



THE COMMITTEE ON ENERGY AND COMMERCE

Memorandum

February 25, 2014

TO: Members, Subcommittee on Oversight and Investigations

FROM: Majority Committee Staff

RE: Hearing on Counterfeit Drugs

On Thursday, February 27, 2014, at 10:00 a.m. in 2322 Rayburn House Office Building, the Subcommittee on Oversight and Investigations will hold a hearing entitled “Counterfeit Drugs: Fighting Illegal Supply Chains.” The purpose of the hearing is to explore the public health threat of counterfeit drugs, and to build on the recent enactment of the Drug Quality and Security Act (DQSA) to identify other areas to strengthen U.S. efforts to combat the growing threat of counterfeit drugs to U.S. patients.

I. WITNESSES

Panel One

- Howard Sklamberg, J.D., Deputy Commissioner for Global Regulatory Operations and Policy, Food and Drug Administration (FDA); and
- Lev Kubiak, Director, National Intellectual Property Rights Coordination Center, Department of Homeland Security, Immigration and Customs Enforcement (ICE).

Panel Two

- Marcia Crosse, Ph.D., Director, Health Care, U.S. Government Accountability Office;
- Prashant Yadav, Ph.D., M.B.A., Director of Health Care Research Initiative, Director of the William Davidson Institute, University of Michigan;
- John P. Clark, Vice President and Chief Security Officer, Global Security, Compliance Division, Pfizer Inc.;
- Jean-Luc Moreau, Global Head of Product Security, Novartis Corporation;
- Bruce Longbottom, J.D., Assistant General Counsel, Eli Lilly and Company; and

- Elizabeth Jungman, J.D., M.P.H., Director, Drug Safety and Innovation, Pew Charitable Trusts.

II. BACKGROUND

Definition. A counterfeit pharmaceutical is a drug (either active pharmaceutical ingredient (API), intermediate or finished dosage form) that is deliberately and fraudulently mislabeled or misbranded with respect to its identity or source.¹ Counterfeiting can apply to both brand name and generic products. Counterfeit drugs may include drugs without the active ingredient, with an insufficient or excessive quantity of the active ingredient, with the wrong active ingredient, or with fake packaging.

Harm. Several tragic cases over the last few years illustrate the risks of dangerous health effects from counterfeits. On June 3, 2011, an emergency room doctor from Texas suffered a stroke from ingesting counterfeit Alli (a weight loss drug) from an online pharmacy. The counterfeit Alli was produced using the controlled substance sibutramine, rather than the approved ingredient, and then shipped to the U.S. for redistribution.² A 27-year-old London paramedic was found dead in her apartment on December 17, 2010, after she accidentally ingested a fatal dose of medication purchased from a rogue Internet pharmacy. The coroner report found four times the therapeutic level of the drug in her blood.³ On April 23, 2013, a 23-year old medical student in the United Kingdom died from a diet drug bought from an online drug seller combined with anti-depressants. The drug, sold through many rogue Internet pharmacies, was actually a pesticide with lethal consequences to humans.⁴ In 2007 and 2008, dozens of patients in the U.S. suffered adverse events and several lost their lives due to intentionally contaminated heparin imported from China that had entered the Chinese heparin supply purporting to be pure heparin.⁵

Problem. Because counterfeiting is difficult to detect and investigate, it is hard to know or even estimate the true extent of the problem. As noted by the Institute of Medicine, it is difficult to measure the population burden of falsified and substandard drugs.⁶ FDA also has found that the extent of the problem of counterfeit drugs is unknown. The Pharmaceutical Security Institute, a network of the security divisions of 25 major pharmaceutical companies, has

¹ John Taylor, FDA Office of Regulatory Affairs, "Counterfeit Drugs," Memorandum to Joe Famulare, *et al.*, of FDA (April 5, 1999).

² U.S. Department of Justice Press Release, "Chinese National Sentenced to Federal Prison for Trafficking Counterfeit Pharmaceutical Weight Loss Drug," (June 3, 2011). <http://www.fda.gov/ICECI/CriminalInvestigations/ucm257912.htm>

³ "Paramedic died after taking tablets she bought over the Internet to help her sleep," The Daily Mail, United Kingdom (May 20, 2011). <http://www.dailymail.co.uk/news/article-1388795/Paramedic-Lorna-Lambden-died-overdosing-sleeping-tablets.html>

⁴ "Banned slimming drug kills medical student: Coroner attacks online dealers who target the vulnerable," The Daily Mail, United Kingdom (April 22, 2013). <http://www.dailymail.co.uk/health/article-2312986/Sarah-Houston-Banned-slimming-drug-DNP-kills-medical-student-coroner-attacks-online-dealers-target-vulnerable.html>

⁵ The Subcommittee held a hearing on April 29, 2008 on this matter, and the Committee has an open investigation on this case.

⁶ Institute of Medicine of the National Academies, COUNTERING THE PROBLEM OF FALSIFIED AND SUBSTANDARD DRUGS 3 (The National Academies Press, 2013).

data that indicates that the illegal trade and manufacture of medicines is a global problem, affecting at least 123 countries in 2013.⁷

Although the full extent of the counterfeit problem cannot be quantified, government and industry experts have told staff that they believe the counterfeit drug problem is growing. This concern helped lead to the enactment of DQSA to secure legal supply chains in November 2013, and the new law is in the process of being implemented. Illegal supply chains are also of concern. One sign is the increasing sophistication of the counterfeiters, suggesting greater business volume, resources, and economic incentives for the counterfeiters to invest in more advanced technologies and methods. The counterfeit drug problem is believed to have worsened for several reasons including: opportunities created by larger, more complex supply chains; high profit margins and high drug prices; more customers through the Internet; more organized crime involvement and a more favorable cost-benefit to engage in counterfeit drugs than in the narcotics business; the often transnational nature of these crimes that frustrates meaningful law enforcement; and the expansion of counterfeiting into therapeutic drugs used for oncology, cardiovascular, or transplant cases.

Penalties. The Federal Food, Drug, and Cosmetic Act (FDCA) penalizes adulteration, misbranding, and counterfeiting at a maximum of \$10,000 or three years in prison.⁸ These penalties were enacted in 1938 and have not been updated. A 2011 Pew Health Group report noted that “[t]hese penalties may be too low to present meaningful deterrents to violations and crime, particularly for pharmaceutical counterfeiting, which is additionally incentivized by high profitability.”⁹ By one estimate, the return on counterfeit drugs may be 10 times greater than that of the sale of illegal narcotics.¹⁰ Penalties for trafficking narcotics can include up to life in prison and fines in the millions of dollars.¹¹ As a result, FDA and some companies have told staff that the presence of organized crime has grown over the last decade. The anti-counterfeiting enforcement model is based on a 1938 law, with a few recent and limited penalty enhancements in other Federal laws structured around economic loss as opposed to loss or threat to human life from crimes against public health. Thus, for example, Paul Bottomley, who pleaded guilty for his role in a scheme to import and distribute fake cancer drugs (Avastin) to U.S. physicians in violation of the FDCA, avoided serving time in prison and was sentenced to six months of house arrest and five years’ probation, even though Federal prosecutors urged a prison sentence.

DQSA. The enactment of the Drug Quality and Security Act of 2013 (known as track-and-trace legislation) was an important step in protecting the integrity of the U.S. legal distribution system and preventing counterfeits from being introduced into the legal supply. The DQSA establishes requirements to secure the legal supply chain which FDA is in the process of

⁷ Pharmaceutical Security Institute, “Counterfeiting Fact Sheet 2013.”

⁸ 21 U.S.C. 333(a)(2).

⁹ Pew Health Group, AFTER HEPARIN: PROTECTING CONSUMERS FROM THE RISKS OF SUBSTANDARD AND COUNTERFEIT DRUGS, 15 (July 12, 2011).

¹⁰ Martin Van Trieste, Chair, Rx360, “Call to Action & Global Perspective,” Presentation at 2010 PDA/FDA Pharmaceutical Supply Chain Workshop (April 26-28, 2010).

¹¹ U.S. Drug Enforcement Administration, Federal Trafficking Penalties. <http://www.justice.dea/druginfo/ftp3.shtml>

implementing, but the need to address the public health threat of counterfeit drugs through illegal supply chains remains.

Illegal supply chains. This Subcommittee hearing will examine illegal supply chains for counterfeit drugs such as: rogue Internet pharmacies, foreign unapproved drugs that include counterfeit drugs with little or no active ingredient, medical practitioners deliberately obtaining unapproved drugs directly from foreign sources for dispensing to patients, business-to-business (B2B) networks, and drug smuggling at the U.S.-Mexican border.

Rogue Internet pharmacies. The majority of all counterfeit drugs introduced in the U.S. are from rogue Internet pharmacies. These websites offer prescription drugs without a prescription and are not appropriately licensed.¹² These rogue Internet pharmacies may sell drugs that are expired, improperly labeled, or are counterfeits of other drugs.¹³ There are approximately 35,000-50,000 active online sellers, 97 percent of which do not comply with U.S. laws.¹⁴ A report from the Partnership at Drugfree.org estimated that 1 in 6 Americans – 36 million people – have bought medicines online without a valid prescription.¹⁵ These illegal “pharmacy” operations can generate big business, with the largest ones estimated to make between \$1 and 2.5 million dollars of sales each month.¹⁶

The problem of online pharmacies dispensing controlled substances over the Internet without a prescription led to the enactment of the Ryan Haight Online Pharmacy Consumer Protection Act of 2008 (the Act), which provided a Federal definition of “valid prescription.” Drug Enforcement Administration (DEA) officials told the GAO that the Act had substantially reduced the extent to which controlled substances are sold online, as domestic pharmacies have stopped fulfilling orders on behalf of rogue Internet pharmacies.¹⁷ However, GAO reported that the DEA did not track data that could demonstrate a reduction in the sale of controlled substances online, and that DEA’s 2011 assessment of Internet pharmacies that advertised the sale of controlled substances revealed that 40 percent were selling such substances.¹⁸

Foreign unapproved drugs. Foreign unapproved drugs are also a major challenge because of the volume, number of firms, and the use of more complex supply chains. When the FDCA was enacted in 1938, the percentage of drugs imported into the U.S. was minimal, the American drug supply chain was far less complicated and there were fewer opportunities for drugs to be counterfeited or stolen. Currently, nearly 40 percent of drugs taken by Americans are made overseas, and 80 percent of the active ingredients are imported from about 3,800 foreign

¹² U.S. Government Accountability Office, *Internet Pharmacies: Federal Agencies and States Face Challenges Combating Rogue Sites, Particularly Those Abroad*, GAO-13-560, 30 (July 2013).

¹³ *Id.*

¹⁴ National Association of Boards of Pharmacy, “Buying Medicine Online: Internet Pharmacies and You,” Website undated (review of over 10,500 Internet sites). <https://www.nabp.net/programs/consumer-protection/buying-medicine-online>; PR Newswire, “LegitScript Shuts Down 6,700 Rogue Internet Pharmacies,” (June 28, 2013).

¹⁵ Alliance for Safe Online Pharmacies, “36 million Americans have bought medications online without a doctor’s prescription. Research about dangerous practice -- and the 11 internet commerce companies partnering together to protect patients – announced as part of White House Forum,” Press Release (December 14, 2010).

¹⁶ C. Kanich, et. al., “Show Me the Money: Characterizing Spam-advertised Revenue,” Proceedings of the 20th USENIX conference on Security, (2011). <http://cseweb.ucsd.edu/~savage/papers/UsenixSec11-SMTM.pdf>

¹⁷ U.S. Government Accountability Office, *supra* note 12, at 30.

¹⁸ *Id.* at 31.

manufacturers, in more than 150 countries.¹⁹ An FDA report²⁰ published in 2011 stated that the number of foreign drug suppliers had doubled in the last seven years with FDA only able to inspect sites once every nine years (compared to FDA inspecting nearly all 2,500 domestic plants every two years).²¹ Most drug imports are sourced from China and India. The FDA estimated in 2010 that as many as 920 manufacturing plants in China may make U.S. drugs and ingredients used in them, and therefore may be subject to inspection by the FDA, an increase from 714 sites in 2007.²² Chinese drug imports have been linked to several counterfeit cases in the U.S. (such as heparin in 2008 and gentamicin sulfate in 1999), and fake cough medicine cases in Haiti and Panama. Drugs from India are a concern as well. The World Health Organization estimated that one in five drugs made in India are fakes and a 2010 survey of New Delhi pharmacies found that 12 percent of sampled drugs were counterfeit.²³ These findings are a U.S. public health concern given that India supplies 40 percent of the over-the-counter and generic prescription drugs in the U.S.²⁴

Doctors and clinics. Physicians and medical clinics buying counterfeit medicines are becoming an increasing problem. The president of the Pharmaceutical Security Institute has noted active efforts by unapproved suppliers to specifically target clinics and doctors.²⁵ The 2012 case of counterfeit Avastin revealed that dozens of physicians had purchased the drugs from an unapproved supplier, outside of the legal supply chain (that will now be secured by the DQSA).

B2B networks. Other potential pipelines for counterfeit drugs are online business-to-business (B2B) networks or trade boards.²⁶ APIs in almost all branded products, mostly generics, and many investigational compounds are advertised openly on B2B networks such as Alibaba, EC21, EC Global, and Tradekey. These trade boards are intended for legitimate trade in goods and materials, but have been “hijacked” by organizations peddling illicit supplies of bulk pharmaceuticals, active ingredients, and packaging components.²⁷ A two-year investigation by OpSec, a security technology provider, found that none of the traders included pedigree information, even when offering to ship to the U.S., where FDA requires pedigree tracking by each link in the distribution chain.²⁸ The availability of bulk pharmaceuticals on B2B trade boards, which are unregulated and anonymous environments, provide a global sourcing platform for buyers and intermediaries in the pharmaceutical supply chain. The B2B trade boards also target physicians and online pharmacies. A second OpSec study found a 60 percent annual

¹⁹ Testimony of Deborah Autor, FDA Deputy Commissioner for Global Regulatory Operations and Policy, Testimony before the U.S. Senate Committee on Health, Education, Labor and Pensions (September 14, 2011).

²⁰ Food and Drug Administration, Pathway to Global Product Safety and Quality, 15 (June 2011).

²¹ U.S. Government Accountability Office, “Drug Safety: FDA Has Conducted More Foreign Inspections and Begun to Improve Its Information on Foreign Establishments, but More Progress Is Needed,” GAO-10-961 (September 2010).

²² *Id.*; U.S. Government Accountability Office, “Drug Safety: Preliminary Findings Suggest Weakness in FDA’s Program for Inspecting Foreign Drug Manufacturers,” GAO-08-224T (November 2007).

²³ Gardiner Harris, “Medicines Made in India Set Off Safety Worries,” New York Times, (February 14, 2014). <http://www.nytimes.com/2014/02/15/world/asia/medicines-made-in-india-set-off-safety-worries.html>

²⁴ *Id.*

²⁵ Bill Berkrot, “Doctors scour drug supplies after fake Avastin found,” Reuters (February 15, 2012).

²⁶ Phil Taylor, “B2B trade boards: a key link in the counterfeit trade?” Securing Pharma, (June 23, 2009).

²⁷ *Id.*

²⁸ *Id.*

increase in trade board listings of prescription drugs and APIs for sale on B2B platforms.²⁹ The same study found that an increasing number of B2B trade board sellers were positioning themselves as drop shippers or order fulfillment centers for Internet pharmacies.³⁰ Test purchases by OpSec confirmed counterfeit and site linkage through order fulfillment, and led to 5 arrests.³¹

Smuggling from Mexico. Recent articles have noted the trend of a cottage industry of smugglers buying prescription drug medicines in bulk from Mexico and bringing them back to the U.S.³² At emergency rooms on the border, physicians say patients are at risk and are increasingly showing up with drugs that appear to be black market.³³ Current enforcement discretion policy allows individuals to bring back small amounts of prescription drugs (including controlled substances) from Mexican border pharmacies for personal use.³⁴

Other Federal interests. Finally, the U.S. government has an interest in ensuring that U.S. taxpayer dollars are not spent on Medicare, Medicaid, or foreign aid that procures counterfeit pharmaceuticals. For example, the U.S. government is a major contributor to the Global Fund to Fight AIDS, Tuberculosis, and Malaria, having contributed close to one billion dollars a year annually for several years. In November 2013, the World Health Organization issued a drug alert about at least four counterfeit anti-malaria drug batches bearing the logo of a facility financed by the Global Fund.

III. ISSUES

- Do drug-counterfeiting crimes warrant more enhanced criminal and civil penalties under the FDCA? If yes, what would be the likely impact from the increased penalties?
- Are there additional actions that could be taken against illegal Internet pharmacies through voluntary cooperative efforts from credit card companies, domain registrars, and ISPs?
- Are there gaps in the law enforcement and industry fight against counterfeit drugs such as the area of B2B networks?

IV. STAFF CONTACTS

If you have any questions regarding this hearing, please contact Alan Slobodin at (202) 225-2927.

²⁹ Business Wire, “OpSec Security Identifies Latest Market Trends in the Online Sales of Prescription Drugs by Internet Pharmacies and B2B Trade Boards, (December 9, 2010).

³⁰ *Id.*

³¹ Tara Steketee, OpSec Security, Inc., “Securing the Online Supply Chain,” May 9, 2012 slide presentation.

³² Lorne Matalon, “Desperate patients smuggle prescription drugs from Mexico, Marketplace, January 20, 2014; Leo Lopez, “On the Texas-Mexico border, a new drug trade emerges,” 382 *The Lancet* 756 (August 2013).

³³ Matalon, *supra* note 20.

³⁴ Food and Drug Administration, “Personal Importation Policy (PIP) Frequently Asked Questions (FAQs).