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PRESCRIPTION DRUGS

Enhanced Efforts and Better Agency Coordination Needed to Address Illegal Importation

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Highlights

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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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.