION

Mr. Chairman and Members of the Subcommittee, I am Mr. William K. Hubbard, Associate Commissioner for Policy and Planning at the U.S. Food and Drug Administration (FDA or the Agency). With me is John M. Taylor, Associate Commissioner for Regulatory Affairs at FDA. We appreciate having this opportunity
to discuss with you the issues relating to the importation of prescription drugs into the United States and the use of the Internet to facilitate the sale of these drugs.

At FDA, our statutory responsibility is to assure the American public that the drug supply is safe, secure, and reliable. For more than 60 years, the Federal Food, Drug, and Cosmetic (FD&C) Act has ensured that Americans can be confident that, when they use an FDA-approved drug, the medicine will be safe and effective and will work as intended in treating their illness and preventing complications. In carrying out this responsibility, FDA is working to do all we can

under the law to make medicines accessible and help doctors and patients to use them as effectively as possible, through such steps as expanding access to generic medicines, reducing the time and cost of showing that new medicines are safe and effective, and providing up-to-date information for health professionals and patients to obtain the benefits and avoid the risks associated with powerful medicines. That is the primary mission of the thousands of dedicated staff, including leading health care experts, doctors, economists and scientists who work tirelessly at FDA in public service for the American people. FDA remains strongly concerned about counterfeit, and/or illegally imported pharmaceuticals whose safety and effectiveness cannot be assured because they are distributed outside the legal structure and regulatory resources provided by Congress.

IMPORTATION OF PRESCRIPTION DRUGS

Sixty-five years ago, Congress responded to widespread instances of unsafe drugs by directing FDA to implement a system for assuring that Americans have a drug supply they can trust will not harm them. Over forty years ago, Congress required that legal drugs be proven to be effective as well, because modern medicines - when they are produced, distributed, prescribed, and used properly - should not only be safe but effective in the treatment of disease. More recently, in 1988, Congress enacted the Prescription Drug Marketing Act (PDMA) to establish additional safeguards to prevent substandard, ineffective, or counterfeit drugs from entering the U.S. Under PDMA, it is illegal for anyone other than the drug's original manufacturer to re-import a prescription drug into the U.S. that was manufactured in the U.S. This law was enacted with strong bipartisan support because of high-profile cases of unsafe and ineffective drugs entering the U.S. in large volumes. In one instance, over 2 million unapproved and potentially unsafe and ineffective Ovulen-21 "birth control" tablets from Panama were distributed into the U.S. as "American goods returned." In another case, a counterfeit version of Ceclor, a widely used antibiotic at the time, found its way into the U.S. drug distribution from a foreign source. Over the years, FDA has employed PDMA and other authorities to build a drug safety infrastructure to ensure that Americans enjoy the highest-quality drug supply in the world.

Unfortunately, the drug supply is under unprecedented attack from a variety of increasingly sophisticated threats. This is evident in the recent significant increase in efforts to introduce counterfeit drugs into the U.S. market. FDA has seen its number of counterfeit drug investigations increase four-fold since the late 1990s. Although counterfeiting was once a rare event, we are increasingly seeing large supplies of counterfeit versions of finished drugs being manufactured and distributed by well-funded and elaborately organized networks. At the same time, inadequately regulated foreign Internet sites have also become portals for unsafe and illegal drugs. For example, FDA recently worked with domestic and international authorities to shut down a website that was advertising "FDA-approved" and safe "European" birth control pills and other drugs, but was actually responsible for importing ineffective, counterfeit drugs. Evidence strongly suggests that the volume of these foreign drug importations is increasing steadily, presenting an increasingly difficult challenge for Agency field personnel at ports-of-entry, mail facilities, and international courier hubs, and our laboratory analysts and border and law enforcement partners.

FDA is doing its best to use its limited resources and international authorities to stop the increasing flow of violative drugs into this country, but the task is daunting. FDA's Office of Regulatory Affairs has inspectors working in the field who perform investigations pertaining to imported prescription drugs, a job that is not limited to inspections at ports-of-entry. Each day, however, thousands of individual packages containing prescription drugs are imported illegally into the U.S., simply because the sheer volume has grown to exceed the capability of FDA field personnel to properly process.

SAFETY CONCERNS RELATING TO IMPORTATION

FDA remains concerned about the public health implications of unapproved prescription drugs from entities seeking to profit by getting around U.S. legal standards for drug safety and effectiveness. Many drugs obtained from foreign sources that either purport to be or appear to be the same as U.S.-approved prescription drugs are, in fact, of unknown quality. Consumers are exposed to a number of potential risks when they purchase drugs from foreign sources or from sources that are not operated by pharmacies properly licensed under state pharmacy laws. These outlets may dispense expired, subpotent, contaminated or counterfeit product, the wrong or a contraindicated product, an incorrect dose, or medication unaccompanied by adequate directions for use. The labeling of the drug may not be in English and therefore important information regarding dosage, warnings and side effects may not be available to the consumer. The drugs may not have been packaged and stored under appropriate conditions to prevent degradation, and there is no assurance that these products were manufactured under current good manufacturing practice (cGMP) standards. When consumers take such medications, they face risks of dangerous drug interactions and/or of suffering adverse events, some of which can be life-threatening. More commonly, if the drugs are subpotent or ineffective, they may suffer complications from the illnesses that their prescriptions were intended to treat, without ever knowing the true cause.

Patients also are at greater risk because there is no certainty about what they are getting when they purchase some of these drugs. Although some purchasers of drugs from foreign sources may receive genuine product, others may unknowingly buy counterfeit copies that contain only inert ingredients, legitimate drugs that are outdated and have been diverted to unscrupulous resellers, or dangerous sub-potent or super-potent products that were improperly manufactured. Furthermore, in the case of foreign-based sources, if a consumer has an adverse drug reaction or any other problem, the consumer may have little or no recourse either because the operator of the pharmacy often is not known, or the physical location of the seller is unknown or beyond the consumer's reach. FDA has only limited ability to take action against these foreign operators.

The Agency has responded to the challenge of importation by employing a risk-based enforcement strategy to target our existing enforcement resources effectively in the face of multiple priorities, including homeland security, food safety and counterfeit drugs. However, this system, as it works today, is already overwhelmed by the number of incoming packages, and this presents a significant ongoing challenge for the Agency.

Recent spot examinations of mail shipments of foreign drugs to U.S. consumers revealed that these shipments often contain dangerous or unapproved drugs that pose potentially serious safety problems. In 2003, inspectors found that the majority of the packages examined in these "blitzes"

contained illegal drugs. Last summer, FDA and the U.S. Customs and Border Protection agency (CBP) conducted blitz examinations on mail shipments at the Miami and New York (JFK Airport) mail facilities in July, and the
San Francisco and Carson, California, mail facilities in August. In each location, the agencies examined packages shipped by international mail over a 3-day time span.
Of the 1,153 shipments examined, the overwhelming majority (1,019 packages, or 88 percent) contained unapproved drugs. The drugs arrived from many countries. For example, 16 percent entered the U.S. from Canada; 14 percent were from India; 14 percent came from Thailand, and 8 percent were shipped from the Philippines.

A second series of import blitz exams, conducted in November 2003, also revealed potentially dangerous, illegally imported drug shipments. Of the 3,375 products examined, the vast majority was found to be violative. FDA found recalled drugs, drugs requiring special storage conditions and controlled substances. These blitz exams were performed at the Buffalo, Dallas, Chicago and Seattle international mail facilities and, for the first time, the private courier hubs at Memphis and Cincinnati. Canadian parcels appeared most frequently (80 percent of the mail parcels), while 16 percent were from Mexico, and the remaining 4 percent came from Japan, the Netherlands, Taiwan, Thailand and the United Kingdom.

Examples of the potentially hazardous products encountered during the exams include:

? Unapproved drugs such as 1) alti-azathioprine, an immunosuppressant drug that can cause severe bone marrow depression and can be associated with an increased risk of infection and cancer development; and 2) human growth hormone, which can have serious side effects if used inappropriately or in excessive doses.

? Controlled substances - FDA and Customs found over 25 different controlled substances, including Diazepam; Xanax; Codeine; Valium, Lorazepam, Clonazepam and anabolic steroids.

? Drugs withdrawn from the U.S. market for safety reasons such as Buscapina, which appears to be the drug dipyrone, removed from the market in 1977 due to reports of association with agranulocytosis -- a sometimes-fatal blood disease.

? Improperly packaged drugs shipped loose in sandwich bags, tissue paper or envelopes.

? Animal drugs not approved for human use such as Clenbuterol, a drug approved for the treatment of horses but also known as a substance of abuse in the "body building" community and banned by the International Olympic Committee.

? Potentially recalled drugs -- Serevent Diskus and Flovent Diskus medicines from Canada for the treatment of asthma. Shortly after the blitz, certain lots of the Canadian versions of these drugs were recalled in Canada.

? Drugs requiring risk management and/or restricted distribution programs -- for example, Canadian-manufactured isotretinoin, which in the U.S. is subject to a stringent risk management plan, under which prescribers are required to screen, educate and monitor patients to avoid certain serious risks such as birth defects.

? Drugs with inadequate labeling such as those with missing dosage information or labeling that is not in English.

COUNTERFEIT DRUGS

Counterfeiting of prescription drugs is a growing global concern. In fact, counterfeiting of drugs is commonplace in many countries.

In the ongoing debate over drug importation, the term "counterfeit drug" has been widely used in different contexts to mean different things. Some use the term as a catch-all to refer to all unapproved new drugs that are imported into the US. Others use it to refer to so-called "foreign versions" of FDA-approved drugs (i.e., versions of FDA-approved drugs that are not approved in the U.S. but are approved in the foreign country in which they are sold).

In fact, the term "counterfeit drug" is defined in the FD&C Act, and it describes a narrow set of drugs. In section 201(g)(2) of the FD&C Act, "counterfeit drug" is defined as "a drug which, or the container or labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, or device, or any likeness thereof, of a drug manufacturer, processor, packer, or distributor other than the person or persons who in fact manufactured, processed, packed, or distributed such drug and which thereby falsely purports or is represented to be the product of, or to have been packed or distributed by, such other drug manufacturer, processor, packer, or distributor.

Note that a key element in this definition is the idea of fraud or deceit. The provision is aimed at products that are labeled as something other than they are. Thus, any product that is labeled or embossed with a drug trade name must be the precise product so identified or it is a counterfeit. For example, an article labeled as Viagra that is not in fact the genuine Pfizer product is a counterfeit. It makes no difference whether the counterfeit drug is an effective, chemically indistinguishable version of Pfizer's. So long as the trade name is used on the label without authorization to suggest the product is something that it is not, the product is counterfeit.

In contrast, an unapproved new drug that is not falsely labeled is not counterfeit within the meaning of section 201(g) of the FD&C Act. This includes "foreign versions" of FDA-approved drugs that are labeled with their approved foreign labeling. Again, the key distinction is the element of fraud. Suppose, for example, that a Canadian pharmacy dispensed into the U.S. a Canadian version of Paxil called "Proxy," which was manufactured by the "ACME Company" and approved for sale in Canada but which was not FDA-approved for sale in the U.S. Whether that drug was also counterfeit within the meaning of section 201(g)(2) of the FD&C Act would depend on how it was labeled. If the pharmacy labeled the Proxy as "Paxil," which is the trade name of an FDA-approved drug manufactured by GlaxoSmithKline, then the drug would be a counterfeit because the unauthorized use of the trade name would falsely suggest to the consumer that the drug he or she received was in fact GSK's FDA-approved product. If, however, the
drug were labeled as Proxy that was manufactured by ACME, the product would not be counterfeit because there would be no false indication that the drug at issue was in fact FDA-approved Paxil. Even though the US consumer might think of the product as Paxil-like, the fact

that the product label did not misrepresent the product's true identity would keep it outside the technical definition of a counterfeit.

In sum, the term "counterfeit drug" has a precise legal definition. Virtually all drugs that are imported by individual consumers into the U.S. are illegal, but not all of them are counterfeit. To determine whether a drug is a "counterfeit," investigators look at the drug and at its label and packaging. If the drug is embossed or labeled with a trade name or identifying mark that suggests it is a genuine FDA-approved product, the drug itself is examined more closely. If the drug has not in fact been manufactured, packaged, processed, or distributed by the person(s) identified on the tablet or labeling, and thereby falsely represents that fact, then the drug is a counterfeit within the meaning of the Act.

In the U.S., Federal and state authorities have kept counterfeiting of drugs to a minimum because of our extensive system of laws, regulations and enforcement. As a result, Americans have a high degree of confidence in the drugs they obtain from their local pharmacy. In recent years, however, FDA has seen growing evidence of efforts by increasingly well-organized counterfeiters, backed by increasingly sophisticated technologies and criminal operations, intent on profiting from drug counterfeiting at the expense of American patients. FDA has seen its counterfeit drug investigations increase to over 20 per year since 2000, after averaging only about five per year through the late 1990's. From October 1996 through June 2004, FDA's Office of Criminal Investigations (OCI) has opened approximately 113 counterfeit drugs cases. These investigations have so far netted 77 arrests and 42 convictions.

Although we believe domestic counterfeiting is not widespread, the Agency has seen both an increase in counterfeiting activities, and a more sophisticated ability to introduce finished dosage counterfeits into otherwise legitimate drug distribution channels. Much of this activity has targeted high volume, high cost drugs where counterfeiters attempt to obtain the highest return possible in a short time period. Many of these drugs are used for treating cancer and AIDS patients. FDA believes the increase and shift in this illicit activity has occurred for a number of reasons, including:

? Better counterfeiting technology, including improved technology to make labeling, packaging and products that appear real.
? Better organized, more effective criminal groups attracted by financial opportunities.
? The use of the Internet as a sales tool by unlicensed pharmacies and/or foreign websites.
? Opportunities for introducing foreign-made counterfeit and unapproved drugs into large and rapidly growing import flows.
? Weak spots in the domestic wholesale drug distribution chain, including some wholesalers who acquire most of their inventory from secondary sources, do not maintain effective due diligence efforts on these sources and ignore warning signs indicative of illegal or unethical behavior.

In July 2003, FDA began a major new initiative to better protect American consumers from drugs that have been counterfeited. FDA's initiative was designed to better identify the risks and threats from counterfeit drugs, coordinate public and private efforts to fight drug counterfeiting and distribution, and develop new tools to aid in identifying, deterring and combating counterfeiting. In addition, FDA is working to establish closer coordination with other Federal agencies and

state and local governments that share the responsibilities for ensuring the safety of the U.S. drug supply and distribution system.

The initiative included the creation of an internal task force to explore modern technologies and other measures to make it more difficult for counterfeit drugs to be distributed with - or deliberately substituted for - safe and effective drugs. The information gathering process included a public hearing held in October 2003.

On February 18, 2004, FDA issued a final report that lays out specific steps the Agency is taking to keep the U.S. drug supply secure against the increasingly sophisticated criminal efforts to introduce counterfeit drugs. The comprehensive report highlights ways to assure that the nation's drug distribution system protects Americans from counterfeit drugs. These measures address six critical areas:

? Securing the actual drug product and its packaging;
? Securing the movement of the product as it travels through the U.S. drug distribution chain;
? Enhancing regulatory oversight and enforcement;
? Increasing penalties for counterfeiters;
? Heightening vigilance and awareness of counterfeit drugs; and
? Increasing international collaboration.

The report addresses the safety and security of the legal U.S. drug supply, over which the Agency has regulatory authority. It must be noted that the counterfeit initiative is not intended to assure the safety and efficacy of drugs purchased from other countries outside this legal drug distribution system, or from unregulated Internet sites that are not run by pharmacies licensed and regulated by states.

The report describes specific steps that can be taken now and in the future to protect consumers from counterfeit drugs and to secure the U.S. drug distribution system. These measures include:

? Implementation of new technologies to better protect legitimate drugs against tampering or replacement with counterfeits.
? Adoption of reliable modern track and trace technology, which the FDA has concluded is feasible by 2007, to accomplish and surpass the goals of the Prescription Drug Marketing Act.
? Adoption and enforcement of stronger anti-counterfeiting measures by the state regulators of drug wholesalers and distributors.
? Increased criminal penalties to deter counterfeiting and more adequately punish those convicted.
? Adoption of secure business practices by all participants in the drug supply chain.
? Development of a system that helps ensure timely and effective reporting of counterfeit drugs to the FDA, and that strengthens the ability of the FDA, other regulatory agencies, and the other participants in the drug distribution system to respond rapidly to such reports.
? Education of consumers and health professionals about the risks of counterfeit drugs and about how to respond if they encounter such products.
? Collaboration with foreign stakeholders to develop strategies to deter and detect counterfeit drugs globally.

Implementing these steps will:

? Help prevent the introduction of counterfeit drugs into the U.S. drug distribution chain;
? Facilitate the identification of counterfeit drugs;
? Minimize the risk and exposure of consumers to counterfeit drugs; and
? Avoid unnecessary additional costs in the prescription drug distribution system, and unnecessary restrictions on lower-cost sources of drugs.

The full Counterfeit Drug Task Force Final Report is available on FDA's website at www.fda.gov/oc/initiatives/counterfeit.

Reporting of Information on Counterfeit Drugs by Manufacturers

In another move to respond to the increase in counterfeit drug cases and to strengthen the Agency's and industry's collaboration in those situations where counterfeit drugs are suspected, on April 22, 2003, the Pharmaceutical Research and Manufacturers of America (PhRMA), which represents the country's major research-based pharmaceutical and biotechnology companies, announced the adoption of a voluntary program to report suspected instances of drug counterfeiting to FDA. The information provided by PhRMA members under this program will assist FDA in carrying out its responsibilities to protect the safety and integrity of the nation's drug supply. It will enhance the Agency's ability to detect quickly and remove counterfeit drugs from the marketplace.

Under this program, PhRMA member companies have agreed to notify OCI within five working days of determining that there is a reasonable basis to believe that a product has been counterfeited. The program also applies to counterfeits discovered in foreign countries if there is clear evidence that the counterfeits are intended for distribution in the U.S. Drug manufacturers already conduct their own investigations of suspected distribution of counterfeit drugs. This formal collaborative agreement will strengthen FDA's ability to assure the safety and effectiveness of drugs used by U.S.
The reporting program went into effect on May 1, 2003 and has already led to some useful tips. To date, thirty-five (35) voluntary counterfeit reports have been submitted to the Agency since this agreement with PhRMA was put in place.

Recent Counterfeit and Unapproved Drug Cases

Counterfeit Viagra

On June 24, 2004 FDA's Office of Criminal Investigations (OCI) received a report of counterfeit Viagra from Pfizer after the company confirmed that the product had been dispensed by two pharmacies in California. Pfizer had received two complaints of suspicious Viagra from two different pharmacies in California and after testing was able to confirm that both the product and the packaging were counterfeit.

Counterfeit Viagra

On June 23, 2004 Khoa Twan Do, also known as Chris Do, pled guilty to charges of conspiracy, trafficking in counterfeit counterfeit goods, and a felony violation of the Federal Food, Drug and Cosmetic Act. In pleading guilty, the defendant admitted that he conspired with a manufacturer in Beijing to import thousands of counterfeit Viagra tablets into the United States that he would then resell. He had told his Beijing supplier that the counterfeit tablets needed to "look like the real thing" because "I can find many customers who want the real thing." In January 2004, U.S. Immigration and Customs Enforcement and FDA intercepted a shipment of thousands of these counterfeit tablets destined for Do.

The defendant is scheduled for sentencing in September, 2004. He faces a maximum possible penalty of 18 years in federal prison and a fine of more than $2 million.

David Palumbo

On June 16, 2004, an indictment was unsealed in San Diego, California that charged David Palumbo, a bodybuilder and editor-in-chief of Rx Muscle magazine, with conspiring to unlawfully distribute human growth hormone and traffic in counterfeit goods. According to the indictment, Palumbo obtained counterfeit Serostim and sold it
to bodybuilders who did not possess lawful prescriptions for the drug. The indictment further alleged that Palumbo sent his payments in cash by commercial interstate carriers such as Federal Express, often contained within the pages of a copy of the bodybuilding magazine he edited. The source of the counterfeit Serostim for Palumbo proved to be Bill Young who pled guilty on February 19, 2003 to trafficking in counterfeit goods.
The counterfeit Serostim produced by the defendants in this case was identified by the fact that the hologram on the box was a sticker, rather than an imprint on the box itself. Palumbo faces 5 years in prison and/or a $250,000 fine.

Omega Pharmaceuticals

On June 9, 2004, Omega Pharmaceuticals of Daphne, Alabama pled guilty to selling and holding for sale counterfeit prescription drugs. In February 2003, OCI investigators executed a federal search warrant at the Daphne, Alabama offices of Omega, a wholesale distributor of prescription drugs. They seized multiple bottles of eleven types of purported brand-name prescription drugs: Viracept (Agouron Pharmaceuticals); Videx EC and Sustiva (Bristol-Meyers Squibb); Crixivan (Merck); Retrovir, Ziagen, and Trizivir (GlaxoSmithKline); Prilosec (Astra Zeneca); Zyprexa (Eli Lilly); and Kaletra and Norvir (Abbott Laboratories). Forensic analysis confirmed that the drugs seized from Omega were, in fact, counterfeit.

Records of Omega seized during the search of its office verified that the company was
in the business of buying and selling prescription drugs throughout the country. As part of its plea agreement, Omega agreed to the destruction of all of the drugs seized by FDA. The company is scheduled to be sentenced in October, 2004, and faces a fine of up to $200,000.

Steven Gabriel Moos

On June 3, 2004, the Department of Justice (DOJ) announced the indictment of Steven Gabriel Moos, an Oregon physician, on multiple criminal charges including the unlawful importation of

misbranded drugs and human growth hormone; falsifying information submitted to DEA; and unlawfully obtaining controlled substances. The indictment stemmed from a multi-Agency investigation which uncovered that Moos had allegedly attempted to import drugs from China which were labeled as vitamin supplements, prednisone or blood pressure medicine but were "misbranded" to appear to be Viagra. Moos also allegedly imported misbranded human growth hormone that was not legitimately manufactured or packaged. According to the indictment, neither of these products included necessary warnings on safe use or contraindications for use; and the lack of appropriate labeling posed significant patient safety concerns.

Moos had been placed on probation by the Oregon Board of Medical Examiners in March, 2000 due to his intended prescription practices. Moos allegedly later filed DEA registration forms misrepresenting his status to practice medicine. After the Board of Medical Examiners acted to further suspend Moos' license to practice medicine in January 2003, Moos allegedly misrepresented his status to drug manufacturers and wholesalers to unlawfully maintain his access to a supply of controlled substances. This investigation was conducted by OCI, FBI, DEA and HHS/OIG. The Oregon Board of Medical Examiners and the Oregon Department of Justice Medicaid Fraud Unit provided assistance.

Counterfeit Contraceptive Patches

On February 4, 2004, the FDA issued a press release warning the public about an Internet site selling contraceptive patches that contained no active ingredient, thereby providing no protection against pregnancy. The website's domain name, www.rxpharmacy.ws, is registered to American Style Products of New Delhi, India. That firm was also listed in the return address of mail parcels containing the bogus contraceptive patches. The website also sold other products that purported to be versions of FDA-approved drugs. FDA is currently analyzing these other products as well, and has urged consumers to treat any drugs purchased from this firm as being suspect. The FDA also sought and obtained the cooperation of the U.S. based Internet service provider (ISP) in discontinuing service to this website.

The bogus contraceptive patches were promoted on the website as Ortho Evra transdermal patches, which are FDA approved, and made by Johnson & Johnson's Ortho-McNeil Pharmaceutical, Inc. subsidiary. Instead of receiving the advertised Ortho Evra patches, customers received patches without the active ingredient necessary to make the patches effective. Moreover, the patches were sent in simple plastic zip-lock bags without identifying materials, lot numbers, expiration dating or any other labeling information needed to safely and effectively use this prescription product.

On February 12, 2004, FDA also obtained the cooperation of a U.S. based Internet Service Provider in discontinuing service for three additional foreign Internet sites associated with www.rxpharmacy.ws. The three newly discovered Internet sites involved were www.usarxstore.com, www.europeanrxpharmacy.com, and www.generic.com. These sites also sold other drugs that purported to be the same as FDA-approved drugs, but were in fact from unknown sources and of unknown safety and efficacy.

The FDA believes these four websites are indicative of the dangers consumers face when they purchase pharmaceuticals off the Internet. The content of each of these websites was written in

perfect English, and to the average US consumer, these websites may appear to be of domestic origin. On closer inspection, none of the websites listed a physical address, telephone number or other identifiers. In fact, all four websites appear to be controlled by largely unknown business entities in various parts of the world, who sell questionable and dangerous products to unsuspecting consumers for pure profit motives.

FDA's Office of Criminal Investigation is working with Johnson & Johnson and the Department of Homeland Security's Bureau of Immigration and Customs Enforcement (ICE) to combat illegal/counterfeit drug imports, to include those facilitated by the Internet. These criminal investigations are ongoing.

Alliance Wholesale Distributors/Local Repack Inc./Phil & Kathy's

On September 15, 2003, FDA announced the seizure of all drug products labeled in a foreign language and/or labeled as repacked by Phil and Kathy's, Inc., d.b.a. Alliance Wholesale Distributor and/or Local Repack, Inc. of Richton Park, Ill.

FDA acted to prevent these drug products from entering the U.S. drug distribution system because there was no assurance that they were safe or effective. Many of the products received and repackaged at Local Repack were of unknown origin and their storage and handling was unverifiable. Local Repack repeatedly failed to comply with cGMP requirements.

FDA inspections conducted after an August 1999 Warning Letter to Local Repack revealed significant and continuing violations. A series of inspections and other recent evidence revealed numerous deficiencies including the failure to properly handle customer complaints, discrepancies surrounding the signatures of quality control employees, records indicating the review and approval of repackaging operations before the operations were completed, incomplete or missing repackaging records, duplicate and inconsistent repackaging records for the same batch, and unreliable receiving and distribution records for drugs.

The September seizure followed the July 9, 2003, seizure of more than 4,500 bottles of prescription drugs that were being repackaged by Local Repack stemming from an investigation of counterfeit Lipitor. Many of the products seized in July were marked with expiration dates to permit them to be sold after similar U.S.-approved drugs would have expired. For example, Portuguese-labeled product that Local Repack labeled as Lipitor had expiration dates well beyond the two-year limit that is based on stability studies performed under the new drug application (NDA) approved in the U.S. for Lipitor.

On April 8, 2004, Phil and Kathy's signed a consent decree agreeing to operate in full compliance with FDA's regulations. Under the consent decree, Phil and Kathy's is prohibited from manufacturing, labeling and distributing any article of drug until it meets certain conditions, the most important of which is the FDA's determination that the firm's repackaging operations comply with cGMPs. In addition, Phil and Kathy's agreed not to repackage any foreign-labeled drugs or drugs that are in any manner inconsistent with FDA's standards for approval.

INTERNET DRUG SALES

With greater and greater frequency, consumers are using the Internet to access health related information and products. Sales of consumer products over the Internet have grown rapidly, including the sale of drugs. The growth in online drug sales by reputable pharmacies has provided significant benefits to consumers. Many managed health care organizations are searching for ways to achieve cost savings and are turning to online prescription plans as a means of providing quality service at a lower cost.

A number of online drug websites, however, present risks to purchasers and unique challenges to regulators, law enforcement officials and policy makers. FDA is concerned about the public health implications of unlawful Internet drug sales, and we are responding to these concerns as we develop and implement risk-based strategies to protect the public health. FDA monitors the Internet to evaluate the quality of products and information being offered, and we encourage consumers to remain vigilant about their purchases and to rely on reputable Internet sites. But we remain concerned about consumers directly purchasing foreign unapproved drugs through the Internet, because
of the Agency's continued concerns that there is not sufficient information or means to assure that these products are as safe and effective as products sold within the United States. Our challenge is to make sure that the protection for consumers who purchase prescription drugs in cyberspace is just as strong as the protection consumers enjoy when they purchase drugs at their corner pharmacy.

Prescription drug sales over the Internet can provide tremendous benefits to consumers. These benefits include:
? Access to drugs for the disabled or otherwise homebound, for whom a trip to the pharmacy can be difficult;
? The convenience of shopping 24 hours a day; and a wide selection of pharmaceutical products;
? Privacy for those who don't want to discuss their medical needs in a public place.

FDA is aware that many reputable Internet pharmacies provide consumers seeking prescription drugs with a measure of safety, privacy and convenience. They can provide detailed information on drug interactions, and may e-mail customers if the drug they ordered has been recalled, a cheaper generic version of the drug becomes available or to remind them of prescription renewals. Some also sell drugs for less than traditional "brick-and mortar" pharmacies. Hyperlinks and search programs provide online customers with written product information and references to other sources of health information more easily than in the traditional storefront. Finally, as data sharing standards are developed and adopted to expand automated transmission of prescriptions from doctors to pharmacies, a reduction in prescription errors may be possible.

While online pharmaceutical sales are important for some customers, brick and mortar pharmacies can offer benefits and services that are often not available through the Internet, such as quick access to prescription drugs needed for immediate treatment. These pharmacies will undoubtedly remain an essential component in the delivery of effective health care.

As beneficial as this technology can be, the Internet also has created a marketplace for the sale of unapproved drugs, prescription drugs dispensed without a valid prescription, or products marketed with fraudulent health claims. Consumers may have difficulty identifying which sites sell legitimate products. As FDA considers the issues related to online drug sales, we recognize

that there are various types of websites engaged in drug sales. Many sites focus on selling prescription drugs and are referred to by some as "Internet pharmacies." These sites offer for sale either FDA-approved prescription drug products, or in some cases, unapproved or illegal versions of prescription drugs. In many cases, FDA cannot provide consumers with assurance that drugs purchased over the Internet were manufactured under cGMP requirements, even if the website appears to be based in the U.S. While the increase in "Internet pharmacies" engaged in illegal sales is seen as a potent threat, FDA believes that some of the non-pharmacy sites are also harmful. We have moved aggressively against these types of sites that unlawfully offer unapproved drug products, products making fraudulent health claims, or drugs for recreational use.

Patients who buy prescription drugs from an illegitimate site are at risk of suffering adverse events, some of which can be life threatening. These risks include potential side effects from inappropriately prescribed medications, dangerous drug interactions or drug contamination. Patients are also at risk because they often don't know what they are getting when they purchase some of these drugs. Although some patients may purchase genuine product, others may unknowingly buy counterfeit copies that contain inert ingredients, legitimate drugs that are outdated and have been diverted to illegitimate resellers, or improperly manufactured sub-potent or super-potent products.

FDA is concerned about the proliferation of sites that substitute a simple online questionnaire for a face-to-face examination and patient supervision by a health care practitioner. According to the American Medical Association, a health care practitioner who offers a prescription for a patient he or she has never seen before, based solely on an online questionnaire, generally does not meet the appropriate medical standard of care. Four years ago, the Federation of State Medical Boards, Special Committee on Professional Conduct and Ethics found that "Prescribing of medications by physicians based solely on an electronic medical questionnaire clearly fails to meet an acceptable standard of care and is outside the bounds of professional conduct." This statement is especially important in light of the primary responsibility of states in regulating the practice of medicine.

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

"Canadian Generics" Website

A recent example illustrates some of the dangers associated with the purchase of prescription drugs from rogue pharmacy sites. Within the last six months, FDA has examined two web sites having identical web pages headlined "Canadian Generics" which were identified through spam e-mails sent to consumers. FDA has purchased prescription drugs from both of these sites, and

has found that these drugs and the manner in which they are sold pose potential threats to the health and safety of consumers.

There is at least one Canadian flag on every page of these sites, as well as the words "Canadian Generics." The web sites say, "Order Canadian to get the biggest discounts!" Both of the URLs from which the orders were placed suggest the sites are located in, and operated out of, Canada. Despite these representations, however, we determined there is no evidence that the dispensers of the drugs or the drugs themselves are Canadian. The registrants, technical contacts, and billing contacts for both web sites have addresses in China. The reordering website for both purchases and its registrant, technical contact, and billing contact have addresses in Belize. The drugs were shipped from Texas, with a customer service and return address in Florida.

FDA purchased drugs described by the website as generic Viagra, generic Lipitor, and generic Ambien. None of these products, however, has a generic version approved in the U.S. or Canada. Both times, to obtain the drugs, an FDA investigator posed as a consumer and filled out an on-line questionnaire. The investigator was never asked to provide a prescription. After each purchase, the drugs arrived packaged in heat-sealed plastic bags within a manila envelope.

Ambien is a controlled substance with a potential for addiction. In addition, for both purchases, FDA's "consumer" said in the on-line questionnaire that he is taking erythromycin. The use of Viagra with erythromycin is contraindicated and, more importantly, there is a warning on the approved labeling for Lipitor about concurrent administration of Lipitor with erythromycin. Despite these critical safety issues, the website operators sent the drugs anyway.

The drugs received from the second purchase were tested in an FDA laboratory. All three samples failed, using the brand-name manufacturer's methodology. While all three samples had some level of active ingredient, the "generic" Lipitor and Viagra were found to be subpotent, while the "generic" Ambien was found to be superpotent. Two of the three drugs failed the dissolution parameters of the brand-name drugs. The third drug passed the dissolution testing, but only because it was superpotent. Two of the three samples also failed purity testing, while all three samples failed the USP criteria for content uniformity.

Consumers can, and should, be cautious when purchasing drugs online. There are legitimate sites that dispense drugs based on valid prescriptions. Consumers should check with their State Board of Pharmacy or the National Association of Boards of Pharmacy to see if the online pharmacy possesses a valid pharmacy license and has met state quality standards.

One means that consumers have at their disposal to protect themselves is the Verified Internet Pharmacy Practice Sites, or VIPPS system, developed by the National Association of Boards of Pharmacy (NABP) in choosing online pharmacies with which
to do business. This program, which verifies the legitimacy of Internet sites dispensing prescription drugs, provides a "seal of approval" to sites that apply and meet state licensure requirements and NABP's standards. Although participation in the VIPPS program is voluntary, the Agency believes this program is an example of one that is helpful in assuring consumers that the Internet site they are using is reputable.

USE OF THE INTERNET TO BYPASS REGULATION

The unique qualities of the Internet, including its broad reach, relative anonymity, and ease of creating new or removing old websites, pose new challenges for the enforcement of the FD&C Act and state laws regulating the practice of medicine and the practice of pharmacy. FDA has found that many Internet sites are actually comprised of multiple related sites and links, thereby making investigations much more complex and resource intensive. The global nature of the Internet creates special problems for effective law enforcement. Different approaches to drug approval and marketing in foreign countries further complicate law enforcement issues for U.S. officials. FDA and other U.S. government agencies must try to work with foreign governments to share information and to develop mechanisms for cooperative law enforcement, but this is a difficult task.

FDA Authority

The types of unlawful conduct that can occur when drugs are sold over the Internet are similar to unlawful activities that occur in other contexts. Under the FD&C Act, FDA has the legal authority to take action against:
? The sale, distribution or importation of an adulterated or misbranded drug;
? The sale, distribution or importation of an unapproved new drug;
? The sale or dispensing of a prescription drug without a valid prescription; and
? Counterfeit drugs.

When the Internet is used for an illegal sale, FDA, working with DOJ, must establish the grounds for a case, develop the same charges, and take the same actions as it would if another sales medium, such as a storefront or a magazine, had been used. FDA has investigated and referred numerous cases for criminal prosecution and initiated civil enforcement actions against online sellers of drugs and other FDA-regulated products, particularly sellers of drugs not approved by the Agency.

State Regulation of the Practice of Medicine and Pharmacy

The states have enacted laws regulating the practice of pharmacy and the practice of medicine to protect patients from harm resulting from the use of unsafe drugs, and the improper practice of medicine and pharmacy. Under many of these laws, to receive a prescription drug, a licensed health care practitioner who determines the appropriate treatment and issues a prescription for an FDA-approved drug generally must examine a patient. The prescription may also authorize refills. The patient then has the prescription filled by a registered pharmacist working in a licensed pharmacy that meets state standards.

Even with these Federal and state systems in place, the Internet provides ample opportunities for circumventing established safeguards. The speed, ease, and anonymity of ordering products on the Internet can attract unscrupulous sellers. Individuals not licensed to sell prescription drugs can easily create websites that appear to represent legitimate pharmacies. The fact that operators can quickly change the location and appearance of their Internet site makes enforcement all the more difficult.

Safeguards are not always maintained when drugs are purchased over the Internet.
A health care practitioner may not examine the consumer prior to the purchase of drugs online.

A patient-doctor relationship may not be established. Unfortunately, attempts to stop some U.S. doctors and online pharmacies from issuing online prescriptions without a physical examination have not always been successful. States face many obstacles when it comes to regulating online pharmacies. State pharmacy and medical boards have
limited resources for enforcement and state regulations may not fully address the Internet context.

Jurisdictional Challenges

Online drug sales pose unique challenges for regulatory and law enforcement agencies at the state, Federal and international level. Internet technology can obscure the source of the product as well as provide a degree of anonymity to those responsible for selling and shipping the product. The parties to a transaction can be dispersed geographically and usually never meet. Thus, the regulatory and enforcement issues cross state, Federal, and international jurisdictional lines.

The sale of drugs to U.S. residents via foreign websites is an extremely challenging area. Medications sold on the Internet that may be legal in foreign countries may not be approved for sale in the U.S. Products not approved for sale in the U.S. often do not conform to the cGMP and quality assurance requirements in U.S. laws and regulations, and it is illegal for a foreign pharmacy to ship such drugs into the U.S. Foreign sales pose the most difficult challenge for U.S. law enforcement because the seller is not within U.S. boundaries. Although FDA may have jurisdiction over a resident in a foreign country who sells in violation of the FD&C Act to a U.S. resident, from a practical standpoint, the Agency working with DOJ has a difficult time enforcing the law against foreign sellers, when they are hard to reach and outside our borders. As a result, the Agency's efforts typically focus on requesting the foreign government to take action against the seller of the product, or asking the CBP to stop the imported drug at a U.S. port-of-entry.

STATE-ENDORSED PHARMACY SITES

Recently, several governors and mayors have proposed to create systems whereby their employees and/or constituents could be directed to Canadian pharmacies for purchasing Canadian drugs. FDA has spoken with a number of such officials about our concerns, and many have declined to proceed and have turned to other legal, proven ways to safely reduce drug costs. However, some states and localities, including the state of Minnesota and the state of Wisconsin, have proceeded to establish state-run websites linking citizens to entities dispensing drugs purportedly from Canada.

Recent research by the state of Minnesota pointed out significant problems related to purchasing non-FDA approved pharmaceuticals from foreign Internet pharmacies.
Minnesota State health officials observed even Canadian pharmacies that participate in the Canadian Internet Pharmacy Association engaging in problematic practices during a single, voluntary, pre-announced "visit." The officials noted dozens of safety problems, such as:

1) several pharmacies used unsupervised technicians, not trained pharmacists, to enter medication orders and to try to clarify prescription questions;
2) one pharmacy had its pharmacists review 100 new prescriptions or 300 refill prescriptions per

hour, a volume so high that it would have been impossible to assure safety;
3) one pharmacy failed to label its products, instead it shipped the labels unattached in the same shipping container, even to patients who received multiple medications in one shipment; and
4) drugs requiring refrigeration were being shipped un-refrigerated with no evidence that the products would remain stable.

At least one of the Canadian pharmacies visited by Minnesota health officials dispensed many drugs that apparently were not even of Canadian origin, and many of the drugs were obtained from prescriptions that had been written and rewritten across multiple Canadian provinces. These types of systematic safety problems would generally be clear regulatory violations that would not be tolerated under the comprehensive system of Federal and state regulation of drug safety in the U.S.

Similar problems have become evident in the operation of the state of Wisconsin's Prescription Drug Resource Center. In reviewing the reports submitted by the three Canadian pharmacies linked to the Wisconsin website, the Pharmacy Society of Wisconsin has identified serious breaches of the agreements under which the pharmacies participate in the state program. The Society found that of the 765 prescriptions dispensed by the pharmacies, 316 (over 41%) violated the state agreements. Specifically, 127 of the dispensed drugs were products not approved by FDA or available in the U.S., while 189 of the drugs were products not authorized by the state program. In six instances, the pharmacies improperly sent drugs requiring refrigeration through the mail. Additionally, one of the Canadian pharmacies advised the state that it intended to obtain drugs from a European supplier, even though that was specifically prohibited by its agreement. Responding to these reports, the Wisconsin Department of Health and Family Services sent letters to the three pharmacies on April 27, 2004 ordering them to cease these prohibited practices. In reaction to these reports, the executive director of the Wisconsin Pharmacy Society, which is the professional association representing licensed pharmacy practitioners in the state, concluded that "no one in Wisconsin has any real idea what these Canadian businesses are doing."

Significant safety issues surfaced when representatives of New Hampshire Governor Craig Benson visited the Canadian Internet pharmacy known as CanadaDrugs.com, located in Winnipeg, Manitoba. The "terms of service" for CanadaDrugs.com requires purchasers to agree that they "will not be liable for damages arising from personal injury or death" from the use of drugs sold by the pharmacy. Under this practice, the consumer has no recourse for injuries arising from the use of drugs from this shipper. Additionally, the website allows patients to send in their prescriptions by fax, when the practice is illegal under the law in New Hampshire and other states. CanadaDrugs.com is "accredited" only by the Internet and Mail order Pharmacy Accreditation Commission, which is a voluntary body with no legal standing and no Federal or state regulatory or enforcement authority.

FDA ACTIONS TO PROTECT PUBLIC HEALTH

FDA has long been engaged in taking steps to minimize the dangers to public health posed by the sales of drugs on the Internet. In July 1999, FDA adopted, and has since been implementing, an Internet Drug Sales Action Plan, which includes five key areas of activity:
? Engaging in public outreach and education;

? Partnering with professional organizations;
? Coordinating action with state and other Federal agencies;
? Cooperating internationally; and
? Enhanced enforcement tailored to the Internet environment.

Coordination with State and Federal Agencies

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

FDA has increased coordination with other governmental bodies and meets regularly with other Federal agencies and state officials to share information, discuss the roles and responsibilities of the parties regarding online drug sales and identify opportunities for partnering in enforcement actions. FDA maintains strong working relationships with DOJ, including the Drug Enforcement Administration (DEA) and Federal Bureau of Investigation (FBI), the U.S. Postal Inspection Service, CBP, the Office of National Drug Control and Policy (ONDCP) and other appropriate Federal and state agencies. FDA believes that cooperation among Federal agencies is particularly critical to address the sale of drugs to U.S. residents by foreign sellers.

FDA is also involved in the effort to combat an increase in the abuse of prescription drugs, which is evident in the increasing illegal sales of controlled substances on the Internet. In announcing the President's National Drug Control Strategy for 2004, ONDCP has brought together the efforts of FDA, Federal substance abuse prevention and treatment agencies, and law enforcement to bear on the factors contributing to rising prescription drug abuse. The Strategy incorporates education of medical professionals and consumers, outreach to businesses involved in Internet commerce, pharmaceutical manufacturers, and pharmacies. The new program includes a range of activities designed to reduce the abuse of prescription drugs, and includes the use of web crawler/data mining technology to identify, investigate and prosecute "pill mills" -- Internet pharmacies that provide controlled substances illegally.

In conjunction with DEA, FDA will implement additional investigative efforts and enforcement actions against the illegal sale, use, or diversion of controlled substances, including those occurring over the Internet. Many of these sellers are foreign-based and expose the purchaser to potentially counterfeit, contaminated, or adulterated products.

Enhanced Enforcement

Since 1999, FDA has aggressively expanded its investigation and enforcement activities relating to Internet drug sales because we believe that illegal online drug sales pose a significant public health risk. FDA has initially focused its enforcement activities in the following areas:
? Unapproved new drugs;
? Health fraud; and
? Prescription drugs sold without a valid prescription.

Through the use of various search tools and by upgrading its data handling capabilities, FDA has increased its capability to monitor the Internet and identify sites that potentially violate the FD&C Act. These actions help the Agency to better understand the type and extent of unlawful conduct on the Internet and to more accurately assess whether its enforcement efforts have had an impact on illegal behavior. FDA has reviewed thousands of websites and identified hundreds involved in the sale of drug products.
But this remains a daunting task and each day new sites are identified.

Starting in 1999, FDA has reviewed potential enforcement actions and coordinated case assignments through the use of a case assessment or "triage" team with representatives from the Office of Enforcement and OCI within the Office of Regulatory Affairs (ORA), the Center for Drug Evaluation and Research (CDER), the Office of Chief Counsel (OCC) and the Office of Policy. Under the triage process, when FDA obtains leads on sites that potentially violate the FD&C Act from internal Internet monitoring activity, state, other Federal or foreign law enforcement agencies, consumers, Congress, or the press, the triage team evaluates leads and decides whether they should be pursued through a civil or criminal investigation. Priority is given to cases involving unapproved new drugs, health fraud, prescription drugs sold without a valid prescription, and products with the potential for causing serious or life-threatening reactions. The triage team makes referrals, when appropriate, to various offices within FDA for follow-up.

The triage process results in a better coordination of criminal and civil enforcement actions at the appropriate Agency components and reduces overlapping effort. This process helps to ensure that decisions are made in a timely way. The Agency seeks an appropriate balance in terms of achieving a maximum deterrent effect while taking action, if needed, to remove harmful products from the market. The team will continue to oversee Internet-related enforcement activities while they are being investigated, and will ensure that they are brought to appropriate conclusion.

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

Recent Internet-Related Cases

The following examples of recent enforcement actions taken by FDA illustrate the serious risks to the public health posed by fraudulent or illegal drug sales utilizing the Internet.

NoPrescriptionpharmacy.com (Alden L. Sears)

The National Association of Boards of Pharmacy forwarded information to OCI that a website called NoPrescriptionpharmacy.com was offering for sale numerous controlled and non-controlled prescription drugs such as Clenbuterol, Clomid, Valium and Viagra without any apparent requirement for on online consultation or a doctor's prescription. Based upon this information, two separate undercover orders were made from the website. In both instances, although money orders were negotiated, no products were received despite numerous e-mail inquiries. In August 2003, search warrants were executed at the domain registrant's residence, during which time numerous anabolic steroids were seized. The domain registrant, Alden L. Spears, was arrested and charged with mail fraud. The defendant pled guilty and was sentenced on April 26, 2004. This case was investigated by both OCI and the U.S. Postal Inspection Service.

Genapharm.com

On March 9, 2004, Hadi M. Ghandour, owner of Genapharm, Inc. of Austin, Texas, pled guilty to four counts of conspiracy to introduce misbranded and unapproved new drugs into interstate commerce, counterfeiting human growth hormone, and possessing controlled drugs with intent to distribute. Ghandour admitted to engaging in a conspiracy to sell unapproved, misbranded, counterfeit and Schedule I controlled drugs from 1999 to 2001. Ghandour sold these drugs through Genapharm, Inc. and Biosculpt Technologies, Inc., and through an Internet website, www.genapharm.com.

The drugs included:
? 1,4 Butanediol, which converts into gamma hydroxybutyric acid or GHB, a Schedule I controlled substance, when metabolized by the human body;
? Counterfeit human growth hormone;
? 4 Bromo-2, 5-dimethoxyphenethylamine (2CB or Nexus), a Schedule I controlled substance;
? BZP, which if combined with 1-(3-trifluoromethylphenyl) piperazine (TFMPP), has stimulant and hallucinogenic effects similar to 3,4-methylenedioxymethamphetamine (MDMA), or ecstasy, a Schedule I controlled substance; and
? Tiratricol, tri-iodothyroacetic acid (TRIAC), a potent thyroid hormone.

Two other persons involved in these offenses were previously convicted and sentenced. Ghandour faces up to five years in prison and a fine of $250,000 on each count. He had previously been convicted in 1998 of counterfeiting drug labels. The investigation was conducted by FDA/OCI and the DEA, with assistance from the Dallas District Office of FDA and the Texas Department of Health.

Vinci-online.com

On August 5, 2003, Christian Frederic Finze pled guilty to charges relating to various counts of conspiracy, distribution, and importation of controlled substances as a result of a case initiated by OCI in July 2000 after Finze was identified as the principal for Vinci-online and CFF Pharma Consult. The website domain used by the defendant, Vinci-online.com, was found to be registered to CFF Pharma Consult, a German business established by the defendant to ship drugs from Germany to customers in the U.S. These shipments included 7,200 units of flunitrazepam, commonly known as Rohypnol or the "date rape drug." Flunitrazepam is not approved for manufacturing or distribution in the U.S. Vinci-online.com also offered other pharmaceutical drug products for sale via its website including controlled substances, antibiotics, anti-allergenics, weight loss medications, steroids, and hormones. Several undercover purchases of prescription drugs were made from the website without providing prescriptions. These purchases were in response to instructions on the website that consumers should place orders via e-mail. Following the e-mail purchase request, an invoice was generated instructing the purchaser to send a money order or cashier's check to Vinci American Ltd. in Las Vegas, Nevada. The products that were received as a result of these on-line purchases were sent from Germany and displayed and contained German labeling. Moreover, the products were shipped from Germany into the U.S. through the use of forged and fraudulent documents designed to deceive employees of CBP and FDA. Finze is awaiting sentencing.

Joan Davis a.k.a. Joan Smith, a co-defendant in the case, pled guilty on September 17, 2003. She was sentenced on February 9, 2004 and received 37 months' confinement and 36 months' probation.

Rx Clinic

On December 3, 2003, a 108-count indictment charging ten individuals and three companies with illegally selling controlled substances and other prescription drugs over the Internet was unsealed. The indictment charges that the defendants used an "online ordering process" to allow consumers to order prescription controlled substances over
the Internet, through such websites as www.get-it-on.com, without ever seeing a doctor. Defendants were charged with, among other things, conspiring to unlawfully distribute Schedule III and IV controlled substances (including weight-loss drugs Bontril, Ionamin, Phentermine, Adipex, and Meridia) without a legitimate medical purpose and outside the usual course of professional practice. Defendants include Vineet (Vincent) K. Chhabra of Florida, an owner, operator, and officer of the businesses, and Sabina S. Faruqui of Florida, an officer, manager, and operator of the businesses. Also indicted were five physicians, a pharmacist, and a partner of Chhabra's who co-owned and operated some of the websites. Various defendants are charged with money laundering, and the indictment
seeks forfeiture of $125 million. Several defendants are charged with violating the FD&C Act by introducing into interstate commerce misbranded prescription drugs, including Bontril, Meridia, Xenical, and Viagra.

On December 19, Marvin Brown, a physician, and Luke Coukos, a pharmacist, entered guilty pleas to charges related to this case. Brown, a retired obstetrician-gynecologist, relinquished his DEA controlled substance registration, and turned in his licenses to practice medicine in Ohio and Massachusetts. Brown pled guilty to conspiracy to dispense and distribute controlled

substances, and admitted that in the course of the conspiracy he authorized more than 22,056 prescriptions for Schedule III and IV controlled substance diet drugs. Coukos pled guilty to conspiracy to dispense and distribute controlled substances and to introduce into interstate commerce prescription drugs without the prescription of a practitioner licensed by law to administer prescription drugs. Coukos admitted that he personally dispensed at least 43,066 Schedule III and IV controlled substance prescriptions, and at least 9,055 prescriptions for non-controlled prescription drugs. Coukos was sentenced on March 12 to 60 months' incarceration and a $140,318 fine. Between April and July, three other physicians and one other pharmacist charged in the Indictment pled guilty to conspiracy to distribute and dispense controlled substances, and await sentencing.

Storefront Pharmacies

FDA has taken recent actions against so-called "storefront pharmacies," which are generally walk-in businesses, sometimes associated with Internet sites, which assist U.S. consumers in ordering prescription drugs from Canadian or other foreign pharmacies and facilitate the filling of these orders. FDA is concerned about these domestic operations that are not properly licensed under state pharmacy laws, and expose consumers to a number of potential risks. As of November 2003, twenty-two states have taken, or are prepared to take, regulatory actions against storefront pharmacies that facilitate illegal imports of prescription drugs from Canada.

Rx Depot Inc.

DOJ and FDA filed an injunction on September 11, 2003, to stop Rx Depot Inc. from causing the importation of prescription drugs from Canada in violation of U.S. law.
The Agency brought the suit because the storefront chain posed a risk to public health by importing unapproved prescription drugs and drugs that may only be imported by the U.S. manufacturer. Earlier in the year, FDA issued a warning letter to Rx Depot in conjunction with the Arkansas State Board of Pharmacy, but the company's response was inadequate. These drugs posed a public health risk because they do not have the same assurance of safety and efficacy as drugs regulated by FDA. Rx Depot and similar companies have incorrectly stated that FDA condones their activities and that their prescription medications are "FDA approved."

On November 6, 2003, Federal District Court Judge Claire V. Eagan, U.S. District Court for the Northern District of Oklahoma, granted a preliminary injunction to immediately prevent the defendants from importing prescription drugs from Canada, because the importation of such unapproved drugs was a clear violation of the FD&C Act. In addition to its unequivocal findings of law, the court found that these companies could not assure the safety of the drugs they have been importing and, as a result, in violating the law, have put Americans at risk. The court stated that "unapproved prescription drugs and drugs imported from foreign countries by someone other than the U.S. manufacturer do not have the same assurance of safety and efficacy as drugs regulated by the Food and Drug Administration." The court continued, "Because the drugs are not subject to FDA oversight and are not continuously under the custody of a U.S. manufacturer or authorized distributor, their quality is less predictable than drugs obtained in the United States."

CanaRx

On September 16, 2003, FDA issued a warning letter to CanaRx notifying the firm of our concerns about supplying prescription drugs from unregulated sources and making unwarranted claims about these products. Specifically, FDA's warning letter stated that CanaRx runs an Internet website and mail operation that illegally causes the shipment of prescription drugs from a Canadian pharmacy into the U.S., thereby exposing U.S. consumers to risky imported drug products. This potential risk is compounded by the fact that CanaRx makes misleading assurances to consumers about the safety of its drugs.

An FDA investigation of this firm showed that CanaRx operates a drug purchasing arrangement that channels drugs through companies that are not U.S. licensed pharmacies and does not consistently use shipping practices necessary to ensure its drugs are safe and effective. For example, FDA has evidence demonstrating that CanaRx shipped insulin, a product that should be stored under refrigeration, in a manner that did not satisfy the storage conditions specified in FDA approved labeling, and which could potentially compromise the safety and effectiveness of the insulin. CanaRx's response to the Agency's warning letter was inadequate, and on November 6, 2003, FDA sent a second letter reiterating our concerns about the potential safety of the product, and the firm's business practices. The investigation is ongoing.

Expedite-Rx, SPC Global Technologies, and Employer Health Options

On January 22, 2004, FDA issued a warning letter to Expedite-Rx, a technological interface, SPC Global Technologies, Ltd., a pharmacy benefits manager, and Employer Health Options, Inc., a pharmacy benefits manager, all of Temple, Texas, notifying them that it considers their drug import program to be illegal and a risk to public health. The letter accuses the firms of facilitating illegal imports of prescription drugs from Canada and misleading the public about the drugs' safety. Expedite-Rx, which does not hold a Texas Pharmacy license, was directed by the Texas State Board of Pharmacy last July to "immediately discontinue receiving/processing prescription drug orders." FDA is reviewing information received from the three firms in response to the Warning Letter.

As these actions indicate, FDA will continue to work closely with its partners in the individual states in support of their efforts to curtail illegal and potentially dangerous operations, especially when they involve misleading claims about drug safety. FDA has been working closely with states and private sector entities like the online search engines to address the problem of illegal Internet pharmacy issues over the past four years to protect the public health.

MEDICARE IMPORTATION STUDY AND TASK FORCE

Last year, when Congress enacted the Medicare Modernization Act, it recognized these safety issues and included language that authorizing a program of drug importation, but only if the Secretary of Health and Human Services could certify that implementation of the program would not compromise the safety of the U.S. prescription drug supply. At the same time, Congress directed the Secretary to conduct a comprehensive study and prepare a report to Congress on whether and how importation could be accomplished in a manner that assures safety. The

Department of HHS is currently working on that analysis and the Secretary has created an intergovernmental task force to steer this effort to completion.

The taskforce includes representatives from FDA, the Centers for Medicare and Medicaid Services, CBP, and DEA. The taskforce has brought together a wide variety of stakeholders to discuss the risks, benefits and other key implications of importing drugs into the U.S., and to offer findings to the Secretary on how to best address this issue in order to advance the public health. The statutory language and the conference report provide detailed, comprehensive requirements for the importation study. As an integral part of the study process, the task force held a series of six meetings to gather information and viewpoints from consumer groups, health care professionals, health care purchasers, industry representatives and international trade experts, and a public docket for comments was opened as well.

CONCLUSION

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

The vigilance of FDA and CBP inspectors is an important tool in detecting imported products that violate the FD&C Act. Given the available resources and competing priorities facing these agencies, however, experience shows that inspectors are unable to visually examine many of the parcels containing prescription drug products that arrive through the mail and private courier services each day. The growing volume of unapproved imported drugs, which often are generated from sales via the Internet, presents a formidable challenge.

The nature of Internet technology presents law enforcement and policy makers with unique challenges. FDA is grappling with these challenges, and we must strive to carefully balance consumer access to information and products with protecting the public health. We are aggressively using our existing educational, compliance and enforcement tools to combat the proliferation of unsafe or fraudulent pharmaceuticals on the Internet, and we will continue to evaluate what changes in our procedures, regulations, or the law might be appropriate to enhance our efforts. Our goal is to ensure that the protections afforded to consumers who purchase drugs from their corner drugstore also extend to consumers in the electronic marketplace.

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