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PRESCRIPTION DRUGS

Preliminary Observations on Efforts to Enforce the Prohibitions on Personal Importation

Statement of Richard M. Stana, Director
Homeland Security and Justice Issues

July 22, 2004

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Highlights

Highlights of GAO-04-839T, a testimony before the Permanent Subcommittee on Investigations, Committee on Governmental Affairs, U.S. Senate

Why GAO Did This Study

American consumers are increasingly drawn to the convenience, privacy, and cost advantages that might be accrued by purchasing prescription drugs over the Internet. However, there is growing concern about the safety of the drugs and the lawfulness of shipping the drugs into the United States through international mail and private carriers. Under current law, the importation of prescription drugs for personal use is illegal, with few exceptions. All prescription drugs offered for import must meet the requirements of the Federal Food, Drug, and Cosmetic Act, and those that are controlled substances also must meet the requirements of the Controlled Substances Import and Export Act. According to the agencies responsible for enforcing these laws, prescription drugs imported for personal use generally do not meet these requirements. The Department of Homeland Security's U.S. Customs and Border Protection (CBP) and the Department of Health and Human Service's Food and Drug Administration (FDA) are responsible for inspecting and interdicting unapproved prescription drugs that are being illegally imported via the U.S. mail or private carrier.

This testimony reflects our preliminary observations from ongoing work to assess federal efforts to enforce the prohibitions on personal importation of prescription drugs.

www.gao.gov/cgi-bin/getrpt?GAO-04-839T.

To view the full product, including the scope and methodology, click on the link above. For more information, contact Richard Stana at (202) 512-8777 or Stanar@gao.gov.

What GAO Found

CBP and FDA officials said that the volume of imported adulterated, misbranded, or unapproved prescription drugs is large and increasing, but complete data do not exist to document these observations. FDA officials said that they cannot assure the public of the safety and quality of drugs purchased from foreign sources that are largely outside the U.S. regulatory system. GAO's recent report on a sample of drugs purchased from Internet pharmacies echoed these concerns.

CBP and FDA officials at mail and private carrier facilities inspect and interdict some packages that contain prescription drugs. However, according to officials, because of resource constraints, many other packages containing prescriptions drugs are either not inspected and are released to addressees or are released after an inspection. CBP and FDA target certain packages for inspection based on the packages' countries of origin and whether the packages are suspected of containing certain prescription drugs. However, packages that are not targeted typically bypass inspection and are released to addressees without an assessment of their contents or admissibility. FDA officials have acknowledged that tens of thousands of packages, containing drug products that may violate current laws and pose health risks to consumers, have been released. They said that time-consuming processing requirements and resource constraints limit their ability to perform more inspections.

Agency efforts to deal with imported prescription drugs are evolving. Two interagency task forces were established to study prescription drug importation and address related law enforcement issues, respectively. Also, to overcome differences in the way officials target and interdict shipments of unapproved prescription drugs at various mail and private carrier facilities, FDA has begun implementing new procedures to promote more uniformity across facilities. It is too soon to tell if these efforts are sufficient to address various health, safety, and law enforcement issues associated with the importation of prescription drugs.

Packages suspected of containing imported prescription drugs awaiting FDA review

Source: GAO with permission of CBP and FDA.

Mr. Chairman and Members of the Subcommittee:

I appreciate the opportunity to be here today to participate in this hearing on prescription drug importation. American consumers are increasingly drawn to the convenience, privacy, and cost advantages that might be accrued by purchasing over the Internet such prescription drugs as Valium, cholesterol-lowering drugs, and Viagra. However, there is growing concern, reported in the media and elsewhere, that persons who purchase prescription drugs from Internet pharmacies, particularly those pharmacies located in foreign countries, run the risk of taking drugs that may be compromised or not the authentic product they intended to purchase. Thus, American consumers may be exposed to potential health and safety risks. Furthermore, consumers may also be violating the law, unknowingly or intentionally, by having these drugs shipped into the United States through the international mail and private carriers.

Under current law, the importation of prescription drugs for personal use is illegal, with few exceptions. Two acts specifically regulate the importation of prescription drugs into the United States. That is, all prescription drugs offered for import must meet the requirements of the Federal Food, Drug, and Cosmetic Act and those that are controlled substances, as defined in the Controlled Substances Act,[1] also must meet the requirements of the Controlled Substances Import and Export Act. Prescription drugs imported for personal use generally do not meet these requirements.

My testimony today reflects our preliminary observations from ongoing work to assess federal efforts to enforce the prohibitions on personal importation of prescription drugs, which was requested by the Chairman and Ranking Minority Member of this Subcommittee and the Ranking Member of the House Energy and Commerce Committee. Much of our work to date has focused on the efforts of the Department of Homeland Security's U.S. Customs and Border Protection (CBP) and the Department of Health and Human Service's Food and Drug Administration (FDA) to

[1]The Controlled Substances Act establishes a classification structure for certain drugs and chemicals that are designated as controlled substances. This structure places controlled substances in one of five schedules, based on their medicinal value, risk to public health, and potential for abuse and addiction, among other factors. Schedule I is reserved for the most dangerous drugs that have no currently accepted medical use, such as heroin and ecstasy. Prescription drugs that are also controlled substances, such as Valium or codeine, fall in schedules II through V.

inspect and interdict prescription drugs that are being imported via the U.S. mail or private carrier, such as FedEx or DHL, for personal use. In this statement, I make the following points:

- CBP and FDA officials said that the amount of unapproved prescription drugs illegally entering the country is large and increasing. The overall healthfulness and safety of these imported drugs is not assured, and limited testing showed that some of these drugs pose risks to consumers.

- CBP and FDA interdict some packages that contain prescription drugs, but many other packages containing these drugs are released to addressees—either not inspected and released or released after inspection. According to CBP and FDA officials, this is because of resource and other constraints.

- CBP and FDA officials told us that their respective requirements for inspecting and processing violative materials can be time-consuming and in some cases hamper their enforcement efforts.

- Agency efforts to address issues concerning the importation of prescription drugs are evolving, but it is still too early to tell whether these efforts will adequately address every aspect of the law enforcement and safety issues associated with the importation of these drugs.

My testimony is based on our ongoing review of federal laws and agency policies, procedures, and practices related to personal importation of prescription drugs; visits to three international mail facilities operated by the U.S. Postal Service and two private carrier facilities; and interviews with officials from CBP, FDA, the Department of Justice's Drug Enforcement Administration (DEA), the U.S. Postal Service, and the Department of Homeland Security's U.S. Immigration and Customs Enforcement. We did the work reflected in this statement from March to July 2004 in accordance with generally accepted government auditing standards. We plan to finish our work and issue a report later this year. Additional information on our scope and methodology can be found in appendix I.

Background

All international mail and packages entering the United States through the U.S. Postal Service and private carriers are subject to potential CBP inspection at the 13 International Mail Branches (IMBs) located at U.S.

Postal Service international mail facilities and 29 express consignment carrier facilities operated by private carriers located around the country. CBP inspectors can target certain packages for inspection or randomly select packages for inspection. CBP inspects for, among other things, illegally imported controlled substances, contraband, and items—like personal shipments of prescription drugs—that may be inadmissible. CBP inspections can include examining the outer envelope of the package, using x-ray detectors, or opening the package to physically inspect the contents. Each year the IMBs and carrier facilities process hundreds of millions of pieces of mail and packages. Among these items are prescription drugs ordered by consumers over the Internet, the importation of which is prohibited under current law, with few exceptions.

Two acts—the Federal Food, Drug, and Cosmetic Act and the Controlled Substances Import and Export Act—specifically regulate the importation of prescription drugs into the United States. Under the Federal Food, Drug, and Cosmetic Act, as amended, FDA is responsible for ensuring the safety, effectiveness, and quality of domestic and imported drugs and may refuse to admit into the United States, any drug that appears to be adulterated, misbranded, or unapproved for the U.S. market as defined in the act.[2] Under the act and implementing regulations, this includes foreign versions of FDA-approved drugs because, for example, neither the foreign manufacturing facility nor the manufacturing methods and controls were reviewed by FDA for compliance with U.S. statutory and regulatory standards. The act also prohibits reimportation of a prescription drug manufactured in the United States by anyone other than the original manufacturer of that drug. According to FDA, prescription drugs imported by individual consumers typically fall into one of these prohibited categories. However, FDA has established a policy that allows local FDA officials to use their discretion to permit personal importation of prescription drugs that do not contain controlled substances under specified circumstances, such as importing for treatment of a serious condition a small quantity, generally not more than a 90-day supply, of a

[2]An unapproved drug includes one that has not been demonstrated to be safe and effective and for which the manufacturing facility, methods, and controls have not been shown to meet FDA standards. Failure to meet other statutory and regulatory standards relating to labeling, handling, and packaging may result in a drug being considered adulterated or misbranded. See 21 U.S.C. §§ 811, 812 §§ 351, 352, 355.

drug not available domestically.[3] The importation of unapproved foreign versions of prescription drugs like Viagra (an erectile dysfunction drug) or Propecia (a hair loss drug), for example, would not qualify under the personal importation policy because approved versions are readily available in the United States.

In addition, the Controlled Substances Import and Export Act, among other things, generally prohibits personal importation of those prescription drugs that are also controlled substances, such as Valium or codeine. (See app. II for general description of controlled substances.) Under the act, the importation of controlled substances is prohibited unless the importer is registered with DEA, and such registration is generally not available for importation for personal use. The act and implementing regulations permit an individual traveler under certain circumstances to carry a personal use quantity of a controlled substance (except a substance in Schedule I) across the U.S. border, but they do not make a similar exception for importation by mail or private carrier.[4]

CBP inspects packages for prescription drugs on behalf of DEA and FDA. Upon inspection, CBP is to seize illegally imported controlled substances on behalf of DEA.[5] CBP may take steps to destroy the seized and forfeited substance or turn the seized substance over to other federal law enforcement agencies for further investigation.[6] CBP is to turn over

[3]According to the policy, other conditions should be met as well, such as (1) provision of the name and address of the doctor licensed in the United States responsible for the importer's treatment with the product or evidence that the product is for continuation of treatment begun in a foreign country and (2) the absence of any known commercialization or promotion to persons residing in the United States by those involved in the distribution of the product at issue. Alternatively, in the case of a drug that is not for a serious condition, the policy also permits FDA officials to use their discretion to allow importation of that drug if the intended use is identified, and the product is not known to represent a significant health risk. A complete description of FDA's personal importation policy can be found in chapter 9 of FDA's Regulatory Procedures Manual, which is available on the agency's web site.

[4]21 U.S.C. 956(a), 957(b)(1)(C); 21 C.F.R. 1301.26. The controlled substance must be in the original container in which it was dispensed to the individual. The individual must declare that it is possessed for personal use or for an accompanying animal and provide the trade or chemical name and schedule of the substance. If the traveler is a U.S. resident, he or she may bring no more than 50 dosage units of the substance without a prescription.

[5]19 USC § 1595a(c)(1)(B); 19 C.F.R. §§ 162.23, 145.59, 145.58, 12.36. Schedule I and II controlled substances are subject to summary forfeiture.

[6]19 CFR §§ 162.31, 162.32, 162.45, 162.45a, 162.46, 162.47, 162.63.

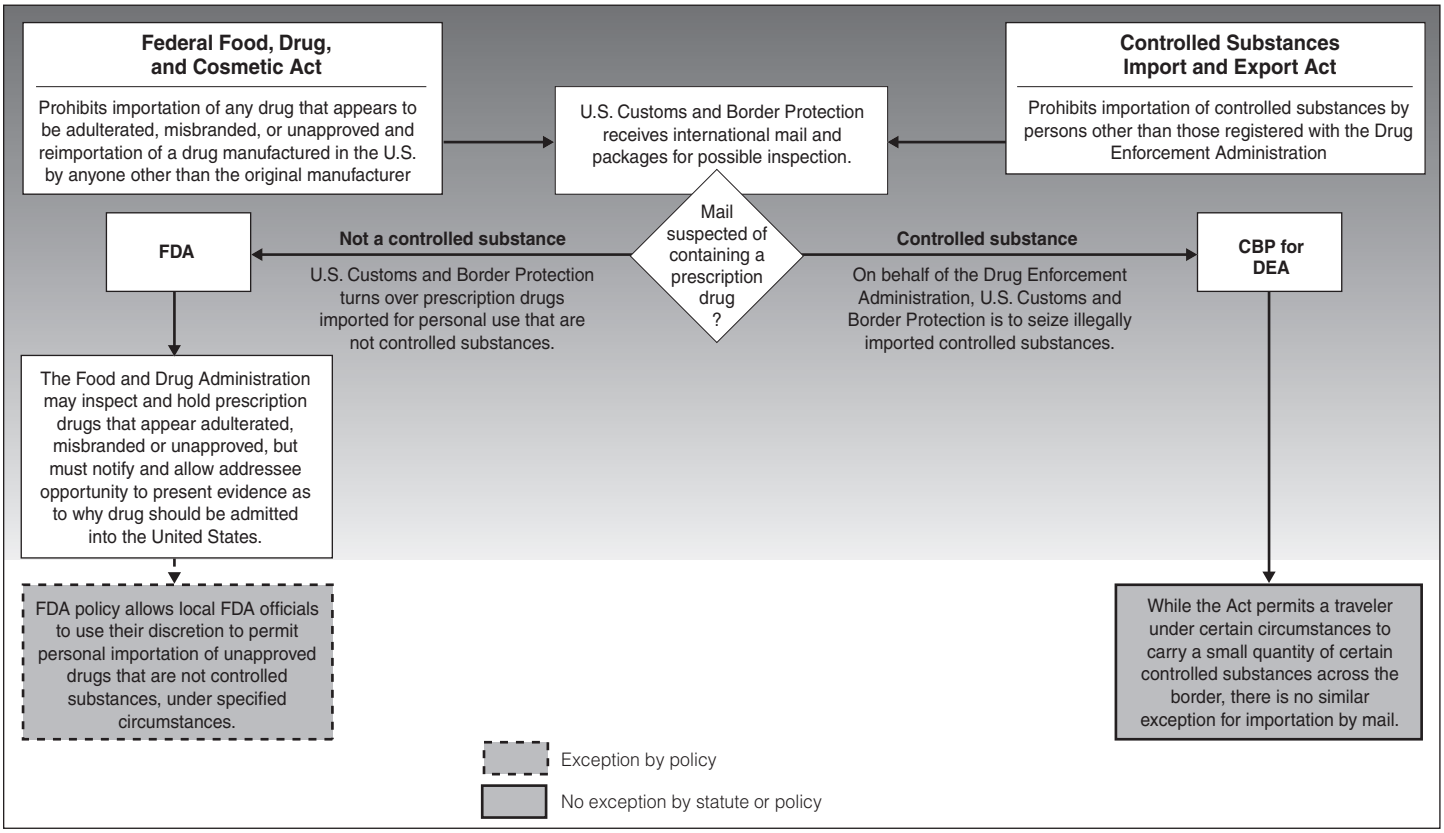
packages suspected of containing prescription drugs that are not controlled substances to FDA.[7] FDA investigators may inspect such packages and hold those that appear to be adulterated, misbranded, or unapproved, but must notify the addressee and allow that individual the opportunity to present evidence as to why the drug should be admitted into the United States.[8] If the addressee does not provide evidence that overcomes the appearance of inadmissibility, then the item is refused admission.

Figure 1 illustrates the two acts that specifically govern the importation of prescription drugs into the United States. It also presents the roles of FDA, DEA, and CBP in implementing those acts.

[7] 21 U.S.C. § 381(a); 19 C.F.R. §§ 12.1(a), 145.57; see also Chapter 9 of FDA's *Regulatory Procedures Manual*, Subchapter Coverage of Personal Importations, "Mail Shipments" http://www.fda.gov/ora/compliance_ref/rpm_new2/ch9pers.html. Downloaded May 18, 2004.

[8] 21 U.S.C. § 381(a); 21 CFR §1.94.

Figure 1: Acts Governing the Personal Importation of Prescription Drugs into the United States and FDA, DEA, and CBP Roles Implementing Those Acts



Source: GAO analysis of 19 U.S.C. § 1595a(c); 21 U.S.C. §§ 381, 956, 957; U.S. Food and Drug Administration, Regulatory Procedures Manual, Chapter 9, Subchapter: Coverage of Personal Importations.

Volume of Prescription Drug Imports Is Said to be Large and Increasing, and the Health and Safety of these Drug Imports is Not Assured

CBP and FDA officials said that the volume of unapproved prescription drugs illegally imported through the IMBs or carrier facilities is large and steadily increasing. However, complete data do not exist to document this observation. During special operations, CBP and FDA have attempted to determine the volume of imported prescription drugs entering through selected IMBs. Generally, these were one-time, targeted efforts to identify and tally all of the packages containing prescription drugs at certain time periods. The limited data collected have shown wide variations in volume. For example, CBP officials at one IMB estimated that approximately 3,300 packages containing prescription drugs entered the facility in one week. In 2004, CBP officials at another IMB determined that 4,300 packages containing prescription drugs entered the facility in one day. While these data may provide estimates regarding the volume entering selected IMBs for certain time periods, the data may not be representative of other time periods or projectable to other locations.

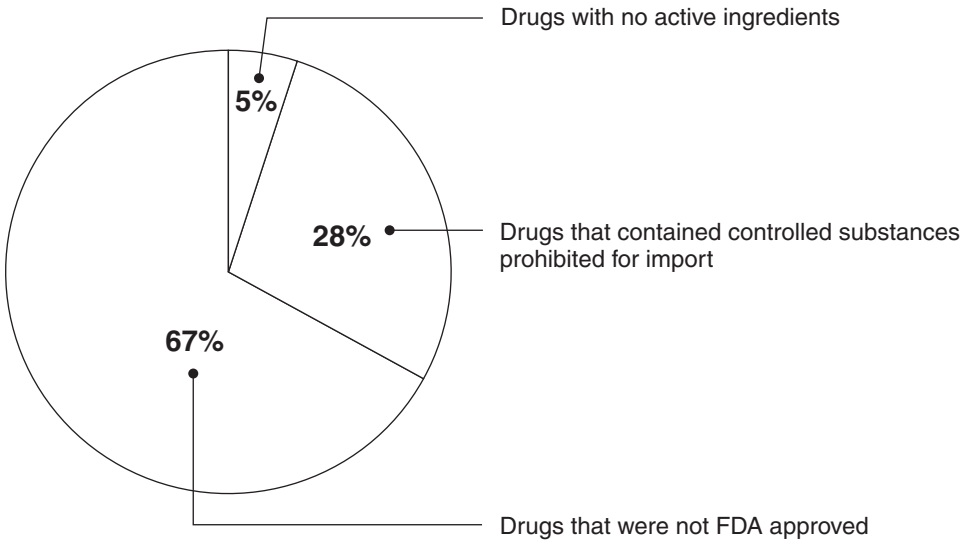
FDA officials have stated that they cannot provide assurance to the public regarding the safety and quality of drugs purchased from foreign sources, which are largely outside of their regulatory system. Additionally, FDA officials indicated that consumers who purchase prescription drugs from foreign-based Internet pharmacies are at risk of not fully knowing the safety or quality of what they are importing. FDA officials also have stated that while some consumers may purchase genuine products, others may unknowingly purchase counterfeit products, expired drugs, or drugs that were improperly manufactured.

CBP and FDA have conducted special operations to do limited assessments of the nature of some imported prescription drugs, and these operations have raised questions about the safety of some of the drugs analyzed. For example, during an operation undertaken in 2003 at four IMBs, CBP and FDA inspected 1,153 packages that contained prescription drugs.[9] According to a CBP report, 1,019, or 88 percent, of the drug products were violative because they were prohibited for import, including Lipitor (a cholesterol-lowering drug), Viagra, and Propecia. A CBP laboratory analyzed 180 drug samples. This analysis showed that the majority of the drugs were never approved by FDA. Furthermore, the operation showed that many of the unapproved drugs could pose safety

[9]According to CBP officials, packages shipped through four IMBs were examined over a 3-day period. Approximately 100 parcels (each of which may have contained multiple drug products) per day per facility were selected based upon their country of origin and historical experience.

risks. The samples included drugs that were withdrawn from the U.S. market for safety reasons; animal drugs not approved for human use; and drugs that carry risks because they require careful dosing, initial screening, or periodic patient monitoring. In addition, other drugs tested were found to contain controlled substances prohibited for import, and some of the drugs contained no active ingredients. Figure 2 illustrates the results of the CBP laboratory analysis.

Figure 2: Results of CBP's Laboratory Analysis of 180 Imported Drugs



Source: GAO analysis of CBP information.

In a recent report and testimony before this Subcommittee, we found that prescription drugs ordered from some foreign-based Internet pharmacies posed safety risks for consumers.[10] Specifically, we identified several problems associated with the handling, FDA approval status, and authenticity of 21 prescription drugs samples purchased from Internet pharmacies located in several foreign countries—Argentina, Costa Rica, Fiji, Mexico, India, Pakistan, Philippines, Spain, Thailand, and Turkey. Our work showed that most of these drug samples, all of which we received via consignment carrier shipment or the U.S. mail, were unapproved for the

[10]See U.S. General Accounting Office, *Internet Pharmacies: Some Pose Safety Risks for Consumers*, GAO-04-820 (Washington, D.C.: June 17, 2004) and U.S. General Accounting Office, *Internet Pharmacies: Some Pose Safety Risks for Consumers and Are Unreliable in Their Business Practices*, GAO-04-888T (Washington, D.C.: June 17, 2004).

U.S. market because, for example, the labeling[11] or the foreign manufacturing facility, methods, and controls were not reviewed by FDA. Of the 21 samples:

- None included dispensing pharmacy labels that provided instructions for use, and only about one-third included warning information.
- Thirteen displayed problems associated with the handling of the drug; three samples that should have been shipped in a temperature-controlled environment arrived in envelopes without insulation; and five samples contained tablets enclosed in punctured blister packs, potentially exposing them to damaging light or moisture.
- Two were found to be counterfeit versions of the products we ordered, and two had a significantly different chemical composition than that of the product we had ordered.

We found fewer problems among 47 samples purchased from U.S. and Canadian Internet pharmacies. Although most of the drugs obtained from Canada were of the same chemical composition as that of their U.S. counterparts, most were unapproved for the U.S. market. We stated that it was notable that we identified numerous problems among the samples received despite the relatively small number of drugs we purchased, consistent with problems recently identified by state and federal regulatory agencies.

Some Packages Containing Prescription Drugs Are Interdicted, but Others Are Released

Our work thus far shows that while CBP and FDA interdicted some packages that contain prescription drugs, other similar packages were released—either not inspected and released or released after inspection. CBP officials told us that certain packages were targeted for inspection. However, packages that were not targeted typically bypass inspection and are released to the addressee without an assessment of their contents or admissibility. Many packages that were held by CBP officials for FDA at the IMBs were also subsequently released to the addressee. FDA has acknowledged that tens of thousands of packages have been released, although they may contain drug products that violate current laws and pose health risks to consumers. FDA officials at the IMBs said that the

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

packages were released to the addressee because FDA investigators were unable to process the volume of packages turned over to them. FDA headquarters officials told us that this occurred because of limited available resources relative to the volume of unapproved prescription drugs entering the country.

Packages Not Targeted for Inspection and Released

According to CBP and FDA officials at the IMBs we visited, CBP and FDA use various approaches to target certain incoming international mail packages for inspection. These include targeting packages from certain countries and/or packages suspected of containing certain prescription drugs. For example, at one IMB we visited, FDA provided CBP with a list of targeted countries—the composition of which changed periodically. A recent list targeted seven countries and specific areas in one other country. FDA officials asked that CBP hold the packages they suspected of containing prescription drugs that were from the targeted countries. Typically, CBP officials told us that when packages containing prescription drugs were detected, but were not from one of the targeted countries, they were released to the addressee without an assessment of their admissibility. Accordingly, CBP officials stated that packages containing prescription drugs unapproved for import were released daily without FDA review.

According to CBP and FDA officials at the carrier facilities we visited, packages containing prescription drugs sent through these facilities may also be released without inspection. Unlike packages at IMBs, packages arriving at carrier facilities we visited were preceded by advance manifest information, which included the shipper's declaration describing the contents and its value. CBP and FDA officials review the manifest information to target packages for inspection before their arrival. Agency officials at two carrier facilities we visited told us that FDA officials were not typically on-site and electronically reviewed the manifests and targeted incoming packages declared as prescription drugs. FDA officials noted that packages containing prescription drugs could potentially avoid their review if the manifest information was not accurate. CBP and FDA officials told us there were no assurances that the shipper's declarations were accurate. For example, CBP and FDA officials at the carrier facility found eight packages containing a human growth hormone—unapproved for import—that were inaccurately manifested as glassware.

Packages Released after Inspection

FDA officials said that some packages that were inspected and determined to contain prescription drugs at the IMBs were released because they could not process them. For example, at one IMB, CBP officials held 16 bins containing roughly 3,000 packages for FDA investigators on a weekly

basis. However, the FDA officials estimated that in one week, they could open and fully inspect about 140 packages. In making the decision regarding what to inspect, two FDA investigators considered whether the packages contained prescription drugs considered to be an enforcement priority, including injectable drugs and certain controlled substances, such as steroids. The FDA officials told us that they typically released packages that did not contain a priority drug, even though the packages were believed to contain other prescription drugs that were not approved for import. Figure 3 shows bins containing packages of suspected prescription drugs being held for FDA review and possible inspection.

Figure 3: Bins Containing Packages of Suspected Prescription Drugs Being Held for FDA Review and Possible Inspection.

Source: GAO with permission of CBP and FDA.

At another IMB, CBP officials said that they usually released packages containing prescription drugs that appeared to be a 90-day supply or less—in line with one of the criteria in FDA's personal importation policy.[12] For example, after viewing an x-ray image of a package, CBP performed a visual inspection of the outer container of a medication, labeled as a treatment for ulcers,[13] determined that it appeared to contain 90 pills, and released it. At this same facility, FDA officials told us that every week CBP turned over to FDA hundreds of packages. CBP told us that these packages contained quantities of prescription drugs that appeared to be more than a 90-day supply. However, the FDA officials stated that they were able to process a total of approximately 20 packages per day. As a result, the FDA officials told us they returned many of the packages to CBP, citing an inability to process every package. The CBP officials said that most of the returned packages were released to the addressees. For example, CBP officials told us that several packages suspected of containing generic Viagra, unapproved for import, were returned by FDA and were released.

Officials Said Process Requirements Are Time-Consuming and Can Hamper Enforcement Effort

FDA officials told us that for packages found to contain prescription drugs, processing requirements are time-consuming and can hamper their ability to process all of the packages that are detained by CBP. FDA processing requirements include identifying the drugs, measuring the volume, entering this information into a FDA database, taking pictures of the drugs, preparing the drugs for temporary storage, and sending notification to the addressees to provide evidence regarding the admissibility of the drug. Processing time varies depending on the quantity and variety of drugs in the package.

In addition, processing time increases if research is required to determine the drug type. For example, FDA officials at one IMB stated that some prescription drugs are not immediately identifiable, particularly when shipped without labels or with labels in a foreign language. Figure 4 illustrates an example of drugs that was sent without labeling.

[12]For a description of some of the other criteria in FDA's personal importation policy, see note 3 and the accompanying text.

[13]This medication was labeled as a Canadian drug, although it had a New Zealand return address.

Figure 4: Drugs Sent without Labeling.

Source: FDA.

FDA officials at the IMBs we visited stated that considering these many factors, processing a single package can take anywhere from a few minutes to several hours. FDA officials who are responsible for reviewing manifest information for drugs shipped through the private carriers stated that it can take several days to process a package, particularly if they need to obtain additional information regarding the shipment.

FDA headquarters officials said that packages that contain prescription drugs that appear to be unapproved for import cannot be automatically refused and returned because of the statutory requirement that FDA hold the package and give the addressee the opportunity to provide evidence of admissibility. Officials said that this requirement applies to all drug imports with few exceptions. According to FDA investigators, in most instances, the addressees did not present evidence to support the drugs' admissibility, and the drugs were ultimately provided to CBP or the U.S. Postal Service for return to sender.

CBP officials at two IMBs told us that they could not turn over all packages they suspected of containing prescription drugs because FDA officials were not able to process all of the packages. FDA officials at one IMB stated that the processing time affected the number of packages they could inspect and was the reason many of the packages that were held up by CBP were ultimately released to the addressee without inspection. A FDA headquarters official stated that considerable storage space is needed to hold the detained packages, while the notice, opportunity to respond, and the agency's decision are pending. For example, one FDA IMB official told us that space limitations have affected the number of packages they

are able to store, including those packages held on-site awaiting a response from the addressee. Figure 5 shows drugs stored at one IMB as they pass through FDA's process, including those awaiting addressees' responses.

Figure 5: Drugs in Storage as They Pass through FDA's Process at One IMB

Source: FDA.

Processing requirements for controlled substances can also be burdensome if an IMB receives a high volume of controlled substances in the mail. According to CBP officials, the seizure process requires that CBP inspectors record the contents of each package—including the type of drugs and the number of pills or vials in each package—before it is turned over to seized property staff for possible investigation by Immigration and Customs Enforcement, forfeiture, and eventual destruction. CBP officials at one IMB told us that in recent months they have observed substantial increases in the volume of prescription drugs containing controlled substances being sent through the international mail because, in their view, of the increased incidence of consumers ordering drugs over the Internet. Although CBP officials had been seizing substantially more of these drugs in recent months, they had also accumulated a sizable backlog

of controlled substances awaiting seizure because, according to officials, they did not have the resources to begin the seizure process. By June 2004, CBP at this IMB had accumulated 123 bins of mail, containing over 40,700 packages of Schedule IV controlled substances—including the tranquilizer Valium, antidepressants, and painkillers. Figure 6 shows some of the bins of controlled substances that were being held awaiting formal seizure, as of May 14, 2004.

Figure 6: Controlled Substances Accumulated and Awaiting Seizure at One IMB

Source: GAO with permission of CBP and FDA.

According to CBP officials at this facility, as the controlled substances continued to accumulate, they became concerned that they would not be able resolve the backlog. In June, a CPB official said that CBP IMB officials asked CBP headquarters for permission to send the products back to the senders as an alternative to seizure, and to keep these drugs from entering U.S. commerce. According to this official, CBP's headquarters office granted them permission to send most of the drugs back to the

sender because the backlog would have taken months to resolve.[14] One CBP official said that the ability to return the controlled substances enabled CBP to clear the backlog in two to three weeks rather than the one to two years they projected it would have taken had CBP been required to begin seizure proceedings for each item. Officials at the facility said that they are now seizing controlled substances as they arrive at the facility.

Agency Efforts to Address the Importation of Prescription Drugs Are Evolving

Our preliminary work revealed a number of efforts, including interagency initiatives that are being undertaken in response to concerns raised about the importation of prescription drugs. For example, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 directed the Secretary of Health and Human Services, in consultation with appropriate government agencies, to conduct a study of the importation of drugs into the United States and submit a report to Congress (P.L. 108-173). The conference report (House Report 108-391) enumerated questions to be addressed in this study including, among other things:

- assessing the scope, volume, and safety of unapproved drugs, including controlled substances, entering the United States via mail shipment; and
- estimating agency resources, including additional field personnel, needed to adequately inspect the current amount of pharmaceuticals entering the country.

In February 2004, the Secretary of Health and Human Services appointed a task force, chaired by the Surgeon General, on drug importation. It included members representing the department, CBP, DEA, Department of Justice trial attorneys, and the Office of Management and Budget. Between March and May, the task force held public hearings to gather information to address the questions posed by Congress. According to an FDA official, as of July 2004, the task force staff was reviewing the testimony from the public hearings and the comments sent to the Federal Register docket to answer the questions posed in the conference report. The official said that the task force report is expected to be completed by this fall so that the

[14]According to a CBP official, most of the drugs returned were Schedule IV controlled substances. They said that a small number of the packages contained nonschedule prescription drugs that were referred to FDA. Also, CBP seized a small number of items that did not have a return address.

Secretary of Health and Human Services can meet his December 2004 deadline for reporting to Congress.

In addition, a CBP official told us that CBP is leading an interagency pharmaceutical task force, established in January 2004 to address various law enforcement issues related to the importation of prescription drugs and miscellaneous pharmaceuticals. The task force, which includes managers and senior managers from CBP, FDA, DEA, the Office of National Drug Control Policy, U.S. Immigration and Customs Enforcement, as well as legal counsel from the Department of Justice and other agencies, meets every two months. According to the CBP official, the task force has established five interagency working groups designed to tackle specific issues identified by the task force. The working groups, which meet more frequently, are focused on improving information sharing and law enforcement targeting criteria, increasing public awareness of potential dangers of imported pharmaceuticals, reviewing and enhancing mail and express mail consignment procedures, working cooperatively with industry, and legal issues. The groups report the results of their enforcement efforts to the task force, which makes suggestions for future efforts.

Our preliminary discussions with CBP about the activities of the working groups revealed initiatives currently under way by two of the groups. In one instance, the working group on mail and express mail consignment procedures has been involved in recent interagency enforcement operations at selected international mail facilities. During these operations, the interagency group targeted and found mail containing nonscheduled prescription drugs as well as controlled substances. According to the CBP official, these operations resulted in investigations of commercial shipments of the prescription drugs by agents from the task force and working group and helped the law enforcement agencies identify Internet addresses for purposes of future investigations. The CBP official told us that, in another instance, the working group focused on increasing public awareness of the potential dangers of imported pharmaceuticals had developed public service announcements that are to be posted on the Internet. Appendix III shows one of these announcements that was recently posted on the CBP web site.

Individual agencies are also taking steps to enhance their ability to deal with inspection and interdiction issues associated with imported prescription drugs. As discussed earlier, during our visits to the three IMBs, we noted that CBP and FDA officials at those facilities had adopted different approaches for targeting and interdicting prescription drugs. FDA

headquarters officials also recognized this and in response indicated that a more uniform approach was needed. According to these officials, FDA has drafted a set of standard operating procedures that will apply to the handling of imported prescription drugs consistently across the 13 International Mail Branches. FDA officials said that these procedures have been developed to apply to the handling of prescription drugs nationwide, but will also give officials at individual facilities some flexibility to adopt procedures that address uniquely local conditions. FDA headquarters officials told us they have begun implementing the procedures at selected IMBs and plan to implement them at more locations. FDA officials also said that they were developing a similar set of standard operating procedures that would apply to the inspection and interdiction of imported prescription drugs at the consignment carrier facilities. CBP officials told us that CBP expects that these guidelines will also discuss CBP responsibilities for handling imported prescription drugs.

In closing, Mr. Chairman, it has been discussed in the media and elsewhere that American consumers are purchasing prescription drugs for importation in increasing numbers. Our preliminary observations indicate that CBP and FDA face considerable challenges inspecting and interdicting these drugs to help ensure compliance with current law. Currently data are unavailable to estimate the volume of prescription drugs entering the country, and the overall health and safety risks of these drugs are unknown. CBP and FDA are inspecting and interdicting some of the unapproved prescription drugs that are entering the country, but others bypass inspection and are sent to consumers who purchased them, often because, according to CBP and FDA officials, time-consuming processing requirements and staffing constraints limit their ability to perform more inspections. Although agencies like CBP, FDA, and DEA have begun initiatives to deal with various aspects of the drug importation issue, it is too early to tell whether these efforts will adequately address every dimension of the law enforcement and safety issues associated with the importation of prescription drugs.

This concludes my prepared statement. In the next several weeks we plan to follow up with CBP and FDA officials on their plans to enhance their enforcement activities. I would be pleased to answer any questions you and the Subcommittee members may have.

GAO Contacts and Staff Acknowledgments

For further information about this testimony, please contact Richard Stana, Director, Homeland Security and Justice Issues, on (202) 512-8777 or at stanar@gao.gov. Major contributors to this testimony included John Mortin, Yelena Harden, Barbara Stolz, Frances Cook, and James Russell.

Appendix I: Scope And Methodology

To understand importation restrictions and enforcement requirements, we reviewed current federal laws on the importation of prescription drugs and controlled substances. We reviewed current CBP and FDA policies, procedures, and guidance related to prescription drugs and controlled substance importation. We reviewed applicable importation and interdiction data from CBP and FDA. We conducted interviews with officials at CBP, FDA, U.S. Postal Service, U.S. Immigration and Customs Enforcement, and DEA.

To understand inspection procedures, we visited three IMBs in Chicago, Los Angeles, and New York and two carrier facilities in Cincinnati (for the DHL Corporation) and in Memphis, (for the FedEx Corporation). We judgmentally selected these facilities based on the overall number of packages processed at the facilities and their geographic dispersion. At these locations, we observed inspection and interdiction practices; met with CBP and FDA management, inspectors, and investigators to discuss issues related to inspection, manifest reviews, and pharmaceutical importation volume; and reviewed relevant documents on inspection and interdiction procedures. At the IMBs we also met with officials from the U.S. Postal Service regarding mail handling and processing procedures.

We did the work reflected in this statement from March to July 2004 in accordance with generally accepted government auditing standards.

Appendix II: General Description of the Controlled Substance Schedules I-V

The drugs and drug products that come under the Controlled Substances Act are divided into five schedules. A general description and examples of the substances in each schedule are outlined below in table 1.

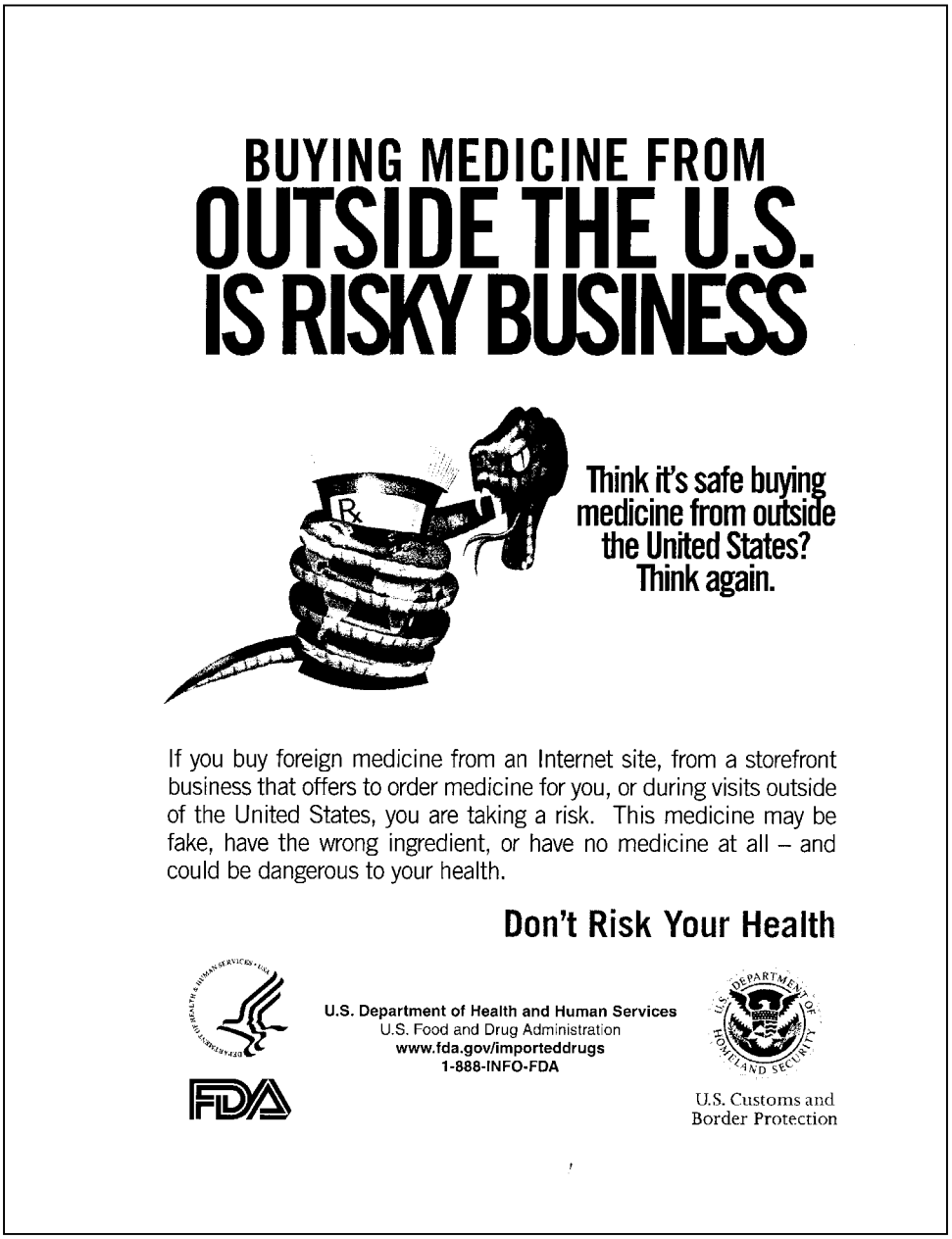
Table 1: General Description of Controlled Substance Schedules I-V

Schedule	Description of substances in the schedule	Examples
I	Substances that have no accepted medical use in the United States and have a high potential for abuse.	Heroin, lysergic acid diethylamide (LSD), marijuana, and gama hydroxybutyric acid (GHB)
II	Substances that have a high potential for abuse with severe psychic or physical dependence liability—certain narcotic, stimulant, and depressant drugs.	Opium, morphine, codeine, methadone, and meperidine (Demerol)
III	Substances that have a potential for abuse that is less than those in Schedules I and II and include compounds containing limited quantities of certain narcotic drugs and non-narcotic drugs.	Anabolic steroids; derivatives of babituric acid (except those listed in another schedule); benzphetamine; and any compound, mixture, preparation or suppository dosage form containing amobarbital, secobarbital, or pentobarbital
IV	Substances that have a potential for abuse that is less than those listed in Schedule III.	Barbital, alprazolam (Xanax), Cathine— constituent of the “Khat” plant, and Diazepam (Valium)
V	Substances that have a potential for abuse that is less than those listed in Schedule IV and consist primarily of preparations containing limited quantities of certain narcotic and stimulant drugs.	Pyrovalerone (Centroton, Thymergix)

Source: GAO analysis of Drug Enforcement Administration information

Note: Schedule I substances are not the subject of this report.

Appendix III: CBP Public Service Announcement Posted on the Internet



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