

GAO

Testimony

Before the Permanent Subcommittee on
Investigations, Committee on
Governmental Affairs, U.S. Senate

For Release on Delivery
Expected at 9:00 a.m. EDT
Thursday, June 17, 2004

INTERNET PHARMACIES

Some Pose Safety Risks for Consumers and Are Unreliable in Their Business Practices

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Highlights of [GAO-04-888T](#), a testimony before the Permanent Subcommittee on Investigations, Committee on Governmental Affairs, U.S. Senate

Why GAO Did This Study

As the demand for and the cost of prescription drugs rise, many consumers have turned to the Internet to purchase them. However, the global nature of the Internet can hinder state and federal efforts to identify and regulate Internet pharmacies to help assure the safety and efficacy of products sold. Recent reports of unapproved and counterfeit drugs sold over the Internet have raised further concerns.

This testimony summarizes a GAO report: *Internet Pharmacies: Some Pose Safety Risks for Consumers*, [GAO-04-820](#) (June 17, 2004). GAO was asked to examine (1) the extent to which certain drugs can be purchased over the Internet without a prescription; (2) whether the drugs are handled properly, approved by the Food and Drug Administration (FDA), and authentic; and (3) the extent to which Internet pharmacies are reliable in their business practices. GAO attempted to purchase up to 10 samples of 13 different drugs, each from a different pharmacy Web site, including sites in the United States, Canada, and other foreign countries. GAO assessed the condition of the samples it received and forwarded the samples to their manufacturers to determine whether they were approved by FDA, safe, and authentic. GAO also confirmed the locations of several Internet pharmacies and undertook measures to examine the reliability of their business practices.

www.gao.gov/cgi-bin/getrpt?GAO-04-888T.

To view the full product, including the scope and methodology, click on the link above. For more information, contact Marcia Crosse at (202) 512-7119.

INTERNET PHARMACIES

Some Pose Safety Risks for Consumers and Are Unreliable in Their Business Practices

What GAO Found

GAO obtained most of the prescription drugs it sought from a variety of Internet pharmacy Web sites without providing a prescription. GAO obtained 68 samples of 11 different drugs—each from a different pharmacy Web site in the United States, Canada, or other foreign countries, including Argentina, Costa Rica, Fiji, India, Mexico, Pakistan, Philippines, Spain, Thailand, and Turkey. Five U.S. and all 18 Canadian pharmacy sites from which GAO received samples required a patient-provided prescription, whereas the remaining 24 U.S. and all 21 foreign pharmacy sites outside of Canada provided a prescription based on their own medical questionnaire or had no prescription requirement. Among the drugs GAO obtained without a prescription were those with special safety restrictions and highly addictive narcotic painkillers.

GAO identified several problems associated with the handling, FDA-approval status, and authenticity of the 21 samples received from Internet pharmacies located in foreign countries outside of Canada. Fewer problems were identified among pharmacies in Canada and the United States. None of the foreign pharmacies outside of Canada included dispensing pharmacy labels that provide instructions for use, few included warning information, and 13 displayed other problems associated with the handling of the drugs. For example, 3 samples of a drug that should be shipped in a temperature-controlled environment arrived in envelopes without insulation. Manufacturer testing revealed that most of these drug samples were unapproved for the U.S. market because, for example, the labeling or the facilities in which they were manufactured had not been approved by FDA; however, manufacturers found the chemical composition of all but 4 was comparable to the product GAO ordered. Four samples were determined to be counterfeit products or otherwise not comparable to the product GAO ordered. Similar to the samples received from other foreign pharmacies, manufacturers found most of those from Canada to be unapproved for the U.S. market; however, manufacturers determined that the chemical composition of all drug samples obtained from Canada were comparable to the product GAO ordered.

Some Internet pharmacies were not reliable in their business practices. Most instances identified involved pharmacies outside of the United States and Canada. GAO did not receive six orders for which it had paid. In addition, GAO found questionable entities located at the return addresses on the packaging of several samples, such as private residences. Finally, 14 of the 68 pharmacy Web sites from which GAO obtained samples were found to be under investigation by regulatory agencies for reasons including selling counterfeit drugs and providing prescription drugs where no valid doctor-patient relationship exists. Nine of these were U.S. sites, 1 a Canadian site, and 4 were other foreign Internet pharmacy sites.

Mr. Chairman and Members of the Subcommittee:

I am pleased to be here today as you discuss the safety of prescription drugs sold by Internet pharmacies.¹ As both the demand for and the cost of prescription medications have increased, the Internet has emerged as a growing marketplace for their purchase. Various types of pharmacies offer prescription drugs over the Internet, including those that require a patient to provide a physician's prescription and are sometimes associated with traditional chain drug stores, and other pharmacies that issue a prescription based on an online medical questionnaire or have no prescription requirement.

Like traditional pharmacies, Internet pharmacies are subject to state and federal statutes and regulations designed to ensure the safety and efficacy of the medications they dispense. However, the global nature of the Internet poses challenges for regulators. States have identified Internet pharmacies that do not comply with state pharmacy laws, but have reported difficulty locating, investigating, and taking action against the pharmacies when they are located beyond state borders. Federal agencies have also taken steps to stop illegal Internet sales of prescription drugs, including by prosecuting Internet pharmacies that dispense medications without a valid prescription.² The Food and Drug Administration (FDA) recently reported instances of drugs sold over the Internet that were improperly handled, such as improperly packaged drugs, drugs that were unapproved, and drugs that were not the authentic products consumers intended to purchase. Consumer complaints regarding the business practices of some Internet pharmacies have raised further concerns associated with the use of Internet pharmacies to obtain prescription drugs.

My testimony will summarize findings of a report we are releasing today that examines issues surrounding the availability and safety of prescription drugs sold over the Internet and the business practices of certain Internet pharmacies.³ In a separate testimony, we are providing

¹Throughout this testimony, each Internet Web site selling prescription drugs is referred to as an Internet pharmacy.

²See U.S. General Accounting Office, *Internet Pharmacies: Adding Disclosure Requirements Would Aid State and Federal Oversight*, [GAO-01-69](#) (Washington, D.C.: Oct. 19, 2000).

³U.S. General Accounting Office, *Internet Pharmacies: Some Pose Safety Risks for Consumers*, [GAO-04-820](#) (Washington, D.C.: June 17, 2004).

further details about our purchases of narcotics from Internet pharmacies.⁴ At your request, Mr. Chairman, we examined (1) the extent to which certain prescription drugs can be purchased over the Internet without a prescription; (2) whether drugs sold by Internet pharmacies are handled properly, are FDA-approved, and authentic; and (3) the extent to which Internet pharmacies are reliable in their business practices. We attempted to place up to 10 orders for each of 13 targeted prescription drugs, each from a different Internet pharmacy.⁵ (See table 1.) We generally attempted to purchase each of the 13 drugs both with and without a prescription, from a range of Internet pharmacies that purported or appeared to be located in the United States, Canada, and other foreign countries.⁶

⁴See U.S. General Accounting Office, *Internet Pharmacies: Hydrocodone, An Addictive Narcotic Pain Medication, Is Available Without a Prescription Through the Internet*, GAO-04-892T (Washington, D.C.: June 17, 2004).

⁵One of the drugs, Humulin N, is prescribed by physicians and is also available without a prescription. We included it among the drugs we ordered because of its special handling requirements.

⁶We determined the location of Internet pharmacies from which we received drug samples based on information contained in the pharmacy Web sites and the return addresses and postmarks on the packages we received. Throughout this testimony, Internet pharmacies from countries other than the United States or Canada are referred to as "other foreign Internet pharmacies."

Table 1: Prescription Drugs Selected for Purchase From Internet Pharmacies

Prescription drug	Condition treated	Remarks
Accutane®	Acne	Has special safety restrictions ^a
Celebrex®	Arthritis	--
Clozaril®	Schizophrenia	Has special safety restrictions ^a
Combivir®	HIV	--
Crixivan®	HIV	--
Epogen®	Anemia	Has special handling requirements
Humulin® N	Diabetes	Has special handling requirements
Lipitor®	High cholesterol	--
OxyContin®	Pain	Schedule II controlled substance, narcotic ^b
Percocet®	Pain	Schedule II controlled substance, narcotic ^b
Viagra®	Male sexual dysfunction	--
Vicodin®/hydrocodone	Pain	Schedule III controlled substance, narcotic ^b
Zoloft®	Depression	--

Source: GAO analysis of information from drug manufacturers and the Drug Enforcement Administration.

^aDue to health risks associated with using this drug, there are special safety restrictions imposed on its use and distribution in the United States, such as a requirement that patients undergo certain medical tests and restrictions on the distribution of this drug to physicians with special training or expertise. Because of the health risks, FDA advises consumers not to purchase this drug over the Internet.

^bThe Controlled Substances Act established a classification structure for drugs and chemicals used in the manufacture of drugs that are designated as controlled substances. Controlled substances are classified into five schedules on the basis of their medicinal value, potential for abuse, and safety or dependence liability. Schedule I is reserved for the most dangerous drugs that have no recognized medicinal use, while Schedule V is the classification used for the least dangerous drugs.

We identified whether the samples we received contained a pharmacy label⁷ with patient instructions for use and whether warnings were included on the labels or along with the packaging and made other observations about the manner in which the drugs were handled and the condition of the packaging. We forwarded the samples to the manufacturers of the drugs to determine whether they were FDA-

⁷The Federal Food, Drug, and Cosmetic Act defines "label" as the display of written, printed, or graphic matter upon the immediate container of any article and information required to be on the label must also be included on the outside container or wrapper, if any, of the retail package. *See* 21 U.S.C. § 321(k).

approved and authentic products, and identify any other safety concerns associated with the drugs or their handling.⁸ We also undertook measures to examine the reliability of Internet pharmacy business practices, such as attempting to confirm the locations of certain Internet pharmacies and identifying the pharmacy sites currently under investigation by federal agencies.

We conducted our work from January through June 2004 in accordance with generally accepted government auditing standards and in accordance with the standards of the President's Council on Integrity and Efficiency.

In summary, we were able to obtain the majority of prescription drugs we targeted for purchase from a wide variety of Internet pharmacies without providing a prescription. We obtained a total of 68 drug samples—each from a different pharmacy in the United States, Canada, or other foreign countries—representing 11 of the 13 drugs we targeted for purchase. Drug samples received from other foreign pharmacies came from Argentina, Costa Rica, Fiji, India, Mexico, Pakistan, Philippines, Spain, Thailand, and Turkey. The samples included drugs with special safety restrictions, and as addressed in our companion statement, we were also able to obtain addictive narcotic painkillers. Among the Internet pharmacies from which we obtained drugs, 5 U.S. and all 18 Canadian pharmacies required the patient to provide a prescription, whereas the remaining 24 U.S. and all 21 other foreign Internet pharmacies issued prescriptions based on their own medical questionnaires or had no prescription requirements.

We identified several problems associated with the handling, FDA-approval status, and authenticity of the 21 drug samples received from other foreign Internet pharmacies, but fewer problems among the 47 samples received from U.S. and Canadian Internet pharmacies. None of the 21 samples from other foreign pharmacies included dispensing pharmacy labels that provided instructions for use, and only about one-third included warning information. Thirteen of the 21 samples displayed other problems associated with the handling of the drugs, such as 3 samples of a temperature-sensitive drug sent in envelopes without insulation, and 5 samples containing tablets enclosed in punctured blister packs, potentially exposing the tablets to damaging light or moisture.

⁸FDA has noted that chemical analysis of prescription drug samples may not always detect slight changes in the manufacturing process or different types or amounts of inactive ingredients, which can affect the comparability and thus therapeutic equivalence of drug samples.

Manufacturers reported that most of the drug samples from other foreign pharmacies (19 of 21 samples) were unapproved for the U.S. market because, for example, the labeling⁹ or the facilities in which they were manufactured had not been approved by FDA; however, they reported that the chemical composition of all but 4 of the other foreign samples was comparable to the product we had ordered. Among the 4 exceptions, 2 samples were found to be counterfeit versions of the product we had ordered, containing a lesser amount of the active ingredient, and 2 samples had a significantly different chemical composition than that of the product we had ordered.¹⁰ In contrast, all 47 of the drug samples we received from U.S. and Canadian Internet pharmacies included dispensing pharmacy labels, 41 included warning information, and none displayed evidence of mishandling. Like the samples from other foreign pharmacies, most of those from Canada were also unapproved for the U.S. market; however, manufacturers determined that the chemical composition of all were comparable to the product we had ordered.

Some Internet pharmacies—mostly other foreign pharmacies—were not reliable in their business practices. We did not receive six of the orders we placed and paid for, five of which were placed with other foreign Internet pharmacies and one of which was placed with a pharmacy whose location we could not determine. Also, we determined that several of the drug samples were sent from locations that raise questions, such as from private residences. We also observed Internet pharmacies that obscured details about the drugs sold, such as other foreign pharmacies from which we ordered brand name drugs, but then received a generic or foreign version of the drug. Finally, about 21 percent of the Internet pharmacies that sent us samples were found to be under investigation by the Drug Enforcement Administration (DEA) or FDA. Reasons for the investigations included allegations of selling adulterated, misbranded, or counterfeit drugs and providing prescription drugs where no valid doctor-patient relationship exists. Nine of these pharmacies were from the United States, one from Canada, and four from other foreign countries.

⁹The term “labeling” is broader than the term “label” and includes all labels and other written, printed, or graphic matter upon an article or its container or wrapper, or that accompanies the article. *See* 21 U.S.C. § 321(m).

¹⁰Under federal law, counterfeit drugs include those sold under a product name without proper authorization, which falsely purport or are represented to be a particular product. *See* 21 U.S.C. § 321(g)(2). Counterfeit products may include products without the active ingredient, with an insufficient quantity of the active ingredient, or with the wrong active ingredient.

Background

In the United States, the practice of pharmacy is regulated by state boards of pharmacy, which establish and enforce standards intended to protect the public. State boards of pharmacy also license pharmacists and pharmacies. To legally dispense a prescription drug, a licensed pharmacist working in a licensed pharmacy must be presented a valid prescription from a licensed health care professional. The requirement that drugs be prescribed and dispensed by licensed professionals helps ensure patients receive the proper dose, take the medication correctly, and are informed about warnings, side effects, and other important information about the drug.

Under the Federal Food, Drug, and Cosmetic Act (FDCA), as amended, FDA is responsible for ensuring the safety, effectiveness, and quality of domestic and imported drugs. To gain approval for the U.S. market, a drug manufacturer must demonstrate that a drug is safe and effective, and that the manufacturing methods and controls that will be used in the specific facility where it will be manufactured meet FDA standards. The same drug manufactured in another facility not approved by FDA—such as a foreign-made version of an approved drug—may not be sold legally in the United States. Drugs are subject to other statutory and regulatory standards relating to purity, labeling, manufacturing, and packaging. Failure to meet these standards could result in a drug being considered illegal for sale in the United States.

The FDCA requires that drugs be dispensed with labels that include the name of the prescriber, directions for use, and cautionary statements, among other things. A drug is considered misbranded if its labeling or container is misleading, or if the label fails to include required information. Prescription drugs dispensed without a prescription are also considered misbranded. In addition, if a drug is susceptible to deterioration and must, for example, be maintained in a temperature-controlled environment, it must be packaged and labeled in accordance with regulations and manufacturer standards. Drugs must also be handled to prevent adulteration, which may occur, for example, if held under unsanitary conditions leading to possible contamination.

FDA-approved drugs manufactured in foreign countries, including those sold over the Internet, are subject to the same requirements as domestic drugs. Further, imported drugs may be denied entry into the United States if they “appear” to be unapproved, adulterated, or misbranded, among other things. While the importation of such drugs may be illegal, FDA has allowed individuals to bring small quantities of certain drugs into the United States for personal use under certain circumstances.

Most of the Targeted Prescription Drugs Were Purchased from Multiple Internet Pharmacies Without Providing A Prescription

We obtained 1 or more samples of 11 of the 13 drugs we targeted, both with and without a patient-provided prescription. Drug samples we received from other foreign pharmacies came from Argentina, Costa Rica, Fiji, India, Mexico, Pakistan, Philippines, Spain, Thailand, and Turkey. Most of the drugs—45 of 68—were obtained without a patient-provided prescription. These included drugs for which physician supervision is of particular importance due to the possibility of severe side effects, such as Accutane, or the high potential for abuse and addiction, such as the narcotic painkiller hydrocodone.¹¹ (See table 2.)

¹¹We purchased generic hydrocodone because it was much more readily available than the brand name drug Vicodin.

Table 2: Prescription Drugs Ordered and Received from Internet Pharmacies

Drug ordered	Orders placed ^a	Drug samples received ^b	Drug samples obtained without a prescription provided by the patient
Accutane	10	6 ^c	3
Celebrex	10	9	7
Clozaril	9	0	0
Combivir	6	5	1
Crixivan	6	6	2
Epogen	1	1	0
Humulin N	7	4	3
Lipitor	10	9	6
OxyContin	1	1	1
Percocet	0	0	0
Viagra	10	9	7
Vicodin/hydrocodone	10	9 ^{c,d}	9
Zoloft	10	9	6
Total	90	68	45

Source: GAO.

Note: The samples were shipped by FedEx (24), UPS (3), the U.S. Postal Service (39), and other couriers (2). Payments were made using Visa and MasterCard credit cards.

^aDoes not include attempted orders that were not accepted. We did not reach our goal of placing 10 orders for each drug because we could not always locate 10 sources from which we could purchase the drugs in a manner consistent with our methodology's protocols.

^bWe did not receive a drug sample for every order placed. Reasons included the drug being out of stock, a requirement that physicians prescribing certain drugs be part of a registry, and pharmacy requests for follow-up information we could not provide. In several instances, we could not determine why an order placed was not received.

^cIncludes one sample we could not link to an order we placed.

^dAlthough we placed orders for Vicodin, we did not receive any samples of the brand name version of the drug; all nine samples received were of the generic equivalent hydrocodone.

Although most of the samples we received were obtained without a patient-provided prescription, prescription requirements varied. Five U.S. and all 18 Canadian pharmacies from which we obtained drug samples required the patient to provide a prescription. The remaining 24 U.S. pharmacies generally provided a prescription based on a general medical questionnaire filled out online by the patient. Questionnaires requested information on the patient's physical characteristics, medical history, and condition for which drugs were being purchased. Several pharmacy Web

sites indicated that a U.S.-licensed physician reviews the completed questionnaire and issues a prescription. The other foreign Internet pharmacies we ordered from generally had no prescription requirements, and many did not seek information regarding the patient's medical history or condition. The process for obtaining a drug from many of these pharmacies involved only selecting the desired medication and submitting the necessary billing and shipping information. (See table 3.)

Table 3: Prescription Requirements of Pharmacies from which We Obtained Samples

Prescription requirement	U.S. Internet pharmacies	Canadian Internet pharmacies	Other foreign Internet pharmacies
Prescription from patient's physician must be provided	5	18	0
Web site provides prescription based on questionnaire	24	0	3
No prescription required	0	0	18

Source: GAO.

Most Problems Identified among Drug Samples Received from Other Foreign Internet Pharmacies

None of the 21 prescription drug samples we received from other foreign Internet pharmacies included a dispensing pharmacy label that provided patient instructions for use, and only 6 of these samples came with warning information.¹² Lack of instructions and warnings on these drugs leaves consumers who take them at risk for potentially dangerous drug interactions or side effects from incorrect or inappropriate use. For example, we received 2 samples purporting to be Viagra, a drug used to treat male sexual dysfunction, without any warnings or instructions for use. (See fig. 1.) According to its manufacturer, this drug should not be prescribed for individuals who are currently taking certain heart medications, as it can lower blood pressure to dangerous levels. Additionally, two samples of Roaccutan, a foreign version of Accutane, arrived without any instructions in English. (See fig. 2.) Possible side effects of this drug include birth defects and severe mental disturbances. Compounding the concerns regarding the lack of warnings and patient instructions for use, none of the other foreign pharmacies ensured patients were under the care of a physician by requiring that a prescription be submitted before the order is filled.

¹²One of the samples we received from other foreign pharmacies included a dispensing pharmacy label; however, this label lacked patient instructions for use.

Figure 1: Drug Sample Received Without Any Warnings or Instructions



Source: GAO.

Note: Sample purporting to be Viagra® arrived without any warning information or instructions for use.

Figure 2: Drug Sample Received Without Any Instructions in English



Source: GAO.

Note: Sample of Roaccutan®, a foreign version of Accutane®, arrived without instructions for use in English.

We observed other evidence of improper handling among 13 of the 21 drug samples we received from other foreign Internet pharmacies. For example, 3 samples of Humulin N were not shipped in accordance with manufacturer handling specifications. Despite the requirement that this drug be stored under temperature-controlled and insulated conditions, the samples we received were shipped in envelopes without insulation. (See fig. 3.) Similarly, 6 samples of other drugs were shipped in unconventional packaging, in some instances with the apparent intention of concealing the actual contents of the package. For example, the sample purporting to be OxyContin was shipped in a plastic compact disc case wrapped in brown packing tape—no other labels or instructions were included, and a sample of Crixivan was shipped inside a sealed aluminum can enclosed in a box labeled “Gold Dye and Stain Remover Wax.” (See fig. 4.) Additionally, 5 samples we received were damaged and included tablets that arrived in

punctured blister packs, potentially exposing pills to damaging light or moisture. (See fig. 5.) One drug manufacturer noted that damaged packaging may also compromise the validity of drug expiration dates.

Figure 3: Drug Sample Shipped Improperly



Source: GAO.

Note: Despite the requirement that Humulin®N be stored under temperature-controlled and insulated conditions, samples we received were shipped in an envelope without insulation.

Figure 4: Drug Samples Shipped in Unconventional Packaging



Source: GAO.

Note: Sample purporting to be OxyContin® was shipped in a plastic compact disc case wrapped in brown packing tape—no other labels or instructions were included.



Source: GAO.

Note: Sample of Crixivan® was shipped inside a sealed aluminum can enclosed in a box labeled “Gold Dye and Stain Remover Wax.”

Figure 5: Drug Sample Received in Damaged Packaging



Source: GAO.

Note: Sample of Crixivan®, a moisture sensitive drug, arrived in punctured blister packs.

Among the 21 drug samples from other foreign pharmacies, manufacturers determined that 19 were not approved for the U.S. market for various reasons, including that the labeling or the facilities in which they were manufactured had not been approved by FDA.¹³ For example, the manufacturer of one drug noted that 2 samples we received of that drug were packaged under an alternate name used for the Mexican market. The manufacturer of another drug found that 3 samples we received of that drug were manufactured at a facility unapproved to produce drugs for the U.S. market. In all but 4 instances, however, manufacturers determined that the chemical composition of the samples we received from other foreign Internet pharmacies was comparable to the chemical composition of the drugs we had ordered. Two samples of one drug were found by the

¹³The manufacturer of one of the remaining two samples determined it was approved for the U.S. market and the manufacturer of the other sample could not make a determination.

manufacturer to be counterfeit and contained a different chemical composition than the drug we had ordered. In both instances the manufacturer reported that samples had less quantity of the active ingredient, and the safety and efficacy of the samples could not be determined. Manufacturers also found 2 additional samples to have a significantly different chemical composition than that of the product we ordered.

In contrast to the drug samples received from other foreign Internet pharmacies, all 47 of the prescription drug samples we received from Canadian and U.S. Internet pharmacies included labels from the dispensing pharmacy that generally provided patient instructions for use and 87 percent of these samples (41 of 47) included warning information. Furthermore, all samples were shipped in accordance with special handling requirements, where applicable, and arrived undamaged. Manufacturers reported that 16 of the 18 samples from Canadian Internet pharmacies were unapproved for sale in the United States, citing for example unapproved labeling and packaging. However, the samples were all found to be comparable in chemical composition to the products we ordered. Finally, the manufacturer found that 1 sample of a moisture-sensitive medication from a U.S. Internet pharmacy was inappropriately removed from the sealed manufacturer container and dispensed in a pharmacy bottle.

Table 4 summarizes the problems we identified among the 68 samples we received.

Table 4: Problems Observed Among Prescription Drug Samples Received

Pharmacy location	No pharmacy label with instructions for use (23 samples)	No warning information (21 samples)	Improperly shipped or dispensed (4 samples)	Unconventional packaging (6 samples)	Damaged packaging (5 samples)	Not approved for U.S. market (35 samples)	Counterfeit or otherwise not comparable to product ordered (4 samples)
Canadian		Celebrex (2) Zoloft (2)				Accutane (3) Combivir (3) Crixivan (3) Humulin N (1) Lipitor (2) Viagra (1) Zoloft (3)	
Other foreign	Accutane (3) Celebrex (3) Combivir (1) Crixivan (2) Humulin N (3) Lipitor (3) OxyContin (1) Viagra (2) Zoloft (3)	Accutane (2) Celebrex (3) Crixivan (2) Lipitor (3) OxyContin (1) Viagra (2) Zoloft (2)	Humulin N (3)	Accutane (1) Celebrex (1) Crixivan (2) OxyContin (1) Viagra (1)	Accutane (2) Celebrex (1) Crixivan (1) Lipitor (1)	Accutane (2) Celebrex (3) Combivir (1) Crixivan (1) Humulin N (3) Lipitor (3) OxyContin (1) Viagra (2) Zoloft (3)	Accutane (1) OxyContin (1) Viagra (2)
U.S.	Celebrex (1) Zoloft (1)	Lipitor (1) Zoloft (1)	Crixivan (1)				

Source: GAO and drug manufacturers.

Notes: Drug names indicated are those that GAO ordered. The samples we received were not the brand name drugs we ordered in all instances.

Drug samples do not add to 68 because some samples exhibited more than one problem.

Some Internet Pharmacies Were Not Reliable in Their Business Practices

We observed questionable characteristics and business practices of some of the Internet pharmacies from which we received drugs. We ultimately did not receive six of the orders we placed and paid for, suggesting the potential fraudulent nature of some Internet pharmacies or entities representing themselves as such.¹⁴ The six orders were for Clozaril, Humulin N, and Vicodin, and cost over \$700 in total. Five of these orders were placed with non-Canadian foreign pharmacies and one was placed with a pharmacy whose location we could not determine. We followed up with each pharmacy in late April and early May of 2004 to determine the

¹⁴The National Association of Boards of Pharmacy has also reported receiving complaints from consumers who state they have provided payment to various Internet pharmacies, but have not received the products ordered.

status. Three indicated they would reshipe the product, but as of June 10, 2004, we had not received the shipments. Three others did not respond to our inquiry.¹⁵

We determined that at least eight of the return addresses included on samples we received from other foreign Internet pharmacies were shipped from locations that raise questions about the entities that provided the samples. For example, we found a shopping mall in Buenos Aires, Argentina, at the return address provided on a sample of Lipitor. Authorities assisting us in locating this address found it impossible to identify which, if any, of the many retail stores mailed the package. The return address for a sample of Celebrex was found to be a business in Cozumel, Mexico, but representatives of that business informed authorities that it had no connection to an Internet pharmacy operation. Finally, the return addresses on samples of Humulin N and Zoloft were found to be private residences in Lahore, Pakistan.

Certain practices of Internet pharmacies may render it difficult for consumers to know exactly what they are buying. Some non-Canadian foreign Internet pharmacies appeared to offer U.S. versions of brand name drugs on their Web sites, but attempted to substitute an alternative drug during the order process. In some cases, other foreign pharmacies substituted alternative drugs after the order was placed. For example, one Internet pharmacy advertised brand name Accutane, which we ordered. The sample we received was actually a generic version of the drug made by an overseas manufacturer.

About 21 percent of the Internet pharmacies from which we received drugs (14 of 68) were under investigation by regulatory agencies. The reasons for the investigations by DEA and FDA include allegations of selling controlled substances without a prescription; selling adulterated, misbranded, or counterfeit drugs; selling prescription drugs where no doctor-patient relationship exists; smuggling; and mail fraud. The pharmacies under investigation were concentrated among the U.S. pharmacies that did not require a patient-provided prescription (nine) and other foreign (four) pharmacies. One Canadian pharmacy was also included among those under investigation.

¹⁵We received no notice from federal agencies indicating that our drug samples had been seized, nor did the Internet pharmacies we contacted about unreceived shipments indicate they had received such notification.

Concluding Observations

Consumers can readily obtain many prescription drugs over the Internet without providing a prescription—particularly from certain U.S. and foreign Internet pharmacies outside of Canada. Drugs available include those with special safety restrictions, for which patients should be monitored for side effects, and narcotics, where the potential for abuse is high. For these types of drugs in particular, a prescription and physician supervision can help ensure patient safety. In addition to the lack of prescription requirements, some Internet pharmacies can pose other safety risks for consumers. Many foreign Internet pharmacies outside of Canada dispensed drugs without instructions for patient use, rarely provided warning information, and in four instances provided drugs that were not the authentic products we ordered. Consumers who purchase drugs from foreign Internet pharmacies that are outside of the U.S. regulatory framework may also receive drugs that are unapproved by FDA and manufactured in facilities that the agency has not inspected. Other risks consumers may face were highlighted by the other foreign Internet pharmacies that fraudulently billed us, provided drugs we did not order, and provided false or questionable return addresses. It is notable that we identified these numerous problems despite the relatively small number of drugs we purchased, consistent with problems recently identified by state and federal regulatory agencies.

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

Contacts and Acknowledgments

For future contacts regarding this testimony, please call Marcia Crosse at (202) 512-7119. Other individuals who made key contributions include Randy DiRosa, Margaret Smith, and Corey Houchins-Witt.

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