

September 2005

PRESCRIPTION DRUGS

Strategic Framework Would Promote Accountability and Enhance Efforts to Enforce the Prohibitions on Personal Importation





Highlights of [GAO-05-372](#), a report to congressional requesters

Why GAO Did This Study

Consumers can be violating the law and possibly risking their health by purchasing imported prescription drugs over the Internet. U.S. Customs and Border Protection (CBP), in the Department of Homeland Security (DHS), and the Food and Drug Administration (FDA), in the Department of Health and Human Services (HHS), work with other federal agencies at international mail and express carrier facilities to inspect for and interdict prescription drugs illegally imported for personal use. This report addresses (1) available data about the volume and safety of personal prescription drug imports, (2) the procedures and practices used to inspect and interdict prescription drugs unapproved for import, (3) factors affecting federal efforts to enforce the laws governing prescription drugs imported for personal use, and (4) efforts federal agencies have taken to coordinate enforcement efforts.

What GAO Recommends

GAO recommends that (1) CBP and other task force agencies develop a strategic framework to enhance their enforcement efforts and (2) HHS assess the effect of modifying the requirement that FDA notify addressees about unapproved drug imports. DHS and most task force agencies generally supported the idea of a strategic framework. HHS agreed to assess modifying the notification requirement, and the U.S. Postal Service said that any proposal should consider international postal obligations.

www.gao.gov/cgi-bin/getrpt?GAO-05-372.

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.

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Strategic Framework Would Promote Accountability and Enhance Efforts to Enforce the Prohibitions on Personal Importation

What GAO Found

The information currently available on the safety of illegally imported prescription drugs is very limited, and neither CBP nor FDA systematically collects data on the volume of these imports. Nevertheless, on the basis of their own observations and limited information they collected at some mail and carrier facilities, both CBP and FDA officials said that the volume of prescription drugs imported into the United States is substantial and increasing. FDA officials said that they cannot assure the public of the safety of drugs purchased from foreign sources outside the U.S. regulatory system.

FDA has issued new procedures to standardize practices for selecting packages for inspection and making admissibility determinations. While these procedures may encourage uniform practices across mail facilities, packages containing prescription drugs continue to be released to the addressees. CBP has also implemented new procedures to interdict and destroy certain imported controlled substances, such as Valium. CBP officials said the new process is designed to improve their ability to quickly handle packages containing these drugs, but they did not know if the policy had affected overall volume because packages may not always be detected.

We identified three factors that have complicated federal enforcement of laws prohibiting the personal importation of prescription drugs. First, volume has strained limited federal resources at the mail facilities. Second, Internet pharmacies can operate outside the U.S. regulatory system and evade federal law enforcement actions. Third, current law requires FDA to give addressees of packages containing unapproved imported drugs notice and the opportunity to provide evidence of admissibility regarding their imported items. FDA and HHS have testified before Congress that this process placed a burden on limited resources. In May 2001, FDA proposed to the HHS Secretary that this legal requirement be eliminated, but according to FDA and HHS officials, as of July 2005, the Secretary had not responded with a proposal. FDA officials stated that any legislative change might require consideration of such issues as whether to forgo an individual's opportunity to provide evidence of the admissibility of the drug ordered.

Prior federal task forces and working groups had taken steps to deal with Internet sales of prescription drugs since 1999, but these efforts did not position federal agencies to successfully address the influx of these drugs imported from foreign sources. Recently, CBP has organized a task force to coordinate federal agencies' activities to enforce the laws prohibiting the personal importation of prescription drugs. The task force's efforts appear to be steps in the right direction, but they could be enhanced by establishing a strategic framework to define the scope of the problem at mail and carrier facilities, determine resource needs, establish performance measures, and evaluate progress. Absent this framework, it will be difficult to oversee task force efforts; hold agencies accountable; and ensure ongoing, focused attention to the enforcement of the relevant laws.

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Abbreviations

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| CBP | Customs and Border Protection |
| DEA | Drug Enforcement Administration |
| DHS | Department of Homeland Security |
| FDA | Food and Drug Administration |
| HHS | Health and Human Services |
| ICE | Immigration and Customs Enforcement |
| ONDCP | Office of Drug Control Policy |
| UPU | Universal Postal Union |
| USPS | U.S. Postal Service |

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United States Government Accountability Office
Washington, DC 20548

September 8, 2005

The Honorable Norman Coleman
Chairman
Permanent Subcommittee on Investigations
Committee on Homeland Security and Governmental Affairs
United States Senate

The Honorable John D. Dingell
Ranking Minority Member
Committee on Energy and Commerce
House of Representatives

The first Internet pharmacies began online service in early 1999. Since that time, American consumers have been increasingly drawn to the convenience, privacy, and cost advantages that might be accrued by purchasing prescription drugs over the Internet. Individual consumers can order over the Internet a range of prescription drugs from controlled substances,¹ such as Valium, to noncontrolled prescription drugs intended to improve an individual's quality of life by addressing non-life-threatening conditions such as baldness, impotence, and obesity. Internet pharmacies, particularly those pharmacies located in foreign countries, can operate outside the U.S. regulatory process, which requires a licensed pharmacist to dispense a prescription drug when presented with a valid prescription from a licensed health care professional. According to FDA, there are legitimate Internet pharmacies that comply with applicable federal and state laws. However, the broad reach and access of the Internet allows the easy creation of online pharmacies that can anonymously traverse state and national borders to prescribe, sell, and dispense prescription drugs without complying with traditional state or federal regulatory safeguards.

¹The Controlled Substances Act establishes a classification structure for certain drugs and chemicals that are designated as controlled substances. This structure places such 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. Controlled substances that may be prescribed by a physician or used in medical facilities fall in schedules II through V (e.g., Valium). For certain law enforcement purposes, however, schedule II drugs are treated more like schedule I drugs. See appendix II for a general description of the controlled substance schedules I-V.

Under current law, the importation of prescription drugs, both controlled and noncontrolled, for personal use is illegal, with few exceptions. However, in recent years, Congress and others have debated whether Americans should be allowed to purchase drugs from pharmacies located in foreign countries. Members of Congress have introduced various bills related to this issue. Proponents argue that American consumers should be allowed to import prescription drugs because drugs purchased from some foreign pharmacies are viewed as safe and more affordable. Opponents contend that drugs from unregulated sources are not proven to be safe and effective and could be harmful. In addition, some allege that packages of prescription drugs purchased on the Internet and imported for personal use could be bundled together and sold to others. Currently, consumers could be violating federal law, unknowingly or intentionally, by having drugs shipped, in effect, imported, into the United States through the international mail and private carriers. 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 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.

Several federal agencies have responsibility for regulating the importation of prescription drugs through the international mail and private carriers. They include the Department of Homeland Security's (DHS) U.S. Customs and Border Protection (CBP), which can inspect international mail and packages for potentially illegal drugs entering the United States through the U.S. Postal Service's (USPS) international mail facilities or private carriers; the Department of Health and Human Services' (HHS) Food and Drug Administration (FDA), which is responsible for ensuring the safety, effectiveness, and quality of domestic and imported drugs; the Department of Justice's Drug Enforcement Administration (DEA), which regulates controlled substances; and the Department of Homeland Security's U.S. Immigration and Customs Enforcement (ICE), which has law enforcement responsibilities that include investigations of prescription drugs coming into the United States through the mail and express carriers. Also, the Office of National Drug Control Policy (ONDCP) formulates the nation's drug control strategy and addresses policy issues concerning the illegal distribution of controlled substances, as its authority does not extend over noncontrolled substances.

You expressed interest in learning how federal agencies are addressing the importation of prohibited prescription drugs through international mail

and carrier facilities. In this report, we address the following questions: (1) What do the available data show about the volume and safety of prescription drugs imported into the United States for personal use through the international mail and private carriers? (2) What procedures and practices are used at selected facilities to inspect and interdict prescription drugs unapproved for import? (3) What factors affect federal agency efforts to enforce the prohibition on prescription drug importation for personal use through international mail and carrier facilities? (4) What efforts have federal agencies undertaken to coordinate the enforcement of the prohibitions on personal importation of prescription drugs?

To answer these questions, we reviewed current federal laws, available studies and reports on the importation of prescription drugs and controlled substances, CBP and FDA procedures and practices related to prescription drugs and controlled substance importation, and applicable importation volume and safety data. We conducted interviews with officials from CBP, FDA, DEA, USPS, ONDCP, and ICE, as well as representatives of MasterCard International and Visa U.S.A., Inc.² We visited five facilities: three international mail facilities located in California, Illinois, and New York and two carrier facilities located in Ohio (for the DHL Corporation) and Tennessee (for the FedEx Corporation). We selected these facilities to include those with a high volume of processed packages and wide geographic dispersion. At these locations, we observed inspection and interdiction practices; met with CBP and FDA management, inspectors, and investigators; and reviewed relevant documents on inspection and interdiction procedures. At the international mail facilities, we also met with officials from USPS regarding mail handling and processing procedures. The information from our site visits is limited to the 3 international mail facilities and 2 carrier facilities and is not generalizable to all 14 international mail facilities and 29 carrier facilities. We conducted our review from April 2004 to August 2005 in accordance with generally accepted government auditing standards. Appendix I provides more details about our scope and methodology.

Results in Brief

The information currently available on the safety of illegally imported prescription drugs is very limited, and neither CBP nor FDA systematically

²Representatives of these two card credit associations testified at congressional hearings in July 2004 on matters related to the illegal importation of prescription drugs. In addition, a DEA official identified these associations as the organizations used by the majority of Internet drug sites.

collects data on the volume of these imports. Nevertheless, on the basis of their own observations and limited information they have collected at some mail and carrier facilities, both CBP and FDA officials said the volume of prescription drugs imported into the United States is substantial. For example, a December 2004 HHS report states that approximately 10 million packages containing prescription drugs enter the United States annually from all over the world. However, this estimate was partially based on extrapolations from limited FDA observations at international mail branch facilities. Without reliable estimates of the volume of importation of prescription drugs, federal agencies cannot determine the full scope of the importation issue, which is of particular concern because of access to potentially unsafe or risky drugs, including highly addictive controlled substances. With regard to safety, the FDA officials told us 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. Consistent with these concerns, in June 2004, we reported that a sample of drugs purchased from some foreign-based Internet pharmacies posed safety risks for consumers.³ Specifically, we identified several problems associated with the handling, FDA approval status, and authenticity of 21 prescription drug samples we purchased from Internet pharmacies located in several foreign countries—Argentina, Costa Rica, Fiji, Mexico, India, Pakistan, the Philippines, Spain, Thailand, and Turkey. We found fewer problems among 47 other samples from U.S. and Canadian Internet pharmacies, although most of the drugs obtained from Canada were unapproved for the U.S. market.

Practices used at the mail and carrier facilities we visited to inspect packages and interdict prohibited prescription drugs are evolving based in part on procedures FDA issued in August 2004 to standardize the selection of packages by CBP and the forwarding of them to FDA for inspection. These procedures include guidelines for inspecting the packages and making admissibility determinations. However, under the current procedures, similar to previous practices, many packages that contain prescription drugs prohibited for import are released to the addressee. For example, packages that contain prescription drugs prohibited for import that have not been processed by FDA inspectors at the end of each workday are returned by FDA for delivery by USPS to the recipient. Also,

³See GAO, *Internet Pharmacies: Some Pose Safety Risks for Consumers*, [GAO-04-820](#) (Washington, D.C.: June 17, 2004) and GAO, *Internet Pharmacies: Some Pose Safety Risks for Consumers and Are Unreliable in Their Business Practices*, [GAO-04-888T](#) (Washington, D.C.: June 17, 2004).

if CBP does not select packages containing prescription drugs for inspection, the packages can bypass FDA review. In our July 2004 testimony, we stated that FDA officials acknowledged that tens of thousands of packages, containing drug products that may violate current laws and pose health risks to consumers, have been released.⁴ CBP has also implemented a new policy to expedite its handling of schedule III through V controlled substances imported as prescription drugs. Until recently, CBP was required to seize and begin forfeiture proceedings on packages of such controlled substances it detected—a process CBP considered to be time-consuming given the volume of controlled substances entering some facilities. In September 2004, CBP determined it could treat schedule III through V controlled substances as abandoned property, thereby (1) reducing the amount of information needed to process the drugs and (2) enabling CBP to destroy the drugs 30 days after notifying the addressee that the drugs would be treated as abandoned property if not claimed. According to CBP officials, treating imported prescription drugs that are controlled substances as abandoned property has enabled them to process these packages faster. However, they acknowledge that they do not know the extent to which the policy is having an effect on the volume of these drugs entering the country because packages can still bypass inspection.

We identified three factors beyond inspection and interdiction issues that have complicated federal efforts to enforce laws prohibiting the importation of prescription drugs for personal use. First, the volume of importation has strained federal resources at the mail and carrier facilities. According to officials we contacted, agencies have multiple priorities, which can constrain the resources they are able to allocate to the inspection and interdiction of prescription drugs and controlled substances imported through mail and carrier facilities. Second, the attributes of Internet pharmacies have posed challenges to law enforcement efforts for multiple reasons. For example, according to DEA officials, foreign-based operations operate outside the U.S. regulatory system and may be located in countries where some drugs, including controlled substances, are legal; thus, U.S. law enforcement agencies have been challenged in obtaining assistance from their foreign counterparts in investigations. Internet sites can also be installed, moved, or removed in a short period of time, making it difficult for law enforcement agencies to

⁴See GAO, *Prescription Drugs: Preliminary Observations on Efforts to Enforce the Prohibitions on Personal Importation*, [GAO-04-839T](#) (Washington, D.C.: July 22, 2004).

identify, track, monitor, or shut down those sites that operate illegally. Additionally, legal and practical considerations can limit the nature and extent to which commercial firms (e.g., Internet providers and credit card organizations) can assist in federal law enforcement actions. Third, the notification process in current law requires FDA to hold packages containing items that appear unapproved for import and give the addressee the opportunity to provide evidence of admissibility. FDA officials told us that this notification process is time-consuming—it can take up to 30 days per import—and can hinder their ability to quickly process packages containing potentially unapproved prescription drugs. FDA and the Secretary of Health and Human Services have expressed concerns about this process during testimony before Congress. Also, in a May 2001 correspondence to the Secretary of HHS, FDA proposed, among other things, that the notification requirement be eliminated. FDA noted that this change would likely require legislation, but as of July 2005, according to an HHS official and FDA officials, the Secretary had not responded with a legislative proposal to change FDA’s notification requirement. FDA officials said that any legislative change might necessitate consideration of some complicated issues, including whether the government would want to forgo an individual’s opportunity to provide evidence of admissibility for the drug(s) they ordered, or what imported prescription drugs and other imported products within FDA’s jurisdiction should be covered by the new law. In addition, USPS indicated that any discussion of options to expedite the processing and disposition of prescription drugs should consider international postal obligations.

CBP has organized a task force to coordinate the activities of federal agencies responsible for enforcing laws prohibiting the personal importation of prescription drugs. Among other things, the task force has performed joint operations to gather data on the type and source of unapproved drugs entering international mail facilities and developed public service campaigns to inform the public about the risks of buying prescription drugs from Internet providers in foreign countries. Although the task force appears to be a step in the right direction, efforts to address many of the challenges facing these agencies could be further enhanced if the task force established a strategic framework to promote accountability and guide resource and policy decisions. Specifically, the task force may be missing opportunities to further enhance its efforts because it has not defined the scope of the problem (i.e., it has not estimated the volume of imported prescription drugs entering specific international mail and carrier facilities), established milestones and performance measures to gauge results, and determined necessary resources and investments while balancing risk reduction with costs and considering task force members’

other law enforcement priorities. Our past work has shown that a strategic framework that includes these key elements, among others, is particularly useful in addressing problems, such as prescription drug importation, that are national in scope and involve multiple agencies with varying jurisdictions. Without such a strategic framework, it will be difficult for agency officials and congressional decision makers to oversee the overall federal effort, hold agencies accountable for their individual efforts, adjust to changing conditions, and ensure consistent and focused attention to the enforcement of prescription drug importation laws.

To help ensure the government maximizes its ability to enforce laws governing the personal importation of prescription drugs, we recommend that the CBP Commissioner, in concert with other agencies responsible for enforcing these laws, develop and implement a strategic framework that, at a minimum, includes establishing an approach to more reliably estimate the volume of prohibited prescription drugs imported through international mail and carrier facilities; determine resource needs and target resources based on priorities; establish performance measures and milestones; and evaluate progress, identify barriers to achieving goals, and suggest modifications. Also, in view of the FDA's continuing concern about the statutory notification requirement and its impact on enforcement, we also recommend that the Secretary of HHS assess the ramifications of removing or modifying the requirement, report on the results of this assessment, and, if appropriate, recommend changes to Congress.

DEA and ONDCP generally agreed with our recommendation that the CBP task force develop a strategic framework. DEA agreed that such a framework needs to be flexible to allow for changing conditions and said DEA will, in concert with other task force agencies, support the CBP Commissioner's strategic framework for the interagency task force. DHS generally agreed with the contents of our report and said that CBP is convening a task force meeting to discuss our recommendation.

While generally concurring with our recommendation for a strategic framework, HHS questioned the need to include an approach for estimating the volume of unapproved drugs entering the country, because it believed its current estimates are valid. HHS also said our statement that the task force agencies could develop statistically valid volume estimates and realistic risk-based estimates of the number of staff needed to interdict parcels at mail facilities did not recognize FDA's current level of effort at these facilities relative to its competing priorities. We believe that developing more systematic and reliable volume estimates might position

agencies to better define the scope of the problem so that decision makers can make informed choices about resources, especially in light of competing priorities. Regarding our recommendation to assess the ramifications of removing or modifying FDA's statutorily required notification process, HHS generally agreed and stated that it intended to pursue an updated assessment.

USPS did not state whether it concurred with our recommendations, but it noted that discussions of options to expedite the processing and disposition of prescription drugs must consider international postal obligations.

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 14 USPS 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 noncontrolled 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 international mail 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.⁵ Under the act and implementing regulations, this includes foreign versions of FDA-approved drugs if, for example, neither the foreign

⁵An 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. §§ 351, 352, 355.

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 not interdict personal prescription drug imports that do not contain controlled substances under specified circumstances, such as importing a small quantity for treatment of a serious condition, generally not more than a 90-day supply of a drug not available domestically.⁶ The importation of prohibited 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.

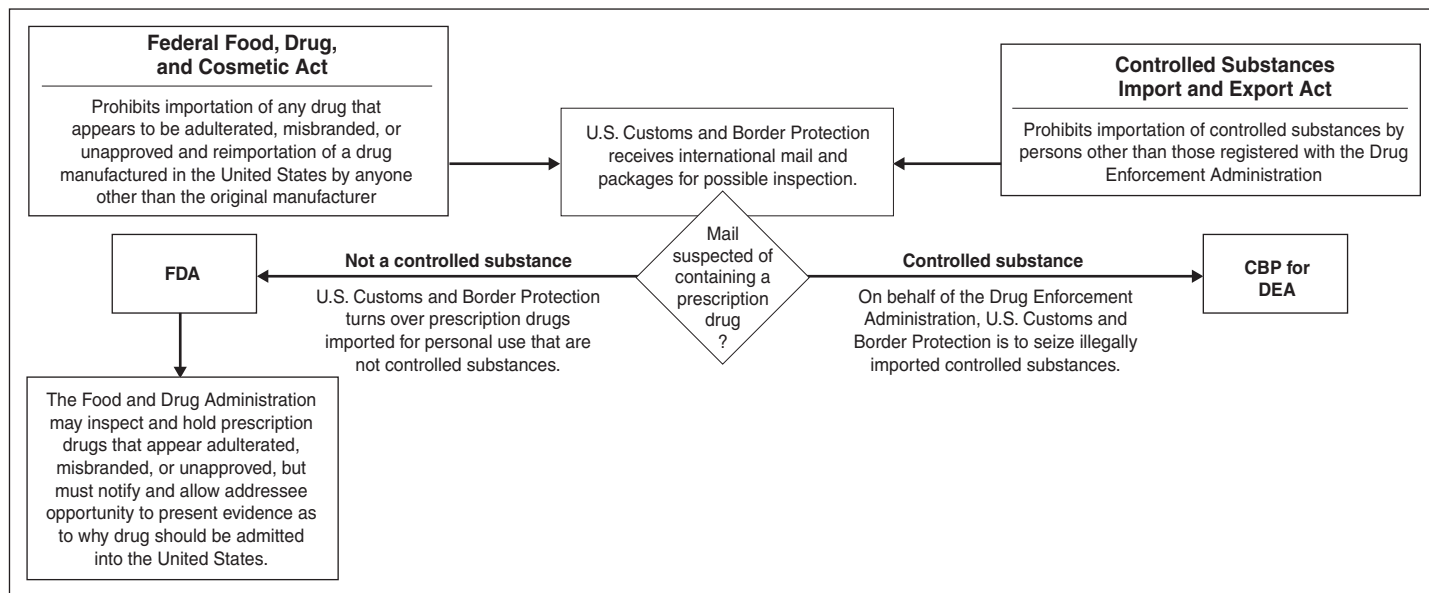
In addition, the Controlled Substances Import and Export Act, among other things, generally prohibits personal importation of those prescription drugs that are controlled substances, such as Valium. (See app. II for a general description of controlled substances.) Under the act, shipment of controlled substances to a purchaser in the United States from another country is only permitted if the purchaser is registered with DEA as an importer and is in compliance with the Controlled Substances Import and Export Act and DEA requirements. As outlined in the act, it would be difficult, if not impossible, for an individual consumer seeking to import a controlled substance for personal use to meet the standards for registration and related requirements.⁷ Figure 1 illustrates the two acts that

⁶According 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.

⁷The 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.

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.

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.

CBP is to seize illegally imported controlled substances it detects on behalf of DEA.⁸ 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.⁹ CBP is to turn over packages suspected of containing prescription drugs that are not controlled substances to FDA.¹⁰ FDA investigators may inspect such

⁸See 19 U.S.C. § 1595a(c)(1)(B); 19 C.F.R. §§ 162.23, 145.59, 145.58, 12.36. Controlled substances in schedules I and II are subject to summary forfeiture without notice, but those in schedule III through V are not. (See app. II for general description of controlled substances schedules I through V.)

⁹See 19 C.F.R. §§ 162.31, 162.32, 162.45, 162.45a, 162.46, 162.47, 162.63.

¹⁰See 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.

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.¹¹ If the addressee does not provide evidence that overcomes the appearance of inadmissibility, then the item is refused admission and returned to the sender.

Investigations that may arise from CBP and FDA inspections may fall within the jurisdiction of other federal agencies. DEA, ICE, and FDA investigators have related law enforcement responsibilities and may engage in investigations stemming from the discovery of illegally imported prescription drugs. Although USPS's Inspection Service does not have the authority, without a federal search warrant, to open packages suspected of containing illegal drugs, it may collaborate with other federal agencies in certain investigations. Also, ONDCP is responsible for formulating the nation's drug control strategy and has general authority for addressing policy issues concerning the illegal distribution of controlled substances. ONDCP's authority does not, however, include prescription drugs that are not controlled substances.

Volume of Prescription Drug Imports Is Unknown but Believed to Be Substantial, and the Safety of These Drug Imports Is Not Assured

CBP and FDA do not systematically collect data on the volume of prescription drugs and controlled substances they encounter at the mail and carrier facilities. On the basis of their own observations and limited information they obtained at selected mail and carrier facilities, CBP and FDA officials believe the volume of prescription drug importation into the United States is substantial and increasing. However, neither agency has developed reliable estimates of the number of prescription drugs imported into the country. Further, the available information shows that some imported prescription drugs can pose safety concerns. We reported in June 2004 that prescription drugs purchased from some foreign-based Internet pharmacies posed safety risks for consumers. 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. Of particular concern is the access to highly addictive controlled substances, which can be imported by consumers of any age sometimes without a prescription or consultation with a physician.

¹¹See 21 U.S.C. § 381(a); 21 CFR §1.94.

CBP and FDA Do Not Know the Full Scope of Prohibited Prescription Drug Importation, but Believe It to Be Substantial

CBP and FDA do not systematically collect data on the volume of prescription drugs and controlled substances they encounter at the mail and carrier facilities. Without an accurate estimate of the volume of importation of prescription drugs, federal agencies cannot determine the full scope of the importation issue. Yet FDA officials have often testified regarding the large and steadily increasing volume of packages containing prohibited prescription drugs entering the United States through the international mail and carrier facilities. CBP and FDA officials have said that in recent years they have observed increasingly more packages containing prescription drugs being imported through the mail facilities. However, neither agency has complete data to estimate volume of importation. For example, a CBP official recently testified that the agency did not have data on the total number of packages containing imported controlled substances. A CBP official at a mail facility told us that to determine the total volume of prescription drug importation would require that the CBP personnel inspect each mail item—which they currently do not do, in part because mail from certain countries bypasses inspection—and tally those that were suspected of containing prescription drugs. This official said that he did not have the resources at his facility for such an undertaking. In addition, neither CBP nor FDA tracked the number of packages suspected of containing prescription drugs that were held for FDA review. FDA officials told us that CBP and FDA currently have no mechanism for keeping an accurate count of the volume of illegally imported drugs, because of the large volume of packages arriving daily through the international mail and carriers. Furthermore, FDA officials told us that FDA did not routinely track items that contained prescription drugs potentially prohibited for import that they released and returned for delivery to the recipient. However, they said that FDA had begun gathering from the field information on the imported packages it handles, but as of July 2005, this effort was still being refined.

CBP and FDA, in coordination with other federal agencies, have conducted special operations to gain insight regarding the volume of imported prescription drugs entering through selected mail facilities. Generally, these were onetime, targeted efforts to identify and tally the packages containing prescription drugs imported through a particular facility during a certain time period and to generate information for possible investigation. The limited data collected have shown wide variations in volume. For example, CBP officials at one mail facility estimated that approximately 3,300 packages containing prescription drugs entered the facility in 1 week. CBP officials at another mail facility estimated that 4,300 packages containing prescription drugs entered the facility in 1 day. While these data provide some insight regarding the

number of packages containing prescription drugs at a selected mail facility during a certain time period, the data are not representative of other time periods or projectable to other facilities.

Debate continues over the estimated volume of prescription drugs entering the United States through mail and express carrier facilities. During congressional hearings over the past 4 years, FDA officials, among others, have presented estimates of the volume of imported prescription drugs ranging from 2 million to 20 million packages in a given year. Each estimate has its limitations; for example, some estimates were extrapolations from data gathered at a single mail facility. More recently, a December 2004 HHS report stated that approximately 10 million packages containing prescription drugs enter the United States—nearly 5 million packages from Canada and another 5 million mail packages from other countries.¹² However, these estimates also have limitations, being partially based on extrapolations from limited FDA observations at international mail branch facilities. Specifically, FDA officials told us that FDA developed its estimate for Canadian drugs entering the country using (1) IMS Health¹³ estimates that 12 million prescriptions sold from Canadian pharmacies were imported into the United States in 2003¹⁴ and (2) FDA's experience during special operations at various locations from which it concluded that there appeared to be about 2.5 prescriptions in each package. According to FDA officials, the estimate for other countries was an extrapolation using the estimated 5 million packages from Canada in conjunction with FDA's observations, likewise made during special operations, that 50 percent of the mail packages enter from countries other than Canada.

Safety of Prescription Drug Imports Is Not Assured

FDA officials have said 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 said that consumers who purchase prescription drugs from

¹²HHS Task Force on Drug Importation, *Report on Prescription Drug Importation*, Department of Health and Human Services, December 2004.

¹³IMS Health is a management consulting firm that provides information to pharmaceutical and health care industries. It operates in more than 100 countries and receives data from data suppliers around the world.

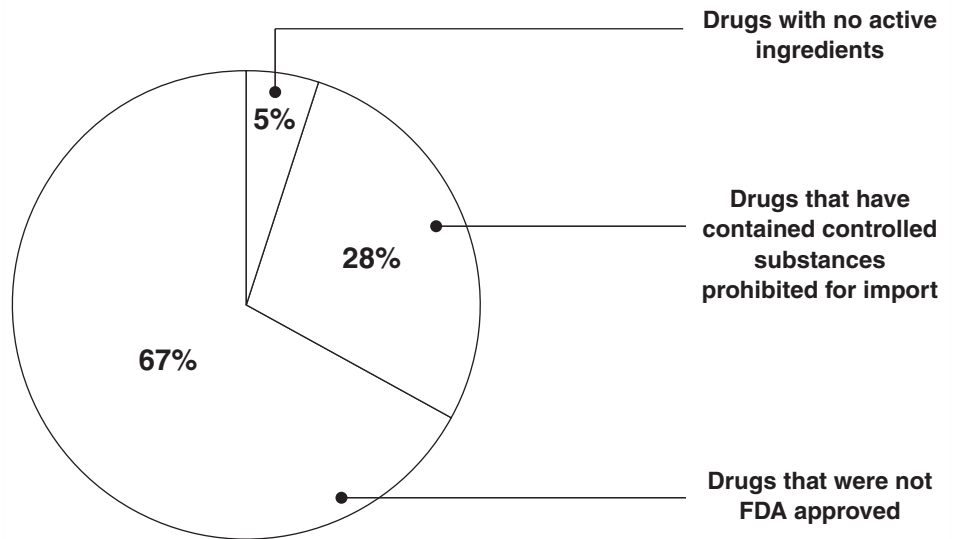
¹⁴FDA officials stated that while IMS's survey of pharmacies was not 100 percent comprehensive, the data were adjusted for the pharmacies not included in its survey.

foreign-based Internet pharmacies are at risk of not fully knowing the safety or quality of what they are importing. They further said 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 done limited analysis of the imported prescription drugs identified during special operations, and the results have raised questions about the safety of some of the drugs. For example, during a special operation in 2003 to identify and assess counterfeit and potentially unsafe imported drugs at four mail facilities, CBP and FDA inspected 1,153 packages that contained prescription drugs.¹⁵ According to a CBP report, 1,019, or 88 percent, of the imported drug products were in violation of the Federal Food, Drug, and Cosmetic Act or the Controlled Substances Import and Export Act. Some of the drugs were foreign versions of U.S.-approved drugs that are unapproved for import, including Lipitor (a cholesterol-lowering drug), Viagra, and Propecia. Other drugs never had FDA approval. For example, Taro-warfarin, an apparent unapproved version of Warfarin, which is used to prevent blood clotting, was imported from Canada. The drug raised safety concerns because its potency may vary depending on how it is manufactured, and it requires careful patient monitoring because it can cause life-threatening bleeding if not properly administered. A CBP laboratory analyzed 180 of the 1,153 drugs inspected, which showed that many of the imported drugs could pose safety risks. The drugs tested included some 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 or initial screening. 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.

¹⁵According to CBP officials, packages shipped through four mail facilities 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 CBP's historical experience.

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



Source: GAO analysis of CBP information.

In a past review we found that prescription drugs ordered from some foreign-based Internet pharmacies posed safety risks for consumers. Specifically, in a June 2004 report, we identified several problems associated with the handling, FDA approval status, and authenticity of 21 prescription drug samples we purchased from Internet pharmacies located in several foreign countries—Argentina, Costa Rica, Fiji, Mexico, India, Pakistan, the Philippines, Spain, Thailand, and Turkey.¹⁶ Our work showed that most of the drugs, all of which we received via consignment carrier shipment or the U.S. mail, were unapproved for the U.S. market because, for example, the labeling 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. For example, three samples that should have been shipped in a temperature-controlled environment arrived in envelopes without insulation, and five

¹⁶GAO-04-820 and GAO-04-888T.

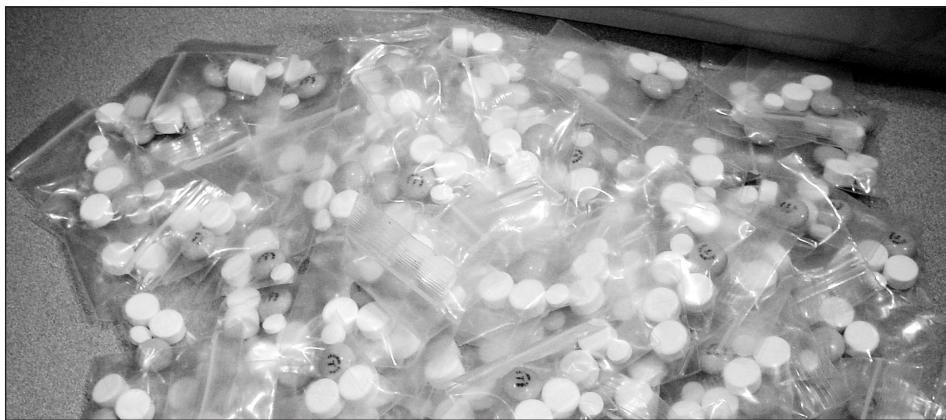
samples contained tablets enclosed in punctured blister packs, potentially exposing them to damaging light or moisture.

- Two were found to be counterfeit versions of the products we ordered.
- 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 said that it was notable that we identified numerous problems among the samples we received despite the relatively small number of drugs we purchased, consistent with problems that had been recently identified by state and federal regulatory agencies.

Similarly, during our current review, we observed that some prescription drugs imported through the mail and carrier facilities were not shipped in protective packages, including some wrapped in foil or in plastic bags. In addition to being shipped without containers, the drugs also lacked product identifications, directions for use, or warning labels. For some drugs, the origin and contents could not be immediately determined by CBP or FDA inspection. Figure 3 illustrates an example of drugs that were sent without labeling.

Figure 3: Drugs Sent without Labeling



Source: FDA.

Highly Addictive Controlled Substances Widely Available via the Internet

Federal agencies and professional medical and pharmacy associations have found that consumers, of any age, can obtain highly addictive controlled substances from Internet pharmacies, sometimes without a prescription or consultation with a physician. For example, a DEA official recently testified that Internet pharmacies that offer to sell controlled substances directly to consumers without a prescription and without requiring consultation with a physician can increase the possibility of addiction, access to counterfeit products, and adverse reactions to medications. According to the Office of National Drug Control Policy, Internet pharmacies that offer controlled substances bypass traditional regulations and established safeguards and expose consumers to potentially counterfeit, adulterated, and contaminated products. Both DEA and ONDCP have found that the easy availability of controlled substances directly to consumers over the Internet has significant implications for public health, given the opportunities for misuse and abuse of these addictive drugs.

The American Medical Association recently testified that Internet pharmacies that offer controlled substances without requiring a prescription or consultation with a physician contribute to the growing availability and increased use of addictive drugs for nonmedical purposes. To demonstrate the ease with which controlled substances can be obtained via the Internet, the National Association of Boards of Pharmacy received prescription drugs from four different Internet pharmacies.¹⁷ From one of the Internet pharmacies, the association reported it received a shipment of Valium—a schedule IV controlled substance used to treat muscle spasm or anxiety—despite providing no prescription and the height and weight information for a small dog. The association also reported that 2 days after it received its shipment of 30 tablets of Xanax—a schedule IV controlled substance used to treat anxiety—the Internet pharmacy sent daily refill reminders via electronic mail.

¹⁷In December 2003 and January 2004, the association ordered eight different drugs from five Web sites and received drugs from four of the sites. All of the drugs received were labeled in a foreign language.

Some Targeted Packages Containing Prescription Drugs Are Interdicted, but Many Others Are Not

In our July 2004 testimony, we reported that while some targeted packages were inspected and interdicted, many others either were not inspected and were released to the addressees or were released after being held for inspection. At the time, FDA officials said that because they were unable to process the volume of targeted packages, they released tens of thousands of packages containing drug products that may violate current prohibitions and could have posed a health risk to consumers. In August 2004, FDA issued standard operating procedures to prioritize package selection, package examination, and admissibility determinations. While the new procedures may encourage uniform practices at the mail facilities, packages that contain potentially prohibited prescription drugs continue to be released to the addressee. Recently, CBP also issued a new policy for processing packages with controlled substances without using time-consuming seizure and forfeiture procedures. While the policy may reduce processing time and encourage the interdiction of more controlled substances, CBP officials do not know whether the new policy has had an impact on the volume of prohibited prescription drug importation.

New Procedures Should Encourage Uniform Practices, but They Still Allow Many Packages Containing Prescription Drugs to Be Released

In our July 2004 testimony, we reported that CBP and FDA officials at selected mail and carrier facilities used different practices and procedures to inspect and interdict packages that contain prescription drugs.¹⁸ While each of the facilities we visited targeted packages for inspection, the basis upon which packages were targeted could vary and was generally based on several factors, such as the inspector's intuition and experience, whether the packages originated from suspect countries or companies, or were shipments to individuals. At that time, CBP officials told us that the factors could also include intelligence gained from prior seizures, headquarters, or other field locations. Specifically, officials at one facility we visited targeted packages on the basis of the country of origin. At this facility, FDA provided CBP with a list of seven countries to target, the composition of which changed periodically, and asked that CBP hold the packages they suspected of containing prescription drugs from those countries. Typically, CBP officials at this facility released packages to the addressee containing prescription drugs that were not from one of the targeted countries.

¹⁸See GAO, *Prescription Drugs: Preliminary Observations on Efforts to Enforce the Prohibitions on Personal Importation*, [GAO-04-839T](#) (Washington, D.C.: July 22, 2004).

Officials at another facility targeted packages based on whether the packages were suspected of containing a certain quantity of prescription drugs. At this facility, CBP officials held packages containing prescription drugs that appeared to exceed a 90-day supply—a violation of one of the criteria in FDA’s personal importation policy.¹⁹ If the package contained prescription drugs, including in some cases controlled substances, that appeared to be 90 pills or less, it was typically released. FDA officials at this facility told us that every week CBP turned over to FDA hundreds of packages that contained quantities of prescription drugs that appeared to exceed the 90-day supply. However, the FDA officials said that they were able to process a total of approximately 20 packages per day and, as a result, returned many of the packages for release to the addressee. FDA officials explained that 20 packages a day is an approximation because some packages can take longer than others to inspect, particularly if the packages contain many different types of drugs that need to be examined.

According to FDA officials and data, in fiscal year 2004, FDA field personnel physically inspected approximately 20,800 packages containing prescription drugs entering the United States through the international mail facilities.²⁰ Of the packages inspected, FDA’s data showed that 98 percent were refused entry and marked returned to sender and the remaining, about 450, were released to the addressee. The FDA data indicate the number of packages physically inspected by FDA personnel and the results of that process; they do not specify the number of individual prescription drugs or smaller packages of drugs within a larger package. Most important, these data do not indicate the universe of packages of prescription drugs coming through the mail facilities.

Figure 4 shows bins containing packages of suspected prescription drugs being held for FDA review and possible inspection at one mail facility.

¹⁹For a description of some of the other criteria in FDA’s personal importation policy, see footnote 6.

²⁰These data are collected in FDA’s OASIS database. According to FDA, information in OASIS is collected as an “entry,” which for international mail usually represents a single package. However, within each package, there may be more than one drug product.

Figure 4: Bins Containing Packages of Suspected Prescription Drugs Being Held for FDA Review and Possible Inspection



Source: GAO with permission of CBP and FDA.

In August 2004, FDA issued standard operating procedures that, according to FDA officials, have been adopted nationwide. According to FDA, the purpose of the new procedures was to “provide a standard operating environment for the prioritized selection, examination and admissibility determination of FDA-regulated pharmaceuticals imported into the United States via international mail.” Under the procedures, CBP personnel are to forward to FDA personnel any mail items, from FDA’s national list of targeted countries and based on local criteria,²¹ that appear to contain prescription drugs. The procedures outline how FDA personnel are to prioritize packages for inspection, inspect the packages, and make admissibility determinations. Deviations from the procedures must be requested by facility personnel and approved by FDA management. While the new procedures should encourage processing uniformity across facilities, many packages that contain prescription drugs are still released.

²¹Local criteria can include other targeted countries and additional intelligence.

Specifically, according to the procedures, all packages forwarded by CBP but not processed by FDA inspectors at the end of each workday are to be returned for delivery by USPS to the recipient. However, according to the procedures, packages considered to represent a significant and immediate health hazard may be held over to the next day for processing.

CBP and FDA officials at two facilities told us that the new procedures resulted in an increase in the number of packages CBP personnel refer to FDA. Officials at one facility estimated that CBP referrals have increased from approximately 500 to an average of 2,000 packages per day. The FDA officials noted that the procedures did not resolve the heavy volume of prescription drug importation or FDA's ability to deal with the volume, nor were they designed to do so. While the packages that are not targeted are released without inspection, so are many packages that are targeted and referred to FDA personnel. At one facility, FDA officials estimated that each week they return without inspection 9,000 to 10,000 of the packages referred to them by CBP. They said these packages were given to USPS officials for delivery to the addressee. If this facility were to maintain that level of release, about half a million packages per year would be delivered to addressees.

New Controlled Substances Policy May Improve Interdiction Efforts, but Impact on Importation Is Unclear

In our July 2004 testimony, we reported that CBP officials were to seize the illegally imported controlled substances they detected. However, at that time, some illegally imported controlled substances were not seized by CBP. For example, CBP officials at one mail facility told us that they experienced an increased volume of controlled substances and, in several months, had accumulated a backlog of over 40,700 packages containing schedule IV substances. To keep the drugs from entering U.S. commerce and to clear the backlog, a CPB official at the facility said that CBP's headquarters office granted them permission to send most of the drugs back to the sender.²² CBP officials at another facility told us that certain controlled substances were a priority and seized when detected; priority substances included anabolic steroids (a category of schedule III drugs that promote muscle growth and potentially boost athletic performance), and gamma hydroxybutyrate (a schedule I drug that acts as a central nervous system depressant). At this facility, other controlled substances

²²According to a CBP official, most of the drugs returned were schedule IV controlled substances. They said that a small number of the packages contained nonscheduled prescription drugs that were referred to FDA. Also, CBP seized a small number of items that did not have a return address.

encountered that were not a priority and that were shipped in small amounts, less than a 90-day supply, could be released to the addressee. CBP officials at another facility we visited turned over packages they suspected of containing controlled substances in small amounts to FDA for processing. Neither returning an illegally imported controlled substance to the sender nor releasing it to the addressee is in accordance with federal law.

CBP field personnel said they did not have the resources to seize all the controlled substances they detected. Officials said that the seizure process can be time-consuming, taking approximately 1 hour for each package containing controlled substances. According to CBP officials, when an item is seized, the inspector records the contents of each package—including the type of drugs and the number of pills or vials in each package. If the substance is a schedule I or II controlled substance, it is to be summarily forfeited without notice, after seizure. However, if it is a schedule III through V controlled substance, CBP officials are to notify the addressee that the package was seized²³ and give the addressee an opportunity to contest the forfeiture by providing evidence of the package's admissibility and trying to claim the package at a forfeiture hearing.²⁴

To address the seizure backlog and give CBP staff more flexibility in handling controlled substances, in September 2004, CBP implemented a national policy for processing controlled substances, schedule III through V, imported through the mail and carrier facilities. According to the policy, packages containing controlled substances should no longer be transferred to FDA for disposition, released to the addressee, or returned to the sender. CBP field personnel are to hold the packages containing controlled substances in schedules III through V as unclaimed or abandoned property as an alternative to a seizure.²⁵ According to a CBP headquarters official, processing a controlled substance as abandoned property is a less arduous process because it requires less information be

²³The seized package could also be submitted to ICE for possible investigation of the addressee and the sender.

²⁴Since schedule I and schedule II controlled substances are subject to summary forfeiture without notice, there is no opportunity to contest the forfeiture of these drugs.

²⁵Under the policy, unless accompanied by a valid DEA Import Permit or DEA Declaration, schedules I and II controlled substances are to be seized pursuant to 19 U.S.C § 1595a(c)(1)(B) and processed in accordance with established seized asset procedures.

entered into a database than if the same property were to be seized. Once CBP deems the controlled substance to be unclaimed property, the addressee is notified that he or she has the option to voluntarily abandon the package or have the package seized. If the addressee voluntarily abandons the package or does not respond to the notification letter within 30 days, the package will be eligible for immediate destruction. If the addressee chooses to have the package seized, there would be an opportunity to contest the forfeiture and claim the package, as described above. CBP also instituted an on-site data collection system at international mail and express carrier facilities to record schedule III through V controlled substances interdicted using this new process.²⁶ From September 2004 to the end of June 2005, CBP reported that a total of approximately 61,700 packages of these substances were interdicted, about 61,500 at international mail facilities and 200 at express carrier facilities.

Generally, CBP officials we interviewed told us that the recent policy improved their ability to quickly process the volume of schedule III through V controlled substances they detected. A CBP official at one facility said that the abandonment process is faster than the seizure process, as it requires much less paperwork. A CBP headquarters official told us that the abandonment process takes an inspector at a mail facility about 1 minute to process a package. He added that the new policy was intended to eliminate the backlog of schedule III through V controlled substances at the facilities. Figure 5 shows schedule III through V controlled substances that were abandoned during a 1-month period at one mail facility and awaiting destruction.

²⁶CBP officials emphasized that these data only include schedule III through V controlled substances interdicted through its new process and do not include those schedule III through V controlled substances seized. According to a CBP headquarters official, the number of interdictions made using the controlled substance policy implemented September 1, 2004, refers to single packages, because these detentions are almost all personal use quantities. In contrast CBP seizure data for schedules III, IV, and V controlled substances are most likely commercial shipments and, therefore, could include multiple packages.

Figure 5: Abandoned Schedule III through V Controlled Substances Awaiting Destruction



Source: GAO with permission of CBP.

While the recent policy may have expedited processing, CBP officials in the field and in headquarters said that they do not know whether the new policy has had any impact on the volume of controlled substances illegally entering the country that reach the intended recipient. Generally, CBP officials do not know the extent of packages that contain controlled substances that are undetected and released. For example, CBP officials at one facility told us that they used historical data to determine the countries that are likely sources for controlled substances and target the mail from those countries. They do not know the volume of controlled substances contained in the mail from the nontargeted countries. A CBP official at another facility said that he believed the volume of controlled substances imported through the facility had begun to decrease but had no

data to support this claim. One CBP official at a carrier facility told us that because the express carrier environment is constantly changing with new routes, service areas, and increasing freight volume and because smuggling trends shift in response to past enforcement efforts, he could not ascertain the quantities of packages containing controlled substances that are undetected by CBP.

Packages Containing Prescription Drugs Can Bypass FDA Review at the Carrier Facilities

Packages containing prescription drugs can also bypass FDA inspection at carrier facilities because of inaccurate information about the contents of the package. Unlike packages at mail facilities, packages arriving at carrier facilities we visited are preceded by manifests, which provide information from the shipper, including a description of the packages' contents. While the shipments are en route, CBP and FDA officials are to review this information electronically and select packages they would like to inspect when the shipment arrives.²⁷ FDA officials at two carrier facilities we visited told us they review the information for packages described as prescription drugs or with a related term, such as pharmaceuticals or medicine. CBP and FDA officials told us that there are no assurances that the shipper's description of the contents is accurate. The FDA officials at the carrier facilities we visited told us that if a package contains a prescription drug but is inaccurately described, it would not likely be inspected by FDA personnel.

²⁷According to FDA officials, express carrier facility personnel electronically enter information into a CBP database that automatically transfers relevant data to FDA's OASIS database. For carrier facilities, FDA said that a data entry is an accounting vehicle that represents all products within a shipment. However, importers have the option to report a single shipment as more than one entry. For fiscal year 2004, approximately 45,000 shipments containing prescription drugs entering the United States were reported by express carrier facilities and recorded in OASIS. FDA officials said that FDA field personnel primarily reviewed this information electronically but physically inspected some packages, with the number physically inspected varying by facility. Approximately 2,000 were refused entry by FDA after physical inspection and marked return to sender. Almost 43,000 were released to the addressee, usually after electronic review. However, FDA officials noted that the information on prescription drugs entered into OASIS at express carrier facilities could vary by carrier, site for the same carrier, CBP local criteria at a site, or local arrangements between FDA and CBP. Accordingly, it is difficult to determine from these data the proportion imported for personal use. Most important, these data do not indicate the universe of shipments of prescription drugs coming through the express carrier facilities.

According to FDA officials, FDA field personnel are not continually on-site at the two carrier facilities we visited. At the FDA field office that has responsibility for inspecting packages at one carrier facility, we observed FDA field personnel reviewing electronic information regarding packages that were en route to the carrier facility. The official said that the field office has electronic information regarding an average of 400 packages per day available for review. If the shipper does not provide enough information about its package, FDA field personnel can request that the carrier detain the package until more information is provided electronically or until the FDA personnel can visit the facility to conduct a physical inspection of the package. The number of physical inspections at the facilities we visited varied depending on the number of packages electronically reviewed. FDA field personnel, responsible for inspection at the other carrier facility, reported that in September 2004 they electronically requested that an average of 20 packages per day be held at the facility for a physical inspection. However, on occasion when the FDA personnel went to the facility to conduct the inspection, the packages were unavailable because they could not be found, had been delivered to the recipient by the carrier, or had been returned to the shipper. According to FDA headquarters officials, since our visit, FDA field personnel may now be visiting the carrier facility on a more routine basis.

In contrast, CBP inspectors are located on-site at the carrier facilities we visited. As a result, CBP personnel are able to inspect packages upon arrival of the shipment. In addition, according to CBP officials at the facility, CBP's on-site presence allows the inspectors to conduct random inspections, on a routine basis, of packages as they are processed at the facility. Instead of relying solely on the information provided by the shipper, CBP personnel said they conduct random inspections, on a daily basis, as another means to identify items that may be unapproved for import. CBP officials told us that they conduct these inspections because the shipper's information can be inaccurate. During our visit we observed the CBP personnel randomly inspect several hundred packages selected. During these random inspections, CBP inspectors told us that they often come across packages containing noncontrolled prescription drugs, which they will set aside for FDA inspectors. For example, during a random inspection, CBP officials found and held for FDA 13 packages containing a human growth hormone—prohibited from import—that were inaccurately described as glassware. In contrast, according to FDA field personnel with inspection responsibility at the two carrier facilities we visited, few random inspections of packages were performed and when they occurred they were typically part of a special operation. For example, an FDA field

official told us that FDA personnel planned to perform one random inspection effort per year.

CBP officials told us that they would like to have FDA personnel on-site to improve coordination efforts. One CBP Port Director said that he would like to have FDA personnel on-site to share data, perform analysis to identify trends from CBP's referrals, and be available to immediately review prescription drugs. A CBP headquarters official also said that it would be helpful if FDA personnel were on-site to enable CBP officials to confer with them to identify controlled substances that are not clearly labeled. FDA officials told us that because FDA personnel review information regarding the packages electronically, there was no advantage to being physically on-site. Further, they said the responsible district can supply personnel to physically work at a given carrier facility for field examinations on an as-needed basis. FDA officials also noted that FDA is not reimbursed by the carriers to maintain staff on-site. By contrast, private express carriers reimburse the federal government for the personnel and equipment costs of the CBP staff located on-site. FDA officials said that there is not a provision under current law that would enable carriers to reimburse FDA so that it could maintain an on-site presence.

Factors beyond Inspection and Interdiction Complicate Efforts to Enforce the Prohibitions on Personal Importation of Prescription Drugs

We identified three factors beyond inspection and interdiction that have complicated federal efforts to enforce the prohibitions on prescription drugs imported for personal use: (1) the volume of importation has strained limited federal resources; (2) Internet pharmacies, particularly foreign-based sites, can operate outside of the U.S. regulatory system for noncontrolled and controlled prescription drugs and can evade federal law enforcement actions; and (3) current law requires that FDA notify addressees that their packages have been detained because they appear unapproved for import and give them the opportunity to provide admissibility evidence regarding their imported items.

Volume of Imports Can Strain Federal Resources

The current volume of prescription drug imports, coupled with competing agency priorities, has strained federal inspection and interdiction resources allocated to the mail facilities. CBP and FDA officials told us that the increased incidence of American consumers ordering drugs over the Internet in recent years has significantly contributed to the increase in imports through the international mail. CBP officials said that they are able to inspect only a fraction of the large number of mail and packages

shipped internationally. In 2004, FDA testified that each day thousands of individual packages containing prescription drugs are imported illegally into the United States. FDA officials have said that the large volume of imports has overwhelmed the resources they have allocated to the mail facilities. Officials add that they have little assurance that the available field personnel are able to inspect all the packages containing prescription drugs illegally imported for personal use through the mail.

Agencies have multiple priorities, which can affect the resources they are able to allocate to the mail and carrier facilities. For example, FDA has multiple areas of responsibility, which include, among other things, regulating new drug product approvals, the labeling and manufacturing standards for existing drug products, and the safety of a majority of food commodities and cosmetics, which, according to FDA officials, all go to FDA's mission of protecting the public health while facilitating the flow of legitimate trade. CBP's primary mission is preventing terrorists and terrorist weapons from entering the United States while also facilitating the flow of legitimate trade and travel. FDA and CBP personnel operate in multiple venues, such as land border crossings and seaports. DEA's multiple priorities include interdicting illicit drugs such as heroin or cocaine, investigating doctors and prescription forgers, and pursuing hijackings of drug shipments. DEA officials told us that they have limited resources and often have to balance efforts to address prescription drug importation with their other priorities.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 required the HHS Secretary to conduct a study on the importation of drugs that included a review of the adequacy of federal agency resources to inspect and interdict drugs unapproved for import.²⁸ The report, issued in 2004, states that substantial resources are needed to prevent the increasing volume of packages containing small quantities of drugs from entering the country. The Secretary found that despite agency efforts, including those with CBP, FDA currently does not have sufficient resources to ensure adequate inspection of the current volume of personal shipments of prescription drugs entering the United States.

²⁸The 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. Pub. L. No. 108-173, § 1122, 117 Stat. 2066, 2469 (2003).

CBP is also in the early stages of assessing the resources it needs at the mail facilities to address the volume of controlled substance imports. However, CBP officials admit that an assessment of resource needs is difficult because they do not know the scope of the problem and the impact of the new procedures. A CBP official told us that CBP has a statistician working on developing estimates on the volume of drugs entering mail facilities; however, he was uncertain whether this effort would be successful or useful for allocating resources. Likewise, in March 2005, FDA officials told us that they had begun to gather from the field information on the imported packages it handles, such as the number of packages held, reviewed, and forwarded for further investigation. However, as of July 2005, they could not provide any data because, according to the officials, this effort was new and still being refined.

Internet Pharmacies Challenge Law Enforcement Efforts

Internet pharmacies, particularly foreign-based sites, which operate outside the U.S. regulatory system, pose a challenge for regulators and law enforcement agencies. In our 2004 report, we described how traditionally, in the United States, the practice of pharmacy is regulated by state boards of pharmacy, which license pharmacists and pharmacies and establish and enforce standards. To legally dispense a prescription drug, a licensed pharmacist working in a licensed pharmacy must be presented a valid prescription from a licensed health care professional. The requirement that drugs be prescribed and dispensed by licensed professionals helps ensure patients receive the proper dose, take the medication correctly, and are informed about warnings, side effects, and other important information about the drug. However, the Internet allows online pharmacies and physicians to anonymously reach across state and national borders to prescribe, sell, and dispense prescription drugs without complying with state requirements or federal regulations regarding imports. Recently, FDA officials have testified that inadequately regulated foreign Internet sites have become portals for unsafe and illegal prescription drugs. FDA officials state that if a consumer has an adverse drug reaction or other problem, he or she may have little to no recourse because the operator of the pharmacy is often not known and FDA has limited authority to take action against foreign operators.

The nature of the Internet has challenged U.S. law enforcement agencies investigating Internet pharmacies, particularly foreign-based sites. Internet sites can easily be installed, moved, or removed in a short period of time. FDA officials said that one Internet site can be composed of multiple related sites and links, thereby making their investigations complex and resource intensive. This fluidity makes it difficult for law enforcement

agencies to identify, track, monitor, or shut down those sites that operate illegally. Further, FDA officials said that some Internet pharmacies do not disclose enough information on their Web sites to allow consumers to determine if the drugs they purchased were approved in the United States and dispensed according to state and federal laws. Some Internet pharmacies also do not disclose enough or accurate information regarding the source of the drugs they offer. An Internet pharmacy can claim that the drugs they offer originate in one country, but the drugs may actually be manufactured in another country. Similarly, the anonymous nature of the Internet allows consumers of any age to obtain drugs without a legitimate medical need.

According to FDA, when the Internet is used for an illegal sale of prescription drugs, to conduct an investigation they may need to work with the Department of Justice to establish grounds for a case, develop charges, and take action as they would if another sales medium, such as a store or magazine, had been used. Investigations can be more difficult when they involve foreign-based Internet sites, whose operators are outside of U.S. boundaries and may be in countries that have different drug approval and marketing approaches than the United States has. For example, according to DEA officials, drug laws and regulations regarding controlled substances vary widely by country. DEA officials told us their enforcement efforts with regard to imported controlled substances are hampered by the different drug laws in foreign countries. Internet pharmacy sites can be based in countries where the marketing and distribution of certain controlled substances are legal. Steroids, for example, sold over the Internet may be legal in the foreign country in which the online pharmacy is located.

Federal agencies can face challenges when working with foreign governments to share information or develop mechanisms for cooperative law enforcement. For example, FDA officials have testified that they possess limited investigatory jurisdiction over sellers in foreign countries and have had difficulty enforcing the law prohibiting prescription drug importation when foreign sellers are involved. A DEA official told us that the agency introduced a resolution at the March 2004 International Narcotics Control Board conference in Vienna, Austria, to encourage member states to work cooperatively on Internet pharmacy issues. However, the DEA official told us that it was difficult to convince some foreign governments that the illegal sales of prescription drugs over the Internet is a global problem and not restricted to the United States.

FDA and DEA officials told us that they work with commercial firms, including express carriers, credit card organizations, Internet providers, and online businesses to obtain information to investigate foreign pharmacies, but these investigations are complicated by legal and practical considerations. FDA and DEA officials said that the companies have been willing to work with government agencies to stop transactions involving prescription drugs prohibited from import, and some have alerted federal officials when suspicious activity is detected. However, officials also identified current legal and practical considerations that complicated obtaining information from organizations, such as credit card organizations. These considerations included privacy laws; federal law enforcement agencies' respective subpoena authority, priorities, and jurisdictions; and the ease with which merchants engaged in illegal activity can enter into a new contract with a different bank to use the same payment system.

For example, privacy laws sometimes limit the extent to which companies (e.g., credit card organizations) will provide information to federal agencies about parties to a transaction. According to FDA, DEA, and ICE officials, credit card organizations²⁹ and banks and other financial institutions³⁰ that issue credit cards will not provide to the agencies information about the parties involved in the transaction without a subpoena. Representatives from the credit card companies we contacted explained that these issues generally are resolved if the agency issues a properly authorized subpoena for the desired information.³¹ (See app. III for information on federal enforcement agencies' work with credit card organizations to enforce prohibitions on prescription drug importation.)

²⁹Two types of credit card organizations handle the four major U.S. credit cards. Credit card associations, such as Visa and MasterCard, license their member banks to issue bank cards, authorize merchants to accept those cards, or both. In contrast, full-service credit card companies, such as American Express and Discover, issue their own brands of cards directly to customers and authorize merchants to accept those cards. See also GAO, *Money Laundering: Extent of Money Laundering through Credit Cards Is Unknown*, GAO-02-670 (Washington, D.C.: July 22, 2002), and *Internet Gambling: An Overview of the Issues*, GAO-03-89 (Washington, D.C.: December 2, 2002).

³⁰When banks and financial institutions, rather than the credit card company, have the direct relationship with the merchants and credit cardholders, the former are the primary source of transactional information needed for law enforcement purposes.

³¹According to a DEA official, the majority of Internet drug sites used the payment systems of the two associations we contacted.

Notification Process Challenges Enforcement Efforts

FDA headquarters officials said that packages that contain prescription drugs for personal use that appear to be prohibited from import pose a challenge to their enforcement efforts because these packages cannot be automatically refused. Before any imported item is refused, the current law requires FDA to notify the owner or consignee that the item has been held because it appears to be prohibited and give the product's owner or consignee an opportunity to submit evidence of admissibility. If the recipient does not respond or does not present enough evidence to overcome the appearance of inadmissibility, then the item can be returned to the sender, or in some cases destroyed.

FDA officials told us that this requirement applies to all drug imports that are held under section 801(a) of the Federal Food, Drug, and Cosmetic Act. Nonetheless, they said that they believe this notification process is time consuming because each package must be itemized and entered into a database; a letter must be written to each addressee; and the product must be stored. The process can take up to 30 days per import—and can hinder their ability to quickly process packages containing prescription drugs prohibited from import. According to FDA investigators, in most instances, the addressee does not present evidence to support the drugs' admissibility, and the drugs are ultimately provided to CBP or the U.S. Postal Service for return to sender. FDA headquarters officials told us that the Standard Operating Procedures, introduced in August 2004 and discussed earlier in this report, were an attempt to help FDA address the burden associated with the notification process because it was designed to focus resources on packages containing drugs considered to be among the highest risk.

FDA concerns about the notification process are not new. In testimony before Congress, FDA and the Secretary of HHS raised concerns about the notification process, noting that it is time-consuming and resource intensive. However, FDA's testimony did not propose any legislative changes to address the concerns it identified. In May 2001, FDA's Acting Principal Deputy Commissioner wrote a memorandum to the Secretary of HHS expressing concern about the growing number of drugs imported for personal use and the dangers they posed to public health. The memorandum explained that because of the notice and opportunity to respond requirements, detaining and refusing entry of mail parcels was resource intensive. The Acting Principal Deputy Commissioner proposed, among other things, the removal of the requirement that FDA issue a notice before it could refuse and return personal use quantities of FDA-regulated products that appear violative of the Food, Drug, and Cosmetic Act. He noted that removal of the notification requirement would likely

require legislation, but without this change, FDA could not effectively prohibit mail importation for personal use.

As of July 2005, according to FDA officials and an HHS official, the Secretary had not responded with a specific legislative proposal to change FDA's notification requirement. FDA officials said that there are some complicating issues associated with eliminating the notification requirement. For example, they said that one of the arguments against eliminating the notification requirement is the importance of providing due process, which basically gives individuals the opportunity to present their case as to why they should be entitled to receive the property, in this case prescription drugs that they ordered from a foreign source. Another is to what extent the law should be changed to cover all imported prescription drugs and other products. In addition, USPS indicated that any discussion of options to expedite the processing and disposition of prescription drugs must consider international postal obligations, specifically the requirements of the Universal Postal Union (UPU).³² FDA officials said that currently, the notification requirement also applies to large commercial quantities of prescription drugs and other nonpharmaceutical products for which the requirement is not a problem. They said it has become a burden only because FDA and CBP are overwhelmed with a large volume of small packages.

FDA officials said that they have considered other options for dealing with this issue, such as summarily returning each package to the sender without going through the process. However, they said that the law would likely need to be changed to allow this, and, as with the current process, packages that are returned to the sender could, in turn, be sent back by the original sender to go through the process again. They said that another option might be destruction, but they were uncertain whether they had the authority to destroy drugs FDA intercepts; they indicated that the authority might more likely lie with CBP. Regardless, FDA officials said that whatever approach was adopted, FDA might continue to encounter a resource issue because field personnel would still need to open and

³²UPU is a specialized agency of the United Nations governing international postal services. According to the USPS, the Universal Postal Convention establishes a general rule that undeliverable items are to be returned to sender. UPU regulations provide that where an item can neither be delivered to the addressee nor returned to the sender, the Postal Service must notify the postal administration of origin of how the item was dealt with, including indicating the prohibition under which the item falls. USPS noted that this is particularly important with respect to registered or insured mail for which the Postal Service can be held financially responsible if it is not delivered or returned.

examine packages to ascertain whether they contained unapproved prescription drugs.

Federal Efforts to Coordinate Law Enforcement Activities Could Benefit from a Strategic Framework

Federal agencies have been taking steps to address Internet sales of prescription drugs since 1999, but these efforts have not positioned them to successfully prevent the influx of prescription drugs that are being imported through foreign pharmacies. CBP has recently organized a task force to coordinate federal efforts related to prescription drugs imported for personal use. This task force appears to be a step in the right direction. However, its efforts could be further enhanced if the task force established a strategic framework to promote accountability and guide resource and policy decisions. In January 2004, CBP organized an interagency task force to address various issues associated with unapproved prescription drugs entering the United States from foreign countries. Although CBP, FDA, ONDCP, DEA, and ICE appear to be working together to address these very complex issues, their efforts could be enhanced by a strategic framework that guides resource and policy decisions and promotes accountability. Such a framework that establishes measurable, quantifiable goals and strategies for achieving these goals, including a determination of resources needed to achieve the goals, would enhance the ability of agency officials and congressional decision makers to ensure accountability and consistent and focused attention to enforcing the prohibitions on personal importation.

Congress enacted the Government Performance and Results Act of 1993 to have agencies focus on the performance and results of programs, rather than on program resources and activities. The principles of the act include (1) establishing measurable goals and related measures, (2) developing strategies for achieving results, and (3) identifying the resources that will be required to achieve the goals. The act does not require agencies to use these principles for individual programs, but our work related to the act and the experience of leading organizations have shown that a strategic approach or framework is a starting point and basic underpinning for performance-based management—a means to strengthen program performance. A strategic framework can serve as a basis for guiding operations and help policy makers, including congressional decision makers and agency officials, make decisions about programs and activities.

Our work has also shown that a strategic framework can be useful in providing accountability and guiding resource and policy decisions, particularly in relation to issues that are national in scope and cross

agency jurisdictions, such as prescription drug importation.³³ When multiple agencies are working to address aspects of the same problem, there is a risk that overlap and fragmentation among programs can waste scarce funds, confuse and frustrate program customers, and limit overall program effectiveness.³⁴ Use of a strategic framework may help mitigate this risk.

Federal Agencies Have Recently Begun to Coordinate Efforts to Focus on Prescription Drugs Imported for Personal Use

Since 1999, federal law enforcement and regulatory agencies have organized various task forces and working groups to address issues associated with purchasing prescription drugs over the Internet; however, recent efforts have begun to focus particular attention on imported prescription drugs. For example, according to an FDA official, many of FDA's efforts, started in 1999, focused on Internet pharmaceutical sales by illicit domestic pharmacies and the risks associated with purchasing those drugs, rather than drugs that are being imported from foreign countries. This official said that although FDA had established working groups and advanced media campaigns to address problems associated with drugs purchased over the Internet from domestic sources, imported drugs have added a new dimension that was only incidentally recognized during efforts begun in 1999. He said that the plans developed by FDA in 1999 are still viable as far as domestic sales are concerned, but they have not been refocused to reflect concerns about imported prescriptions and did not position federal law enforcement agencies to anticipate the increased volume of drugs that are imported by individuals.

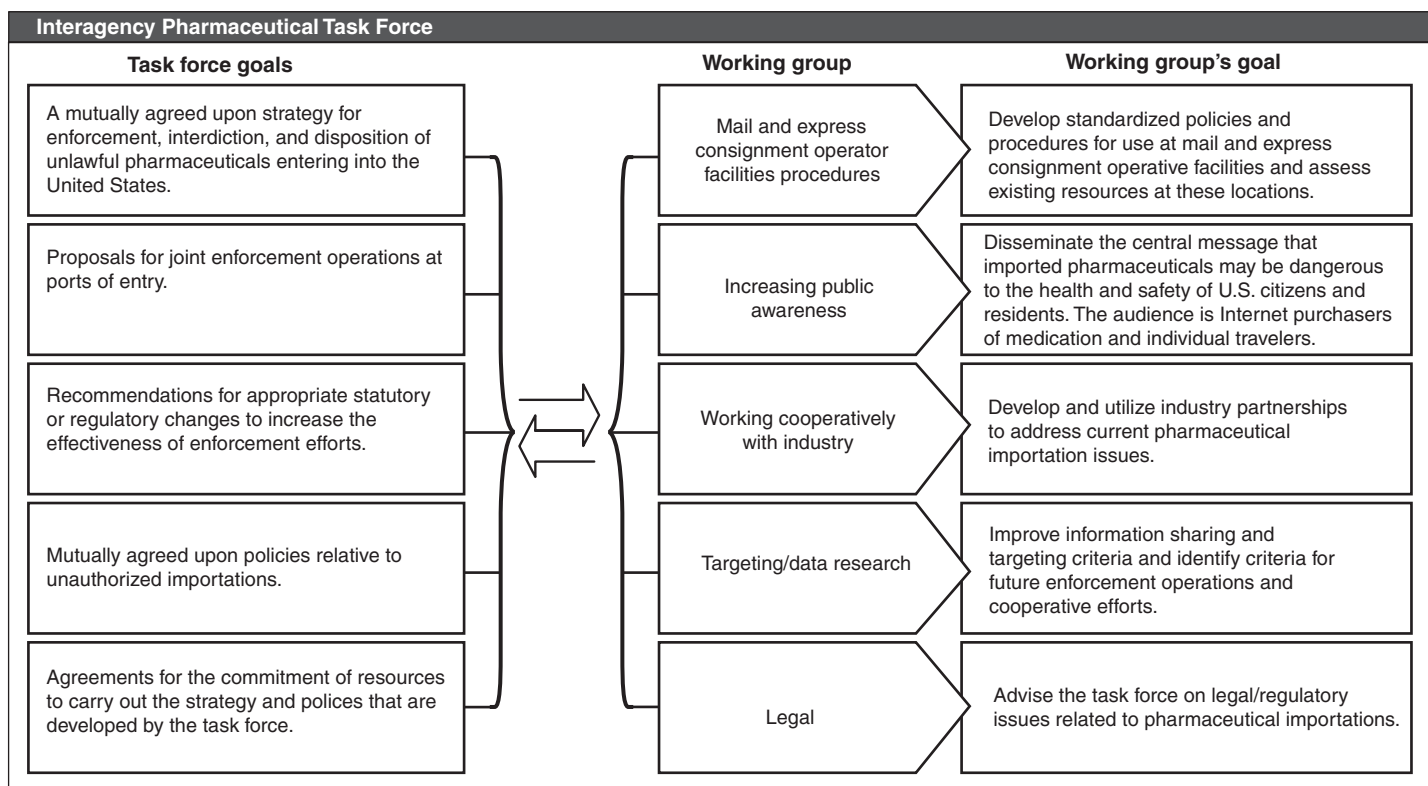
More recent efforts have focused on prescription drugs entering international mail and express carrier facilities. In January 2004, the CBP Commissioner initiated an interagency task force on pharmaceuticals, composed of representatives from CBP, FDA, DEA, ICE, and ONDCP as well as legal counsel from the Department of Justice. According to the Commissioner, the proposal to create the task force was prompted by "intense public debate and congressional scrutiny, which has resulted in increasing pressure being applied to regulatory and law enforcement agencies to develop consistent, fair policies" to address illegal

³³GAO, *Combating Terrorism: Evaluation of Selected Characteristics in National Strategies Related to Terrorism*, [GAO-04-408T](#) (Washington, D.C.: February 2004).

³⁴GAO, *Agencies Annual Performance Plans under the Results Act: An Assessment Guide to Facilitate Congressional Decisionmaking*, [GAO/GGD/AIMD-10.1.18](#) (Washington D.C.: February 1998).

pharmaceuticals entering the United States. The Commissioner proposed that the task force achieve five specific goals, and according to a CBP official, five working groups were established to achieve these goals. Figure 6 shows the task force goals, the five working groups, and the goals of each working group.

Figure 6: Interagency Pharmaceutical Task Force and Working Group Goals



Source: GAO analysis of CBP documents.

A CBP official told us that the task force is designed to foster cooperation among the agencies responsible for enforcing the laws governing prescription drugs imported for personal use. The task force was created to go beyond interdiction at the mail and carrier facilities. The official also said that the task force was fashioned to deal with supply and demand issues, thereby reducing the volume of drugs entering these facilities. For example, on the demand side, the public awareness working group is responsible for conveying information about the health and safety risks of imported prescription drugs, and on the supply side, the working cooperatively with industry group is responsible for, among other things,

ways of identifying rogue Internet sites. CBP officials and other members of the task force provided examples of activities being carried out or planned by task force working groups that are discussed below.

- The working group on mail and express consignment operator facilities procedures has carried out special operations at five international mail and three express carrier facilities to examine parcels suspected of containing prohibited prescription drugs over specific periods of time, such as 2 or 3 days. While similar operations have occurred since 2000, a CBP official told us that those conducted under the task force are multiagency efforts. Among other things, task force members gather data about the source, type, and recipients of the drugs and test the contents of the parcels to determine whether they are counterfeit or otherwise prohibited. These operations are expected to continue during the remainder of 2005 at all of the remaining mail facilities and some of the carrier facilities.
- The working group on targeting/data research is using the results of special operations to analyze data retrieved during the special operations and determine how these data can be used to guide future operations and enforcement efforts. Also, ICE was working with CBP and the government of an Asian country to identify and track controlled substances destined for the United States. ICE plans to use this approach to identify and take possible law enforcement action against illegal enterprises.
- The working group on increasing public awareness has been developing and disseminating public service announcements on the risks associated with purchasing drugs over the Internet. The working group has placed public service announcements on the FDA and CBP Web sites and is coordinating with FDA on its efforts, ongoing since 1999, to disseminate similar material in magazines, online, and in pharmacies. Also, the working group has entered into an agreement with a major Internet service provider and others to have a public service announcement link on screen when someone tries to access online pharmacy sites.
- The working group on working cooperatively with industry has met with Internet businesses, such Internet service providers and companies that operate search engines, to discuss how task force members can work with Internet businesses to stem the flow of imported drugs coming into the country, including discussing standards for identifying legitimate Web sites. It has also met with representatives of express carriers and plans to meet with representatives of credit card organizations in late summer 2005.

In addition, task force members are working with ONDCP to address the importation of controlled substances through international mail and carrier facilities. In October 2004, ONDCP issued a plan for addressing demand and trafficking issues associated with certain man-made controlled substances—such as pain relievers, tranquilizers, and sedatives.³⁵ Among other things, ONDCP recommended that DEA, CBP, ICE, State Department, National Drug Intelligence Center, and FDA work with USPS and private express mail delivery services to target illegal mail order sales of chemical precursors, synthetic drugs, and pharmaceuticals, both domestically and internationally. ONDCP officials said that a multiagency working group is meeting to discuss what can be done to confiscate these controlled substances before they enter the country. An ONDCP official said that participants at these meetings included officials from CBP, USPS, and DEA.

Finally, USPS is exploring what additional steps it can take to further help the task force. Although USPS has participated in task force activities, USPS officials said USPS is concerned about a conflict between its mission to keep the mail moving and whether it is positioned to determine the admissibility of mail. USPS officials said that they proposed, during a July 2004 hearing, the possibility of cross-designating U.S. Postal Inspectors with Customs' authority so that Postal Inspectors can conduct warrant-less searches, at the border, of incoming parcels or letters suspected of containing illegal drugs. According to USPS officials, such authority would facilitate interagency investigations. They said that their proposal has yet to be finalized with CBP. In addition, internationally, USPS has drafted proposed changes to the U.S. listing in the Universal Postal Union List of Prohibited Articles.³⁶ A U.S. Postal Service official told us that USPS is awaiting a response to a letter it sent to FDA last year requesting FDA's views on the proposed changes. The official said that, without FDA input, USPS does not have the expertise to determine

³⁵ ONDCP, *National Synthetic Drugs Action Plan: The Federal Government Response to the Production, Trafficking, and Abuse of Synthetic Drugs and Diverted Pharmaceutical Products* (Washington D.C.; October 2004). According to ONDCP, the *Action Plan* is to provide a blueprint for action under the President's National Drug Control Strategy and "focuses primarily on illicitly manufactured synthetic drugs which are not of primarily organic origin" and "selected pharmaceutical products which are sometimes diverted from legitimate commerce."

³⁶ The Universal Postal Union List of Prohibited Articles is a listing of articles prohibited for importation into the United States, as well as other member countries of the UPU. The listing is shared with foreign postal administrations to enable them to educate their customers on country prohibitions for international mail.

whether the proposed changes are accurate. In August 2005, FDA officials said that after receiving the letter last year, they met with USPS officials regarding drug importation, including this proposal. However, according to FDA officials, USPS had not subsequently engaged FDA on this particular issue, and FDA did not believe USPS was awaiting a formal written response. FDA officials stated that if USPS would like to discuss this matter further, they would be happy to work with USPS.

Strategic Framework Would Further Enhance Task Force Efforts

Although the task force has taken positive steps toward addressing issues associated with enforcing the laws on personal imports, it has not fully developed a strategic framework that would allow the task force to address many of the challenges we identify in this report. Carrying out enforcement efforts that involve multiple agencies with varying jurisdictions is not an easy task, especially since agencies have limited resources and often conflicting priorities. The challenges identified in this report could be more effectively addressed by using a strategic framework that more clearly defines the scope of the problem by estimating the volume of drugs entering international mail and carrier facilities, establishes milestones and performance measures, determines resources and investments needed to address the flow of imported drugs entering the facilities and where those resources and investments should be targeted, and evaluates progress.

Our review showed that the task force has already begun to establish some elements of a strategic framework, but not others. For example:

- In light of the Commissioner's January 2004 memo discussed earlier, the task force has a clear picture about its purpose and why it was created. However, it has not defined the scope of the problem it is trying to address because, as discussed earlier, CBP and FDA have yet to develop a way to estimate the volume of imported prescription drugs entering specific international mail and carrier facilities. Without doing so, it is difficult to assess what resources are necessary to effectively inspect parcels and interdict those that contain unapproved drugs.
- Whereas the task force and individual working groups have goals that state what they are trying to achieve, the task force has not established milestones and performance measures to gauge results. A CBP official said that the goals are intended to be guidelines rather than goals to be measured; he would expect progress or results to be measured within the context of strategic plans prepared by individual agencies. However, without task force-specific milestones and performance measures, it is difficult to measure improvement over time and ensure accountability,

particularly if the goals and measures of individual task force members do not directly address, or are not in harmony with, the goals of the task force.

- The task force has not addressed the issue of what its efforts will cost so that it can target resources and investments, balancing risk reduction with costs and considering task force members' other law enforcement priorities. Instead, according to a CBP official, working group projects are done on an ad hoc basis wherein resources are designated for specific operations. Nonetheless, the absence of cost and resource assessments makes effective implementation harder to achieve because over time, alternative agency priorities and resource constraints may hinder the ability of the task force to meet its goals.

We acknowledge that such a strategic framework needs to be flexible to allow for changing conditions, but it could be helpful to organize it in a logical flow, from conception to implementation. Specifically, the strategy's purpose leads to definition of the problems and risks it intends to address, which in turn leads to specific actions for tackling those problems and risks, allocating and managing appropriate resources, identifying different organizations' roles and responsibilities, and finally integrating action among all the relevant parties and implementing the strategy.

Advancing a strategic framework could establish a mechanism for accountability and oversight and set the stage for defining specific activities needed to achieve results and specific performance measures for monitoring and reporting on progress. In so doing, task force officials could measure progress over time, identify new and emerging barriers or obstacles to carrying out goals and objectives, develop strategies to overcome them, and inform decision makers about the implications of taking or not taking specific actions. For example, CBP, FDA, and the other agencies could work jointly to develop statistically valid estimates of the number of parcels suspected of containing imported prescription drugs entering particular facilities and begin to develop realistic risk-based estimates of the number of CBP and FDA staff needed to interdict parcels at mail facilities.

Task force members could also take steps to explore how they can work more collaboratively and strategically with private organizations, such as credit card organizations and express carriers. In doing so, task force members and representatives of these organizations could examine what can be done within the context of current law and establish strategies and

goals for overcoming any practical considerations that act as barriers to enforcing the prohibition on imported pharmaceuticals, including controlled substances. They could also identify any legislative barriers they face in aggressively enforcing the prohibition and work together to develop legislative proposals aimed at stemming the flow of imported prescription drugs into the country.

In addition, agencies could work collaboratively among themselves to examine the resources and investments needed to address particular strategies. Any effort to implement task force objectives would require sustained high-level leadership and commitment to ensure that resources are available to carry out task force goals, commensurate with the goals and priorities of the individual agencies involved with the task force. According to a CBP official involved in the task force, agencies have made a high-level commitment to supporting the task force. Nonetheless, in the absence of a strategic framework and, in particular, measurable goals and milestones, there is little assurance that this commitment will continue as the goals and priorities of individual agencies change.

A strategic framework could also enable the task force to adjust to changing conditions. As mentioned earlier, FDA had developed plans and initiated steps in 1999 to deal with Internet sales of prescription drugs, but most of those efforts focused on domestic sales. However, plans to address Internet sales had not been refocused to reflect prescriptions imported from foreign countries for personal use, partly because FDA and other agencies did not anticipate that the volume of imported drugs would overwhelm available resources. A strategic framework, with ongoing problem definition and risk assessment, might help task force members, including FDA and others to identify the impact of this emerging threat and give the task force members the opportunity to adjust their enforcement strategies to address the threat on a proactive, rather than a reactive, basis. It also might help them consider interrelationships between the enforcement strategies and priorities of the task force and their own strategies and priorities.

Furthermore, a strategic framework could help agencies adjust to potential changes in the law governing the importation of prescription drugs for personal use. During recent sessions of Congress, members introduced a number of bills that could have changed how personal prescription drug imports were treated under the law. Some proposals would have allowed importation of selected prescription drugs under certain conditions, for example, allowing importation from certain countries, such as Canada. Another proposal would have maintained the

current prohibitions, but would have allowed for expedited disposal of illegally imported prescription drugs, such as controlled substances available by prescription. Those bills that would have allowed some personal importation also included provisions for expediting the process of disposing of those drugs that still may not be imported for personal use. Although none of these changes were adopted, continued congressional interest could prompt changes in the future. If that occurred, a strategic framework could better position agencies to adjust to any changes; identify any new threats or vulnerabilities; and redefine strategies, roles, and responsibilities.

Conclusions

Enforcing the laws governing prescription drug imports for personal use is a complex undertaking that involves multiple agencies with various jurisdictions and differing priorities. We acknowledge these complexities, but current inspection and interdiction efforts at the international mail branches and express carrier facilities have not prevented the reported substantial and growing volume of prescription drugs from being illegally imported from foreign Internet pharmacies into the United States. CBP and other agencies have taken a step in the right direction by establishing a task force designed to address many of the challenges discussed in this report. Although agencies responsible for enforcing these laws have a mechanism in place to jointly address the threat posed by prohibited and sometimes addictive drugs entering the country via the international mail and express carriers, many packages that may contain these drugs enter the United States daily. Furthermore, according to officials, resources are strained as the volume of prescription drugs entering the country is large and increasing.

Our past work has shown how a strategic framework can be useful in promoting accountability and guiding policy and resource decisions. In the case of the task force, a strategic framework that facilitates comprehensive enforcement of prescription drug importation laws and measures results would provide it an opportunity to better focus agency efforts to stem the flow of prohibited prescription drugs entering the United States. The task force could become more effective as it becomes more accountable. An assessment of the scope of the problem would help the task force prioritize activities and help ensure that resources are focused on the areas of greatest need. With milestones and performance measures, it could be able to better monitor progress and assess efforts to enforce the laws. An analysis of resources and investments is critical because of current resource constraints, a point highlighted by the Secretary of Health and Human Services' report under the Medicare

Modernization Act. Moreover, without these elements culminating in concrete plans for implementation, it will be difficult for the task force to maximize effectiveness in reducing the flow of prohibited imported prescription drugs into the United States.

In addition to the broader issues being addressed by the task force, FDA has said it faces a significant challenge handling the substantial volume of prescription drugs imported for personal use entering international mail facilities. Specifically, in recent years, FDA has expressed continuing concern to Congress that it encounters serious resource constraints enforcing the law at mail facilities because packages containing personal drug imports cannot automatically be refused. Instead, under current law, FDA is to notify recipients that they are holding packages containing drugs that appear to be prohibited from import and give them the opportunity to provide evidence of admissibility. FDA has stated that it cannot effectively enforce the law unless the requirement to notify recipients is changed. FDA has suggested that the HHS Secretary consider proposing changes to this requirement, but the HHS Secretary has not yet responded with a legislative proposal. Although there may be complex issues associated with changing the requirement to notify, including an individual's due process right to provide evidence of admissibility and consideration of Universal Postal Union requirements, assessing the ramifications of such a proposal would help decision makers as they consider how best to address FDA's resource constraints and responsibility to enforce the law and protect the health and safety of the American public.

Recommendations

To help ensure that the government maximizes its ability to enforce laws governing the personal importation of prescription drugs, we recommend that the CBP Commissioner, in concert with ICE, FDA, DEA, ONDCP, and USPS, develop and implement a strategic framework for the task force that would promote accountability and guide resource and policy decisions. At a minimum, this strategic framework should include

- establishment of an approach for estimating the scope of the problem, such as the volume of drugs entering the country through mail and carrier facilities;
- establishment of objectives, milestones, and performance measures and a methodology to gauge results;
- determination of the resources and investments needed to address the flow of prescription drugs illegally imported for personal use and where resources and investments should be targeted; and

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- an evaluation component to assess progress, identify barriers to achieving goals, and suggest modifications.

In view of the FDA’s continuing concern about the statutory notification requirement and its impact on enforcement, we also recommend that the Secretary of HHS assess the ramifications of removing or modifying the requirement, report on the results of this assessment, and, if appropriate, recommend changes to Congress.

Agency Comments and Our Evaluation

We requested comments on a draft of this report from the Secretary of Homeland Security, Attorney General, Director of the Office of National Drug Control Policy, Secretary of Health and Human Services, and Postmaster General. DHS, DEA, ONDCP, HHS, and USPS provided written comments, which are summarized below and included in their entirety in appendixes IV through VIII.

DHS generally agreed with the contents of our report. Since our recommendation that the CBP-led task force develop and implement a strategic framework to address prescription drug importation issues affects other agencies, DHS said that CBP would convene a task force meeting to discuss our report and recommendation and is to provide us with additional information after the meeting.

Responding for DOJ, DEA generally agreed with our recommendation that the CBP task force develop and implement a strategic framework. Specifically, DEA agreed that a strategic framework can be useful in promoting accountability and guiding policy and resource decisions, but it said that the interagency task force is a cooperative initiative and DEA must balance priorities in accordance with agency mandates. DEA also said that its strategic plan clearly establishes a framework to articulate agency priorities and assess its performance. Noting that our report acknowledges that such a framework needs to be flexible to allow for changing conditions, DEA stated that, in concert with other task force agencies, it will support the CBP Commissioner’s strategic framework for the interagency task force.

ONDCP generally concurred with our recommendation that the CBP-led task force develop and implement a strategic framework. ONDCP also “strongly” suggested that the ONDCP-led Synthetic Drug Interagency Working Group play a significant role in integrating prescription drug considerations with all of the other synthetic drug concerns that potentially inflict harm on our society. ONDCP noted that our report documented well the problems associated with effectively policing Internet purchases and identified the significance played by credit card

use as a facilitator of the problem. In addition, ONDCP stated that it encouraged law enforcement proposals that may curtail some of these dangerous practices and concurred with our identification of the cumbersome nature of currently required enforcement practices dealing with the use of the mails to transfer illicit narcotics.

HHS generally concurred with both recommendations. With regard to the strategic framework, HHS said that it would work with its federal partners to discuss the development of a more formalized approach for addressing the issues associated with the importation of unapproved drugs. However, HHS questioned whether the framework should include an approach for developing more reliable volume estimates, because HHS believes the volume estimates already provided in HHS's December 2004 report on drug importation are valid. HHS said that volume may depend on the incentive for the public to import unapproved drugs, as well as other external factors, and said that, short of opening and counting each package as it enters the United States, the reliability of estimates would always be in question given the fluid nature of unapproved prescription drug imports and the number of mail and courier facilities involved. HHS also stated that volume estimates would not alter the resource calculations articulated in HHS's December 2004 report, which, according to HHS, were derived from special operations, called blitzes, by CBP and FDA at various international mail facilities. According to HHS, these calculations were based on personnel time and salaries needed to process each package. HHS further noted that our statement that the task force agencies could develop statistically valid volume estimates and realistic risk-based estimates of the number of staff needed to interdict parcels at mail facilities did not recognize that FDA is not always able to process the current number of packages set aside by CBP. In addition, HHS said that FDA must always be cognizant of competing priorities regardless of fluctuations in the volume of illegally imported prescription drugs.

We recognize that any number of factors can influence the volume of unapproved drugs entering the country at any point in time or location. However, HHS's current estimates are based on estimates of drugs imported from Canada during 2003 and, in part, on extrapolations from FDA's limited observations during special operations at international mail branch facilities. We believe a more reliable and systematic approach might begin by using information already being collected by CBP and FDA at the various field locations, including the number of packages deemed abandoned by CBP and the number of imported packages FDA handles. With regard to resource calculations, as more reliable estimates are developed, FDA and other task force agencies would be better positioned to define the scope of the problem so that the task force and other

decision makers can make informed choices about resources devoted to this problem, especially in light of competing priorities.

Regarding our recommendation that the HHS Secretary assess FDA's statutorily required notification process, HHS said that it intends to pursue an updated assessment. HHS observed that, given the increased volume of illegally imported prescription drugs since its initial request for modification of FDA's notification process, other actions might be needed, and HHS would work with its federal partners to determine the actions required. HHS also provided technical comments that have been included, as appropriate.

USPS did not state whether it agreed or disagreed with our recommendations but expressed a concern about possible procedural and legislative changes to the current notification requirements governing the processing and disposition of imported pharmaceuticals. Specifically, USPS requested that the report acknowledge the United States's international postal obligations and stated that any discussion of options to expedite the processing and disposition of prescription drugs should consider these obligations. USPS further noted that recognizing these obligations is particularly important with respect to registered or insured mail for which the Postal Service can be held financially responsible if it is not delivered or returned. We acknowledge USPS's concerns and have added language to the report accordingly.

As arranged with your offices, unless you publicly announce its contents earlier, we plan no further distribution of this report until 30 days after its issue date. At that time, we will send copies of this report to the Secretary of the Department of Homeland Security, the Secretary of Health and Human Services, and interested congressional committees. We will also make copies available to others upon request. In addition, the report will be available at no charge on GAO's Web site at <http://www.gao.gov>.

If you or your staff have any questions concerning this report, please contact me on (202) 512-8777 or stanar@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. Major contributors to this report are listed in appendix IX.



Richard M. Stana, Director
Homeland Security and Justice Issues

Appendix I: Objectives, Scope, and Methodology

This report addresses the following questions: (1) What do available data show about the volume and safety of prescription drugs imported into the United States for personal use through the international mail and private carriers? (2) What procedures and practices are used at selected facilities to inspect and interdict prescription drugs unapproved for import? (3) What factors affect federal agency efforts to enforce the prohibition on prescription drug importation for personal use through international mail and carrier facilities? (4) What efforts have federal agencies undertaken to coordinate the enforcement of the prohibitions on personal importation of prescription drugs?

We performed our work at the Department of Homeland Security's U.S. Customs and Border Protection (CBP) and U.S. Immigration and Customs Enforcement (ICE), the Department of Health and Human Services' (HHS) Food and Drug Administration (FDA), the Department of Justice's Drug Enforcement Administration (DEA), the U.S. Postal Service (USPS), and the Office of National Drug Control Policy (ONDCP). We also carried out work at 3 of the 14 international mail facilities—New York, Los Angeles, and Chicago—and 2 of the 29 carrier facilities—Cincinnati (DHL Corporation) and Memphis (FedEx Corporation). We selected the New York and Los Angeles mail facilities because they (1) processed among the highest overall number of packages,¹ representing 27 percent of the total number of estimated packages going through international mail facilities in 2002 and (2) also received prescription drugs.² The Chicago facility was selected because it received prescription drugs and provided geographic dispersion. The 2 carrier facilities selected were (1) different companies; (2) handled the highest overall number of packages, according to data provided by CBP; and (3) were located near each other. At each of these locations, we collected and reviewed available relevant importation and interdiction data from FDA and CBP; observed inspection and interdiction practices; met with CBP and FDA management, inspectors, and investigators to discuss issues related to inspection and pharmaceutical importation volume; and reviewed relevant documents on inspection and interdiction procedures. At the international mail facilities, we also met with USPS officials to discuss mail handling and processing procedures. The information from our site visits is limited to the 3 international mail

¹Data on the number of packages processed were provided to us by CBP from the U.S. Postal Service.

²On January 27, 2005, CBP began operations at one additional international mail facility in San Juan, Puerto Rico. We did not include the San Juan facility as part of our original selection because it was not in operation when we began our review.

facilities and 2 carrier facilities and is not generalizable to the remaining 10 international mail facilities and 27 carrier facilities.

To determine what the available data show about the volume and safety of imported prescription drugs, we interviewed CBP, FDA, DEA, ICE, and USPS headquarters officials and CBP and FDA officials at the 3 international mail facilities and 2 carrier facilities. We obtained and analyzed available data on the volume and safety of imported prescription drugs (1) collected from the facilities we visited and (2) gathered through multiagency special operations at selected mail facilities and provided to us by CBP headquarters. The available CBP and FDA information on the volume and safety of prescription drugs imported through the mail and carrier facilities we visited was primarily based on estimates and limited to observations at these locations. To obtain additional views on the overall volume or safety of imported prescription drugs, we reviewed ONDCP and HHS reports and testimony from the American Medical Association. We discussed with FDA officials the methodology used to develop the volume estimates presented in the 2004 HHS report on prescription drug importation³ and we reviewed the methodology to determine any limitations. In addition, we interviewed an official and reviewed documents from the National Association of Boards of Pharmacy to obtain the association's findings on the safety of prescription drugs imported from foreign-based Internet pharmacies. We also relied on existing GAO work on the safety of prescription drugs imported from some foreign-based Internet pharmacies.

To understand procedures and practices, we reviewed current federal law and CBP and FDA policies, procedures, and guidance regarding or applicable to prescription drugs and controlled substance importation. We interviewed officials at CBP, FDA, DEA, ICE, and USPS headquarters. To understand inspection procedures and practice, at each of 3 international mail facilities and 2 carrier facilities, we carried out site visits, observing the inspection process and interviewing CBP and FDA officials. At the selected international mail facilities, we also interviewed USPS officials to obtain information about their procedures and practices. In addition, when FDA and CBP implemented new procedures at the international mail facilities and carrier facilities, we carried out additional interviews at FDA and CBP headquarters, pursued telephone interviews with CBP and FDA

³HHS Task Force on Drug Importation, *Report on Prescription Drug Importation*, Department of Health and Human Services, December 2004.

officials at the facilities we had visited, and revisited 2 of the mail facilities to determine how the new procedures were being implemented, working in practice; and being monitored and evaluated. We also obtained from FDA fiscal year data on the number of mail packages containing prescription drugs it processed. From CBP we obtained data on the number of packages interdicted using its new procedures for processing schedule III through V controlled substances. Because these data were used for contextual purposes, we did not assess the reliability of these data. However, we discussed the scope of the FDA and CBP data with the respective agency officials and have noted the limitations in the report.

To determine what factors affect federal agency efforts to enforce the prohibitions on prescription drug importation for personal use through international mail and carrier facilities, we interviewed CBP, FDA, DEA, ICE, and USPS officials. We asked these officials to identify any factors that affected their respective agency's efforts to process or interdict prescription drugs imported through the mail and carriers. The information presented in this report is limited to the views expressed by the officials interviewed. In addition, we met with representatives from MasterCard International and Visa U.S.A., Inc., the two credit card associations identified by DEA as the organizations used by the majority of Internet drug sites. These associations also testified in July 2004 at congressional hearings on matters related to the illegal importation of prescription drugs. We discussed with them each association's efforts to assist federal enforcement of the prohibitions on prescription drug importation.

To determine what efforts federal agencies have undertaken to coordinate the enforcement of the prohibitions on personal importation of prescription drugs, we interviewed CBP, USPS, FDA, DEA, ICE, and ONDCP headquarters officials. We obtained and reviewed documents describing these initiatives, their status, and any studies or data describing the results of the initiatives. These documents included agency guidelines and memorandums, indicating changes to agency policies and procedures; congressional hearings; and selected legislative proposals. We obtained these documents from agency officials; agency Web sites, as directed by agency officials; and congressional Web sites. We also interviewed CBP and FDA field officials at the selected international mail facilities and private carrier facilities to ascertain the status of the implementation of these initiatives. We analyzed and synthesized the information gathered from the interviews and documents.

In addition, in appendix III of this report, we used data from FDA on the number of open and closed investigations it had undertaken related to Internet drug sales and imported prescription drugs. We also used data from DEA on the number of arrests related to the illegal diversion of pharmaceuticals. Because these data were used for contextual purposes, we did not assess their reliability.

We conducted our review between April 2004 and August 2005 in accordance with generally accepted government auditing standards.

Appendix II: General Description of the Controlled Substance Schedules I through 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.

Table 1: General Description of Controlled Substances, 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 gamma 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 babiluric 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

Appendix III: Federal Agencies Work with Credit Card Organizations to Enforce Prohibitions on Prescription Drugs

During congressional hearings in July 2004, representatives from MasterCard International and Visa U.S.A., Inc., testified on issues concerning the use of credit cards to purchase prescription drugs for importation from Internet pharmacies, including discussions with federal law enforcement agencies to address these issues.¹ Accordingly, we met with Drug Enforcement Administration (DEA), Food and Drug Administration (FDA), and Immigration and Customs Enforcement (ICE) officials, as well as representatives from MasterCard International and Visa U.S.A., Inc. to more fully understand how these organizations are working together to address prohibitions on prescription drug importation.² The agency officials and credit card association³ representatives described their working relationship as cooperative, but complicated by legal and practical considerations. The following section summarizes our discussions.

Investigations of Credit Card Purchases of Prescription Drugs Imported from Internet Pharmacies Can Be Complicated by Legal and Practical Considerations

According to FDA, DEA, and ICE officials, their agencies have worked with credit card organizations to obtain information to investigate the importation of prescription drugs purchased with a credit card from Internet pharmacies, but these investigations were complicated by legal and practical considerations. Such considerations included privacy laws; federal law enforcement agencies' respective subpoena authority, priorities, and jurisdictions; and the ease with which merchants engaged in illegal activity can enter into a new contract with a different bank to use the same payment system. In addition, according to the two credit card associations we contacted, their respective associations have also undertaken searches of the Internet for Web sites that appeared to be selling problematic materials and accepting their respective payment cards, but these investigations can also be complicated by legal considerations.

¹*Buyer Beware: The Danger of Purchasing Pharmaceuticals over the Internet: Federal and Private Sector Responses: Hearing Before the Permanent Subcomm. on Investigations of the Senate Comm. on Government Affairs, 108th Cong. (July 22, 2004).*

²According to a DEA official, the majority of Internet drug sites used these two companies' payment systems.

³Two types of credit card organizations handle the four major U.S. credit cards. Credit card associations, such as Visa and MasterCard, license their member banks to issue bank cards, authorize merchants to accept those cards or both. In contrast, full-service credit card companies, such as American Express and Discover, issue their own brands of cards directly to customers and authorize merchants to accept those cards. See also: GAO, *Internet Gambling: An Overview of the Issues*, GAO-03-89 (Washington, D.C.: December 2, 2002)

Privacy laws can sometimes limit the extent to which companies, including credit card organizations, will provide information to federal law enforcement agencies about parties to a transaction. FDA and DEA officials told us that credit card organizations and/or banks and other financial institutions, when they have the direct contractual relationship with the merchants, have provided to the agencies information regarding transactions involving prescription drugs prohibited from import, as well as alerting federal officials when suspicious activity is detected. However, they said that the companies do not provide information about the parties involved in the transaction without a subpoena. Representatives from the two associations with whom we met explained that law enforcement usually needs to issue a subpoena because of company concerns about possible legal action by the subject of the investigation (for example, if the subject asserted that information was provided by the association or bank to law enforcement in violation of federal privacy laws). They further noted, however, that their respective associations would provide law enforcement information without a subpoena, when properly requested under certain circumstances, including matters of national security or when a human life was in immediate jeopardy.

DEA, ICE, and FDA officials confirmed that they are able to obtain information from credit card companies and/or banks and other financial institutions through subpoenas, although the agencies have different subpoena authority with regard to entities, such as banks and credit card companies. DEA and ICE have the authority to subpoena information directly from such entities, but FDA must ask a U.S. Attorney to obtain a grand jury subpoena requesting the information.⁴ DEA and ICE may also use grand jury subpoenas. For example, DEA officials told us that usually they are able to obtain needed information using administrative subpoenas; however, they may use a grand jury subpoena if a company will not provide the requested information or a U.S. Attorney prefers that approach. DEA, FDA, and ICE could not readily provide data on the

⁴FDA has the authority to inspect certain records of those entities processing drugs under section 704 of the Federal Food, Drug, and Cosmetic Act, such as, a drug manufacturer, but not the records of third parties, such as credit card organizations. However, section 704 is an administrative authority, and it may not be relied upon when the agency is solely interested in obtaining evidence for a criminal prosecution. According to FDA, when criminal Internet/importation investigations mature to the point that a grand jury becomes involved, FDA's Office of Criminal Investigations (OCI) routinely uses grand jury subpoenas to obtain information from credit card companies and banks. Use of a grand jury subpoena to obtain this kind of information is a standard investigatory practice. FDA stated that when served with grand jury subpoenas, the banks and credit card companies have consistently been cooperative and have provided OCI with the information requested.

number of subpoenas served because (1) data on DEA and ICE administrative subpoenas were maintained at the field office requesting the subpoena and were not organized according to payment method and (2) none of the agencies could share grand jury information.⁵

Agencies' priorities also affect their ability to conduct investigations of credit card purchases of prescription drugs for importation. According to FDA, DEA, and ICE officials, their investigations, including those involving imported prescription drugs, focused on commercial quantities, rather than quantities to be consumed for personal use.⁶ DEA officials also said that DEA seeks to dismantle major drug supply and money laundering organizations; therefore, its investigations of prescription drug violations focused on the suppliers of Internet pharmacies, not individual consumers. DEA reported no active cases on individuals who were illegally importing controlled substance pharmaceuticals over the Internet for personal consumption.⁷ FDA, DEA, and ICE officials said that investigations involving smaller quantities may be handled by state and local law enforcement.

In addition to the quantity of drugs being imported, federal enforcement agencies consider jurisdiction when determining whether to pursue an investigation, including investigations of Internet pharmacies using credit card payment systems that cross U.S. borders. For a federal enforcement agency to determine whether it has jurisdiction to investigate potential illegal activity outside the United States, it generally needs to consider whether (1) the federal statute or statutes violated apply to activity outside the country and (2) there is sufficient evidence of an intent to produce effects in the United States or some other connection to the United States, such as a U.S. distributor. Pursuit of investigations of Internet pharmacies using credit card payment systems presents both jurisdictional and practical limitations, when some or all of the operations (e.g., pharmacies, Web sites, and bank accounts) are located in foreign countries and there is

⁵Rule 6(e) of the Federal Rules of Criminal Procedure codifies the traditional practice of grand jury secrecy. With certain limited exceptions, Rule 6(e) generally prohibits disclosure of "matters occurring before the grand jury."

⁶FDA officials noted, however, that in matters of public health and safety, FDA would seek a prosecution no matter what the quantity of illegal drugs involved.

⁷According to DEA, as of June 21, 2005, it had made 560 arrests related to the diversion of pharmaceuticals; those arrested included retailer dealers, leaders within organizations, and heads of organizations, among others. However, DEA data do not include information on which of the arrests involved Internet sales for importation or use of credit card payment systems.

no U.S. distributor. According to FDA officials, in cases that FDA does not have jurisdiction to pursue, it may ask its foreign counterparts for assistance.⁸ ICE officials told us that they focused on transporters of commercial quantities across U.S. borders from a foreign country into the United States.

By contrast, DEA enforces a statute that specifically applies to manufacturers or distributors of certain prescription drugs who are located in foreign countries. Specifically, DEA has jurisdiction over a manufacturer or distributor of schedule II controlled substances in a foreign country who knows or intends that such substances will be unlawfully imported into the United States.⁹ However, the relevant statute does not apply to prescription drugs that are schedules III through V controlled substances. Therefore, according to a DEA official, to pursue such investigations, DEA has to devise other ways to reach those operating outside the United States.

A DEA official said that another practical consideration affecting investigations of credit card purchases of imported prescription drugs was the ease with which merchants engaged in illegal activities were able to open new merchant credit card accounts. Credit card association representatives confirmed that the reappearance of the same violators using a different name or bank, or even disguising the illegal activity as a different and legal activity, can be a problem. They said that unlike law enforcement, credit card organizations do not have the authority to arrest the violators, and some of the merchants engaged in such illegal activities are skilled at moving from bank to bank and masking their illegal activities.

In addition to investigations by federal law enforcement agencies, each of the credit card associations we contacted had also undertaken searches of the Internet for Web sites that appeared to be selling problematic

⁸According to FDA, as of June 2005, FDA's OCI has closed 24 full-scale investigations related to Internet drug sales and imported prescription drugs. These 24 investigations resulted in 7 judicial cases where a defendant was brought before a court; each of these cases may include one or more prosecutions. During 5 of the 24 investigations, FDA worked cooperatively with foreign governments. In addition, FDA reported that as of June 2005, OCI had 23 pending full-scale investigations related to Internet drug sales and imported prescription drugs, 5 of which had matured into pending prosecutions. In 7 of the 23 investigations, OCI was working cooperatively with foreign governments.

⁹21 U.S.C. § 959.

materials and using its payment cards.¹⁰ One association used a vendor to carry out the searches and then provided the information to its member banks regarding their merchants who appear to have been involved in selling controlled substances. The other association's security personnel conducted the Internet search, identified the sites, and then attempted to contact the member bank that had contracted with the merchant. Representatives of the latter association told us that as a result of this effort, at the association's request, contracts with approximately 500 merchants had been terminated by the member banks that had authorized the particular merchants to accept the association's credit card.

Representatives from both associations agreed that federal law enforcement agencies were in the best position to enforce the prohibition on prescription drug importation, because they have arrest authority and can remove the violators. However, these representatives had differing opinions concerning the desirability of their taking any additional enforcement steps in this area. Representatives of one association told us they did not want the authority to make purchases to confirm that illegal transactions were occurring. They said once their investigators identified a site willing to sell drugs, they contacted the bank that authorized the merchant's account so that the bank could take appropriate action. Further, they told us that the association was not set up to make such purchases safely and its mail room was not structured to take delivery. Representatives of the other association told us that their association would like the authority to make such purchases, noting that their investigations were complicated by the inability of the association's security personnel to purchase controlled substances. However, these representatives told us that, if they were allowed to make such transactions, they would expect to turn over the controlled substances to federal law enforcement immediately upon receipt.

¹⁰The associations' role in the day-to-day management of their operations includes responsibilities for, among other things, (1) establishing standards and procedures for the acceptance and settlement of each of their members' transactions on a global basis; (2) conducting the due diligence for the financial soundness of potential members and requiring periodic reporting of members on fraud, chargeback, counterfeit card, and other matters that may impact the integrity of the association as a whole; and (3) operating the security and risk systems to minimize risk to the member banks, including operating fraud controls to allow members to monitor transactions with their cardholders and establishing specific design features of the bankcard to enhance security features. See also GAO, *Money Laundering: Extent of Money Laundering through Credit Cards Is Unknown*, [GAO-02-670](#) (Washington, D.C.: July 22, 2002).

A DEA official told us that currently credit card organizations are not exempt from the general prohibition against possessing controlled substances,¹¹ and therefore it is illegal for them to purchase controlled substances from an Internet pharmacy to show that the pharmacy is acting illegally.¹² He also said that even if the law were changed to allow such transactions, executing them could be unmanageable, because the companies would have to comply with federal regulations for handling and storing controlled substances.¹³ For example, federal regulations require that controlled substances be stored in a safe, vault, steel cabinet, or cage. The regulations also specify the methods and materials to be used to construct the storage facility, as well as the type of security system (alarms, locks, and anti-radiation devices) required to prevent entry. Even if a credit card company planned to turn over purchased controlled substances to federal law enforcement upon receipt, it would need to have a facility as prescribed by federal regulations to hold and store the substances until a DEA agent could take possession of them.

Federal Enforcement Agencies and Credit Card Associations Have Discussed Credit Card Enforcement Issues

Federal enforcement agencies and credit card organizations have had periodic discussions about credit card enforcement issues involving purchases of prescription drugs for importation from Internet pharmacies. In addition, the associations told us that they had provided information about this issue to banks and other financial institutions.

According to FDA and DEA officials and representatives of the two credit card associations we contacted, meetings have been held periodically, between individual agencies (e.g., DEA and FDA) or as part of the Customs and Border Protection (CBP) Interagency Task Force (discussed earlier in this report) and with representatives of one or more companies present. Association representatives told us that they believed that the meetings, which began in late 2003, have provided an educational opportunity for both the credit card companies and the federal law enforcement agencies. For example, the representatives of one association said that during the meetings they had described how the association's payment system operated, explaining (1) the relationship among the association, the banks and other financial institutions, merchants, and

¹¹21 U.S.C. § 844(a).

¹²The official emphasized that the current U.S. system for handling controlled substances is a closed system of distribution. It can account for every tablet produced from raw product coming into the country to the final tablet.

¹³21 C.F.R. § 1301.72.

cardholders, and (2) which entities maintained the transactional information needed by law enforcement for investigations of Internet pharmacies. They said that DEA and FDA had explained federal laws related to the importation of prescription drugs, both controlled and noncontrolled substances. Representatives of the other association said that the meetings helped to educate its officials about issues, concerns, and risks related to the illegal importation of prescription drugs. In addition, agency officials and association representatives said that they had discussed the role credit card organizations can play with regard to illegal importation. No minutes of these meetings are maintained.

According to association representatives, information obtained at these meetings was disseminated to the banks and other financial institutions through bulletins. Through association bulletins, both credit card associations provided to banks and other financial institutions information concerning the illegal importation of prescription drugs. The bulletins reminded the recipients of their obligation to ensure that the credit card system was not to be used for illegal activity, alerted them to the risk of illegal activity involving transactions for prescription medications purchased over the Internet, and underscored the need for due diligence to ensure that merchants were not engaged in illegal activities. One association also issued a press release that, according to the association's representatives, was to communicate to the public information similar to that which had been sent to the banks.

FDA and DEA officials and association representatives said that the dialogue was continuing and described the relationship between the agencies and associations as good. A meeting between credit card organizations and the CBP task force is to be held in late summer 2005. Moreover, they noted that informal contacts between the agencies and the credit card organizations occurred, as needed, on specific matters related to prescription drug importation. However, agency officials confirmed that they had no plan or written strategy for dealing with credit card organizations related to the illegal importation of prescription drugs purchased with a credit card.

Appendix IV: Comments from the Department of Homeland Security

U.S. Department of Homeland Security
Washington, DC 20528



**Homeland
Security**

August 22, 2005

Mr. Richard M. Stana
Director, Homeland Security and Justice Issues
U.S. Government Accountability Office
441 G Street, NW
Washington, DC 20548

Dear Mr. Stana:

RE: Draft Report GAO-05-372, Prescription Drugs: Strategic Framework Would Promote Accountability and Enhance Efforts to Enforce the Prohibitions on Personal Importation (GAO Job Code 440282)

The Department of Homeland Security (DHS) appreciates the opportunity to review and comment on the Government Accountability Office's draft report. We generally agree with the contents of the report. The report acknowledges that enforcing laws governing prescription drug imports for personal use is a complex undertaking involving multiple agencies with various jurisdictions and differing priorities. The draft credits DHS's U.S. Customs and Border Protection (CBP) with establishing an interagency task force in January 2004 to address challenges discussed in the report, and recognizes CBP's effort to expedite the handling of certain controlled substances imported as prescription drugs. It also discusses resource limitations associated with the significant volume of imports.

The task force is designed to foster cooperation among the agencies responsible for enforcing the laws governing prescription drugs imported for personal use and goes beyond interdiction at mail and carrier facilities. Your report includes examples of ongoing activities by task force working groups and notes that the task force had established some elements of a strategic framework. The task force is composed of CBP, U.S. Immigration and Customs Enforcement (ICE), the Department of Health and Human Services' Food and Drug Administration (FDA), the Department of Justice's Drug Enforcement Administration (DEA), the Office of National Drug Control Policy (ONDCP) as well as legal counsel. Working groups were established to accomplish specific task force goals including developing: (1) a mutually agreed upon strategy for enforcement, interdiction, and disposition of unlawful narcotics entering the United States; (2) mutually agreed upon policies relative to unauthorized imports; (3) proposals for joint enforcement operations at ports of entry; and (4) agreements for committing resources to carry out the task force's strategy and policies.

www.dhs.gov

The Government Accountability Office (GAO) makes two recommendations, only one of which involves the DHS. Specifically, you recommend that the CBP Commissioner, in concert with ICE, FDA, DEA, ONDCP, and the United States Postal Service, develop and implement a strategic framework for the task force that would promote accountability and guide resource and policy decisions. The recommendation also discusses what the framework should include.

A task force meeting with the concerned agencies has been scheduled for August 31 to discuss the GAO report and the recommendation. Since the recommendation affects task force members as well as CBP, we will provide GAO with additional information after the meeting.

Sincerely,

for Michael M. Poland

Steven Pecinovsky
Director
Departmental GAO/OIG Liaison Office

Appendix V: Comments from the Department of Justice, Drug Enforcement Administration



U. S. Department of Justice
Drug Enforcement Administration

www.dea.gov

Washington, D.C. 20537

AUG 22 2005

MEMORANDUM

TO: Richard M. Stana
Director, Homeland Security and Justice Issues
Government Accountability Office

FROM: *Michele M. Leonhart*
Michele M. Leonhart
Deputy Administrator

SUBJECT: Draft Audit Report: *PRESCRIPTION DRUGS: Strategic Framework Would Promote Accountability and Enhance Efforts to Enforce Prohibitions on Personal Importation*, (GAO-05-372)

The Drug Enforcement Administration (DEA) has reviewed the Government Accountability Office's (GAO) draft audit report entitled *PRESCRIPTION DRUGS: Strategic Framework Would Promote Accountability and Enhance Efforts to Enforce Prohibitions on Personal Importation*. The report addresses the available data about the volume and safety of personal prescription drug imports, the procedures and practices used to inspect and interdict prescription drugs unapproved for import, factors affecting federal efforts to enforce the laws governing prescription drugs imported for personal use, and efforts federal agencies have undertaken to coordinate enforcement efforts. DEA submits the following information for consideration in conjunction with GAO's report.

The Internet has brought drug dealers from the back alleys directly into every American home wired for email and the World Wide Web. Extremely dangerous, addictive, and potentially life-threatening drugs are now sold illegally every day, just one click beyond virtually every email box. These drugs are peddled by multimillion dollar organizations every bit as sophisticated as international cartels.

The scope of this problem is too broad for DEA or any single agency to tackle alone. DEA has enlisted the support of the private sector, the legitimate businesses essential to the on-line trade in diverting pharmaceutical drugs through the Internet. For example, DEA is working with FedEx and UPS, who are acutely aware that their businesses are being exploited and alert us with any unusual patterns. Similarly, consistent with DEA's emphasis on denying revenue and financial services to drug trafficking organizations, both Visa and MasterCard are assisting us in

Richard M. Stana, Director

Page 2

investigations and with financial leads. Both shippers and credit card companies have agreed to shut down sites determined to be conducting illegal activities.

A significant aspect of the pharmacy problem is located abroad. DEA is cooperating with our Federal and foreign counterparts and we have assumed a leadership role in the international forum on Internet diversion. DEA also is increasing staffing and resources dedicated to the problem of diversion over the Internet to improve our capacity to identify and stop illicit Internet pharmacy operations, and working more closely with agencies and companies inside and outside the government to coordinate and improve our efforts. DEA's voluntary role on the interagency task force on pharmaceuticals is testament to its commitment in this area.

GAO recommends the Customs and Border Protection (CBP) Commissioner develop and implement a strategic framework for the interagency task force on pharmaceuticals. DEA agrees that strategic frameworks can be useful in promoting accountability and guiding policy and resource decisions but shares similar concerns reported to GAO by other agencies' officials. The interagency task force on pharmaceuticals is a cooperative initiative, and DEA must balance priorities in accordance with agency mandates. Additionally, DEA's Strategic Plan clearly establishes a framework to articulate agency priorities and assess its performance.

DEA notes that GAO "acknowledges that such a strategic framework needs to be flexible to allow for changing conditions, but could be helpful to organize it in a logical flow, from conception to implementation." Allowing for this flexibility, in concert with the Immigration and Customs Enforcement, Food and Drug Administration, Office of National Drug Control Policy, and United States Postal Service, DEA will support the CBP Commissioner's strategic framework for the interagency task force on pharmaceuticals.

DEA appreciates the opportunity to provide comments on the draft report. If you have any questions regarding this information, please contact Sheldon Shoemaker, Audit Liaison at (202) 307-4205.

Cc: Richard P. Theis
Acting Assistant Director, Audit Liaison Group
Management and Planning Staff

Appendix VI: Comments from the Department of Health and Human Services



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of Inspector General

Washington, D.C. 20201

AUG 18 2005

Mr. Richard M. Stana
Director, Homeland Security and Justice
U.S. Government Accountability Office
Washington, DC 20548

Dear Mr. Stana:

Enclosed are the Department's comments on the U.S. Government Accountability Office's (GAO's) draft report entitled, "PRESCRIPTION DRUGS: Strategic Framework Would Promote Accountability and Enhance Efforts to Enforce the Prohibitions on Personal Importation" (GAO-05-372). These comments represent the tentative position of the Department and are subject to reevaluation when the final version of this report is received.

The Department provided several technical comments directly to your staff.

The Department appreciates the opportunity to comment on this draft report before its publication.

Sincerely,

A handwritten signature in cursive script that reads "Daniel R. Levinson".

Daniel R. Levinson
Inspector General

Enclosure

The Office of Inspector General (OIG) is transmitting the Department's response to this draft report in our capacity as the Department's designated focal point and coordinator for U.S. Government Accountability Office reports. OIG has not conducted an independent assessment of these comments and therefore expresses no opinion on them.

**HHS COMMENTS ON THE U.S. GOVERNMENT ACCOUNTABILITY OFFICE'S
DRAFT REPORT ENTITLED, "PRESCRIPTION DRUGS: STRATEGIC
FRAMEWORK WOULD PROMOTE ACCOUNTABILITY AND ENHANCE EFFORTS
TO ENFORCE THE PROHIBITIONS ON PERSONAL IMPORTATION" (GAO-05-372)**

The Department of Health and Human Services (HHS) appreciates the opportunity to comment on the U.S. Government Accountability Office's (GAO) draft report.

General Comments

The HHS, Food and Drug Administration (FDA) is responsible for helping to ensure that the U.S. drug supply is safe, secure, and reliable for the American public. For decades, the Federal Food, Drug, and Cosmetic Act has ensured that Americans can be confident that, when they use an FDA-approved drug, the medicine will be safe and effective and will work as intended in treating their illness.

Since 1999, FDA has taken many steps to prevent the illegal importation of unapproved drugs, including coordination of activities with other Federal agencies, enhanced enforcement, coordination with international entities, partnerships with professional organizations, and development of public outreach and education campaigns. FDA continues to engage in these activities in addition to participating in the multi-agency task force cited in the GAO report.

The substantial volume of personal drug importations presents a difficult challenge for FDA field personnel at ports-of-entry, international mail facilities, and international courier hubs. FDA remains strongly concerned about unapproved, imported drugs for which safety cannot be assured because they are outside of the FDA drug approval system.

GAO Recommendation #1:

To help ensure that the Government maximizes its ability to enforce laws governing the personal importation of prescription drugs, we recommend that the CBP Commissioner, in concert with ICE, FDA, DEA, ONDCP, and USPS, develop and implement a strategic framework for the task force that would promote accountability and guide resource and policy decisions. Among other issues, GAO recommended that the strategic framework include an approach to estimate the scope of the problems including the volume of drugs entering the country through the mail and carrier (courier) facilities and determination of the resources and investments needed to address the flow of prescription drugs illegally imported for personal use.

HHS Comment:

We appreciate GAO's recommendation that the task force develop and implement a strategic framework. As GAO knows, CBP Commissioner Bonner set out clearly delineated goals for the task force when it was established. These goals provide a general framework for the work of the

task force; however, a more formalized approach may be useful to address the issues associated with the importation of unapproved drugs. We will work with our Federal partners to discuss the development of a more formalized approach.

The recommendation to include an approach to estimate the scope of the problems including the volume of drugs entering the country through the mail and carrier (courier) facilities in the strategic framework does raise questions. We believe that the volume estimates provided in the HHS Task Force Report (which included CBP and DEA as part of the Task Force) are valid. If other members of the pharmaceutical task force develop a better way to estimate the volume of illegal drug importation, we are willing to use those estimates in evaluating current resource and staffing demands. We do have concerns, however, about the ability to obtain any more valid estimates than these contained in the HHS Task Force Report. The estimate of total packages per year was calculated using a variety of figures from IMS Health data, specific counts of packages reviewed, overall import line entry data, and courier line entries from FDA's Operational and Administrative System for Import Support (OASIS). No matter what method is used to estimate the current or future volume, it is difficult to anticipate the volume of illegal activity. The volume may depend on the incentive for the public to import unapproved drugs, as well as other external factors that change over time. Thus, short of opening and counting each package as it enters the U.S., the reliability of an estimate will always be in question given the fluid nature of illegal prescription drug imports and the number of mail and courier facilities involved.

In addition, it is worth noting that the volume estimates will not alter the resource calculations already provided in the HHS Task Force Report. The calculations for what FDA resources are needed *per package* are well formed and will not be impacted by a change in the overall volume of illegal drug importation. The resource estimate in the HHS Task Force Report was derived from the mail blitzes conducted by FDA and CBP at various international mail facilities. During these blitzes, packages that were reviewed by FDA personnel were counted, identified as containing or not containing unapproved drugs, and the personnel time devoted to these activities and the follow-up activities of notification to the individual addressees was derived from FDA work records. Personnel salaries were used to calculate the resources devoted to all of the work done during the processing of each package. Even if a new volume estimate differs from the estimate provided in the HHS Task Force Report, FDA resources needed for a per package review will not change. GAO's statement that "statistically valid estimates" would allow us to develop "realistic risk-based estimates" of the number of staff needed to "interdict parcels at mail facilities" does not recognize that FDA is not always able to process the current number of packages already set aside by CBP. The HHS Task Force found that "there is no realistic level of resources that could ensure that personally imported drugs are adequately inspected to assure their safety since visual inspection, testing, and oversight of all personally imported prescription drugs are not feasible or practical at this time." Although we currently devote a significant amount of FDA resources to illegal mail importation, we must always be cognizant of competing priorities regardless of fluctuations in volume.

GAO Recommendation #2

In view of the FDA's continuing concern about the statutory notification requirement and its impact on enforcement, we also recommend that the Secretary of HHS assess the ramifications of removing or modifying the requirement, report on the results of this assessment, and, if appropriate, recommend changes to Congress.

HHS Comment:

We agree with this recommendation and intend to pursue an updated assessment. As is noted in the GAO report, the original proposal was submitted in 2001. Although we still believe that modifications to the statutory notification requirement will assist in our efforts to handle the mail importation of illegal prescription products once they are in the United States, it will not solve or prevent the problem of illegal importation. In addition, given our current estimates of the volume are greater than the estimates made when we requested modification of the notification requirement, other actions may need to be considered to address the importation of illegal prescription products. We will work with our Federal partners to determine the actions required.

Appendix VII: Comments from the Office of National Drug Control Policy



EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF NATIONAL DRUG CONTROL POLICY
Washington, D.C. 20503

August 19, 2005

Mr. Richard M. Stana
Director
Homeland Security and Justice Issues
United States General Accountability Office
Washington, DC 20548

Dear Mr. Stana:

The purpose of this letter is to provide Agency comment on GAO's draft report on "Prescription Drugs – Strategic Framework Would Promote Accountability and Enhance Efforts to Enforce the Prohibitions on Personal Importation" (GAO-05-372). We appreciate the opportunity to comment on this important issue involving one aspect of drug diversion. Although prescription drug abuse can also be influenced by "doctor shopping" and other means, such as thefts from pharmacies and other legitimate outlets; the availability of drugs on the internet from sources outside the United States remains a constant concern of our National Drug Control Policy.

The problems associated with effectively policing internet purchases are well documented in the report. Additionally, the report identifies the significance played by credit card use as a facilitator of the problem. We, likewise, encourage law enforcement proposals that may curtail these dangerous practices. Further, we concur in your identification of the cumbersome nature of currently required enforcement practices dealing with the use of the mails to transfer illicit narcotics.

In addition to the recommendation that the CBP Commissioner develop and implement a strategic framework for a task force, we would strongly suggest that the currently established Synthetic Drug Interagency Working Group (SDIWG), led by our office, play a significant role in integrating these considerations with all of the other synthetic drug concerns that inflict potential harm on our society.

Sincerely,

A handwritten signature in black ink, appearing to read "S.A. Katsurinis".

Stephen A. Katsurinis
Chief of Staff

Appendix VIII: Comments from the U.S. Postal Service

MARY ANNE GIBBONS
SENIOR VICE PRESIDENT, GENERAL COUNSEL



August 19, 2005

Mr. Richard M. Stana
Director, Homeland Security and Justice Issues
United States Government Accountability Office
441 G Street, NW MS-6Q26H
Washington, DC 20548-0001

Dear Mr. Stana:

Thank you for providing the U.S. Postal Service with the opportunity to review and comment on the draft report titled *Prescription Drugs: Strategic Framework Would Promote Accountability and Enhance Efforts to Enforce the Prohibitions on Personal Importation* (GAO-05-372).

We wish to express a concern with possible procedural and legislative changes dealing with revisions to the current notification requirements. The report discusses the effects of notification of the addressee on the process of interdicting prescription drugs that are not on Schedules I and II of the Controlled Substances list. The report further indicates that federal agencies have considered the merits of legislation to change existing procedures governing the processing and disposition of imported pharmaceuticals.

While we understand the government's interest in devising effective solutions to stem illegal trade in pharmaceuticals, we believe it is important that the report also acknowledge the United States' international obligations under the Universal Postal Union (UPU) Acts. Article RE 501 of the UPU Letter Post Regulations and article RE 302 of the UPU Parcel Post Regulations establish a general rule that items that are not admitted to the post for delivery are to be returned to the sender. In those cases where an item can neither be delivered to the addressee nor returned to the sender, the Postal Service must notify the postal administration of origin of the disposition of the article. This notice must also clearly indicate the prohibition under which the item falls. This is particularly important with respect to registered or insured mail for which the Postal Service can be held financially responsible if it is not delivered or returned. Accordingly, in any discussion of options that might expedite the processing and disposition of prescription drugs, the international legal requirement that postal administrations of origin be notified when items have not been delivered as addressed and the reasons therefor need to be taken into account.

If you or your staff wish to discuss any of these comments further, I am available at your convenience.

Sincerely,

A handwritten signature in black ink, appearing to read "Mary Anne Gibbons".

Mary Anne Gibbons

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Appendix IX: GAO Contact and Acknowledgments

GAO Contact

Richard M. Stana (202) 512-8777

Acknowledgments

In addition to the above, John F. Mortin, Assistant Director; Leo M. Barbour; Frances A. Cook; Katherine M. Davis; Michele C. Fejfar; Yelena T. Harden; James R. Russell; and Barbara A. Stolz made key contributions to this report.

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