



Highlights of [GAO-04-820](#), a report to the Chairman, Permanent Subcommittee on Investigations, Committee on Governmental Affairs, U.S. Senate

Why GAO Did This Study

As the demand for and the cost of prescription drugs rise, many consumers have turned to the Internet to purchase drugs. However, the global nature of the Internet can hinder state and federal efforts to identify and regulate Internet pharmacies to help assure the safety and efficacy of products sold. Recent reports of unapproved and counterfeit drugs sold over the Internet have raised further concerns.

GAO was asked to examine (1) the extent to which certain drugs can be purchased over the Internet without a prescription; (2) whether the drugs are handled properly, approved by the Food and Drug Administration (FDA), and authentic; and (3) the extent to which Internet pharmacies are reliable in their business practices. GAO attempted to purchase up to 10 samples of 13 different drugs, each from a different pharmacy Web site, including sites in the United States, Canada, and other foreign countries. GAO determined whether the samples contained a pharmacy label with patient instructions for use and warnings on the labels or the packaging and forwarded the samples to their manufacturers to determine whether they were approved by FDA and authentic. GAO also confirmed the locations of several Internet pharmacies and identified those under investigation by regulatory agencies.

www.gao.gov/cgi-bin/getrpt?GAO-04-820.

To view the full product, including the scope and methodology, click on the link above. For more information, contact Marcia Crosse at (202) 512-7119 or Robert J. Cramer at (202) 512-7455.

INTERNET PHARMACIES

Some Pose Safety Risks for Consumers

What GAO Found

GAO obtained most of the prescription drugs it targeted from a variety of Internet pharmacy Web sites without providing a prescription. GAO obtained 68 samples of 11 different drugs—each from a different pharmacy Web site in the United States, Canada, or other foreign countries, including Argentina, Costa Rica, Fiji, India, Mexico, Pakistan, Philippines, Spain, Thailand, and Turkey. Five U.S. and all 18 Canadian pharmacy sites from which GAO received samples required a patient-provided prescription, whereas the remaining 24 U.S. and all 21 foreign pharmacy sites outside of Canada provided a prescription based on their own medical questionnaire or had no prescription requirement. Among the drugs GAO obtained without a prescription were those with special safety restrictions and highly addictive narcotic painkillers.

GAO identified several problems associated with the handling, FDA approval status, and authenticity of the 21 samples received from Internet pharmacies located in foreign countries outside of Canada. Fewer problems were identified among pharmacies in Canada and the United States. None of the foreign pharmacies outside of Canada included required dispensing pharmacy labels that provided instructions for use, few included warning information, and 13 displayed other problems associated with the handling of the drugs. For example, 3 samples of a drug that should be shipped in a temperature-controlled environment arrived in envelopes without insulation. Manufacturer testing revealed that most of these drug samples were unapproved for the U.S. market; however, manufacturers found the chemical composition of all but 4 was comparable to the product GAO ordered. Four samples were determined to be counterfeit products or otherwise not comparable to the product GAO ordered. Similar to the samples received from other foreign pharmacies, manufacturers found most of those from Canada to be unapproved for the U.S. market; however, manufacturers determined that the chemical composition of all drug samples obtained from Canada were comparable to the product GAO ordered.

Some Internet pharmacies were not reliable in their business practices. Most instances identified involved pharmacies outside of the United States and Canada. GAO did not receive six orders for which it had paid. In addition, GAO found questionable entities located at the return addresses on the packaging of several samples, such as private residences. Finally, 14 of the 68 pharmacy Web sites from which GAO obtained samples were found to be under investigation by regulatory agencies for reasons including selling counterfeit drugs and providing prescription drugs where no valid doctor-patient relationship exists. Nine of these were U.S. sites, 1 a Canadian site, and 4 were other foreign Internet pharmacy sites.

In commenting on a draft of this report, FDA generally agreed with its findings and conclusions.