

# GAO Highlights

Highlights of [GAO-14-386T](#), a testimony before the Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, House of Representatives

## Why GAO Did This Study

While some Internet pharmacies are legitimate businesses that offer consumers a safe and convenient way to purchase their prescription drugs, the FDA and NABP have reported that thousands are fraudulent enterprises. Among other things, these rogue Internet pharmacies often sell counterfeit or otherwise substandard drugs. Consumers have experienced health problems as a result of purchasing drugs from rogue Internet pharmacies, and the proliferation and patronage of such entities has rendered them a public health threat. A number of federal and state agencies share responsibility for administering and enforcing laws related to Internet pharmacies, including FDA, DOJ, CBP, and ICE, as well as state boards of pharmacy.

This statement is based on GAO's July 2013 report, entitled *Internet Pharmacies: Federal Agencies and States Face Challenges Combating Rogue Sites, Particularly Those Abroad* ([GAO-13-560](#)). In this report, GAO identified (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 federal agencies, reviewed federal laws and regulations, and examined agency data and documents. GAO also interviewed officials from stakeholders including NABP, drug manufacturers, and companies that provide services to Internet businesses.

View [GAO-14-386T](#). For more information, contact Marcia Crosse, (202) 512-7114, or [CrosseM@gao.gov](mailto:CrosseM@gao.gov).

February 27, 2014

## INTERNET PHARMACIES

### Most Rogue Sites Operate from Abroad, and Many Sell Counterfeit Drugs

#### What GAO Found

Although the exact number of rogue Internet pharmacies is unknown, one estimate suggests that there were over 36,000 in operation as of February 2014, and these rogue sites violate a variety of federal 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), including drugs that are counterfeit or are otherwise substandard. Many also illegally sell prescription drugs without a prescription that meets federal and state requirements. Foreign rogue Internet pharmacies use sophisticated methods to evade scrutiny by customs officials and smuggle drugs into the country. Their operators also often violate other laws, including those related to fraud and money laundering.

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 in countries that are unable or unwilling to aid U.S. agencies. 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 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. For example, FDA took action against 1,677 rogue Internet pharmacy websites in 2013 as part of a worldwide enforcement initiative. Other federal agencies such as U.S. Customs and Border Protection (CBP) and U.S. Immigration and Customs Enforcement (ICE) have also taken actions—for example, by interdicting counterfeit drug shipments from rogue Internet pharmacies at the border.

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. NABP's recent analysis shows that 97 percent of the over 10,000 Internet pharmacies that it reviewed were out of compliance with laws or industry standards. Some rogue sites seek to assure consumers of the safety of their drugs by purporting to be "Canadian" despite being located elsewhere or selling drugs sourced from other countries.