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PRESCRIPTION DRUGS

Preliminary Observations on Efforts to Enforce the Prohibitions on Personal Importation

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Highlights

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

Why GAO Did This Study

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

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

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

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

What GAO Found

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

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

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

Packages suspected of containing imported prescription drugs awaiting FDA review

Source: GAO with permission of CBP and FDA.