



Testimony

Before the Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, House of Representatives

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INTERNET PHARMACIES

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

Statement of Marcia Crosse Director, Health Care

GAOHighlights

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 roque 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.

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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.

Chairman Murphy, Ranking Member DeGette, and Members of the Subcommittee:

I am pleased to be here today as you discuss the danger posed by counterfeit drugs. 1 One source of counterfeit drugs is Internet pharmacies. While some Internet pharmacies are legitimate businesses that offer consumers a safe, convenient, and cost-effective way to obtain their medications, the Food and Drug Administration (FDA) and the National Association of Boards of Pharmacy (NABP) have reported that thousands are fraudulent enterprises.² In addition to counterfeit drugs, these "rogue" Internet pharmacies often sell prescription drugs that have not been approved for sale in the United States, are substandard and have no therapeutic value, or are harmful to consumers.³ Drugs sold by roque Internet pharmacies have been found to contain too much, too little. or no active pharmaceutical ingredient, or the wrong active ingredient. They have also been found to contain dangerous contaminants, such as toxic yellow highway paint, heavy metals, and rat poison. Consumers who have taken prescription drugs purchased from rogue Internet pharmacies have experienced health problems, required emergency treatments, and died. Despite the risks, buying prescription drugs on the Internet is not uncommon. According to a recent survey conducted by FDA, nearly one in four adult U.S. Internet consumers surveyed reported purchasing prescription drugs online.4 At the same time, nearly 30 percent said that they lacked confidence about how to safely purchase medicine online. The proliferation and widespread patronage of rogue Internet pharmacies

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¹Counterfeit drugs include those sold under a product name without proper authorization—where the drug is mislabeled in a way to mimic an authentic product—as well as unauthorized generic versions of drugs approved by the Food and Drug Administration that mimic trademarked elements of such drugs. 21 U.S.C. § 321(g)(2).

²We refer to each website that fulfills first-time orders of prescription drugs as an Internet pharmacy, regardless of whether the company that operates the website is licensed as a pharmacy.

³Both counterfeit drugs and substandard drugs may be contaminated or otherwise harmful. Counterfeit drugs may contain no active ingredient or may contain the same active ingredient as the authentic product they mimic, but at the wrong dose. Substandard drugs include those that are adulterated and that differ in strength, quality, or purity from approved products, as well as those that are not manufactured in conformity with good manufacturing practices.

⁴FDA, "BeSafeRx Survey Highlights," accessed May 7, 2013, http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/BuyingMedicinesOvertheInternet/BeSafeRxKnowYourOnlinePharmacy/ucm318497.htm.

has prompted public officials to identify them as a continuing public health threat.

Like brick-and-mortar pharmacies, Internet pharmacies are subject to federal and state statutes and regulations that are designed to ensure the safety, efficacy, and proper administration of medications. No one federal agency is designated as the lead in combating roque Internet pharmacy activity. Instead, a number of federal and state agencies share responsibility for regulating prescription drugs that are marketed and sold to U.S. consumers, including by Internet pharmacies. The federal agencies have separate and distinct roles and often work together. For example, FDA is responsible for ensuring the safety and effectiveness of prescription drugs, and FDA approval is required prior to marketing prescription drugs in the United States. U.S. Customs and Border Protection (CBP) is responsible for enforcing laws prohibiting the illegal importation of goods, including prescription drugs that have not been approved for marketing in the United States by FDA. U.S. Immigration and Customs Enforcement (ICE) is responsible for, among other things, investigating violations of customs and trade laws, including those related to trafficking in counterfeit goods. ICE also operates the National Intellectual Property Rights Coordination Center, the mission of which is to share information across 17 federal government agencies and four foreign regulatory agencies, coordinate enforcement actions, and conduct investigations related to intellectual property theft—including those that occur through rogue Internet pharmacies. The Department of Justice (DOJ) may investigate and prosecute an operator of an Internet pharmacy that is suspected of violating federal laws. State agencies regulate the practice of pharmacy through state boards of pharmacy and, similarly, the practice of medicine though state medical boards.

My statement will highlight some of the key findings from our July 2013 report on Internet pharmacies, and includes selected updates to the report. Among other things, our report identified (1) how rogue Internet pharmacies are selling prescription drugs in violation of federal laws, (2) challenges associated with federal investigations and prosecutions of rogue Internet pharmacies, (3) efforts to combat rogue Internet pharmacies, and (4) efforts to educate consumers about the risks of

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⁵GAO, Internet Pharmacies: Federal Agencies and States Face Challenges Combating Rogue Sites, Particularly Those Abroad, GAO-13-560 (Washington, D.C.: July 8, 2013).

rogue Internet pharmacies and how to recognize legitimate online pharmacies.

To identify how rogue Internet pharmacies are selling prescription drugs in violation of federal laws, we interviewed officials from federal agencies such as FDA, CBP, ICE, and DOJ, reviewed federal laws and regulations, and examined agency documents. To obtain additional information, we interviewed a variety of knowledgeable stakeholders, including NABP and LegitScript, an online pharmacy verification service, both of which routinely review Internet pharmacy websites to determine compliance with federal and state laws.

To identify challenges involved in investigating and prosecuting rogue Internet pharmacies, as well as efforts to combat rogue Internet pharmacies, we interviewed officials from federal agencies, including FDA, CBP, ICE, and DOJ. We obtained data from several federal agencies that summarize their efforts to combat Internet pharmacies. We discussed these data with agency officials, reviewed them for reasonableness and consistency, and determined that they were sufficiently reliable for our purposes. We also interviewed officials from stakeholders involved in combating rogue Internet pharmacies, drug manufacturers, and private companies that provide services to Internet-based companies. Finally, we reviewed published reports on rogue Internet pharmacy operations.

To identify efforts to educate consumers about the risks of rogue Internet pharmacies and how to recognize legitimate online pharmacies, we interviewed officials from federal agencies and stakeholders to discuss their consumer education efforts. We also reviewed available educational campaign materials.

We conducted the work for the report on which this statement is based from October 2012 to June 2013, and made selected updates in February 2014, in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

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Most Rogue Internet Pharmacies Operate From Abroad and Many Violate a Variety of Federal Laws, Including by Selling Counterfeit Drugs Although the exact number of rogue Internet pharmacies is unknown, most operate from abroad. According to LegitScript, an online pharmacy verification service that applies NABP standards to assess the legitimacy of Internet pharmacies, there were over 36,000 active roque Internet pharmacies as of February 2014. Federal officials and other stakeholders we interviewed consistently told us that most rogue Internet pharmacies operate from abroad, and many have shipped drugs into the United States that are not approved by FDA, including counterfeit drugs. In doing so, they violate Federal Food, Drug and Cosmetic Act (FDCA) provisions that require FDA approval prior to marketing prescription drugs to U.S. consumers, as well as customs laws that prohibit the unlawful importation of goods, including unapproved drugs. 6 Many rogue Internet pharmacies sell counterfeit, misbranded, and adulterated drugs, in violation of FDCA provisions. 7 Counterfeiting and trafficking or selling counterfeit drugs also violate laws that protect intellectual property rights.⁸ Many also illegally sell certain medications without a prescription that meets federal and state requirements. Indeed, nearly 10 years ago, we made sample purchases from a variety of rogue sites without a prescription and we subsequently received several drugs that were counterfeit or otherwise not comparable to the product we ordered. 10

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⁶See, e.g., 21 U.S.C. § 355(a); 18 U.S.C. § 545.

⁷Misbranded drugs include those that are sold without a prescription that meets applicable requirements, as well as those whose labeling or container is misleading or does not include required information, such as the name of the drug, adequate directions for use, and cautionary statements. 21 U.S.C. §§ 331(a), (b), 352, 353(b). Adulterated drugs include those that differ in strength, quality, or purity from approved products, as well as those that are not manufactured in conformity with good manufacturing practices. 21 U.S.C. §§ 331(a), (b), 351.

⁸Intellectual property is any innovation, commercial or artistic, or any unique name, symbol, logo, or design used commercially. Intellectual property rights protect the economic interests of the creators of these works by giving them property rights over their creations. Generally, individual countries grant and enforce these rights.

⁹The FDCA requires that certain drugs be dispensed pursuant to a prescription that is issued by a licensed practitioner. See 21 U.S.C. § 353(b). The FDCA, however, does not define how this requirement is to be met. Instead, each state's pharmacy and medical practice laws and regulations define what constitutes a valid prescription in that state.

¹⁰GAO, *Internet Pharmacies: Some Pose Safety Risks for Consumers*, GAO-04-820 (Washington, D.C.: June 17, 2004).

To sell drugs to their U.S. customers, foreign rogue Internet pharmacies use sophisticated methods to evade scrutiny by customs officials and smuggle their drugs into the country. For example, rogue Internet pharmacies have misdeclared the contents of packages, in violation of customs laws. ¹¹ Rogue Internet pharmacies have disguised or hidden their drugs in various types of packaging; for example, CBP has found drugs in bottles of lotion and in tubes of toothpaste. Some of the drugs we obtained when conducting work for our 2004 report were shipped in unconventional packaging, including in a plastic compact disc case and in a sealed aluminum can that was mislabeled as dye and stain remover wax. ¹² In addition, rogue Internet pharmacies also often violate other federal laws, including those related to fraud and money laundering.

The Complex and Global Nature of Rogue Internet Pharmacies Poses Substantial Challenges for Federal Investigators and Prosecutors 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. The ease with which operators can set up and take down websites also makes it difficult for agencies to identify, track, and monitor rogue websites and their activities, as websites can be created, modified, and deleted in a matter of minutes. Officials also face challenges investigating and prosecuting operators because they are often located abroad, with components of the operations scattered in several countries. For example, as displayed in figure 1, one rogue Internet pharmacy registered its domain name in Russia, used website servers located in China and Brazil, processed payments through a bank in Azerbaijan, and shipped its prescription drugs from India.

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¹¹See, e.g., 18 U.S.C. §§ 542, 545.

¹²See GAO-04-820.

1. Customer places order
Customer orders prescription drugs from a rogue Internet pharmacy in Russia. The pharmacy swebsite uses servers in Brazil and China.

2. Payments processed
Customer payments for the prescription drugs are shipped from India to the customer.

Azerbaijan.

3. Prescription drugs sent
Prescription drugs are shipped from India to the customer.

Figure 1: Map of a Rogue Internet Pharmacy Operation

 $Source: Christian \ Kreibich, @\ 2011\ Institute\ of\ Electrical\ and\ Electronics\ Engineers\ (data); Map\ Resources\ (map).$

Notes: This figure is based on a figure that was published in Kirill Levchenko et al., "Click Trajectories: End-to-End Analysis of the Spam Value Chain" (paper presented at the Institute of Electrical and Electronics Engineers Symposium on Security and Privacy, Oakland, CA, May 22-25, 2011), accessed October 1, 2012, http://cseweb.ucsd.edu/~savage/papers/Oakland11.pdf. The study was funded in part by grants from the National Science Foundation.

Even when federal agencies are able to identify rogue Internet pharmacy operators, agency officials told us that they face jurisdictional challenges investigating and prosecuting them. Agencies may need assistance from foreign regulators or law enforcement in order to obtain information and gather evidence. However, rogue Internet pharmacies often deliberately and strategically locate components of their operations in countries that are unable or unwilling to aid U.S. agencies. In addition, foreign law

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enforcement authorities that are willing to aid investigations can be slow in responding to requests for help, according to officials from several federal agencies.

As a result of competing priorities and the complexity of rogue Internet pharmacies, federal prosecutors may not always prosecute these cases. Such cases are often resource intensive and often involve the application of specialized investigative techniques, such as Internet forensics and undercover work. Components of DOJ routinely prioritize cases for prosecution by applying minimum thresholds associated with illicit activities in order to focus their limited resources on the most serious crimes. Accordingly, agencies may not pursue cases if it appears that such cases do not meet relevant thresholds.

In addition, basing a prosecution on violations of the FDCA can be challenging, which may contribute to prosecutors declining to pursue rogue Internet pharmacy cases. Though rogue Internet pharmacy activity clearly violates the FDCA, proving violations of the act's misbranding and counterfeiting provisions can be difficult, according to a DOJ official. In addition, violations of these provisions of the FDCA are subject to relatively light criminal penalties, which may limit prosecutors' interest. When federal prosecutors pursue charges against rogue Internet pharmacy operators, they often charge them for violating other laws, such as smuggling, mail fraud, wire fraud, or money laundering, since such violations can be less onerous to prove and carry stronger penalties.¹³

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¹³See, e.g., 18 U.S.C. §§ 545 (smuggling), 1341 (mail fraud), 1343 (wire fraud), 1956 (money laundering). These crimes are subject to penalties of up to 20-30 years in jail or fines ranging from \$500,000 to \$1 million, or both. Violations of FDCA misbranding and counterfeiting provisions are subject to maximum penalties of 3 years in jail or a fine of \$10,000, or both, under 21 U.S.C. § 333, and 18 U.S.C. § 3571 provides for a \$250,000 fine or twice the gross gain or loss for individual defendants for all felony violations, including FDCA felony violations.

Federal Agencies
Have Taken a Variety
of Steps to Combat
Rogue Internet
Pharmacies

Despite these challenges, federal agencies and others 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. Agencies have investigated rogue Internet pharmacies independently and conducted collaborative investigations with other federal agencies through ICE's National Intellectual Property Rights Coordination Center. Since our report was published in July 2013, DOJ has continued to pursue those that import and traffic in counterfeit drugs, as well as those that purchase from them. ¹⁴ In addition, FDA formed a Cyber Crimes Investigation Unit in 2013, and in 2014, the agency announced its plans to expand its law enforcement presence overseas by placing its first permanent agent at Europol—the European Union's law enforcement agency.

Agencies have also collaborated with law enforcement agencies around the world to disrupt rogue Internet pharmacy operations. For example, FDA and other federal agencies have participated in Operation Pangea, an annual worldwide, week-long initiative in which regulatory and law enforcement agencies from around the world work together to combat rogue Internet pharmacies. In 2013, FDA took action against 1,677 rogue Internet pharmacy websites during Operation Pangea. FDA officials told us that the effect of such shutdowns is primarily disruptive since rogue Internet pharmacies often reopen after their websites get shut down; officials from federal agencies and stakeholders we spoke with likened shutting down websites to taking a "whack-a-mole" approach. One stakeholder noted that rogue Internet pharmacies own and keep websites in reserve so that they can redirect traffic and maintain operations if any of their websites get shut down.

Federal agencies responsible for preventing illegal prescription drug imports have also interdicted rogue Internet pharmacy shipments. For example, from fiscal years 2010 through 2012, CBP reported seizing

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¹⁴See, for example, Department of Justice, "Two Turkish Nationals Indicted for Smuggling Counterfeit Cancer Drug", accessed February 10, 2014, http://www.justice.gov/usao/moe/news/2014/january/semizoglu_ozkan.html, Department of Justice, "Guilty Plea in Counterfeit Viagra® and Cialis® case", accessed February 10, 2014, http://www.justice.gov/usao/txs/1News/Releases/2014%20January/140110%20-%20Rashid.html, and Department of Justice, "Seven Ohio Oncologists Ordered to Pay \$2.6 Million", accessed February 19, 2014, http://www.justice.gov/usao/ohn/news/2014/29jancan.html.

more than 14,000 illicit shipments of prescription drugs. However, FDA officials noted that the sheer volume of inbound international mail shipments makes it difficult to interdict all illicit prescription drug imports.

FDA and Others Have Taken Steps to Educate Consumers about the Risks of Purchasing Prescription Drugs from Internet Pharmacies, but Challenges Remain

FDA and others have taken steps to educate consumers about the dangers of buying prescription drugs from rogue Internet pharmacies. In September 2012, FDA launched a national campaign to raise public awareness about the risks of purchasing drugs online. The campaign provides information about the dangers of purchasing drugs from rogue Internet pharmacies, how to identify the signs of rogue Internet pharmacies, as well as how to find safe Internet pharmacies. Other federal agencies have also taken steps to educate consumers about the dangers of purchasing drugs online; for example, by posting information on their websites.

NABP also posts information about its quarterly review of Internet pharmacies, which most recently showed that 97 percent of the over 10,000 Internet pharmacies that it reviewed were out of compliance with federal or state laws or industry standards. 15 NABP also directs consumers to purchase medicines from legitimate Internet pharmacies that it has accredited. To assist consumers in more readily identifying legitimate online pharmacies. NABP is working to launch a new top-level domain name called .pharmacy. The association intends to grant this domain name to appropriately licensed, legitimate Internet pharmacies operating in compliance with regulatory standards—including pharmacy licensure, drug authenticity, and prescription requirements—in every jurisdiction that the pharmacy does business. LegitScript also helps consumers to differentiate between legitimate and rogue Internet pharmacies. It regularly scans the Internet and, using NABP's standards, classifies Internet pharmacies into one of four categories: (1) legitimate, (2) not recommended, (3) roque, or (4) pending review. When visiting its publicly available website, consumers can enter the website address of any Internet pharmacy and immediately find LegitScript's classification. As of February 3, 2014, LegitScript had classified 213 Internet pharmacies as legitimate and therefore safe for U.S. consumers, on the basis of NABP standards.

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¹⁵National Association of Boards of Pharmacy, *Internet Drug Outlet Identification Program, Progress Report for State and Federal Regulators: October 2013* (Mount Prospect, IL: Nov. 1, 2013).

Despite these actions of agencies and stakeholders, consumer education efforts face many challenges. In particular, many rogue Internet pharmacies use sophisticated marketing methods to appear professional and legitimate, making it challenging for even well-informed consumers and health care professionals to differentiate between legitimate and rogue sites. For example, some Internet pharmacies may fraudulently display an NABP accreditation logo on their website, despite not having earned the accreditation, or may fraudulently display Visa, MasterCard, PayPal, or other logos on their website despite not holding active accounts with these companies or being able to process such payments. Figure 2 displays a screenshot of a rogue Internet pharmacy website that may appear to be legitimate to consumers, but whose operators pled guilty to multiple federal offenses, including smuggling counterfeit and misbranded drugs into the United States.

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Figure 2: Screenshot of a Rogue Internet Pharmacy Website Whose Operators Pled Guilty to Multiple Federal Offenses, 2007



Source: Internet Archive.

Notes: The image displayed is a screenshot of the www.newpharm.net website at as of June 25, 2007, as retrieved from http://web.archive.org/web/20070625062436/http://www.newpharm.net/ on June 5, 2013. The Food and Drug Administration, Immigration and Customs Enforcement, and the United States Postal Inspection Service conducted a joint investigation into this rogue Internet pharmacy, and in April 2012, its two operators pled guilty to smuggling counterfeit and misbranded

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drugs into the United States. We reviewed agency press releases, the indictments, and the court's judgments related to this investigation. The operators were prosecuted after federal agents conducted a series of undercover purchases from several of the operators' Internet pharmacies, including www.newpharm.net. Federal agents were able to purchase prescription medications without providing a valid prescription. Drugs were typically shipped to the United States from China and India, and exterior packaging typically falsely described the contents of the shipments as "gifts" that had "no commercial value". The Internet pharmacy's website operators were located in Israel, customer service was located in the Philippines, and banking and money laundering were conducted in Cyprus and the Seychelles. Federal agents collaborated with law enforcement authorities in Hong Kong and Israel as part of the investigation. Laboratory results of drug samples purchased by federal agents revealed that the drugs were not genuine versions of the approved drugs that they purported to be. As part of their sentences, the operators were fined a total of \$45,000 and forfeited a total of \$65,000 as well as the domain names of their rogue Internet pharmacy websites. One of the operators was sentenced to 10 months of imprisonment, and the other was sentenced to 1 year of probation.

Some roque Internet pharmacies seek to assure consumers of the safety of their drugs by purporting to be "Canadian." Canadian pharmacies have come to be perceived as a safe and economical alternative to pharmacies in the United States. Over the last 10 years, several local governments and consumer organizations have organized bus trips to Canada so that U.S. residents can purchase prescription drugs at Canadian brick-andmortar pharmacies at prices lower than those in the United States. More recently, some state and local governments implemented programs that provided residents or employees and retirees with access to prescription drugs from Canadian Internet pharmacies. 16 Despite FDA warnings to consumers that the agency could not ensure the safety of drugs not approved for sale in the United States that are purchased from other countries, the prevalence of such programs may have contributed to a perception among U.S. consumers that they can readily save money and obtain safe prescription drugs by purchasing them from Canada. Many rogue Internet pharmacies seek to take advantage of this perception by purporting to be located in Canada, or sell drugs manufactured or approved for sale in Canada, when they are actually located elsewhere or selling drugs sourced from other countries.¹⁷

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¹⁶For example, Maine recently enacted a law that allows licensed retail pharmacies located in Canada, the United Kingdom, Australia, and New Zealand to export prescription drugs to Maine residents for personal use without obtaining a license from the state. See 2013 Me. Legis. Serv. Ch. 373 (S.P. 60) (L.D. 171).

¹⁷A 2005 FDA study of drugs ordered from so-called "Canadian" Internet pharmacies found that 85 percent were from 27 other countries around the globe, and a number of these were counterfeit medicines.

Chairman Murphy, Ranking Member DeGette, and Members of the Subcommittee, this completes my prepared statement. I would be pleased to respond to any questions that you may have at this time.

GAO Contact and Staff Acknowledgments

If you or your staff have any questions about this testimony, please contact me at (202) 512-7114 or crossem@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this statement. GAO staff who made key contributions to this statement include Geri Redican-Bigott, Assistant Director; Michael Erhardt; Patricia Roy; and Lillian Shields.

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