

Why GAO Did This Study

The Internet offers consumers a convenient method for purchasing drugs that is sometimes cheaper than buying from traditional brick-and-mortar pharmacies. According to a recent FDA survey, nearly 1 in 4 adult U.S. Internet consumers have purchased prescription drugs online. However, many Internet pharmacies are fraudulent enterprises that offer prescription drugs without a prescription and are not appropriately licensed. These rogue Internet pharmacies may sell drugs that are expired, improperly labeled, or are counterfeits of other drugs. A number of federal and state agencies share responsibility for administering and enforcing laws related to Internet pharmacies, including state boards of pharmacy, FDA, DOJ, CBP, and ICE.

The Food and Drug Administration Safety and Innovation Act directed GAO to report on problems with Internet pharmacies. This report identifies (1) how rogue sites violate federal and state laws, (2) challenges federal agencies face in investigating and prosecuting operators, (3) efforts to combat rogue Internet pharmacies, and (4) efforts to educate consumers about the risks of purchasing prescription drugs online. To conduct this work, GAO interviewed officials from FDA, DOJ, CBP, ICE, and other federal agencies, reviewed federal laws and regulations, and examined agency data and documents. GAO also interviewed officials from five state boards of pharmacy with varied approaches to regulating Internet pharmacies, and stakeholders including NABP, drug manufacturers, and companies that provide services to Internet businesses, such as payment processors.

View [GAO-13-560](#). For more information, contact Marcia Crosse at (202) 512-7114 or CrosseM@gao.gov.

July 2013

INTERNET PHARMACIES

Federal Agencies and States Face Challenges Combating Rogue Sites, Particularly Those Abroad

What GAO Found

Rogue Internet pharmacies violate a variety of federal and state laws. Most operate from abroad, and many illegally ship prescription drugs into the United States that have not been approved by the Food and Drug Administration (FDA), an agency within the Department of Health and Human Services (HHS), that is responsible for ensuring the safety and effectiveness of prescription drugs. Many also illegally sell prescription drugs without a prescription that meets federal and state requirements. Rogue sites also often violate other laws, including those related to fraud, money laundering, and intellectual property rights.

Rogue Internet pharmacies are often complex, global operations, and federal agencies face substantial challenges investigating and prosecuting those involved. According to federal agency officials, piecing together rogue Internet pharmacy operations can be difficult because they may be composed of thousands of related websites, and operators take steps to disguise their identities. Officials also face challenges investigating and prosecuting operators because they are often located abroad. The Department of Justice (DOJ) may not prosecute such cases due to competing priorities, the complexity of these operations, and challenges related to bringing charges under some federal laws.

Despite these challenges, federal and state agencies as well as stakeholders have taken actions to combat rogue Internet pharmacies. Federal agencies have conducted investigations that have led to convictions, fines, and asset seizures from rogue Internet pharmacies as well as from companies that provide services to them. FDA and other federal agencies have also collaborated with law enforcement agencies around the world to disrupt rogue Internet pharmacy operations. The Department of Homeland Security's (DHS) U.S. Customs and Border Protection (CBP) and U.S. Immigration and Customs Enforcement (ICE), which are responsible for enforcing laws related to the importation of goods such as prescription drugs, have also worked with other agencies, including FDA, to interdict rogue Internet pharmacy shipments at the border. Given that most rogue Internet pharmacies operate from abroad, states have faced challenges combating them, and generally focus their oversight on licensed in-state entities that fulfill orders for rogue Internet pharmacies. Companies that provide services to Internet-based businesses, such as search engines and payment processors, have also taken action—primarily by blocking services to them.

FDA and others have taken steps to educate consumers about the dangers of buying prescription drugs from rogue Internet pharmacies. FDA recently launched a national campaign to raise public awareness about the risks of purchasing drugs online, and the National Association of Boards of Pharmacy (NABP) posts information on its website about how to safely purchase drugs online. However, rogue Internet pharmacies use sophisticated marketing methods to appear legitimate, making it hard for consumers to differentiate between legitimate and rogue sites.

HHS, DOJ, and DHS provided technical comments on a draft of this report, which GAO incorporated as appropriate.