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Report to the Chairman, Permanent Subcommittee on Investigations, Committee on Governmental Affairs, U.S. Senate

June 2004

INTERNET PHARMACIES

Some Pose Safety Risks for Consumers

GAO-04-820

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GAO Accountability • Integrity • Reliability

Highlights

Highlights of GAO-04-820, a report to the Chairman, Permanent Subcommittee on Investigations, Committee on Governmental Affairs, U.S. Senate

Why GAO Did This Study

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

GAO was asked to examine (1) the extent to which certain drugs can be purchased over the Internet without a prescription; (2) whether the drugs are handled properly, approved by the Food and Drug Administration (FDA), and authentic; and (3) the extent to which Internet pharmacies are reliable in their business practices. GAO attempted to purchase up to 10 samples of 13 different drugs, each from a different pharmacy Web site, including sites in the United States, Canada, and other foreign countries. GAO determined whether the samples contained a pharmacy label with patient instructions for use and warnings on the labels or the packaging and forwarded the samples to their manufacturers to determine whether they were approved by FDA and authentic. GAO also confirmed the locations of several Internet pharmacies and identified those under investigation by regulatory agencies.

www.gao.gov/cgi-bin/getrpt?GAO-04-820.

To view the full product, including the scope and methodology, click on the link above. For more information, contact Marcia Crosse at (202) 512-7119 or Robert J. Cramer at (202) 512-7455.

What GAO Found

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

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

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

In commenting on a draft of this report, FDA generally agreed with its findings and conclusions.

Contents

Abbreviations

DEA	Drug Enforcement Administration
FDA	Food and Drug Administration
FDCA	Federal Food, Drug, and Cosmetic Act
NABP	National Association of Boards of Pharmacy
VIPPS	Verified Internet Pharmacy Practice Sites

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Accountability * Integrity * Reliability

United States General Accounting Office
Washington, D.C. 20548

June 17, 2004

The Honorable Norm Coleman
Chairman
Permanent Subcommittee on Investigations
Committee on Governmental Affairs
United States Senate

Dear Mr. Chairman:

As both the demand for and the cost of prescription medications have increased, the Internet has emerged as a growing marketplace for the purchase of prescription drugs. Internet pharmacies offer benefits for consumers, such as the convenience of shopping from home 24 hours a day and the ability to compare prices offered by multiple vendors. Various types of pharmacies offer prescription drugs over the Internet, including pharmacies that sell a wide range of drugs, require a patient to provide a prescription, and are sometimes associated with traditional chain drug stores, and other pharmacies that issue a prescription based on an online medical history questionnaire or have no prescription requirement.[1]

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

[1] Throughout this report, we refer to each Internet Web site selling prescription drugs as an Internet pharmacy.

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

regarding the business practices of some Internet pharmacies have raised further concerns associated with the use of Internet pharmacies to obtain prescription drugs.

You asked us to assess:

1. the extent to which certain prescription drugs can be purchased over the Internet without a prescription;

2. whether drugs sold by Internet pharmacies are handled properly, are FDA-approved, and authentic; and

3. the extent to which Internet pharmacies are reliable in their business practices.

To determine the extent to which certain prescription drugs can be purchased over the Internet, we attempted to place up to 10 orders for each of 13 drugs, each from a different online pharmacy. The 13 targeted drugs included top selling drugs, drugs with special safety restrictions or handling requirements, drugs that have been counterfeited in the past, and narcotics.[3,4] (See table 1.) We generally attempted to purchase each of the 13 drugs with and without a prescription and produced our own prescriptions to enable us to do so. [5]

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

[4] The Controlled Substances Act established a classification structure for drugs and chemicals used in the manufacture of drugs that are designated as controlled substances. Controlled substances are classified into five schedules on the basis of their medicinal value, potential for abuse, and safety or dependence liability. Schedule I is reserved for the most dangerous drugs that have no recognized medicinal use, while Schedule V is the classification used for the least dangerous drugs. We attempted to purchase Schedule II and Schedule III narcotics. *See* 21 U.S.C. §§ 811 and 812.

[5]Due to the heightened regulation of controlled substances, we did not attempt to purchase narcotics from pharmacies that required patients to submit a prescription from their physicians.

Table 1: Prescription Drugs Selected for Purchase from Internet Pharmacies

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

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

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

We purchased drugs from Internet pharmacies that purported or appeared to be located in the United States, Canada, and other foreign countries.[6] We purchased drugs from Internet pharmacies with varying prescription requirements—some required purchasers to provide a prescription; some required purchasers to fill out an online medical history questionnaire, based on which a physician affiliated with the pharmacy issued a prescription; and some had no prescription requirement. We also purchased drugs from Internet pharmacies that are licensed online

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

providers of prescription drugs.[7] To identify the Internet pharmacies, we relied upon a list of Internet pharmacy Web sites compiled by a private consultant and provided to us by FDA; used Internet search engines, including Google, Yahoo, and Excite; and joined Internet pharmacy members-only Web sites, which provide enrolled members with lists of Web sites selling various prescription drugs. Because the universe of Internet pharmacies is not known, and because we obtained only one drug sample[8] from each pharmacy, our findings cannot be generalized.

To assess whether the drug samples we received were handled properly, we identified whether the samples contained a pharmacy label[9] with patient instructions for use and whether warnings were included on the labels or along with the packaging. We define handling as the manner in which Internet pharmacies labeled, packaged, and shipped the prescription drug samples we received. In addition, we made other observations about the manner in which the drugs were handled and the condition of the packaging.[10] To assess whether the drug samples we received were FDA-approved and authentic products, we forwarded the samples to manufacturers of the drugs that we ordered to make these determinations[11] and identify any other safety concerns associated with the drugs or their

[7] We selected these Internet pharmacies from among those associated with large drugstore chains and those certified as Verified Internet Pharmacy Practice Sites (VIPPS) by the National Association of Boards of Pharmacy (NABP). VIPPS certification is voluntary and indicates that the pharmacy meets applicable state licensure requirements and certain other criteria established by NABP.

[8] This report uses the word "samples" to refer to our purchases of drugs from Internet pharmacies rather than to those drugs provided to practitioners and others for the purpose of promoting drug sales. *See* 21 U.S.C. § 353(c)(1)(2000).

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

[10] We did not conduct a comprehensive review of the pharmacies' compliance with all applicable federal and state laws and regulations.

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

handling.[12] Where manufacturers commented on the adequacy of patient instructions for use or warnings, we relied upon their assessments rather than our own judgment. We did not disclose to the manufacturers information concerning the source of the drug samples we purchased, including whether the pharmacy purported to be located in the United States, Canada, or in another foreign country.

To examine the reliability of the business practices of Internet pharmacies, we contacted Internet pharmacy customer service staff and several of the processing centers or brokers that handled the transactions. We also compared the return addresses of some drug samples received against the business addresses provided by the processing centers or brokers and listed on the Internet Web sites. Where the packaging of the drug samples received from foreign Internet pharmacies raised questions, we coordinated with Drug Enforcement Administration (DEA) to obtain information about the physical entity located at the return address on the package and the tenants or owners of the property. Finally, we obtained information from DEA and FDA regarding their ongoing investigations of organizations associated with the Internet pharmacies from which we purchased drugs.

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

Results In Brief

We were able to obtain the majority of prescription drugs we targeted for purchase from a wide variety of domestic and foreign Internet pharmacies without providing a prescription. We obtained a total of 68 drug samples—each from a different pharmacy in the United States, Canada, or other foreign countries—representing 11 of the 13 drugs we targeted for purchase.[13] Drug samples received from other foreign pharmacies came from Argentina, Costa Rica, Fiji, India, Mexico, Pakistan, Philippines, Spain, Thailand, and Turkey. The samples included drugs with special

[12] We sent samples of the generic drug hydrocodone to the manufacturer of Vicodin for testing.

[13] We did not obtain samples of 2 of the 13 drugs we targeted for purchase. We placed nine orders for one of the drugs but received none, and we identified no source from which to purchase the other drug in a manner consistent with our methodology's protocols.

safety restrictions and addictive narcotic painkillers. Among the Internet pharmacies from which we obtained drugs, 5 U.S. and all 18 Canadian pharmacies required the patient to provide a prescription, whereas the remaining 24 U.S. and all 21 other foreign Internet pharmacies issued prescriptions based on their own medical questionnaires or had no prescription requirements. The availability and ease with which the drugs could be purchased varied by drug type. Top selling drugs such as Celebrex, Lipitor, Viagra, and Zoloft were readily available from multiple Internet pharmacies. Other drugs, such as those with special safety restrictions—Accutane and Clozaril—and narcotic painkillers—Percocet, OxyContin, and Vicodin—were offered for sale by fewer Internet pharmacies or were otherwise more difficult to obtain.

We identified several problems associated with the handling, FDA-approval status, and authenticity of the 21 drug samples received from other foreign Internet pharmacies, but fewer problems among the U.S. and Canadian Internet pharmacies. None of the 21 samples from other foreign pharmacies included dispensing pharmacy labels that provided instructions for use, and only about one-third included warning information. Thirteen of the 21 samples displayed other problems associated with the handling of the drugs. For example, 3 samples of a drug that should be shipped in a temperature-controlled environment arrived in envelopes without insulation, and 5 samples contained tablets enclosed in punctured blister packs, potentially exposing the tablets to damaging light or moisture. Finally, manufacturers reported that most of the drug samples from other foreign pharmacies (19 of 21 samples) were unapproved for the U.S. market because, for example, the labeling[14] or the facilities in which they were manufactured had not been approved by FDA; however, they reported that the chemical composition of all but 4 of the other foreign samples was comparable to the product we had ordered. Among the 4 exceptions, 2 samples were found to be counterfeit versions of the product we had ordered, containing a lesser amount of the active

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

ingredient, and 2 samples had a significantly different chemical composition than that of the product we had ordered.[15] In contrast, all 47 of the drug samples we received from U.S. and Canadian Internet pharmacies included dispensing pharmacy labels that generally provided patient instructions for use, 41 included warning information, and none displayed evidence of mishandling. Like the samples received from other foreign pharmacies, most of those from Canada were also unapproved for the U.S. market; however, manufacturers determined that the chemical composition of all were comparable to the product we had ordered. Finally, manufacturer testing identified 1 sample from a U.S. pharmacy that was inappropriately removed from the sealed manufacturer container and dispensed in a pharmacy bottle.

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

We provided a draft of this report to FDA, which generally agreed with our findings and conclusions. We provided a draft of this report to DEA for a technical review and it informed us it had no comments. We also provided each manufacturer with segments of this draft report that related to its product(s). They provided technical comments, which we incorporated where appropriate.

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

Background

Three general types of Internet pharmacies sell prescription drugs directly to consumers. First, some Internet pharmacies operate much like traditional drugstores, selling a wide range of prescription drugs and requiring consumers to submit a prescription from their physicians before their orders are filled. In some instances, these Internet pharmacies are affiliated with traditional chain drug stores. Second, other Internet pharmacies may sell a more limited range of drugs, often specializing in certain lifestyle medications, such as those that treat sexual dysfunction or assist in weight control. These Internet pharmacies typically require consumers to fill out an online medical history questionnaire in place of a traditional examination by a physician, and issue a prescription after a physician affiliated with the pharmacy reviews the questionnaire. Still other Internet pharmacies dispense drugs without a prescription.

In the United States, the practice of pharmacy is regulated by state boards of pharmacy, which establish and enforce standards intended to protect the public. State boards of pharmacy also license pharmacists and pharmacies.[16] To legally dispense a prescription drug, a licensed pharmacist working in a licensed pharmacy must be presented a valid prescription from a licensed health care professional.[17] The requirement that drugs be prescribed and dispensed by licensed professionals helps ensure patients receive the proper dose, take the medication correctly, and are informed about warnings, side effects, and other important information about the drug.

[16] Most states also license out-of-state pharmacies that dispense drugs to state residents, and some states regulate Internet pharmacies in a similar manner. See GAO-01-69.

[17] States also license health care professionals, grant them prescribing privileges, and outline standards of practice in state medical practice laws.

Under the Federal Food, Drug, and Cosmetic Act (FDCA), as amended, FDA is responsible for ensuring the safety, effectiveness, and quality of domestic and imported drugs. To do so, FDA establishes standards for the safety, effectiveness, and manufacture of drugs that must be met before they are approved for the U.S. market. To gain approval, a drug manufacturer must demonstrate that a drug is safe and effective, and that the manufacturing methods and controls that will be used in the specific facility where it will be manufactured meet FDA standards. The same drug manufactured in another facility not approved by FDA—such as a foreign-made version of an approved drug—may not be sold legally in the United States. Drugs are subject to other statutory and regulatory standards relating to purity, labeling, manufacturing, and packaging.[18] Failure to meet these standards could result in a drug being considered adulterated or misbranded and therefore illegal for sale, which could result in FDA enforcement action.[19]

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

[18] *See, e.g.*, 21 U.S.C. §§ 351(b), 352(g), 352(h), 352(p), 355(d); 21 C.F.R. pts. 201 and 210 (2003). Additional requirements apply to controlled substances under the Controlled Substances Act and DEA's implementing regulations.

[19] Other federal agencies also play a role with respect to the regulation of prescription drugs under various circumstances. See GAO-01-69. GAO is currently reviewing available data on the volume of prescription drugs entering the United States through the Postal Service and private couriers and the policies and practices of federal agencies charged with preventing unapproved prescription drugs from entering the country.

FDA-approved drugs manufactured in foreign countries, including those sold over the Internet, are subject to the same requirements as domestic drugs.[20] Further, imported drugs may be denied entry into the United States if they "appear" to be unapproved, adulterated, or misbranded, among other things. While the importation of such drugs may be illegal, FDA has allowed individuals to bring small quantities of certain drugs into the United States for personal use under certain circumstances.[21]

Internet pharmacies pose challenges for regulators. State boards of pharmacy in many states have reported difficulty identifying Internet pharmacies located outside of their borders and have limited ability and authority to investigate and act against pharmacies that do not comply with state pharmacy laws when they are identified. In 2000, nearly half of the state boards had identified consumer complaints against Internet pharmacies or reported problems with Internet pharmacies not complying with state pharmacy laws. Additionally, state medical boards have reported receiving complaints about physicians prescribing drugs over the Internet without performing an examination of the patient.[22] Federal agencies have taken steps to stop the illegal sales of prescription drugs and other substances by Internet pharmacies. For example, FDA has taken enforcement actions against Internet pharmacies; the Department of Justice has prosecuted Internet pharmacies and physicians for dispensing medications without a valid prescription; and DEA has investigated Internet pharmacies for illegal distribution of controlled substances.

[20] The recently enacted Medicare Prescription Drug, Improvement, and Modernization Act of 2003 directed the Secretary of Health and Human Services to create a system for the importation of prescription drugs from Canada upon certification that the implementation of the program would (1) pose no additional risk to the public's health and safety and (2) result in a significant reduction in the cost of covered products to the American consumer. The act directed the Secretary to complete a study on drug importation from Canada within 1 year of enactment. *See* Pub. L. No. 108-173, §§ 1121, 1122, 117 Stat. 2066, 2464-69 (to be codified at 21 U.S.C. §§ 384, 384 note).

[21] FDA guidelines indicate that agency officials may use their discretion to allow importation if (1) the intended use is identified, is not for a serious condition, and the product is not known to represent a significant health risk; or (2) if the intended use is unapproved and for a serious condition for which effective treatment may not be available domestically, and other conditions are also met. See Chapter 9 of FDA's *Regulatory Procedures Manual*. http://www.fda.gov/ora/compliance_ref/rpm/default.htm. Downloaded June 10, 2004.

[22] In 2000, 39 of 45 state medical boards responding to our survey indicated that a physician who issued a prescription on the basis of an online questionnaire would not satisfy the standard of good medical practice required under their states' laws. See GAO-01-69.

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

We were able to obtain the majority of prescription drugs we targeted for purchase from a wide variety of domestic and foreign Internet pharmacies without providing a prescription. Five U.S. and all 18 Canadian pharmacies from which we obtained drug samples required a patient-provided prescription, whereas the remaining 24 U.S. and all 21 other foreign pharmacies from which we obtained samples either provided a prescription based on an online medical questionnaire or had no prescription requirement. Although we obtained samples of most of the drugs we targeted for purchase, some drugs, such as those with special safety restrictions and narcotics, were available from fewer sources or were more difficult to obtain.

Samples of 11 of 13 Targeted Drugs Obtained from Internet Pharmacies

We obtained 1 or more samples of 11 of the 13 drugs we targeted, both with and without a patient-provided prescription. In total, we placed 90 orders—each with a different Internet pharmacy in the United States, Canada, and other foreign countries—and received 68 samples. Drug samples we received from other foreign pharmacies came from Argentina, Costa Rica, Fiji, India, Mexico, Pakistan, Philippines, Spain, Thailand, and Turkey. Most of the drugs—45 of 68—were obtained without a patient-provided prescription. These included drugs for which physician supervision is of particular importance due to the possibility of severe side effects, such as Accutane, or the high potential for abuse and addiction, such as the narcotic painkiller hydrocodone. (See table 2.)

Table 2: Prescription Drugs Ordered and Received from Internet Pharmacies

Drug ordered	Orders placed[a]	Drug samples received[b]	Drug samples obtained without a prescription provided by the patient
Accutane	10	6[c]	3
Celebrex	10	9	7
Clozaril	9	0	0
Combivir	6	5	1
Crixivan	6	6	2
Epogen	1	1	0
Humulin N	7	4	3
Lipitor	10	9	6
OxyContin	1	1	1

(Continued From Previous Page)

Drug ordered	Orders placed[a]	Drug samples received[b]	Drug samples obtained without a prescription provided by the patient
Percocet	0	0	0
Viagra	10	9	7
Vicodin/hydrocodone	10	9[c,d]	9
Zoloft	10	9	6
Total	**90**	**68**	**45**

Source: GAO.

Note: The samples were shipped by FedEx (24), UPS (3), the U.S. Postal Service (39), and other couriers (2).

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

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

[c]Includes one sample we could not link to an order we placed.

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

Although most of the samples we received were obtained without a patient-provided prescription, prescription requirements varied. Five U.S. and all 18 Canadian pharmacies from which we obtained drug samples required the patient to provide a prescription. The remaining 24 U.S. pharmacies generally provided a prescription based on a general medical questionnaire filled out online by the patient. Questionnaires requested information on the patient's physical characteristics, medical history, and condition for which drugs were being purchased. Several pharmacy Web sites indicated that a U.S.-licensed physician reviews the completed questionnaire and issues a prescription. The other foreign Internet pharmacies we ordered from generally had no prescription requirements, and many did not seek information regarding the patient's medical history or condition. The process for obtaining a drug from many of these pharmacies involved only selecting the desired medication and submitting the necessary billing and shipping information. (See table 3.)

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

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

Source: GAO.

The Availability and Ease of Purchase Varied by Drug

While we obtained samples of most of the drugs we targeted for purchase on the Internet, certain drugs were more widely available and easier to purchase than others. The top selling drugs Celebrex (a pain reliever), Lipitor (a cholesterol-lowering drug), Viagra (a medication for male sexual dysfunction), and Zoloft (an antidepressant) were available from multiple pharmacies. We placed 10 orders for each of these four drugs with little difficulty.

Other drugs were available from fewer sources or were more difficult to obtain. Some of our orders for drugs with special safety restrictions were more closely scrutinized. For example, one order we placed for Accutane was declined by a U.S. pharmacy. Accutane is an acne medication that may cause birth defects and serious mental disturbances leading to suicide among some users. The pharmacy indicated that it declined our order because the physician was not included on a national registry of qualified prescribers.[23] Similarly, one U.S. and one Canadian Internet pharmacy declined our order for Clozaril. According to its manufacturer, patients taking Clozaril, an antipsychotic medication, must have ongoing blood tests to monitor for the development of a fatal blood disorder that can occur during treatment. The U.S. pharmacy that declined our order indicated that Clozaril should not have been offered for sale on its Web site, and the Canadian pharmacy indicated that more stringent prescription

[23] Risk management protocols developed by the manufacturer in agreement with FDA prohibit U.S. pharmacies from accepting electronic prescriptions for this drug.

requirements prevented it from dispensing the drug to patients outside of Canada.

Narcotic pain medications—OxyContin, Percocet, and Vicodin—were also less readily available. Despite extensive searching of Internet pharmacy sites, we found few that sold these drugs without a prescription. Other factors also hindered our ability to purchase these drugs. For example, some pharmacies that advertised the narcotics did not actually sell them. Rather, they attempted to substitute a different, often less potent and nonnarcotic drug once the order was placed. In addition, several pharmacies that offered narcotics required payment by means that were beyond our scope, such as check, bank transfers, or "e-gold" exchanges.[24] We were able to place orders for the generic version of Vicodin at several U.S. pharmacies; however, some of these pharmacies required not only an online medical questionnaire, but also a telephone consultation with a pharmacy-designated physician in order to obtain a prescription. Finally, we were able to place only one order for a drug purporting to be OxyContin, and only after locating the source by paying a membership fee and joining an Internet pharmacy drug club, which referred us to the site.

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

We identified several problems associated with the handling, FDA-approval status, and authenticity of the 21 drug samples we received from other foreign Internet pharmacies. None included required pharmacy labels that provided patient instructions for use, and few provided warning information. Thirteen were shipped improperly, were packaged unconventionally, or arrived damaged. Manufacturers reported that most of the samples they reviewed at our request from other foreign pharmacies were not approved by FDA for the United States—although most had a comparable chemical composition to the product we ordered—and 4 were either counterfeit products or otherwise not comparable to the product we ordered. While most of the samples received from Canadian Internet pharmacies were unapproved for the U.S. market, they otherwise had a comparable chemical composition, and the samples from U.S. and Canadian pharmacies exhibited few problems otherwise. Table 4 summarizes the problems we identified among the 68 samples we received.

[24] "e-gold" is a system where sellers and buyers can establish accounts and electronically exchange values or amounts of gold in order to complete Internet transactions.

Table 4: Problems Observed Among Prescription Drug Samples Received

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

Source: GAO and drug manufacturers.

Notes:

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

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

All Drug Samples Received from Other Foreign Pharmacies Exhibited Problems Associated with Their Handling

None of the 21 prescription drug samples we received from other foreign Internet pharmacies included a dispensing pharmacy label that provided patient instructions for use, and only 6 of the samples came with warning information.[25] Lack of instructions and warnings on these drugs leaves consumers who take them at risk for potentially dangerous drug interactions or side effects from incorrect or inappropriate use. For example, we received 2 samples purporting to be Viagra, a drug used to treat male sexual dysfunction, without any warnings or instructions for use. (See fig. 1.) According to its manufacturer, this drug should not be

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

prescribed for individuals who are currently taking certain heart medications, as it can lower blood pressure to dangerous levels. Additionally, 2 samples of Roaccutan, a foreign version of Accutane, arrived without any instructions in English. (See fig. 2.) As noted, possible side effects of this drug include birth defects and severe mental disturbances. Compounding the concerns regarding the lack of warnings and patient instructions for use, none of the other foreign pharmacies ensured patients were under the care of a physician by requiring that a prescription be submitted before the order is filled.

Figure 1: Drug Sample Received Without Any Warnings or Instructions

Source: GAO.

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

Figure 2: Drug Sample Received Without Any Instructions in English

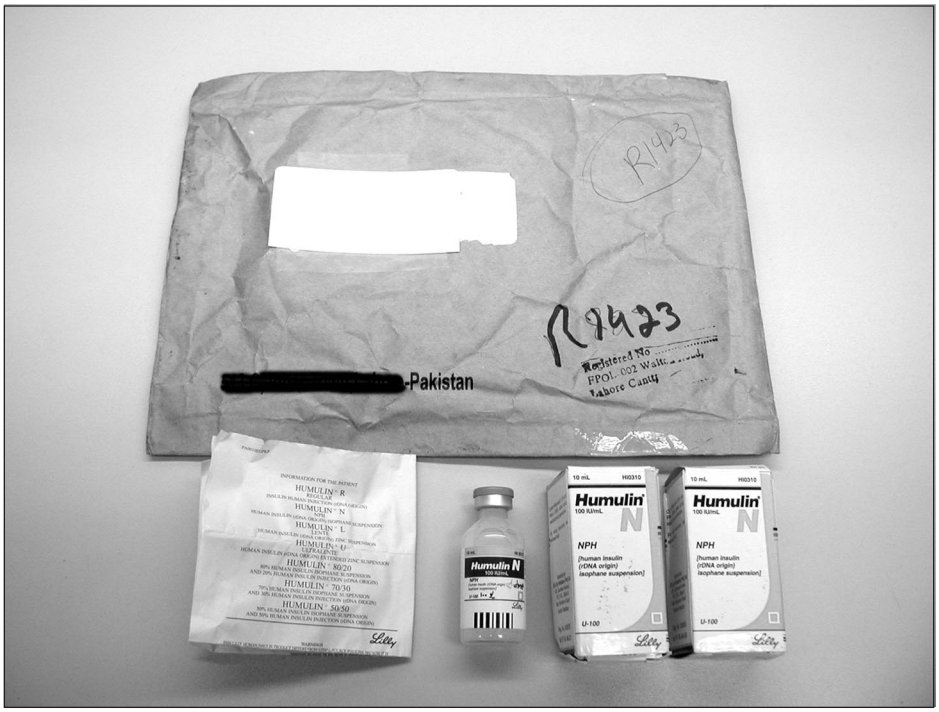
Source: GAO.

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

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

samples we received were damaged and included tablets that arrived in punctured blister packs, potentially exposing pills to damaging light or moisture. (See fig. 5.) One drug manufacturer noted that damaged packaging may also compromise the validity of drug expiration dates.

Figure 3: Drug Sample Shipped Improperly



Source: GAO.

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

Figure 4: Drug Samples Shipped in Unconventional Packaging

Source: GAO.

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

Source: GAO.

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

Figure 5: Drug Sample Received in Damaged Packaging

Source: GAO.

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

Most Drug Samples Received from Other Foreign Pharmacies Were Unapproved, Four Were Not Authentic

Among the 21 drug samples from other foreign pharmacies, manufacturers determined that 19 were not approved for the U.S. market for various reasons, including that the labeling or the facilities in which they were manufactured had not been approved by FDA.[26] For example, the manufacturer of one drug noted that 2 samples we received of that drug were packaged under an alternate name used for the Mexican market. The manufacturer of another drug found that 3 samples we received of that drug were manufactured at a facility unapproved to produce drugs for the U.S. market. In all but 4 instances, however, manufacturers determined that the chemical composition of the samples we received from other foreign Internet pharmacies was comparable to the chemical composition

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

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

Drugs Received from Canadian and U.S. Internet Pharmacies Exhibited Fewer Problems

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

Some Internet Pharmacies Were Not Reliable in Their Business Practices

We observed questionable characteristics and business practices of some of the Internet pharmacies from which we received drugs. Most, but not all, involved other foreign pharmacies. These included pharmacies that accepted payment but did not provide the drugs ordered, shipments of drugs with questionable return addresses, pharmacies that obscured details about the drugs sold, and pharmacies that were under investigation by regulatory agencies.

We ultimately did not receive six of the orders we placed and paid for, suggesting the potential fraudulent nature of some Internet pharmacies or entities representing themselves as such.[27] The six orders were for Clozaril, Humulin N, and Vicodin, and cost over $700 in total. Five of these orders were placed with non-Canadian foreign pharmacies and one was placed with a pharmacy whose location we could not determine. We followed up with each pharmacy in late April and early May of 2004 to determine the status. Three indicated they would reship the product, but as of June 10, 2004, we had not received the shipments. Three others did not respond to our inquiry.[28]

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

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

[27] NABP has reported receiving complaints from consumers who state they have provided payment to various Internet pharmacies, but have not received the products ordered.

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

About 21 percent of the Internet pharmacies from which we received drugs (14 of 68) were under investigation by regulatory agencies. The reasons for the investigations by DEA and FDA include allegations of selling controlled substances without a prescription; selling adulterated, misbranded, or counterfeit drugs; selling prescription drugs where no doctor-patient relationship exists; smuggling; and mail fraud. The pharmacies under investigation were concentrated among the U.S. pharmacies that did not require a patient-provided prescription (9) and other foreign (4) pharmacies. One Canadian pharmacy was also included among those under investigation.

Concluding Observations

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

Agency and External Comments

In commenting on a draft of this report, FDA generally agreed with our findings and conclusions and made suggestions to clarify or expand upon its contents (see app. II). FDA commented that, while the draft report noted Internet pharmacy Web sites purported or appeared to be from various countries, the draft did not demonstrate that the drug samples we received were actually sent from those countries, such as by discussing

return addresses and postmarks on the samples. FDA suggested we indicate the methods we used to determine the samples' origins. We modified the report to indicate that we determined the location of the Internet pharmacy Web sites from which we received drug samples based on information contained in the pharmacy Web sites and the return addresses and postmarks on the packages we received. FDA also commented that our finding that certain unapproved drugs were chemically equivalent to the brand name products we ordered was misleading. FDA noted that chemical equivalence testing may not always determine whether a drug is comparable in all respects to the FDA-approved drug and therefore fully therapeutically equivalent. We relied on manufacturers to determine whether the drug samples we received were comparable to their own FDA-approved brand name version of the drug, and manufacturers conducted a range of tests to make this determination. Nevertheless we modified the final report to note the potential limitations to chemical equivalence testing. FDA also made several observations about the practices of Internet pharmacies and provided technical comments, which we incorporated where appropriate.

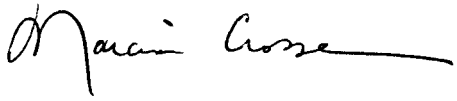
We also provided a draft of this report to DEA for technical comments and to ensure information we reported did not compromise its ongoing investigations. The agency responded that it had no comments.

Finally, we provided segments of the draft report to the manufacturer of each drug sample we received. Each manufacturer reviewed the segments of the draft report relating to its own product(s), and provided technical comments, which we incorporated as appropriate.

As agreed with your office, unless you publicly announce this report's contents, we plan no further distribution until 30 days after its issue date. At that time, we will send copies to the Acting Commissioner of FDA, the Administrator of DEA, and others upon request. In addition, this report will be available at no charge at the GAO Web site at http://www.gao.gov.

Please call Marcia Crosse at (202) 512-7119 or Robert Cramer at (202) 512-7455 if you have any questions. Another contact and other major contributors are listed in appendix I.

Sincerely yours,



Marcia Crosse
Director, Health Care—Public Health and Military Health Care Issues

Robert J. Cramer
Managing Director, Office of Special Investigations

Comments from the Food And Drug Administration

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

June 4, 2004

Marcia Crosse
Director, Health Care-Public Health
and Military Health Care Issues
United States General Accounting Office
441 G Street, N.W.
Washington, D.C. 20548

Dear Ms. Crosse:

Please find the enclosed comments from the Food and Drug Administration on the GAO draft report entitled *INTERNET PHARMACIES: Some Pose Safety Risks for Consumers (GAO-04-820).* The Agency provided technical comments directly to your staff.

We appreciate the opportunity to review and comment on this draft report before its publication as well as the opportunity to work with your staff in finalizing this report.

Sincerely,

Lester M. Crawford, D.V.M., Ph.D. Acting
Acting Commissioner of Food and Drugs

Enclosure

General Comments by the Department of Health and Human Services' Food and Drug Administration on GAO's Draft Report, *INTERNET PHARMACIES: Some Pose Safety Risks for Consumers* (GAO-04-820)

The FDA appreciates the opportunity to review and comment on GAO's draft report. FDA concurs with the overall conclusions contained in this report that many imported prescription drugs appear to be of poor quality, are mishandled, have questionable authenticity and approval status, and that these drugs are readily available and can be easily purchased by consumers via Internet pharmacies. Our general comments follow:

1. The report repeatedly states that the Internet sites "purported" or "appeared" to be from Canada, the U.S., or other foreign countries. The study does not demonstrate with any certainty, particularly for the U.S. or Canadian websites, that the products were sent from or manufactured for use in those countries. It also does not discuss return address labels, post marks or other indicators of the origin of the packages. If Congress were to legalize importation of prescription drugs, we anticipate a proliferation of websites claiming to be Canadian pharmacies and entry of unscrupulous individuals into the marketplace. It is easy to design a fraudulent Canadian website that looks completely legitimate. We request that GAO make clear in its report how they determined the origin of the products they purchased. Further, when GAO refers to a "Canadian Internet pharmacy," how is that defined? Even if Canadian drugs are absolutely reliable, American consumers would still need a way to make sure that the medicines they order are actually coming from Canada and not simply transshipped through the country.

2. Many Canadian Internet Pharmacies market specifically to U.S. citizens seeking lower drug prices. The numerous storefront Canadian pharmacy operations in the U.S. are a direct offshoot of these business initiatives.

3. In several places throughout the report, GAO comments that, while "unapproved", the drugs obtained from abroad were chemically equivalent to FDA-approved drugs. We think this claim is misleading. Whether a foreign product contains the same active ingredient is no guarantee that it is identical to the FDA-approved product. For example, the foreign drug may contain different inactive ingredients (to which some persons may be allergic), and there is no guarantee that the foreign and FDA-approved drugs are bioequivalent.

   Because two drug products are "chemically equivalent" does not make them therapeutically equivalent. Most of a generic drug's application review is directed to demonstrating its bioequivalence to the innovator drug.

   Drug products are considered to be therapeutic equivalent only if they are pharmaceutical equivalents and if they can be expected to have the same clinical effect and safety profile when administered to patients under the conditions specified in the labeling.

4. The report does not mention the fact that criminal enforcement of the FD&C Act as it relates to the "online questionnaire" used in most domestic sites selling non-controlled prescription pharmaceuticals depends on individual States interpretation of what constitutes a valid prescription. This, in turn depends on their interpretation of what constitutes an adequate "doctor/patient relationship". Some states do not require a "face to face" medical evaluation. Where this is the case, FDA is deprived of the "misbranding" charge that results from the allegation that a prescription based solely on review of an online questionnaire is not valid.

5. Many U.S. Internet pharmacy sites selling drugs through the use of an online questionnaire do not offer lower prices, but cater to persons seeking so called "lifestyle" drugs, or to others wanting to avoid a doctor's visit or those intent on self-prescribing. These sites sell such drugs as Viagra, Zenical, Propecia and minor tranquilizers usually at a higher price than in a traditional brick and mortar or Internet pharmacy.

6. Sites that sell controlled substances do so usually at substantial mark up. For example, the AWP for generic Percocet is $11 but it sells for $265 per hundred on the Internet. These Internet sites are often sought out by drug abusers. Sites that are identified in the report as operating legally, like traditional drug stores, do not sell controlled substances because of DEA restrictions. FDA has found an increased number of controlled substances in the two "port blitzes" it did in 2003. In 2004 the large volume of controlled substances coming into the U.S. continues.

7. The sampling GAO conducted is extremely small when viewed in the context of the vast number of Internet sites offering prescription drugs for sale. Although the size of the study demonstrates the gravity of the situation regarding "other foreign" Internet sites, a much larger study that has statistical significance should be considered.

GAO Contact and Staff Acknowledgments

GAO Contact

Randy M. DiRosa, (312) 220-7671

Acknowledgments

Major contributors to this report were Margaret Smith, Corey Houchins-Witt, Andrew O'Connell, Ramon Rodriguez, Julian Klazkin, Helen Desaulniers, Robert Copeland, and Harold Lewis.

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