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Testimony

Before the Subcommittee on Oversight  
and Investigations, Committee on Energy  
and Commerce, U.S. House of  
Representatives

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For Release on Delivery  
Expected at 1:00 p.m. EST  
Tuesday, December 13, 2005

## PRESCRIPTION DRUGS

# Enhanced Efforts and Better Agency Coordination Needed to Address Illegal Importation

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





Highlights of [GAO-06 175T](#), a testimony before the Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, U.S. House of Representatives

## Why GAO Did This Study

This testimony summarizes a GAO report on federal efforts to address the importation of prohibited prescription drugs through international mail and carrier facilities for personal use. 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 these drugs. This testimony addresses (1) available data about the volume and safety of these drugs, (2) the procedures and practices used to inspect and interdict them, (3) factors affecting federal efforts to enforce the laws governing these drugs, and (4) federal agencies' efforts to coordinate enforcement of the prohibitions on personal importation of these drugs.

## 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.

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For more information, contact Richard Stana at (202) 512-8777 or [StanaR@gao.gov](mailto:StanaR@gao.gov).

# PRESCRIPTION DRUGS

## Enhanced Efforts and Better Agency Coordination Needed to Address Illegal 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.

GAO identified three factors that have complicated federal enforcement of laws prohibiting the personal importation of prescription drugs. First, the volume of imports has strained limited federal resources at 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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Mr. Chairman and Members of the Subcommittee:

I appreciate the opportunity to provide a summary of our recent report on federal agencies' efforts to address the importation of prohibited prescription drugs through international mail and carrier facilities.<sup>1</sup>

The advent of online Internet pharmacy services in early 1999, enabled American consumers to order over the Internet a range of prescription drugs from controlled substances,<sup>2</sup> 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. The broad reach and access of the Internet allow the easy creation of online pharmacies that anonymously traverse state and national borders to prescribe, sell, and dispense prescription drugs without complying with traditional state or federal regulatory safeguards.

Under current law, the importation of prescription drugs, both controlled and noncontrolled, for personal use is illegal, with few exceptions. In

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<sup>1</sup>See GAO, *Prescription Drugs: Strategic Framework Would Promote Accountability and Enhance Efforts to Enforce the Prohibitions on Personal Importation*, [GAO-05-372](#) (Washington, D.C.: September 8, 2005).

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recent years, Congress and others have debated whether Americans should be allowed to purchase drugs from pharmacies located in foreign countries. However, 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

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<sup>2</sup>The 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.

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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.

This statement presents a summary of our latest work on federal efforts to enforce prohibitions on personal importation of prescription drugs through the international mail and carrier facilities, which was requested by the Chairman of the Senate Permanent Subcommittee on Investigations, Committee on Homeland Security and Governmental Affairs and the Ranking Minority Member of the House Energy and Commerce Committee. My testimony today, requested by the Chairman of this Subcommittee, provides a summary of our report and will focus on the following issues:

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- what 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,
  - what procedures and practices are used at selected facilities to inspect and interdict prescription drugs unapproved for import,
  - what factors affect federal agency efforts to enforce the prohibition on prescription drug importation for personal use through international mail and carrier facilities, and
  - what efforts federal agencies have undertaken to coordinate the enforcement of the prohibitions on personal importation of prescription drugs.

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## Summary

Our report on illegal prescription drug importation notes that 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 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 has limitations, being partially based on extrapolations from limited FDA

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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.<sup>3</sup>

Regarding the practices used at the mail and carrier facilities we visited to inspect packages and interdict prohibited prescription drugs, our report states that both FDA's and CBP's procedures are evolving. FDA issued procedures 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 addressees. For example, packages

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<sup>3</sup>See 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).

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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. 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 recorded about 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.

In our report, we also identify 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



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enforcement efforts for multiple reasons. For example, Internet sites can be installed, moved, or removed in a short period of time, making it difficult for law enforcement agencies to 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 requiring FDA to hold packages containing items that appear unapproved for import and give the addressee the opportunity to provide evidence of admissibility is, according to FDA officials, time-consuming — taking 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. However, FDA officials told us 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) that had been 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

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prescription drugs should consider international postal obligations established by the Universal Postal Union (UPU).<sup>4</sup>

We also report that 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. Our past work has shown that a strategic framework 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

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<sup>4</sup>UPU 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.

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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.

Accordingly, our report recommends 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. DEA and ONDCP generally agreed with this recommendation. DHS generally agreed with the contents of our report and said that CBP is convening a task force meeting to discuss it. While generally concurring with this recommendation, HHS questioned the need to include an approach to estimate the volume of unapproved drugs entering the country, believing its current estimates to be valid. 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. Considering FDA's continuing concern about the statutory notification requirement, we also

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recommend that the Secretary of HHS assess the ramifications of removing or modifying the requirement, report the assessment results, and, if appropriate, recommend changes to Congress. HHS generally agreed with this recommendation; USPS noted that discussions of such options must consider international postal obligations.

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## 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.

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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.<sup>5</sup> Under the act and implementing regulations, this includes foreign versions of FDA-approved drugs if, for example, neither the foreign manufacturing facility nor the manufacturing methods and controls were reviewed by FDA for compliance with U.S. statutory and regulatory standards. The act also prohibits reimportation of a prescription drug manufactured in the United States by anyone other than the original manufacturer of that drug. According to FDA, prescription drugs imported by individual consumers typically fall into one of these prohibited categories. However, FDA has established a policy that allows local FDA officials to use their discretion to 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

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<sup>5</sup>An unapproved drug includes one that has not been demonstrated to be safe and effective and for which the manufacturing facility, methods, and controls have not been shown to meet FDA standards. Failure to meet other statutory and regulatory standards relating to labeling, handling, and packaging may result in a drug being considered adulterated or misbranded. See 21 U.S.C. §§ 351, 352, 355.

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serious condition, generally not more than a 90-day supply of a drug not available domestically.<sup>6</sup> 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. 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

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<sup>6</sup>According to the policy, other conditions should be met as well, such as (1) provision of the name and address of the doctor licensed in the United States responsible for the importer's treatment with the product or evidence that the product is for continuation of treatment begun in a foreign country and (2) the absence of any known commercialization or promotion to persons residing in the United States by those involved in the distribution of the product at issue. Alternatively, in the case of a drug that is not for a serious condition, the policy also permits FDA officials to use their discretion to allow importation of that drug if the intended use is identified and the product is not known to represent a significant health risk. A complete description of FDA's personal importation policy can be found in chapter 9 of FDA's *Regulatory Procedures Manual*, which is available on the agency's Web site.

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seeking to import a controlled substance for personal use to meet the standards for registration and related requirements.<sup>7</sup>

CBP is to seize illegally imported controlled substances it detects on behalf of DEA.<sup>8</sup> 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.<sup>9</sup> CBP is to turn over packages suspected of containing prescription drugs that are not controlled substances to FDA.<sup>10</sup> FDA investigators may inspect such packages and hold those that appear to be adulterated, misbranded, or unapproved, but must notify the addressee and allow that individual the opportunity to present evidence as to why the drug should be admitted into the United States.<sup>11</sup> If the addressee does not provide evidence that overcomes the appearance of inadmissibility, then the item is refused admission and returned to the sender.

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<sup>7</sup>The act and implementing regulations permit an individual traveler under certain circumstances to carry a personal use quantity of a controlled substance (except a substance in schedule I) across the U.S. border, but they do not make a similar exception for importation by mail or private carrier.

<sup>8</sup>See 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.

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

<sup>10</sup>See 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](http://www.fda.gov/ora/compliance_ref/rpm_new2/ch9pers.html).

<sup>11</sup>See 21 U.S.C. § 381(a); 21 CFR §1.94.

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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.

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

My statement will now focus on what 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.



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**CBP and FDA Do Not Know the Scope of Prohibited Prescription Drug Importation, but They Believe it to Be Substantial**

In our report, we state that 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. 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, but neither agency has complete data to estimate the volume of importation. 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.

We also report that CBP and FDA, in coordination with other federal agencies, have conducted special operations targeted 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, at one mail facility CBP officials estimated that approximately 3,300 packages containing prescription

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drugs entered the facility in 1 week and at another mail facility CBP officials estimated that 4,300 such packages 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.

Our report also notes that during congressional hearings over the past 4 years, FDA officials, among others, have presented estimates of the volume of prescription drugs imported into the United States through mail and express carrier facilities 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.<sup>12</sup> However, these estimates also have limitations, being partially based on extrapolations from limited FDA

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

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observations at international mail branch facilities.<sup>13</sup> Without an accurate estimate of the volume of importation of prescription drugs, federal agencies cannot determine the full scope of the importation issue.

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## The Safety of Prescription Drug Imports Is Not Assured

Regarding the safety of prescription drug imports, we report that 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. FDA officials also said that consumers who purchase prescription drugs from foreign-based Internet pharmacies are at risk of not fully knowing the safety or quality of what they are importing. While some consumers may purchase genuine products, others may unknowingly purchase counterfeit products, expired drugs, or drugs that were improperly manufactured.

In addition, we report on CBP's and FDA's limited analysis of the imported prescription drugs identified during special operations. The results of these efforts have raised questions about the safety of some of the drugs.

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<sup>13</sup>FDA officials told us that FDA developed its estimate for Canadian drugs entering the country using (1) IMS Health estimates (IMS Health is a management consulting firm that provides information to pharmaceutical and health care industries) that 12 million prescriptions sold from Canadian pharmacies were imported into the United States in 2003 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.

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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.<sup>14</sup> 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.

Consistent with these concerns, we report on the findings of our June 2004 report in which 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.<sup>15</sup> 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. We observed during the site visits undertaken for our current report that in addition to some prescription drugs imported through the mail and carrier facilities not being shipped in protective

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<sup>14</sup>According 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.

<sup>15</sup>[GAO-04-820](#) and [GAO-04-888T](#).

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packages, some drugs also lacked product identifications, directions for use, or warning labels. Furthermore, for some drugs, the origin and contents could not be immediately determined by CBP or FDA inspection.

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**Highly Addictive  
Controlled Substances Are  
Widely Available via the  
Internet**

Our report also noted that 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. 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. In addition, 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.

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

My statement will now focus on the procedures and practices used at selected facilities to inspect and interdict prescription drugs unapproved for import.

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

With regard to procedures and practices used at selected facilities to inspect and interdict prescription drugs unapproved for import, our report cites our July 2004 testimony in which 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.<sup>16</sup> 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, we also 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. 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 outlining how FDA personnel are to prioritize packages for inspection, inspect the packages, and make admissibility determinations of FDA-regulated

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<sup>16</sup>See GAO, *Prescription Drugs: Preliminary Observations on Efforts to Enforce the*

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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,<sup>17</sup> that appear to contain prescription drugs. Deviations from the procedures must be requested by facility personnel and approved by FDA management. According to FDA officials, these procedures have been adopted nationwide. While the new procedures should encourage processing uniformity across facilities, many packages that contain prescription drugs are still released. 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.

Our report cites CBP and FDA officials at two facilities who 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

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*Prohibitions on Personal Importation*, [GAO-04-839T](#) (Washington, D.C.: July 22, 2004).

<sup>17</sup>Local criteria can include other targeted countries and additional intelligence.

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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.

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

Regarding the procedures and practices used to inspect and interdict certain controlled substances, our report cites our July 2004 testimony in which we reported that CBP officials were to seize the illegally imported controlled substances they detected.<sup>18</sup> 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.

According to our report, 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

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<sup>18</sup> [GAO-04-839T](#).



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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 seized<sup>19</sup> 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.<sup>20</sup>

Our report goes on to say that 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

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<sup>19</sup>The seized package could also be submitted to ICE for possible investigation of the addressee and the sender.

<sup>20</sup>Since 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.

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or abandoned property as an alternative to a seizure.<sup>21</sup> According to a CBP headquarters official, processing a controlled substance as abandoned property is a less arduous process because it requires less information be 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.<sup>22</sup> CBP reported that from September 2004 to the end of June 2005, a total of approximately 61,700 packages of these substances were interdicted,

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<sup>21</sup>Under 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.

<sup>22</sup>CBP 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 on 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.

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about 61,500 at international mail facilities and 200 at express carrier facilities.

We report that generally, CBP officials we interviewed told us that the recent policy improved their ability to record information about and destroy 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. However, we also report that 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

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substances imported through the facility had begun to decrease, but he had no data to support his claim.

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

According to our report, 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. 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.

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

My statement will now focus on the three factors that our report identified as affecting federal agency efforts to enforce the prohibition on prescription drug importation for personal use through international mail and carrier facilities.

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## The Volume of Imports Can Strain Federal Resources

In our report, we state that 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 recent increase in American consumers ordering drugs over the Internet has significantly contributed to increased importation of these drugs 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. FDA officials have said that the large volume of imports has overwhelmed the resources they have allocated to the mail facilities and 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. In addition, agencies have multiple priorities, which can affect the resources they are able to allocate to the mail and carrier facilities. For example, FDA's multiple areas of responsibility include, among other things,

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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. DEA's multiple priorities include interdicting illicit drugs such as heroin or cocaine, investigating doctors and prescription forgers, and pursuing hijackings of drug shipments.

We also report on HHS and CBP assessments of resources needed to address the volume of illegally imported drugs coming into the country. In a 2004 report on the importation of prescription drugs, the Secretary of HHS stated that substantial resources are needed to prevent the increasing volume of packages containing small quantities of drugs from entering the country.<sup>23</sup> 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

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<sup>23</sup>HHS Task Force on Drug Importation, *Report on Prescription Drug Importation*, Department of Health and Human Services, December 2004. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 directed the Secretary of Health and Human Services, in consultation with appropriate government agencies, to conduct a study of the importation of drugs into the United States, including, according to the conference report for the legislation, a review of the adequacy of federal agency resources to inspect and interdict drugs unapproved for import, and submit a report to Congress. Pub. L. No. 108-173, § 1122, 117 Stat. 2066, 2469 (2003), H.R. Conf. Rep. No. 105-39, at 833-34 (2003).

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prescription drugs entering the United States. 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.

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**Internet Pharmacies  
Challenge Law  
Enforcement Efforts**

According to our report, Internet pharmacies, particularly foreign-based sites, which operate outside the U.S. regulatory system, pose a challenge for regulators and law enforcement agencies. In an earlier 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

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professional. 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.

In addition, we report that 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. This fluidity makes it difficult for law enforcement agencies to identify, track, monitor, or shut down those sites that operate illegally. Moreover, 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 also face challenges when working with foreign governments to share information or develop mechanisms for



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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 it was difficult to convince some foreign governments that the illegal sale of prescription drugs over the Internet is a global problem and not restricted to the United States.

In our report, we also note that 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. For example, according to FDA, DEA,

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and ICE officials, credit card organizations<sup>24</sup> and banks and other financial institutions<sup>25</sup> 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.<sup>26</sup>

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## The Notification Process Challenges Enforcement Efforts

We also report that 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

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<sup>24</sup>Two 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 do 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).

<sup>25</sup>When 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.

<sup>26</sup>According to a DEA official, the majority of Internet drug sites used the payment systems of the two associations we contacted.

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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 handle 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 the procedures were designed to focus resources on packages containing drugs considered to be among the highest risk.

Our report further indicates that FDA and the Secretary of HHS have raised concerns about FDA's notification process, noting that it is time-consuming and resource intensive, in testimony before Congress, but did

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not propose any legislative changes to address the concerns 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, the importance of providing due process, which basically gives individuals the opportunity to present the case as to why they should be entitled to receive the property (e.g., prescription drugs that they ordered from a foreign source), and/or the extent the law should be changed to cover all imported prescription drugs and other products. In

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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). 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.

Furthermore, we report that 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 examine packages to ascertain whether they contained unapproved prescription drugs.

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

My statement will now focus on efforts federal agencies have undertaken to coordinate the enforcement of the prohibitions on personal importation of prescription drugs.

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

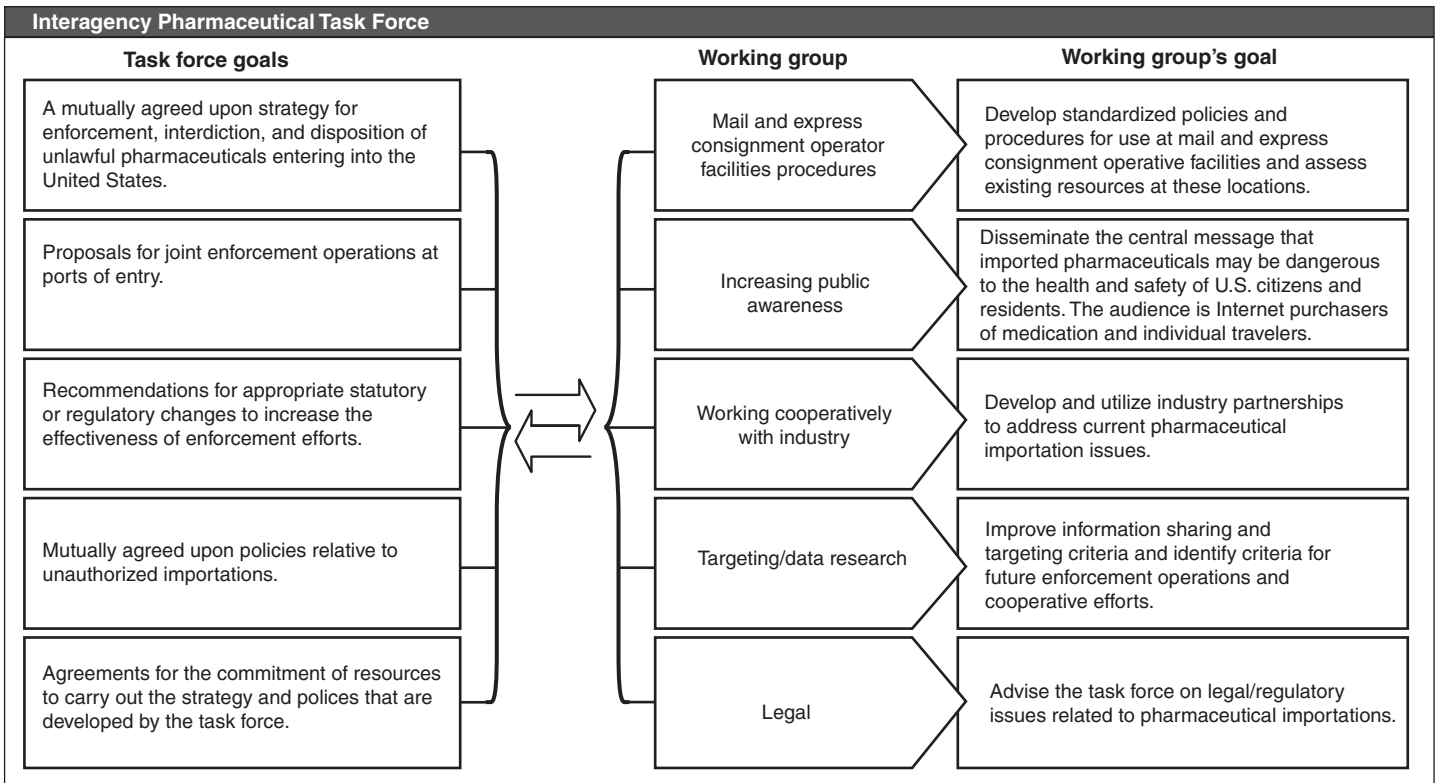
According to our report, since 1999, federal law enforcement and regulatory agencies have organized various task forces and working groups to address issues associated with purchasing prescription drugs over the Internet; however, recent efforts have begun to focus particular attention on imported prescription 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. As our report discusses, 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

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resulted in increasing pressure being applied to regulatory and law enforcement agencies to develop consistent, fair policies” to address illegal 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 1 shows the task force goals, the five working groups, and the goals of each working group.

**Figure 1: Interagency Pharmaceutical Task Force and Working Group Goals**



Source: GAO analysis of CBP documents.

CBP officials and other members of the task force provided examples of activities being carried out or planned by task force working groups. For example, 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



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task force are multiagency efforts; they are expected to continue during the remainder of 2005 at all of the remaining mail facilities and some of the carrier facilities. Our report describes activities of the other working groups.

In addition, we report that the 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.<sup>27</sup> 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.

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<sup>27</sup> 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."

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Finally, we report that USPS is exploring what additional steps it can take to further help the task force. 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.<sup>28</sup> This action is still pending.

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### A Strategic Framework Would Further Enhance Task Force Efforts

In our report, we state that 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. Our review showed that the task force has already begun to establish some elements of a strategic framework, but not others. For example, the Commissioner's January 2004 memo laid out the purpose of the task force and why it was created. However, it has not defined the scope of the

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<sup>28</sup>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.

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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. In addition, while 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. Furthermore, 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.

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. According to our report, the challenges we identify 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. Advancing such a strategic framework could establish a mechanism for accountability and oversight. Our report

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acknowledges that such a strategic framework needs to be flexible to allow for changing conditions and could help agencies adjust to potential changes in the law governing the importation of prescription drugs for personal use.

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## GAO Conclusions, Recommendations, and Agency Responses

While acknowledging the complexities of enforcing the laws governing prescription drug imports for personal use, including the involvement of multiple agencies with various jurisdictions and differing priorities, our report concludes that 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. However, a strategic framework that facilitates comprehensive enforcement of prescription drug importation laws and measures results would provide the task force with an opportunity to better focus agency efforts to stem the flow of prohibited prescription drugs entering the United States. In addition to the issues addressed by the task force, FDA has also expressed continuing concern to Congress that it encounters serious resource constraints enforcing the law at mail facilities because packages containing personal drug imports must be handled in accordance with FDA's time-consuming and resource-

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intensive notification process. FDA has stated that it cannot effectively enforce the law unless the requirement to notify recipients is changed.

Accordingly, to help ensure that the government maximizes its ability to enforce laws governing the personal importation of prescription drugs, our report recommends 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
- an evaluation component to assess progress, identify barriers to achieving goals, and suggest modifications.

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In view of FDA's continuing concern about the statutory notification requirement and its impact on enforcement, our report also recommends 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.

In commenting on our report, 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

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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.

Mr. Chairman, this concludes my prepared testimony. I would be happy to respond to any questions you or other members of the committee may have at this time.

#### **GAO Contacts and Staff Acknowledgments**

For further information about this testimony, please contact me at (202) 512-8816. John F. Mortin, Leo M. Barbour, Frances A. Cook, Katherine M. Davis, Michele C. Fejfar, and Barbara A. Stolz made key contributions to this statement.

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# Related GAO Products

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*Prescription Drugs: Strategic Framework Would Promote Accountability and Enhance Efforts to Enforce the Prohibitions on Personal Importation.* [GAO-05-372](#). Washington, D.C.: September 8, 2005.

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

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

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

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



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