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COUNTERFEIT DRUGS: FIGHTING ILLEGAL SUPPLY CHAINS

HEARING

BEFORE THE

SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS

OF THE

COMMITTEE ON ENERGY AND COMMERCE

HOUSE OF REPRESENTATIVES

ONE HUNDRED THIRTEENTH CONGRESS

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[1] The attachment to Mr. Yadav's response is available at: *http://docs.house.gov/meetings/if/if17/20140228/101812/hhrg-113-if17-wstate-manneg-20140228-sd002.pdf*.

[2] The information is available at: *http://docs.house.gov/meetings/IF/IF02/20140227/101804/HHRG-113-IF02-20140227-SD005.pdf*.

[3] The information is available at: *http://docs.house.gov/meetings/IF/IF02/20140227/101804/HHRG-113-IF02-20140227-SD007.pdf*.

COUNTERFEIT DRUGS: FIGHTING ILLEGAL SUPPLY CHAINS

THURSDAY, FEBRUARY 27, 2014

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS,
COMMITTEE ON ENERGY AND COMMERCE,
Washington, DC.

The subcommittee met, pursuant to call, at 10:02 a.m., in room 2322 of the Rayburn House Office Building, Hon. Tim Murphy (chairman of the subcommittee) presiding.

Members present: Representatives Murphy, Burgess, Blackburn, Griffith, Johnson, Long, Ellmers, DeGette, Braley, Tonko, Dingell, and Waxman (ex officio).

Staff present: Karen Christian, Chief Counsel, Oversight; Noelle Clemente, Press Secretary; Brad Grantz, Policy Coordinator, Oversight and Investigations; Brittany Havens, Legislative Clerk; Sean Hayes, Counsel, Oversight and Investigations; Alan Slobodin, Deputy Chief Counsel, Oversight; Tom Wilbur, Digital Media Advisor; Jessica Wilkerson, Legislative Clerk; Brian Cohen, Democratic Staff Director, Oversight and Investigations, and Senior Policy Advisor; Eric Flamm, Democratic FDA Detailee; Kiren Gopal, Democratic Counsel; Hannah Green, Democratic Staff Assistant; and Stephen Salsbury, Democratic Investigator.

OPENING STATEMENT OF HON. TIM MURPHY, A REPRESENTATIVE IN CONGRESS FROM THE COMMONWEALTH OF PENNSYLVANIA

Mr. MURPHY. Good morning, and welcome to the Oversight and Investigations Subcommittee hearing of Energy and Commerce titled "Counterfeit Drugs: Fighting Illegal Supply Chains."

This hearing could also be titled "Poison Pills in Your Medicine Cabinet, or Counterfeiters Deliver Deadly Drugs," and it is due to the fact that we need to examine the growing problem of counterfeit drugs in our country.

Last year Congress took an important first step against this threat by enacting the new track-and-trace law known as the Drug Quality and Security Act of 2013. This new law will secure the legitimate distribution channels, and when implemented will solve the legal supply chain part of the counterfeit drug problem.

However, many Americans purchase medicines through illegal supply chains, such as rogue Internet pharmacies and other black markets. It is that part of the counterfeit drug threat that we address today. This hearing focuses on the illegal supply chains of

counterfeit drugs, and on efforts to deter and disrupt these illegal supply chains.

The legitimate U.S. drug supply is safe. But counterfeit drugs from illegal sources are a significant and growing global public health threat, potentially causing treatment failure or death and contributing to increased antimicrobial resistance. The policy of the U.S. government is not to wait for a full-blown crisis before taking appropriate action.

Drug counterfeiters do not just steal intellectual property. They recklessly and intentionally endanger human lives. They sell counterfeits that do not contain active ingredients and provide no treatment benefit to the patient. Thus, a child suffering from malaria who takes a fake anti-malaria drug might die within 48 hours because the malaria remains untreated. The counterfeiters sell fakes that may contain incorrect ingredients, improper dosages, hazardous or poisonous ingredients. For example, an emergency room doctor from Texas in 2011 took a counterfeit weight loss drug he bought from an online pharmacy. The drug was contaminated with a controlled substance and he suffered a stroke.

The counterfeiters sell drugs with risks for harmful side effects or allergic reactions. For example, in 2007 and 2008, dozens of heart surgery and kidney dialysis patients in the United States suffered unexpected allergic-like reactions 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.

The counterfeiters do not care about the patients who are hurt. One counterfeiter, Richard Taylor, was notified in May 2011 that two patients who had been on a counterfeit cancer drug he had distributed had started to shake in the middle of being transfused and had to be disconnected from treatment.

However, the penalties for drug counterfeiters under the Federal Food Drug and Cosmetic Act have not been updated since 1938. As the FDA Commissioner has said, there is a steeper penalty for counterfeiting a designer purse under the Federal Criminal Code than a drug product under current FDA law.

Drug counterfeiting is highly profitable, and the criminals only face the maximum penalties under the FDA law of $10,000 or 3 years in prison. In contrast, penalties for trafficking narcotics can have prison sentences up to life and fines in the millions of dollars. There is one estimate that the return on counterfeit drugs may be 10 times greater than that of the sale of illegal narcotics.

Now, experts tell us the counterfeit drug problem has worsened over the last decade, and the reasons for this disturbing trend include increasing opportunities created by larger, more complex supply chains; more customers reachable through the Internet; more cases where the counterfeiting crimes occur in several countries making enforcement more difficult; and the expansion of counterfeiting from so-called lifestyle drugs into therapeutic medicines used to treat cancer, heart disease or other illnesses.

The illegal supply chains are numerous and global. Rogue Internet pharmacies are now proliferating. There are believed to be about 35,000 to 50,000 active online sellers, 97 percent of which do not comply with U.S. laws, according to one review of over 10,000

Internet sites. One report estimated that one in six Americans—36 million people—have bought medicines online without a valid prescription. These illegal pharmacy operations are big business, with the largest ones reportedly making $1 to 2.5 million of sales each month.

The sheer volume of imported drugs into the United States is overwhelming and opportunities have never been greater for foreign, unapproved drugs to get into the United States. 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 manufacturers, in more than 150 countries. According to a 2011 FDA report, the number of foreign drug suppliers has doubled in the last 7 years. The Government Accountability Office has found FDA is only able to inspect foreign drug plants every 9 years while FDA inspects domestic drug manufacturers every 2 years.

The subcommittee will also examine other illegal supply chains such as medical clinics and doctors who purchase drugs from illegal sources, business-to-business networks, and smugglers bringing unapproved or counterfeit drugs from Mexico into the United States.

I welcome all of today's outstanding witnesses and I look forward to your testimony.

[The prepared statement of Mr. Murphy follows:]

PREPARED STATEMENT OF HON. TIM MURPHY

The subcommittee meets to examine the growing problem of counterfeit drugs. Another fitting title for our hearing today: "Poison Pills in Your Medicine Cabinet: Counterfeiters Deliver Deadly Drugs."

Last year Congress took an important first step against this threat by enacting the new track-and-trace law known as the Drug Quality and Security Act of 2013. This new law will secure the legitimate distribution channels, and when implemented will solve the legal supply chain part of the counterfeit drug problem.

However, many Americans purchase medicines through illegal supply chains, such as rogue Internet pharmacies and other black markets. It is that part of the counterfeit drug threat we address today. This hearing focuses on the illegal supply chains of counterfeit drugs, and on efforts to deter and disrupt these illegal supply chains.

The legitimate U.S. drug supply is safe. But counterfeit drugs from illegal sources are a significant and growing global public-health threat, potentially causing treatment failure or death and contributing to increased anti-microbial resistance. The policy of the U.S. government is not to wait for a full-blown crisis before taking appropriate action.

Drug counterfeiters do not just steal intellectual property. They recklessly and intentionally endanger human lives.

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Experts tell us the counterfeit drug problem has worsened over the last decade. The reasons for this disturbing trend include: increasing opportunities created by larger, more complex supply chains; more customers reachable through the Internet; more cases where the counterfeiting crimes occur in several countries making enforcement more difficult; and the expansion of counterfeiting from so-called lifestyle drugs into therapeutic medicines used to treat cancer, heart disease, or other illnesses.

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I welcome all of today's outstanding witnesses and look forward to their testimony.

Mr. MURPHY. And now I turn to recognize my friend, and the Ranking Member, Ms. DeGette of Colorado.

OPENING STATEMENT OF HON. DIANA DEGETTE, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF COLORADO

Ms. DEGETTE. Thank you very much, Mr. Chairman. I really appreciate you having this hearing.

We had a number of hearings some years ago in this committee on drug counterfeiting, and it was shocking and appalling to see how serious this problem is. While we did pass that great bill last year, still I think that drug counterfeiting is a terrible problem that we need to address in a bipartisan fashion.

As you said, counterfeit drugs can contain dangerous impurities, incorrect ingredients, improper dosages, and also have improper handling, and legitimate drugs have been diverted or stolen from the supply chain and they have been handled improperly or stored at the wrong temperature, and then of course, these fraudsters spend a lot of time recreating labels and packaging for the dangerous drug so that they look exactly like the real thing.

I got some samples today. These are Lipitor samples, and they look exactly the same. The blister packs are the same, the pills are exactly the same, the alleged dosages are exactly the same, and if you ordered these online, you would think that you were getting

Lipitor. However, which one is the real and which one is the fake? You couldn't possibly tell except where there is a label on the package. Here is the fake and here is the real. And this is what these counterfeiters do. They spend more time worrying about what the packaging is going to like look so it will fool the consumer and a lot less time worrying about whether there's actual medication inside that's going to help people.

We have seen a number of troubling cases recently. Criminals have tampered with pharmaceuticals used to treat illnesses like cancer and HIV/AIDS. Drugs used to treat schizophrenia were replaced with aspirin. Counterfeit cancer drugs were tainted with non-sterile tap water, and counterfeit AIDS drugs have been found to lack any ingredient, and as you said, the Internet is really especially problematic for these unsafe drugs, and according to a recent FDA survey, approximately one in four Americans has purchased prescription drugs online. Most consumers purchase drugs from reputable businesses but there are thousands of rogue Internet pharmacies, some of which you couldn't tell from just looking onsite that sell drugs of dubious quality without a prescription. I couldn't believe it that you said that there was a doctor who bought these drugs online. I mean, surely if anybody should know, it should be a doctor.

Now, Congress passed the Ryan Haight Act in 2008 and then last year, as you said, the Drug Quality and Security Act, which provide additional enforcement tools, and so I am eager to hear from the GAO whether these laws have had an impact in combating this problem and what more can be done. I am also interested to learn from the stakeholders and agencies how we can increase awareness and education in the medical community and the public more broadly about the prevalence of and risks associated with counterfeit drugs.

I must say, I talk to my constituents, and people assume if they are buying drugs from a pharmacy online that it would be safe, and that is an incorrect assumption to make. I think we need to have partnerships between the pharmaceutical companies, between government agencies, between nonprofit agencies and a variety of sources to let people know how dangerous it can be to buy drugs from an Internet source.

And I want to commend the FDA, ICE, and the other federal agencies for their work in protecting consumers from unsafe drugs, but I also want to learn more about what we can do about counterfeiting drug activity and whether we need more authorities or stricter penalties to effectively carry out this work.

Globally, the FDA works with World Health Organization and Interpol to build global capacity to monitor counterfeit drugs and to coordinate international law enforcement action, and so I know that our witness from the University of Michigan, Dr. Yadav, will talk about the global health implications of counterfeit drug activity and how existing international efforts can be strengthened. Prosecuting these wrongdoers is difficult because they are shady and they are international, but I think if we have domestic and international partnerships, we can do it.

Consumers should never have to fear the prescription drug they need may actually make them sick or endanger the lives of their

loved ones, and so that is why these partnerships are critical. I look forward to hearing from our witnesses and continuing to work together to make sure that when a consumer buys a drug, they know that it is going to be safe.

Thank you, Mr. Chairman, and I yield back.

Mr. MURPHY. The gentlelady yields back and I now recognize the vice chairman of the subcommittee, Dr. Burgess, for 5 minutes.

OPENING STATEMENT OF HON. MICHAEL C. BURGESS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS

Mr. BURGESS. I thank the chairman for the recognition. I thank our witnesses for being here, a terribly important hearing that we are having this morning.

Let me begin my statement with a quote: "The market for prescription drugs has been the catalyst for a continuing series of frauds against American manufacturers and has provided cover for counterfeit drugs. The effect of these practices and conditions is to create an unacceptable risk that counterfeit, adulterated, misbranded, subpotent or expired drugs will be sold to American consumers."

Now, you might think I am reading from today's hearing memo but in fact they were from the findings of the Prescription Drug Marketing Act of 1987. That bipartisan law was the result of a series of hearings conducted with Chairman Dingell in this very subcommittee. In the report accompanying the bill from 1987, this subcommittee found, again quoting, "American consumers cannot purchase prescription drugs with the certainty that the products are safe and effective. This is not to say that the shelves of the Nation's pharmacies are lined with substandard products or that there are inadequate controls in the manufacturing process. Rather, the integrity of the distribution system is insufficient to prevent the introduction and the eventual retail sale of substandard, ineffective or even counterfeit pharmaceuticals," again, quoting from the findings in 1987.

The United States has the best drug supply chain in the world, and this committee's work has been long and notable and medications have become more advanced. Our supply chain has become more global in its reach. The equally consistent and sophisticated attacks each and every day by counterfeiters, rogue distributors and those willing to adulterate products and put patients at risk are no less today than they were in 1987.

According to the World Health Organization, in 2010 worldwide counterfeit medicine sales topped $75 billion. That was almost doubling in 5 years, and some speculate the number will continue to grow by 20 percent each year.

At its most extreme, these criminals are willing to literally risk patients' lives to sell counterfeits. As a doctor, such immorality of knowingly sentencing a patient to death by either denying them treatment or selling them an adulterated product, that is an absolutely chilling proposition. In my opinion, punishment for counterfeiting prescription medications is so far from adequate as to be laughable.

From fake flu vaccines to oncology drugs, counterfeit medications have been able to enter the supply chain and in fact administered

to patients. Detecting counterfeit drugs is difficult, if not impossible. There is no field test that we can send people out to perform to indicate whether a drug is fake or real, and even the trained experts are often unable to detect whether a drug is what it purports to be. Counterfeit and other adulterated drugs present an unreasonable risk to Americans.

Thankfully, this committee, this subcommittee has remained vigilant, and I believe the passage of the Drug Quality and Security Act last year will provide a valuable tool. Some will argue it took too long but nevertheless, it does tighten our distribution system. While our system may be the best in the world, our health care workforce does not have the confidence that they should have that the drugs they are dispensing or administering are the ones that came from the manufacturer.

I will also note that a December 2005 report found that nearly half of the imported drugs the Food and Drug Administration intercepted from four selected countries to fill orders placed with firms that consumers thought were Canadian, in fact, 85 percent came from 27 other countries around the globe. A number of these products were also found to be counterfeit.

Just as a practical matter, I will never forget the day in my practice back in north Texas when the story broke that fake oral contraceptives had been introduced into the market. Our phones melted down that morning, and many anxious patients spent many anxious hours trying to determine if they had the pill or the lot number from the inappropriate counterfeit pills and whether or not they would have the potency to provide the protection they were purported to provide.

Maintaining the integrity of the United States prescription drug supply is a compelling national priority and requires national solutions involving business, health care providers and governments coming together and being vigilant in the face of threats. The vigilance of this committee, this subcommittee, has been established in the past and continues today.

I thank the chairman for the recognition. I will yield back the balance of my time.

Mr. MURPHY. The gentleman yields back. I now recognize the ranking member of the full committee, Mr. Waxman, for 5 minutes.

OPENING STATEMENT OF HON. HENRY A. WAXMAN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA

Mr. WAXMAN. Thank you very much, Mr. Chairman. I am pleased that we are having an important oversight hearing where 20 minutes so far into the opening statements, no one has blamed the problem on President Obama. This is rare for this committee.

But we are doing the job that we should be doing because the entry of counterfeit drugs into our drug supply chain poses a great public health threat. Time and again, we have read stories about patients getting drugs from Internet pharmacies or even their doctors or local pharmacies that were unsafe or ineffective counterfeits, or that were stolen, or not stored properly so they no longer worked.

We have taken legislative steps on a bipartisan basis to address this problem. In 2012, we passed the bipartisan Food and Drug Administration Drug Safety and Innovation Act. The law requires companies to notify FDA of drug thefts and counterfeit or adulterated drugs that could cause serious harm. It requires manufacturers and importers to register annually with the FDA and provide unique facility identifiers so that FDA knows who and where they are. It bans imports of drugs from foreign facilities that delay, deny or limit FDA inspection, and it enhances criminal penalties for intentionally counterfeiting or adulterating a drug in a way that could cause serious adverse health consequences.

Last year, we passed the bipartisan Drug Quality and Security Act. This law gives the FDA and industry new tools to deter, discover and remedy the entry of illegal drugs into the supply chain. However, the legislation was not designed for sophisticated criminal enterprises intent on evading the law and the most useful of the new tools, an electronic unit-level tracking and tracing system is not required to be in place until 2023. So it is hard to reach a conclusion other than more needs to be done.

Today the government has to prove an intent to violate the law before it can even win a criminal case, and even then, the maximum penalty for some violations with potentially life-threatening consequences is only 3 years. We need a stronger deterrent.

We also need to consider what to do about the fact that so many of our drugs are sourced from abroad. This can create serious drug safety and security issues. In India, where FDA inspections have tripled since FDASIA, FDA is finding serious lapses in quality. And as the New York Times reported recently, even India's top drug regulator concedes that most of the drug facilities supplying the domestic Indian market do not meet FDA standards. This is a serious problem because India is the second largest exporter of drugs to the U.S., supplying 40 percent of our generic and over-the-counter drugs.

In China, the U.S. government had to negotiate for almost a full year just to get visas for the additional inspectors that FDA needs to conduct more frequent and timely inspections. It could put much of our drug supply at risk because the crucial ingredients for nearly all antibiotics, steroids and many other lifesaving drugs are now made exclusively in China.

Well, Mr. Chairman, I look forward to hearing from our witnesses today, and I thank you for holding this important hearing. It is appropriate, it is legitimate, it is what oversight committees should be doing, and I hope it is the first step towards passing legislation that will effectively deter and punish those who put Americans' health at risk with counterfeit pharmaceuticals.

And I want to say in my closing minute, Mr. Chairman, unfortunately, there is another subcommittee meeting at the same time so I will be in and out of this hearing. I will review the testimony of the witnesses that will be making a presentation. Thank you.

Mr. MURPHY. Thank you. Mr. Waxman yields back.

I would now like to introduce our witnesses on the first panel for today's hearing. We do have two panels of distinguished people. First, Mr. Howard Sklamberg is the Deputy Commissioner for Global Regulatory Operations and Policy for the Food and Drug

Administration. I would like to note that due to the amount of exhibits the FDA would like to show in support of the testimony, both sides agree to allow Mr. Sklamberg 10 minutes for his oral testimony instead of the usual 5.

And Mr. Lev Kubiak, welcome, the Director of the National Intellectual Property Rights Coordination Center for the Department of Homeland Security's Immigration and Customs Enforcement.

I will now swear in the witnesses. You are aware that the committee is holding an investigative hearing, and when doing so has the practice of taking testimony under oath. Do either of you object to testifying under oath? The Chair then advises you that under the rules of the House and the rules of the committee, you are entitled to be advised by counsel. Do either of you desire to be advised by counsel during the testimony today? In that case, would you please rise and raise your right hand, and I will swear you in.

[Witnesses sworn.]

Mr. MURPHY. You are now under oath and subject to the penalties set forth in Title XVIII, section 1001 of the United States Code.

Mr. Sklamberg, you may now give your opening statement and video.

TESTIMONY OF 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)

TESTIMONY OF HOWARD SKLAMBERG

Mr. SKLAMBERG. Thank you very much, Mr. Chairman, Ranking Member DeGette, and members of the subcommittee. I am Howard Sklamberg, Deputy Commissioner for Global Regulatory Operations and Policy at the Food and Drug Administration, and thank you for this opportunity to be here today to discuss the important issue of counterfeit drugs.

Counterfeit drugs raise significant public health concerns. A counterfeit drug could be made using ingredients that are toxic to patients and processed under poorly controlled and unsanitary conditions. In the United States, a relatively comprehensive system of laws, regulations and enforcement by federal and State authorities has kept drug counterfeiting incidents in the United States relatively rare. FDA continues to believe and works to ensure that Americans can have a high degree of confidence in the drugs they obtain through legal channels. Nonetheless, with the dramatic increase in the complexity of the global supply chain, we face enormous challenges regarding supply chain security.

FDA is not alone in its effort to address the problem of counterfeit drugs, and I want to note the efforts of my colleagues on this panel and on the other panels in their work on this problem as well.

Growth in counterfeiting may be spurred by several things including the increasing volume of drugs, longer supply chains, the

development of technologies that make it easier to counterfeit drugs, and the involvement of international organized crime. This growth also is exacerbated by the relatively low criminal penalties for distribution of adulterated, unapproved or misbranded drugs under the Federal Food, Drug and Cosmetic Act compared to other types of crime.

In addition, the Internet presents another layer of complexity by introducing more players and more opportunities for criminals to reach consumers. The global anonymity of the Internet can provide a safe haven for illicit prescription drug sales. Many Web sites leave unsuspecting customers in the United States to believe the dispensing pharmacy is in the United States or Canada.

FDA has made it a priority to investigate reports of counterfeit products. As part of these efforts, FDA's Office of Criminal Investigations, or OCI, aggressively investigates reports of counterfeit products in order to protect U.S. citizens. OCI's investigations have led to some notable successes. I would like to provide some examples from our investigations.

The first is from an investigation into counterfeit Alli, and would the clerk please pull up the Alli video?

[Video shown.]

Thank you. And would the clerk please load picture one?

[Slide shown.]

And as it is being loaded, the picture shows a refrigerator used to store illegally imported, adulterated and misbranded prescription drugs that were smuggled into the United States. These drugs were discovered in the home of a repacker who had subsequently shipped the drugs to doctors throughout the United States.

Would the clerk please load picture two?

[Slide shown.]

One of the ways some traffickers obtain prescription drugs is to buy them from customers at various pharmacies whose medications were paid for by Medicaid. In order to be able to reuse the bottle with the original label, they would have to clean the pharmacy label and the Medicaid sticker off of the label using things such as lighter fluid. Where we have observed bottle washing with a solvent, we generally observe chemicals in the solvent that have migrated through the bottle onto the drug.

Would the clerk please load picture three?

[Slide shown.]

Well, through the particular bottle, I am not sure in the instances what type of bottle it is but we can get back to you on that, but it is common for things to migrate through plastic.

Would the clerk please load picture three?

[Slide shown.]

The following photos were taken from a Belize-based manufacturing facility involved in selling unapproved prescription drugs and controlled substances. The pills from the trashcans in this picture were transferred into plastic bags to be counted and bagged by using a scoop. The same scoop was used for many different drugs including controlled drugs. This led to cross-contamination.

Would the clerk please load picture four?

[Slide shown.]

This picture shows some of the conditions at the manufacturing facility.

Would the clerk please load picture five?

[Slide shown.]

This picture shows the condition of a tablet room at the facility. I want to show a comparison of what a legitimate tablet press should look like. Would the clerk please load picture six?

[Slide shown.]

So you can see the difference.

FDA has been working with industry and international partners to develop new methods to address the problem of counterfeit drugs. FDA scientists have developed and have been testing a counterfeit detection device, CD–3, at U.S. ports of entry and elsewhere for use by FDA investigators to check for suspect counterfeit products. CD–3, which I am now holding, is a battery-operated, handheld and inexpensive tool that costs a fraction of the price of existing laboratory-based and field-deployed technologies. Would the clerk please play the CD–3 video?

[Video shown.]

It is important to note that while this technology is helpful it won't solve the problem, particularly given the volume of products that come through ports of entry.

FDA also participates in Operation Pangaea, which is a global cooperative effort in partnership with international regulatory and law enforcement agencies to combat the online sale and distribution of potentially dangerous counterfeit and illegal medical products. As part of the 2013 annual effort, the partnership took action against more than 13,700 Web sites illegally selling potentially dangerous unapproved prescription medicines to customers. These actions included the issuance of regulatory warnings and the seizure of offending Web sites and over $36 million worth of illegal medicines worldwide. FDA in coordination with the U.S. Attorney's Office for the District of Colorado seized and shut down 1,677 illegal pharmacy Web sites.

The case of Manuel Calvelo illustrates the inherently international and thus difficult-to-prosecute nature of the Internet pharmacy investigations. Calvelo is a Belgian citizen operating a global Internet pharmacy with a call center in the Philippines and a credit processor in the Netherlands. Calvelo's Web sites offered for sale more than 40 prescription drugs such as Viagra, Glucophage, Zoloft, Lipitor, Cialis, Xanax, Ativan and Klonopin. Note that Xanax, Ativan and Klonopin are controlled substances. OCI was able to arrest Calvelo in Costa Rico and extradite him to the United States after an extended undercover operation in which OCI agents posed as pharmaceutical wholesalers seeking to do business with them/him.

Public education is very important as a first line of defense against counterfeit drugs. The agency is conducting proactive educational outreach to the medical community and other stakeholders. In September 2012, FDA launched a national campaign called Be Safe RX: Know Your Online Pharmacy. Be Safe RX provides resources for patients and caregivers who might purchase prescription drugs online to enable them to better understand who

they are buying from and to help ensure the drugs they buy match the product the doctor prescribed.

The Food and Drug Administration Safety and Innovation Act, or FDASIA, enacted in July 2012, provided the agency with new authorities that help to secure the safety and integrity of drugs imported into and sold in the United States. For example, the law provides the FDA with the authority to administratively detain drugs believed to be adulterated or misbranded and the authority to destroy certain adulterated, misbranded or counterfeit drugs offered for import. The law also requires foreign and domestic companies to provide complete information on threats to the security of the drug supply chain and to improve current registration and listing information. The recently enacted Drug Quality and Security Act outlines critical steps to build an electronic and operable system to identify and trace certain prescription drugs. Within 10 years after enactment, the system will facilitate the exchange of information at the individual package level about where a drug has been in the supply chain.

While the new authorities under FDASIA and the DQSA help address some of the risks posed by counterfeit drugs, they will not prevent all types of illegal diversion or distribution schemes. These laws would not prevent the numerous instances FDA has uncovered of medical practitioners deliberately obtaining unapproved drugs, some of which have been counterfeits directly from foreign sources for administering to patients. The reality is that the criminal penalty under the Food, Drug and Cosmetic Act for the risky and inherently dangerous practice of importing unapproved foreign drugs is simply not sufficient to deter the criminal element. The penalty for such conduct, which generally falls under the misbranding and unapproved new drugs provisions of the FD&C Act is 3 years imprisonment and then only if the government can show there is a specific intent to defraud or mislead. Otherwise it is a misdemeanor punishable only by a maximum of one year of imprisonment.

The Ryan Haight Act also sets forth for the first time under federal law the definition of a valid prescription with regard to controlled substances. Many online pharmacies, however, sell prescription drugs that are not controlled substances. These drug sales are regulated under the FD&C Act and require a valid prescription, but the FD&C Act does not define what constituents a valid prescription. In the online pharmacy context where numerous doctors and their respective customers are often located in different States, this can complicate criminal prosecution under the FD&C Act.

Given the challenges and threats posed by an increasingly globalized marketplace, it is important that FDA regulatory and law enforcement partners and industry continue to work together to address the problem and threat of counterfeit drugs and that we continue to ensure authorities keep pace with the complex system that counterfeiters and traffickers take advantage of. We look forward to continuing to work together to achieve our shared goal of protecting American consumers.

I would be happy to answer any questions. Thank you.

[The prepared statement of Mr. Sklamberg follows:]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring, MD 20993

STATEMENT

OF

HOWARD SKLAMBERG

DEPUTY COMMISSIONER FOR GLOBAL REGULATORY OPERATIONS AND POLICY

FOOD AND DRUG ADMINISTRATION

DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE

SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS

COMMITTEE ON ENERGY AND COMMERCE

U.S. HOUSE OF REPRESENTATIVES

"COUNTERFEIT DRUGS: FIGHTING ILLEGAL SUPPLY CHAINS"

FEBRUARY 27, 2014

RELEASE ONLY UPON DELIVERY

INTRODUCTION

Mr. Chairman, Ranking Member DeGette, and Members of the Subcommittee, I am Howard Sklamberg, Deputy Commissioner for Global Regulatory Operations and Policy at the Food and Drug Administration (FDA or the Agency), which is part of the Department of Health and Human Services (HHS). Thank you for the opportunity to be here today to discuss the important issue of counterfeit drugs.

Recent incidents of counterfeiting and adulteration have caused serious threats to public health. The consequences around the world have been tragic. Counterfeit drugs raise significant public health concerns because their safety and effectiveness is unknown. A counterfeit drug could be made using ingredients that are toxic to patients and processed under poorly controlled and unsanitary conditions. Substandard drugs are also a major public health concern, especially regarding infectious disease drugs, such as anti-HIV and anti-malarial drugs. In the United States, a relatively comprehensive system of laws, regulations, and enforcement by Federal and state authorities has kept drug counterfeiting incidents in the United States relatively rare, and FDA continues to believe—and works to ensure—that Americans can have a high degree of confidence in the drugs that they obtain through legal channels. Nonetheless, with the dramatic increase in the complexity of the global supply chain, FDA and its regulatory and law enforcement partners around the world face enormous challenges regarding supply chain security.

Those who manufacture and distribute counterfeit medical products not only defraud patients and consumers, they also prevent patients from getting the safe, effective drugs that can improve health, alleviate suffering, and possibly save their lives. They put people at risk of harm from drugs that may contain too much or too little active ingredient, the wrong active ingredient, or even toxic ingredients. But even a counterfeit drug with no active ingredient could prove harmful to patients who think they are taking a lifesaving or life-sustaining medication.

FDA is not alone in its effort to address the problem of counterfeit drugs. FDA works closely with the White House's Intellectual Property Enforcement Coordinator (IPEC) to develop and coordinate the U.S. Government's strategy to address counterfeit pharmaceuticals.[1] I also want to note the efforts of our colleagues in the National Intellectual Property Rights Coordination Center—in which FDA participates and is a full partner—and other domestic and foreign regulatory and law enforcement partners working to help secure the supply chain. The State Department and the U.S. Agency for International Development (USAID) have also served as key partners, ensuring that the issues of drug quality and supply chain security are raised in our diplomatic and development efforts. I also want to thank the Government Accountability Office (GAO) and the Institute of Medicine (IOM) for their reports drawing attention to illegal online pharmacies and global challenges with substandard, counterfeit, and falsified products. In addition, industry partners have made valuable contributions to address supply chain issues. These collaborative efforts are imperative to bring counterfeiters and traffickers to justice and to protect consumers from counterfeit or substandard products. A counterfeit or substandard drug with too little active ingredient could cause a patient to develop drug resistance and

[1] See *Administration's 2013 Joint Strategic Plan on Intellectual Property Enforcement* *http://www.whitehouse.gov/sites/default/files/omb/IPEC/2013-us-ipec-joint-strategic-plan.pdf.*

potentially spread that resistant strain to the community, eroding our arsenal of effective medicines.

Challenges of Protecting the Supply Chain

Our efforts to secure the supply chain both in the United States and abroad include minimizing risks that arise anywhere along the supply chain continuum, from the source of a product's ingredients through the product's manufacture, storage, transit, sale, and distribution. A breach at any point in this continuum could lead to dangerous and even deadly outcomes for consumers. Supply chain safety threats can also affect manufacturers' bottom lines due to costs associated with both recalls and decreased public confidence.

Nearly 40 percent of the drugs Americans take are made elsewhere, and about 80 percent of manufacturing sites of active pharmaceutical ingredients (APIs) used in drugs manufactured in the United States are located outside our borders—in more than 150 countries, many with less-sophisticated manufacturing and regulatory systems than our own. In addition to the sheer volume of imports and foreign facilities, there has been an increase in the variety of sources, shippers, methods of transportation, and supply chain complexity of products. Combined, these factors create great challenges to FDA and industry in ensuring that all drugs and drug components are high quality and travel safely throughout their complex supply chains. These factors also provide opportunities for criminals to adulterate drugs for economic or other malevolent reasons.

Growth in counterfeiting may be spurred by the economic incentives provided by an increasing volume of drugs, longer (often international) supply chains, the development of technologies that make it easier to counterfeit drugs, the involvement of international organized crime, and the ability to sell drugs directly to consumers through the Internet, without face-to-face contact. This growth also is exacerbated by the relatively low criminal penalties for distribution of adulterated, unapproved, or misbranded drugs provided under the Federal Food, Drug, and Cosmetic Act (FD&C Act), compared to other types of crimes.

The Internet presents an additional layer of complexity by introducing more players into the system and more opportunities for criminals to reach consumers, and as a result, it continues to be a major source for counterfeit and unapproved prescription drugs, many of which are dispensed without prescriptions. The global anonymity of the Internet can provide a safe haven for illicit prescription drug sales. Many websites look like legitimate pharmacies, leading unsuspecting customers in the United States to believe the dispensing pharmacy is in the United States or Canada.

FDA's Efforts to Protect the Supply Chain

FDA has responded to this threat by working to protect and further strengthen the integrity of our country's closed drug distribution system in multiple ways. We have made it a priority to investigate reports of counterfeit products. FDA also has worked with U.S. drug supply chain stakeholders to improve our ability to prevent, detect, and respond to threats of counterfeit and substandard drugs. We are developing standards for tracking and tracing prescription drugs. In addition, we are educating consumers and the health care community about the risks of, and

minimizing exposure to, counterfeit and substandard drug products through recalls, public awareness campaigns, and other steps.

As part of these efforts, FDA's Office of Criminal Investigations (OCI) aggressively investigates reports of counterfeit products in order to protect U.S. citizens. A number of these investigations involve sales of foreign unapproved drugs, many of which we suspect are portals for counterfeiters. Because of OCI's focus on protecting the medical product supply chain, and the good communication within FDA between the regulatory and criminal investigative functions, we have had some notable successes.

For example, when FDA discovered that foreign, unapproved, and counterfeit versions of the cancer drug Avastin had entered the U.S. supply chain, we mobilized our resources to counter the threat. We expanded an existing investigation, which thus far resulted in the conviction of the foreign source of supply, wholesalers, middlemen in Canada and the United States who bought and sold these sophisticated drugs, and physicians who knowingly put their patients' well-being at risk in order to turn a profit by buying drugs at a discount. As part of the investigation, we recently arrested two Turkish nationals as the source of supply of counterfeit and unapproved cancer medications. These drugs, the indictment alleges, were shipped to the United States with false customs declarations. Moreover, the defendants are alleged to have shipped some prescription drugs requiring constant cold temperatures to maintain their stability and effectiveness in shipping boxes without useful or effective insulation or temperature protection. Given the length of time required to ship products from Turkey to the United States, it is alleged that defendants were aware that on many occasions their packages of prescription

drugs arrived in the United States at temperatures outside the constant cold temperature range discussed on the drugs' labeling.[2] FDA was also able to arrest the United-Kingdom-based distributor of counterfeit and unapproved cancer drugs, who was ultimately sentenced to 18 months imprisonment.[3] We have investigated this black market supply chain, including wholesalers based in the United States,[4] and U.S. pharmacies peddling unapproved foreign and potentially counterfeit drugs, leading to a number of arrests and convictions.[5] We also investigated and arrested a number of health care providers who knowingly put their patients' health at risk by buying foreign, unapproved cancer medications at a discount, but billing government health care insurance at full price. This included a California oncologist who purchased over $3.4 million in foreign unapproved cancer drugs,[6] a Tennessee physician purchasing over $3 million in foreign unapproved drugs,[7] seven Ohio physicians purchasing and administering over $2.6 million in unapproved cancer medications,[8] a Texas-based oncologist administering over $1 million in unapproved drugs,[9] and others.[10]

As part of a coordinated effort alongside the criminal investigation, our Center for Drug Evaluation and Research (CDER) issued alerts to the medical community and public at large

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[2] http://www.fda.gov/ICECI/CriminalInvestigations/ucm383001.htm
[3] http://www.fda.gov/ICECI/CriminalInvestigations/ucm360652.htm
[4] http://www.fda.gov/ICECI/CriminalInvestigations/ucm360948.htm
http://www.justice.gov/usao/cas/press/2012/cas12-0928-BeanandIdrissPR.pdf
http://www.justice.gov/usao/moe/news/2012/june/behe_sandra.html
http://www.fda.gov/ICECI/CriminalInvestigations/ucm316986.htm
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http://www.fda.gov/ICECI/CriminalInvestigations/ucm377434.htm
[5] http://www.fda.gov/ICECI/CriminalInvestigations/ucm378038.htm
http://www.fda.gov/ICECI/CriminalInvestigations/ucm380566.htm
[6] http://www.fda.gov/ICECI/CriminalInvestigations/ucm359636.htm
[7] http://www.fda.gov/ICECI/CriminalInvestigations/ucm379431.htm
[8] http://www.justice.gov/usao/ohn/news/2014/29jancan.html
[9] http://www.fda.gov/ICECI/CriminalInvestigations/ucm380564.htm
[10] http://www.fda.gov/ICECI/CriminalInvestigations/ucm332118.htm
http://www.fda.gov/ICECI/CriminalInvestigations/ucm294706.htm
http://www.fda.gov/ICECI/CriminalInvestigations/ucm267356.htm

about the potential for harm. When we first learned of the issue, we issued a general alert.[11] Later, as the scope of the illegitimate distribution chain became more known, we alerted over 1,500 medical practices in the United States that they had purchased or received unapproved drugs—which may have included counterfeit drugs—from foreign suppliers, some of which used wholesalers in the United States to distribute the products. We were also able to alert the medical community about specific wholesalers that the criminal investigation had determined had been selling foreign unapproved drugs.[12] The specialization and coordination between the criminal and regulatory functions of FDA enabled us to respond in an integrated manner to emerging public health threats.

While we recognize that we may not be able to eliminate all problem products from the supply chain, we are committed to making the drug supply chain more secure, keeping illegitimate products out of the U.S. drug supply chain, and tackling the roots of the problem globally.[13] FDA is reaching beyond our U.S. borders and working with our foreign counterparts to identify global supply chain vulnerabilities as well as identify and implement realistic solutions, nationally and internationally.

FDA has also been working with industry and international partners to develop new methods to address the problem of counterfeit drugs. FDA scientists have developed and have been testing a counterfeit detection device, CD-3, at U.S. ports of entry and elsewhere for use by FDA investigators to check for suspected counterfeit products. CD-3 is a battery-operated, hand-held

[11] http://www.fda.gov/downloads/Drugs/DrugSafety/DrugIntegritvandSupplyChainSecurity/UCM287717.pdf
[12] http://www.fda.gov/Drugs/DrugSafety/ucm291960.htm; http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/CounterfeitMedicine/ucm338283.htm
[13] In February 2013, IOM issued a report entitled "Countering the Problem of Falsified and Substandard Drugs," identifying a combination of actions for regulators, industry, and other stakeholders that could reduce counterfeit and substandard drugs domestically and globally.

and inexpensive tool that costs a fraction of the price of existing laboratory-based and field-deployable technologies. It works much like a high-powered flashlight, and does not require special scientific or technical training to operate effectively. Moreover, extensive tests have shown it to be effective in identifying counterfeit products and packaging. The tool has successfully helped to detect counterfeit goods and has been helpful in discovering product tampering and checking questionable documents. FDA is working with Corning Incorporated to refine and improve the tool for eventual manufacturing on a larger scale. Partners in the CD-3 effort include the Skoll Global Threats Fund, U.S. Pharmacopeia (USP), National Institutes of Health (NIH), Centers for Disease Control and Prevention (CDC), and the multi-agency President's Malaria Initiative (PMI), led by USAID.

To address threats posed by illegitimate pharmacies operating over the Internet, FDA participates in the annual International Internet Week of Action (IIWA), or Operation Pangea, a global cooperative effort in partnership with international regulatory and law enforcement agencies, to combat the online sale and distribution of potentially counterfeit and illegal medical products. INTERPOL reports that as part of the 2013 annual effort (Operation Pangea VI), the partnership took action against more than 13,700 websites illegally selling potentially dangerous, unapproved prescription medicines to consumers. These actions included the issuance of regulatory warnings and the seizure of offending websites and over $36 million worth of illegal medicines worldwide.[14] OCI, in coordination with the U.S. Attorney's Office for the District of Colorado, seized and shut down 1,677 illegal pharmacy websites. OCI conducted a number of undercover purchases from these websites, all of which advertised themselves as selling Canadian drugs. The agents, who were able to purchase prescription drugs without a

[14] *http://www.interpol.int/Crime-areas/Pharmaceutical-crime/Operations/Operation-Pangea*

prescription, received drugs directly from India and Singapore. The drugs were not approved for use in the United States, contained no directions for use, and were often in unfamiliar dosage forms and of unknown quality and purity. None of the drugs, as far as the investigation could tell, ever came through Canada or were subject to Canadian regulation.

GAO recently noted the substantial challenges in the criminal investigation of rogue Internet pharmacy operators, including the increasingly complex nature of the criminal organizations and the difficulties in pursuing investigations and prosecutions of conduct that occur mainly overseas and often span several foreign countries.[15]

Nevertheless, OCI has had success in investigating Internet pharmacies. For example, we were able to successfully investigate Andrew Strempler, who ran a website under the RxNorth.com banner. Strempler falsely represented that RxNorth was selling safe prescription drugs in compliance with regulations in Canada, the United Kingdom, and the United States. In fact, he obtained the prescription drugs from various other source countries without properly ensuring the safety or authenticity of the drugs. Some of the drugs sold by Strempler included counterfeit drugs.[16] Another example, the case of Manuel Calvelo, illustrates the inherently international, and thus difficult-to-prosecute nature of Internet pharmacy investigations. Calvelo was a Belgian citizen operating a global Internet pharmacy, with a call center in the Philippines, and a credit card processor in The Netherlands. Calvelo's websites offered for sale more than 40 prescription drugs, including brand names such as Viagra, Depakote, Glucophage, Zoloft, Lipitor, Cialis, Xanax, Ativan and Klonopin. Note that Xanax, Ativan, and Klonopin are

[15] *http://www.gao.gov/assets/660/655751.pdf, at 19-22.*
[16] *http://www.fda.gov/ICECI/CriminalInvestigations/ucm323949.htm*

controlled substances. OCI was able to arrest Calvelo in Costa Rica and extradite him to the United States after an extended undercover operation, in which OCI agents posed as pharmaceutical wholesalers seeking to do business with him.[17]

One other investigation, in which we worked with U.S. Immigration and Customs Enforcement, Homeland Security Investigations, involved the selling of counterfeit drugs to U.S. customers by a website that claimed to be a "Pharmacy You Can Trust." Although the website was hosted in New York, the drugs were manufactured in clandestine laboratories in China, shipped to the United States (via packages whose contents were falsely represented on Customs forms to be something other than pharmaceuticals), and received by U.S.-based confederates, known as drop shippers, who would break down the shipments and then send the U.S. customer a package from a domestic address, giving the appearance that the drugs were dispensed from a U.S. pharmacy. Our investigation showed that the payments were processed by a credit card processor in The Netherlands, and funds were transferred to Cyprus, then to Hong Kong, and finally, to Israel. Although the website listed a 1-800 number for customer service, the calls were routed to customer service personnel in the Philippines. The actual operators of this website were conducting operations using a wireless Internet connection onboard their yacht docked in Tel Aviv. From 2005 to 2007, the website processed over $1.8 million in sales from approximately 12,000 orders.[18]

To further its success in this area, in March 2013, FDA formed a new Cyber Crimes Investigation Unit, a special team within OCI, devoted to combating rogue Internet pharmacies.

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[17] *http://www.fda.gov/ICECI/CriminalInvestigations/ucm257945.htm*
[18] *http://www.fda.gov/ICECI/CriminalInvestigations/ucm301685.htm*

This unit works with other domestic and international agencies to track down the operators and suppliers of websites that illegally sell prescription drugs. The agents' methods include high-tech detection in which they follow the cyber-trail of these pharmacies and go undercover to infiltrate the criminal world.

Because of the difficulties in criminal investigation and prosecution, public education is very important as a first-line defense against counterfeit drugs. Health care practitioners who expose patients to unapproved or counterfeit drugs are risking their patients' health. Therefore, the Agency is conducting proactive educational outreach to the medical community and other stakeholders to ensure they have an understanding of how to purchase drugs both legally and safely. It is crucial that they understand why they should not circumvent the safeguards that Federal and state authorities have in place to ensure the purchase of safe and effective prescription drugs. In September 2012, FDA launched a national campaign targeted at patients and health care professionals to raise public awareness about the prevalence of fraudulent Internet pharmacies, called BeSafeRx – Know Your Online Pharmacy. BeSafeRx provides resources for patients and caregivers who might purchase prescription drugs online to enable them to better understand who they are buying from and to help ensure that the drug they buy matches what their doctor prescribed. The campaign provides information about the dangers of purchasing drugs from fraudulent Internet pharmacies, as well as how to identify such pharmacies and how to find legitimate Internet pharmacies.

New Authorities

Recognizing the potential threats posed by the increasingly complex global supply chain, Congress has recently enacted legislation to help address some of the risks posed by counterfeit drugs and other substandard drugs. The Food and Drug Administration Safety and Innovation Act (FDASIA; Public Law 112-144) provided the Agency with new authorities that will help to secure the safety and integrity of drugs imported into, and sold in, the United States. For example, the law provides FDA with the authority to administratively detain drugs believed to be adulterated or misbranded, and the authority to destroy certain adulterated, misbranded, or counterfeit drugs offered for import. The law also requires foreign and domestic companies to provide complete information on threats to the security of the drug supply chain and to improve current registration and listing information, making sure FDA has accurate and up-to-date information about foreign and domestic manufacturers.

The recently enacted Drug Quality and Security Act (DQSA) outlines critical steps to build an electronic, interoperable system to identify and trace certain prescription drugs as they are distributed in the United States.[19] Drug manufacturers, wholesale drug distributors, repackagers, and many dispensers (primarily pharmacies) will be called on to work in cooperation with FDA to develop the new system over the next 10 years. Within 10 years after enactment, the system will facilitate the exchange of information at the individual package level about where a drug has been in the supply chain. The new system will: enable verification of the legitimacy of the drug product identifier down to the package level; enhance detection and notification of illegitimate

[19] In the *Administration's White Paper on Intellectual Property Enforcement Legislative Recommendations*, March 2011, at p. 2 ("White Paper"), the Administration recommended legislation to adopt a track-and-trace system for pharmaceuticals and related products. See *http://www.whitehouse.gov/sites/default/files/ip_white_paper.pdf*.

product in the drug supply chain; and facilitate more efficient recalls of drug products.[20] Manufacturers, wholesale distributors, repackagers, and pharmacies will immediately quarantine and promptly investigate drug products deemed suspect or illegitimate for potentially being counterfeit, unapproved, or dangerous, such as a recalled drug product; they will alert FDA to these findings. The system will improve detection and removal of potentially dangerous drugs from the drug supply chain to protect U.S. consumers.

Remaining Challenges

Despite recent successes, the continued threat of counterfeits in the United States and the global supply chain has reinforced the need for FDA, its regulatory and law enforcement partners, industry, and others to continue to take action in multiple areas to create a comprehensive system to better protect against counterfeit drugs.

While the new authorities under DQSA and FDASIA help address some of the risks posed by counterfeit drugs, they will not prevent all types of illegal diversion or distribution schemes that FDA has discovered in recent years. For example, FDA has uncovered numerous instances of medical practitioners deliberately obtaining unapproved drugs—some which have been counterfeits—directly from foreign sources for administering to patients. These laws would not prevent situations where consumers purchase drugs from rogue Internet websites or where a pharmacy purchases product from outside the legitimate supply chain and dispenses directly to a patient.

[20] Under current law, recalls are voluntary as FDA does not have the authority to issue mandatory recalls of drug products.

Given the high profit potential of trafficking in counterfeit and unapproved drugs and the relatively low penalties for non-compliance, bad actors still have incentives to find ways to circumvent the new requirements. The reality is that the criminal penalty for the risky and inherently dangerous practice of importing unapproved foreign drugs is simply not sufficient to deter the criminal element. The penalty for such conduct, which generally falls under the "misbranding" and "unapproved new drugs" provisions of the FD&C Act, is three years imprisonment, and only if the Government can show that there was a specific intent to defraud or mislead. Otherwise, it is a misdemeanor, punishable only by a maximum of one year imprisonment.

The penalties for health and safety violations for distributing unapproved or misbranded drugs have not been revised in decades and are substantially less severe than penalties for violations relating to intellectual property or economic loss. Title 18 Counterfeiting, designed to protect the trademark holder, carries with it a 20-year maximum penalty for counterfeit pharmaceuticals. However, risky conduct such as trafficking in foreign unapproved or adulterated drugs, carrying with it the same risk to the public health, is subject to a one- or three-year penalty—same risk to public health, dramatically different results.[21]

For example, this summer, a Utah man was convicted of trafficking in Internet sales of various pharmaceuticals unapproved for distribution in the United States. He obtained these drugs from a variety of international sources, with no idea as to whether the medicines were counterfeit or substandard or how they were stored. Because of the nature of the investigation, we had no way

[21] See *White Paper*, at 2, recommending an increase in the statutory maxima under the FD&C Act. See also, *Administration's Counterfeit Pharmaceutical Inter-Agency Working Group Report to the Vice President of the United States and the Congress*, at 17, *http://www.whitehouse.gov/sites/default/files/ip_white_paper.pdf*, and Inter-Agency Working Group Report.

of proving whether the drugs were counterfeit or adulterated, because they had already been distributed to unsuspecting American consumers, but the sketchy supply chain and the high-value nature of the drugs dramatically increased the odds that they were. This man shipped over $5 million of unapproved drugs, but because of the restrictive nature of the statutory scheme, received only a one-year sentence.[22] There is some evidence that increasing penalties can have an important and beneficial impact. The GAO noted that the Ryan Haight Act, which substantially increased penalties for online distribution of controlled substances, has significantly reduced the extent to which controlled substances are sold online.[23]

There are additional lessons that can be learned from law enforcement's experiences with the Ryan Haight Act. In addition to its penalty provisions, the Ryan Haight Act was also important because it set forth, for the first time under Federal law, the definition of a "valid prescription" with regard to controlled substances. Many online pharmacies sell prescription drugs that are not controlled substances under Federal law. These drug sales are regulated under the FD&C Act and require a valid prescription, but the FD&C Act does not define what constitutes a valid prescription. In the online pharmacy context, where numerous doctors and their respective customers are often located in different states, this can complicate criminal prosecution under the FD&C Act.[24]

CONCLUSION

Given the challenges and threats posed by an increasingly globalized marketplace, it is important that

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[22] *http://www.fda.gov/ICECI/CriminalInvestigations/ucm363279.htm*
[23] *http://www.gao.gov/assets/660/655751.pdf*, at 30.
[24] In the Administration's White Paper on Intellectual Property Enforcement Legislative Recommendations, the Administration recommended extending the Ryan Haight Act's definition of a "valid prescription" to the FD&C Act. See White Paper, at 13, *http://www.whitehouse.gov/sites/default/files/ip_white_paper.pdf*.

FDA, regulatory and law enforcement partners, and industry continue to work together to address the problem and threat of counterfeit drugs, and that we continue to ensure authorities keep pace with the complex system that counterfeiters and traffickers take advantage of. We look forward to continuing to work together to achieve our shared goal of protecting American consumers. I would be happy to answer any questions.

Mr. MURPHY. Thank you, Mr. Sklamberg.

Mr. Kubiak, you are now recognized for 5 minutes.

TESTIMONY OF LEV KUBIAK

Mr. KUBIAK. Good morning, Chairman Murphy, Ranking Member DeGette and distinguished subcommittee members, thank you very much for this opportunity to speak today about the efforts of ICE—Immigration and Customs Enforcement—and the Center that I run, the National Intellectual Property Rights Center.

I currently serve as the Director of that Center. It is led by ICE, and the Center operates as a task force model comprised of 21 federal and international partners including FDA, which I am pleased to join today here on this panel. It is this collection of agencies partnered together pooling resources, expertise and authorities that makes the IPR Center truly unique and effectively. No subset of agencies has the individual capacity or capability to address the significant and growing threat of IP crime alone. The Center optimizes the effectiveness of each agency and provides a single location for industry collaboration and reporting.

Can you put the second slide up, please?

[Slide shown.]

As the picture that you are about to see illustrates, our biggest challenge right now is that criminals now counterfeit and effectively market virtually any product with no regard to public health and safety, be it exploding airbags, as it represented in the right hand of the screen, to counterfeit industrial bearings used in mineshafts and mining equipment, to drugs without active ingredient, the callous nature of counterfeiting results in dangerous, even deadly outcomes.

Another significant challenge we face is while ocean-crossing shipping containers are necessary for the bulk movement of quantities of counterfeit items like handbags, batteries or razor blades, other high-value items including counterfeit pharmaceuticals and semiconductors used by our United States military are being smuggled in thousands of smaller packages through mail and express courier packages. Next slide, please.

[Slide shown.]

As this slide shows, the Internet poses yet another significant challenge. Criminals operating unregulated Web sites, providing counterfeit pharmaceuticals continue to be a growing global phenomenon. In April 2013, Legit Script, an online pharmaceutical verification service, stated there were over 34,000 active rogue Internet pharmacies selling substandard, counterfeit or harmful prescription drugs. The screenshot you see here is from an actual criminal Web site that we seized as one of the 686 Web sites seized as a result of Operation Better Pill, a worldwide operation run by ICE through the IPR Center targeting the online sale of counterfeit illegal medicine. This Web site was run by a criminal organization based overseas and purported, as you can see, to be a legitimate Canadian health care facility.

With this type of ambiguity, consumer fraud can run rampant. Next slide, please.

[Slide shown.]

In early 2010, law enforcement authorities from the United Kingdom provided FDA information on an intercepted shipment of unapproved oncology drugs. The package, derived from Pakistan, was destined for California. Together, ICE, FDA, FBI, the U.S. Postal Service, and Customs and Border Protection collaborated on the investigation discovering that Martin Paul Bean of Florida ordered the unapproved drugs from foreign sources in Turkey, India and Pakistan and then sold those drugs to doctors in the United States at substantially reduced prices. In September, Bean was sentenced to 2 years' incarceration for distributing more than $7 million worth of unapproved and misbranded oncology drugs through his illicit pharmaceutical scheme, significant harm caused by just one criminal.

This case example on the screen illustrates our strategy, which is to attack the criminal network throughout the entire global supply chain from the point of manufacturer through shippers of illegal commodities to those that distribute the illegal drugs to unsuspecting people in need of effective medicine. This strategy requires a robust collaboration through our attach AE1e network with foreign counterparts where the majority of counterfeit items are made and through which they are transhipped en route to the United States and our trading partners worldwide.

I know we are not going to be able to arrest and seize our way out of this growing problem, and that is why the IPR Center has committed significant effort to close collaboration with industry and education to the public. I do believe that we can reduce demand through education and I also believe that this is the most critical component of any long-term viable solution. Next slide, please.

[Slide shown.]

As part of our robust public education efforts, we have developed the IPR Center Web site, which includes information on efforts of all of our partner agencies and where they can report IP crime through our "report IP theft" button. Industry and other U.S. government agencies have joined the fight by placing the "report IP theft" button on their Web sites as well, now totaling more than 100 industry and embassy Web sites worldwide, including this one from the Pharmaceutical Security Institute pictured on the screen. New leads to the Center have increased nearly 500 percent since fiscal year 2012 as a result of this. I encourage the members of this committee to visit our Web site, and I invite you to place our "report IP theft" button on your page as well. Recently we had Congressman Green visit the Center himself and we are working with his staff to do just that for his constituents. And I also welcome other members of this committee to visit the Center. It is one thing to hear about it; it is another to see it, and we are just across the river in Crystal City.

Once again, thank you very much for the opportunity to appear before you today, and I am pleased to answer any questions you may have at this time.

[The prepared statement of Mr. Kubiak follows:]

U.S. Immigration and Customs Enforcement

STATEMENT

OF

LEV KUBIAK
DIRECTOR

NATIONAL INTELLECTUAL PROPERTY RIGHTS
COORDINATION CENTER

HOMELAND SECURITY INVESTIGATIONS
U.S. IMMIGRATION AND CUSTOMS ENFORCEMENT

REGARDING A HEARING ON

"COUNTERFEIT DRUGS: FIGHTING ILLEGAL SUPPLY CHAINS"

BEFORE THE

U.S. HOUSE OF REPRESENTATIVES
COMMITTEE ON ENERGY AND COMMERCE
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS

Thursday, February 27, 2014 – 10:00 a.m.
2322 Rayburn House Office Building

Introduction

Chairman Murphy, Ranking Member DeGette, and distinguished members of the Subcommittee:

On behalf of the Department of Homeland Security (DHS), thank you for the opportunity to testify before you today to discuss the efforts of U.S. Immigration and Customs Enforcement (ICE) to combat the illegal importation and sale of counterfeit, unapproved, and/or adulterated pharmaceuticals.

ICE primarily consists of two operational programs: Enforcement and Removal Operations (ERO) and Homeland Security Investigations (HSI). Guided by ICE's prioritized enforcement principles, ERO identifies and apprehends criminal and other removable aliens, detains these individuals, and, removes individuals who are illegally present (or otherwise subject to removal) from the United States. HSI is responsible for a wide range of domestic and international criminal investigations arising from the illegal movement of people and goods into, within, and out of the United States, often in coordination with other federal agencies.

ICE's Role

ICE has a legacy of engagement in enforcement against intellectual property (IP) crime that spans from our past as U.S. Customs Service investigators to our present role as Homeland Security investigators. ICE is the lead agency in the investigation of intellectual property violations involving the illegal importation and exportation of counterfeit merchandise and pirated works, as well as associated money laundering violations. In coordination with U.S. Customs and Border Protection (CBP), we target and investigate counterfeit merchandise

and pirated works and we seize and forfeit goods associated with these investigations, such as those that infringe on trademarks, trade names, and copyrights. Investigating counterfeit pharmaceuticals falls within ICE's broad IP mandate.

ICE recognizes that no single U.S. law enforcement agency alone can succeed in the fight against IP crime. Rather it is essential that all relevant federal agencies work together and with IP industry partners to confront this challenge. Furthermore, law enforcement efforts alone will not fully address this growing problem. Indeed, public education, demand reduction, and global collaboration are critical to the success of this effort. To focus government efforts and to enhance efficiency, the former U.S. Customs Service, now known as ICE, formed the National Intellectual Property Rights Coordination Center (IPR Center), which combats violations of intellectual property rights, with a focus on trademark and copyright infringement.

Pursuant to the Prioritizing Resources and Organization for Intellectual Property Act of 2008 (Pro-IP Act, Public Law 110-403), U.S. government-wide intellectual property enforcement is coordinated by the White House Office of the U.S. Intellectual Property Enforcement Coordinator (IPEC), which is responsible for strategic planning and coordinating Federal efforts to address IP infringement. The IPR Center collaborates regularly with IPEC on IP policy issues.

The IPR Center

The former U.S. Customs Service established the IPR Center in 1999, but following the events of 9/11, priorities were necessarily shifted and the IPR Center could not be adequately staffed. ICE rejuvenated the IPR Center in 2008, and it now stands at the forefront of the U.S. Government's law enforcement response to global intellectual property theft.

The mission of the IPR Center is to address the theft of innovation that threatens U.S. economic stability and national security, undermines the competitiveness of U.S. industry in world markets, and places the public's health and safety at risk. The IPR Center brings together many of the key domestic and foreign investigative agencies to efficiently and effectively leverage resources, and promotes the skills and authorities to provide a comprehensive response to IP crime.

The IPR Center, located in Arlington, Virginia, operates on a task force model and is comprised of 21 relevant federal and international partners. While I serve as the Director of the IPR Center, I work with Deputy Directors from both CBP and the Federal Bureau of Investigation (FBI). The IPR Center includes embedded team members from: HSI, CBP, the Food and Drug Administration (FDA), the FBI, the U.S. Postal Inspection Service (USPIS), the Department of Commerce's International Trade Administration and U.S. Patent and Trademark Office, the Defense Criminal Investigative Service, the U.S. Consumer Product Safety Commission (CPSC), the National Aeronautics and Space Administration (NASA), the Naval Criminal Investigative Service, the Army Criminal Investigative Command Major Procurement Fraud Unit, the U.S. Air Force Office of Special Investigations, the Nuclear Regulatory Commission, the U.S. Department of State's Office of International Intellectual Property Enforcement, the Defense Logistics Agency, and the Inspector General's Office from the General Services Administration.

In 2010, the Government of Mexico and INTERPOL joined the IPR Center as our first international partners. Since then, the Royal Canadian Mounted Police and Europol have joined as partners as well. While the Department of Justice (DOJ) is not a formal partner at the IPR

Center, trial attorneys from the Computer Crime and Intellectual Property Section (CCIPS) regularly provide input on ongoing enforcement operations and policy.

Protecting Health and Safety

The illegal importation, distribution and sale of counterfeit pharmaceuticals pose a significant and growing threat to public health and safety. Working collaboratively with our law enforcement partners, the IPR Center has developed numerous initiatives and interdiction efforts to combat the infiltration of counterfeit, unapproved, and/or adulterated drugs entering the United States through a variety of means, including ports of entry, international mail facilities and express courier hubs. Our strategy is to attack the entire international supply chain, from manufacturer to distribution point and identify, disrupt, and dismantle the international criminal networks responsible for distributing counterfeit pharmaceuticals, by seizing the counterfeit product, criminal proceeds, and assets facilitating the crime, and bringing the individuals responsible for the criminal activity to the justice system to hold them accountable for their actions. This strategy requires a robust collaboration through our Attaché network with foreign counterparts where the majority of counterfeit items are made or through which they are transshipped en route to the United States and all of our trading partners worldwide.

Operation Guardian

Operation Guardian (Guardian) is the IPR Center's public health and safety initiative. Guardian was initiated in October 2007 in response to the Interagency Working Group on Import Safety and several incidents in which hazardous imports into the United States caused serious public safety concerns.

In developing Guardian, HSI, through the IPR Center, solicited the assistance of numerous law enforcement and regulatory agencies, including CBP, FDA, USPIS, DOJ CCIPS, CPSC, and the U.S. Department of Agriculture (USDA). These agencies formed a Headquarters Working Group to target high-risk commodities from foreign sources. The template we use today for surge group operations is based on the findings of this working group.

Since the inception of Guardian in fiscal year (FY) 2008, HSI has initiated 916 investigations resulting in 334 criminal arrests, obtained 419 indictments, secured 288 convictions, and worked with CBP to make more than 3,000 seizures valued at over $195 million (based on the Manufacturers Suggested Retail Price (MSRP) for the items if genuine).

Operation Apothecary

Operation Apothecary (Apothecary), which falls under the auspices of Operation Guardian, works to combat the growing use of the Internet in illegal drug distribution. Criminals, posing as legitimate pharmaceutical providers, use the Internet to advertise purportedly FDA-approved prescription drugs, and/or less expensive unapproved foreign alternatives, all without requiring a valid prescription. The consumer purchases the pharmaceutical with the belief that the product advertised is a legitimate product, but in fact, is often purchasing a counterfeit or unapproved version of the drug manufactured under unknown conditions or not subjected to any safeguards or quality control regimes. Apothecary addresses, measures, and attacks potential vulnerabilities in the entry process to attack the smuggling of commercial quantities of counterfeit, unapproved, and/or adulterated drugs through the Internet, international mail facilities, express courier hubs, and land borders.

Through Apothecary, participants detect, seize and forfeit commercial shipments of illegally sold, shipped, and/or imported pharmaceuticals and scheduled drugs. The ultimate goal of Apothecary is to identify and dismantle domestic and foreign organizations that illegally sell, ship, import and/or distribute pharmaceuticals and scheduled drugs in the United States.

In support of the Apothecary mission, IPR Center personnel coordinated and conducted periodic enforcement surges in conjunction with ICE, CBP, FDA and USPIS at international mail facilities and express courier hubs throughout the United States. Since FY 2010, as part of Apothecary, HSI has arrested 115 individuals and obtained 112 indictments resulting in 99 convictions. There also have been 1,048 seizures worth approximately $20 million (MSRP).

Operation Pangea

Websites offering counterfeit pharmaceuticals are a growing global phenomenon in the area of IP crime. Patients and consumers around the world are suffering from the negative side effects of counterfeit medications, which often contain unapproved, dangerous, substandard products. In response, Operation Pangea was organized by INTERPOL, with participation by ICE, CBP, FDA, and USPIS, to target the advertisement, sale, and distribution of counterfeit drugs and medical devices that threaten worldwide public health and safety.

Conducted on a yearly basis, the intent of each Pangea operation is to build upon global best practices identified from previous operations and collectively develop a collaborative worldwide approach to combat the illegal trade of counterfeit and illicit medical products, particularly products that represent a serious risk to public health. In addition to the individual countries participating in Pangea, other major international organizations have joined the effort as well, including the Universal Postal Union and the World Customs Organization (WCO).

In 2013, nearly 100 countries participated in Pangea VI, which resulted in 213 arrests worldwide and the seizure of more than 10 million potentially dangerous medicines worth approximately $36 million. More than 13,763 websites linked to illicit online pharmacies were identified and shut down, in addition to the suspension of payment facilities of illegitimate pharmacies. Worldwide, approximately 534,562 packages were inspected by customs and regulatory authorities, of which 41,954 were seized. Among the fake medicines seized during Operation Pangea were antibiotics, cancer medication, anti-depression pills, and erectile dysfunction medication, in addition to illegal products labeled as dietary supplements.

Other Interagency Efforts

ICE shares its border security and trade mission responsibilities with its sister agency, CBP[1]. Therefore, ICE and CBP work closely to target counterfeit pharmaceuticals and other illicit goods crossing the borders, including through the co-location of personnel at the first Trade Enforcement Coordination Center (TECC). In May 2012, ICE and CBP formed the first TECC in Los Angeles, which services the Ports of Long Beach and Los Angeles. The TECC enhances communication and combines resources to identify and combat trade fraud and IP crime, including counterfeit pharmaceuticals. The TECC proactively identifies, interdicts, and investigates inbound cargo that may enter the U.S. commerce in violation of U.S. customs and trade laws. TECCs ensure joint CBP and ICE oversight and prioritization of the enforcement and interdiction process in the local area, and involve ICE early in the enforcement process. The

[1] CBP has broad authority to act against imports that violate U.S. laws and is the primary federal agency responsible for securing America's borders and facilitating lawful international trade and travel.

ICE is the principal investigative arm of DHS. ICE's primary mission is to promote homeland security and public safety through the criminal and civil enforcement of federal laws governing border control, customs, trade and immigration.

TECC concept is under development to be expanded to other ports of entry, with the next in Port Elizabeth, New Jersey, which will service ICE and CBP in New York City and Newark.

ICE also collaborates closely with personnel at CBP's Centers of Excellence and Expertise (CEE), including their CEE focused on pharmaceuticals, the Commercial Targeting and Analysis Center, and through the creation of the HSI-led National Targeting Center – Investigations (NTC-I). CBP established the CEE as a central point of contact for inquiries and resolution of issues regarding pharmaceutical, health and chemical imports. By having a central point of contact for importer participants at the CEEs, CBP is able to increase uniformity of practices across ports of entry, facilitate the timely resolution of trade compliance issues nationwide, and further strengthen critical agency knowledge on key industry practices. The CTAC is a CBP facility designed to streamline and enhance federal efforts to address import safety issues by improving communication and information-sharing and reducing redundant inspection activities. The NTC-I is a CBP and HSI collaboration to enhance the current partnership with the existing CBP equities at the NTC-Passenger and NTC-Cargo and ICE's Trade Transparency Unit. The cornerstone of the NTC-I is enhance and support ongoing HSI investigations, provide quality investigative referrals and intelligence to HSI field offices, and expand current collaboration with CBP.

ICE participates in several other interagency efforts to protect the health and safety of the public, including through initiatives led by the Intellectual Property Enforcement Coordinator (IPEC). For example, ICE played a significant role in helping develop the IPEC's 2013 Joint Strategic Plan on Intellectual Property Enforcement and the Counterfeit Pharmaceutical Inter-agency Working Group Report to the Vice President and Congress, and is carrying out the pertinent recommendations in those reports. Through the IPEC, the U.S. Government is

pursuing an innovative and multi-pronged strategy to combat infringing foreign-based and foreign-controlled websites by encouraging cooperation by law enforcement, development of voluntary best practices, and international leadership. The IPR Center shares the investigative outcomes and trend information that we obtain with interagency partners and the IPEC to further inform their policy development, including strategic plans, the U.S. Trade Representative's Special 301 Process and the Administration's legislative recommendations.

ICE's International Efforts

ICE-HSI International Operations represents DHS's largest investigative law enforcement presence abroad and strongest protection beyond the border. HSI-International Operations has the broadest international footprint in DHS with 67 offices in 48 countries, which includes representatives at eight Department of Defense Unified Combatant Commands, staffed by nearly 400 personnel.

Cooperation with our international law enforcement partners is critical in combatting copyright and trademark infringement overseas and effectively protecting and enforcing American intellectual property rights holders. U.S. Government Attachés in a number of agencies, including HSI, Department of Justice, FDA, and the U.S. Patent and Trademark Office, work with international organizations and foreign law enforcement counterparts to build capacity, strengthen relationships, and conduct joint enforcement activities. ICE, as the world's largest customs investigative entity, is recognized as a worldwide subject matter expert on criminal customs matters, and holds the Chair for the Enforcement Committee within the WCO, an international organization that shares best practices among Customs officials and seeks multilateral cooperation to address emerging threats.

Our efforts to work with our international counterparts have resulted in numerous successful IP enforcement efforts. For example, in September 2013, Martin Paul Bean, III, of Boca Raton, Florida was sentenced to two years in federal custody for operating an illicit pharmaceutical scheme out of his home that sold more than $7 million worth of unapproved and misbranded oncology drugs. The HSI and FDA investigation began in early 2010 after law enforcement authorities from the United Kingdom's Medicines and Healthcare Regulatory agency advised U.S. authorities they had intercepted a shipment of an unapproved form of an oncology drug sent from a company in Pakistan to Oberlin Medical Supply in San Diego. Bean ordered the unapproved drugs from foreign sources in Turkey, India, and Pakistan and sold the drugs to doctors in the United States at substantially discounted prices. The FBI and the U.S. Postal Service also assisted with the investigation as well.

In August 2012, the IPR Center, HSI Attaché Brazil, the Brazilian Federal Highway Police, Brazilian Customs, the Brazilian Health Agency, and local police participated in a two day IP crime training. Following the training, federal law enforcement officers in Brazil initiated a five day operation at highways connecting the Tri-border region to Sao Paulo. The operation resulted in 36 arrests, and the seizure of counterfeit goods valued at approximately $2.4 million. The goods included counterfeit pharmaceuticals, 490 kilograms of marijuana, six guns, and 38 vehicles, and the equivalent of $86,000 in United States currency.

The IPR Center successfully brings together members of industry, state and local partners, federal government and international counterparts to train, exchange best practices and ultimately remove counterfeit and pirated products from the marketplace and put the criminals behind them in jail.

Challenges Ahead

I am regularly asked what challenges lie ahead in IP crime enforcement -- what tools or new laws are needed. As ICE conducts multiple enforcement operations, some of which I described above, we observe trends in IP crime and we have made a number of critical observations.

Our biggest challenge is that criminals are now willing to counterfeit and market any product that will sell, regardless of whether it could result in serious and significant injury to consumers or the public. ICE has investigated cases involving counterfeit toothpaste that contained a component found in antifreeze. In May 2013, following a probe by HSI, with assistance from CBP, an Argentine man was sentenced to a year in prison for conspiracy to distribute a controlled substance, including several drugs used to treat anxiety (e.g., Lorazepam, Diazepam, and Alprazolam); Ketamine, which is used for inducing anesthesia; and Sibutramine, an anorexiant not available in the United States. When HSI searched a storage unit and apartment rented by the defendant they discovered nearly 60 boxes containing more than 700,000 prescription tablets and thousands of empty pill bottles and bottles with labels, as well as a computer containing spreadsheets documenting sales of pharmaceuticals to customers throughout the United States. CBP laboratory analysis revealed many counterfeit or unapproved drugs with and without active substances. Some subject tablets were observed to be severely under-potent or containing the incorrect drug substance.

The IPR Center recognizes that law enforcement efforts alone are not enough to succeed in the fight against intellectual property crime. Rather it is essential that all relevant federal

agencies work together with industry to confront this challenge. Furthermore, public education, demand reduction, and global collaboration are critical to the success of this effort.

To help educate consumers on emerging dangers of counterfeit products and facilitate productive partnerships with the public and private sectors, the IPR Center launched Operation Joint Venture. This effort is designed to increase support, communication, and cooperation for our ongoing IPR enforcement initiatives and our critical public health and safety efforts. Operation Joint Venture is the IPR Center's method to provide industry with valuable information about our efforts to combat the importation of hazardous and counterfeit products, and it gives industry a point of contact they can use to provide us with leads and tips regarding efforts to compromise intellectual property rights. Also, we have developed a website, www.iprcenter.gov, where the public can obtain information on the efforts of all IPR Center partner agencies to combat IP crime and we have placed a button on the website where consumers can report allegations of counterfeit or pirated products.

Criminals' use of the Internet also poses a significant challenge to law enforcement. When a criminal never has to meet his victim face-to-face, but can hide behind what appears to be a legitimate site, consumer fraud can run rampant. Criminal networks are becoming increasingly sophisticated in conducting fraud over the Internet, which in return requires us to have sophisticated cyber investigators. Increasingly, criminal networks using multiple servers located in different countries across the world, including countries that may not be willing to cooperate with the United States on law enforcement issues, has created a challenge for criminal investigators because of the complexity of collecting electronic evidence. Approximately 250 of ICE's nearly 7,000 agents are trained and classified as Computer Forensic Agents (CFAs). These CFAs are essential to IPR Center efforts to combat counterfeit pharmaceuticals. A recent

Operation In Our Sites[2] enforcement action saw the deployment of five percent of ICE's CFAs on one day to secure the electronic evidence from just nine websites, and they will be heavily involved in sorting through the evidence for potential prosecutions.

Additionally, while ocean-crossing shipping containers are necessary to move bulk quantities of counterfeit items such as handbags, shoes, batteries or holiday lights, other high value items, including counterfeit pharmaceuticals, are being smuggled in smaller quantities through mail and/or express courier parcels. IP thieves are taking advantage of the lack of advance information or formal entry process at mail and courier facilities to smuggle products into the United States. ICE is working closely in tandem with CBP to improve targeting, information sharing, and adopting best practices to ensure that our limited resources are focused on finding the most egregious violators.

Finally, IP cases demand attention from criminal investigators and regulatory agencies. At a recent industry open house hosted by the IPR Center, more than 15 diverse industries were represented that collectively employ hundreds of thousands of Americans and produce substantial revenue in sales and taxes. This included pharmaceutical companies, electronics manufacturers, luxury goods corporations, software and electronic game developers, footwear and apparel producers, and entertainment conglomerates. Each of these industries makes a compelling case for government assistance in IP crime enforcement. We take our responsibility to these companies and their employees and most importantly, to the U.S. consumers very seriously. While ICE is committed to working with each of these industries and others who want

[2] Operation In Our Sites identifies, targets and seizes Internet domain names that defraud U.S. consumers and businesses by trafficking infringing goods, pursues assets and criminally prosecutes principals. In Operation In Our Sites, HSI and DOJ pursue the seizure and civil forfeiture of domain names under 18 U.S.C. § 981, civil forfeiture, which is the same authority used to seize tangible property or assets used in the commission of crimes.

to cooperate with us on this issue, due to limited resources, ICE's priorities in IP crime enforcement remain to protect health and safety, the military supply chain, and the American economy.

Conclusion

Thank you once again for the opportunity to appear before you today to discuss the work of ICE and the IPR Center in protecting U.S. consumers from dangerous counterfeit, unapproved, and/or adulterated pharmaceuticals. This is an issue of critical importance as it directly threatens worldwide health and safety.

I would be pleased to answer any questions that you may have at this time.

Mr. MURPHY. I thank you both our witnesses today for giving us some honest, solid and somewhat chilling testimony of this huge public health risk.

Mr. Sklamberg, in your video you showed Alli, that drug there. I had referenced something in my opening statement about an emergency room doctor in Texas ordering this drug from a rogue Internet pharmacy. Was that the same pharmacy, do you know?

Mr. SKLAMBERG. I don't believe it was the same one.

Mr. MURPHY. But he suffered a stroke. Is that correct?

Mr. SKLAMBERG. Yes, the one you are referring to, Mr. Chairman.

Mr. MURPHY. And unfortunately, he wasn't alone. I mean, many, many Americans, there are dozens of cases of death or serious injury suffered from these counterfeit, unapproved drugs from these rogue Internet pharmacy sites. Is that correct?

Mr. SKLAMBERG. That is correct, and in fact, the illnesses that we know about would severely understate what is actually happening because, as you pointed out, Mr. Chairman, and some of your colleagues have, a lot of times the patients who are receiving these drugs are already quite sick, so if you are taking Avastin and you have cancer, the Avastin, let's say it is counterfeit and let's say completely doesn't work, it has no active ingredients, you may well end up dying from your cancer. The doctor who is giving you the Avastin might not know that, in fact, the Avastin was counterfeit and might think that you had died from your cancer despite getting real Avastin, and so it is very hard to establish the cause and effect. So what instances we have we think severely and absolutely understate the effect and the problem.

Mr. MURPHY. Thank you. Are you aware that the National Association of Boards of Pharmacy and Legit Script indicate that 97 percent of online pharmacies are actually rogue Web sites that operate in violation of federal law?

Mr. SKLAMBERG. Yes, I have seen that statistic. The number of them is astonishing. I believe the GAO report as well has a rather astonishing number.

Mr. MURPHY. And my understanding is, when they don't recover any prescription, that number may go closer to 100 percent.

Mr. SKLAMBERG. It would go up.

Mr. MURPHY. Are you aware that according to a report from the PartnershipforDrug-Free.org, one in six Americans, or 36 million people, have bought medication online without a valid prescription?

Mr. SKLAMBERG. Yes.

Mr. MURPHY. And given all this, would it be fair to conclude there are probably millions and millions of Americans right now who have in their purse, their medicine cabinet, their pocket some significant safety risk of some medication that they may be taking today?

Mr. SKLAMBERG. There are millions of Americans now who may very well have what they think is medication but that in reality could make them very sick.

Mr. MURPHY. While I am asking these questions, I went into an online pharmacy, and there's cancer drugs here and hypertension and psychiatric drugs, et cetera. I could just tap a button here, buy these. No one is asking me any questions, and I would assume that

none of that is helpful. So this is really a major public health nightmare.

Mr. SKLAMBERG. It is a major and growing problem.

Mr. MURPHY. Could the CD–3 device that the FDA is developing be made available to pharmacies or clinical settings or others to help spot counterfeit drugs?

Mr. SKLAMBERG. Right now it is still in the early stages. We developed it a short time ago. We have something like about 25 of them now. There are, to put the number in perspective, 1.2 million international mail entries in the United States every day, so we have about 25 of these. We are testing them. We are working on agreements with private industry to scale it up.

Mr. MURPHY. Just make sure that those aren't counterfeit?

Mr. SKLAMBERG. Yes. No, this one is real. But they are an important tool because they can do kind of a quick test, but they are not a panacea for two reasons. First of all, in terms of building a criminal law enforcement case, it catches what you think is counterfeit. If you are actually going to build a criminal case, then you have to test it and send it to a lab and do that right because the criminal law has standards for evidence that are, you know, awfuly stringent.

Mr. MURPHY. There are also spectrometers that test the chemical content, and we will probably hear about that from the second panel.

Mr. SKLAMBERG. Yes.

Mr. MURPHY. Let me ask this. Heather Bresch, who is the CEO of Mylan Laboratories, which is headquartered in my district, has plants in the United States and India, and the New York Times recently stated that the increased regulatory scrutiny in India was long overdue. Do you agree that we need to have greater scrutiny in places like India and China, and what are the concerns about counterfeit drugs specifically related to India?

Mr. SKLAMBERG. I would say that as the supply chain of both legitimate and counterfeit drugs grows and becomes more international, FDA has to step up its international presence, which is what we have been doing. So for the legitimate supply chain, we have been using the tools that you gave us in FDASIA, for example, with ways of defining risk more clearly, ways of keeping drugs out, to keep drugs that are suspected of being adulterated out. We have increased foreign presence and increased the number of foreign inspections, of the legitimate supply chain.

We have to act aggressively in the legitimate supply chain when we encounter fraud that calls into question the integrity of the products, the integrity of the applications, and of course, as the legitimate industry grows, there is also the illegitimate industry around the world that is growing and what is happening that makes it particularly challenging for us from a law enforcement perspective is, it is no accident that in the counterfeit industry, it is developing in places where we do not have mutual legal assistance treaties, in places where we don't have extradition agreements, and it makes it harder for us to investigate those folks if they are in a country where we don't have the normal—we don't have the avenues of federal criminal law enforcement cooperation that we do in some other countries. So they are smart, they are

careful, and what they are doing is evil, and so we have to, when we do catch them, be very aggressive and try to get penalties that will not only put the person in prison but send a very, very strong message.

Mr. MURPHY. Thank you. I hope some other members will follow up and get some more details and recommendations for Congress.

I am out of time now, and turn to Ms. DeGette for 5 minutes.

Ms. DEGETTE. Thank you very much, Mr. Chairman.

Mr. Sklamberg, I just want to ask you quickly, it sounds like the penalties are too low for these counterfeiters, but on the other hand, if we increase the penalties, I want to make sure that that is going to have a deterrent effect. And I have a background before I came to Congress in criminal law, and one thing is that penalties don't deter people unless they think there is a likelihood that they might get caught. So I want to ask you, under the current system, if Congress just increased penalties and did nothing else, would that solve the problem?

Mr. SKLAMBERG. I think obviously penalties are an important step in the process, and let me agree with you, Ranking Member DeGette, and particularly single out one penalty that is particularly low. Foreign unapproved drugs which pose the same public health risk as a counterfeit drug, they could be——

Ms. DEGETTE. I understand. I am sorry, I don't have very much time. So if we increase those penalties, do you think that would defer people from counterfeiting those drugs?

Mr. SKLAMBERG. I think it would increase the frequency at which those cases are investigated. I think it would increase the frequency which——

Ms. DEGETTE. Because prosecutors would take it more seriously?

Mr. SKLAMBERG. Yes, and it would increase the penalties.

Ms. DEGETTE. Thanks. Now, do you think the problem of counterfeit drugs has gotten worse in recent years?

Mr. SKLAMBERG. Yes, and more sophisticated?

Ms. DEGETTE. And what new methods are the counterfeiters using to evade detection?

Mr. SKLAMBERG. They are more effectively hiding their money around the world and they are more effectively using Web sites around the world, hundreds and hundreds of rogue Web sites linked together. They resemble international organized crime and they are using the tools of it.

Ms. DEGETTE. OK. And that is why you think we need more serious investigation and prosecution?

Mr. SKLAMBERG. Yes. It is hard to prosecute international organized crime.

Ms. DEGETTE. They are going to be more sophisticated on that end, and we have got to be more sophisticated.

Can you talk to us for a minute about the Office of Drug Security, Integrity and Recalls, about when the office was created, what its mission is, and has it been successful in addressing the supply chain threat?

Mr. SKLAMBERG. Yes, the Office of Drug Supply, Integrity, and Recalls is part of the Center for Drugs' Office of Compliance, which I used to be director of. That office, ODSIR, as it is called, was created in 2011, I believe, and the part it plays in this is, it is the

office charged with implementing the track-and-trace aspect of the DQSA, and number two, when we have a counterfeit incident, part of it is law enforcement, part of it is public health notification.

Ms. DEGETTE. Right.

Mr. SKLAMBERG. So when we have an incident like with Avastin a couple of years ago, ODSIR sent out 1,500 letters to the medical community that note, here is a drug that you have that you think is Avastin that is actually a counterfeit. This protects patients, and also works to educate the medical community.

Ms. DEGETTE. So do you think it is working, or could it be working better?

Mr. SKLAMBERG. I think it is working quite well, and of course, we always want it to work better.

Ms. DEGETTE. And what could you do to make it work better?

Mr. SKLAMBERG. We would, and are, putting more resources into the problem, and we think working on implementing track and trace and further educating the medical community——

Ms. DEGETTE. Will help? OK.

Mr. DINGELL. Would the gentlewoman yield?

Ms. DEGETTE. I would love to yield to my friend, Mr. Dingell.

Mr. MURPHY. Just so people could hear, his microphone wasn't on, he is asking if you could submit to the committee what changes you would suggest that we make.

Mr. SKLAMBERG. We would be glad to.

Ms. DEGETTE. Thank you.

Now, I want to talk about resources for a minute because this FDA report that the chairman referenced in his opening statement says that the FDA is inspecting the foreign sites once every 9 years compared with the domestic sites every 2 years. Is that because of a lack of resources, Mr. Sklamberg?

Mr. SKLAMBERG. That was a relic of the way the drug industry looked years ago. FDASIA has——

Ms. DEGETTE. No, no, I mean why only once every 9 years? Is that because of a lack of resources to do it?

Mr. SKLAMBERG. That was the difficulty and expense of foreign inspections and the logistics.

Ms. DEGETTE. So your answer is yes?

Mr. SKLAMBERG. It is more challenging to do foreign inspections than domestic ones.

Ms. DEGETTE. OK. So what would the FDA need to do more frequent inspections? Would you need more resources to do that?

Mr. SKLAMBERG. As we have gotten more resources, we are able to increase the foreign inspections.

Ms. DEGETTE. So do you have enough resources to do these foreign inspections at the regularity you think you need to do them?

Mr. SKLAMBERG. We found that as the resources have increased with user fees, generic drug user fees, we have been able to increase it, so there is a direct relationship.

Ms. DEGETTE. So answer my question, please. Do you have enough resources to be able to do these inspections with the regularity you think you need to do them?

Mr. SKLAMBERG. We have the resources to do that now. The thing is, the situation is going to grow and grow and grow in the future as the percentage——

Ms. DEGETTE. You may not have the resources in the future?

Mr. SKLAMBERG. We would have to evaluate that in the future, but the situation is growing.

Ms. DEGETTE. OK. Thank you.

I yield back.

Mr. MURPHY. The gentlelady yields back. I now recognize the vice chair of the full committee.

Mrs. BLACKBURN. Thank you, Mr. Chairman. I want to thank you all for being with us today, and as you can see, it is an issue that we are all quite concerned about.

Mr. Sklamberg, CSIP, are you familiar with the Center for Safe Internet Pharmacies?

Mr. SKLAMBERG. I am.

Mrs. BLACKBURN. OK. Talk a little bit about who they are and how you are working with them, and just for the audience so that they will know, this is a group that is working Google, Go Daddy, IPEC, and trying to root out and keep some of these rogue Web sites out, and I would love to hear how you are interfacing with them because it seems as if they as an industry voluntarily are seeing some results.

Mr. SKLAMBERG. Yes. What we do with CSIP and with other folks in industry, be they credit card companies and others, is when we obtain information about a counterfeit or when industry does, they report it. Now, it is important that, for example, if it is a Web site, that the Web site be taken down; if it is a credit card company, that the credit account be disabled.

Mrs. BLACKBURN. Right.

Mr. SKLAMBERG. That is challenging.

Ms. BLACKBURN. Right, and payment processors.

Mr. SKLAMBERG. And payment processors as well.

Mrs. BLACKBURN. They have to participate with it. Has Google using the AdWords program to permit only U.S.-based online pharmacies, has that been helpful?

Mr. SKLAMBERG. Well, Google, as you know, entered into an agreement a couple of years ago where they forfeited $500 million because of the AdWord program had let in Canadian unapproved drugs. As a result of that, Google has been cooperating with us in our efforts.

Mrs. BLACKBURN. I think all of us have a tremendous amount of concern about the rogue Web sites and the rogue pharmacies and the damage that it does, and also the phishing and the data security issues, you know, it is just a really sticky ball of wax. So I am pleased to know that you are working with them and that you all are information sharing. Do you have the right authority to share information back and forth, or is there some changes that we should make to allow that?

Mr. SKLAMBERG. We have authority but one of the things that is difficult is, just as an example, Internet service providers want to be cooperative with us, so we have all these Web sites. Right now we have to get grand jury subpoenas to obtain information that they want to give to us about Internet service providers. We don't have an administrative subpoena authority targeted even to just Internet service providers. That is incredibly time-consuming and cumbersome for the Assistant United States Attorney who would

get the case and then for us, and it slows us down. We have to get court orders for some of our actions and subpoenas from others, and there would be a series of tools that we could get that would make these investigations move more quickly, and since we are dealing basically with organized crime, and that is what it is, organized crime using medicine, fake medicine, we have to have tools that are as fast as the criminals are.

Mrs. BLACKBURN. So as we look at data security and privacy issues, we need to review the elements that would allow you greater access and speed, a little bit of clarity?

Mr. SKLAMBERG. I think that would help.

Mrs. BLACKBURN. OK. Just as I have a little bit of time left, the botulinum issues, and I know everybody thinks in terms of just Botox but of course some of my researchers at our facilities in Tennessee, migraines, Parkinson's, cerebral palsy for children and they are using the drug there, and I know you all have had some processes in place dealing with the unlicensed suppliers of the botulinum and also your security supply chain pilot project. I am hopeful that you are seeing companies that are applying for this pilot. How many——

Mr. SKLAMBERG. Twelve so far, and the program basically just started, so——

Mrs. BLACKBURN. And you can take up to 100?

Mr. SKLAMBERG. That is correct.

Mrs. BLACKBURN. OK. And in what countries are the companies located?

Mr. SKLAMBERG. A variety of countries. I don't have the information. I can get that to you.

Mrs. BLACKBURN. I would like you to submit for the record just for our understanding as we go through and monitor it.

Mr. SKLAMBERG. We would be glad to.

Mrs. BLACKBURN. And I think also we are going to want to look at the successes that you have in analyzing the project, how you are equating the variables, and then what you see as your deliverables from that project as we move forward. But thank you for the update.

Mr. SKLAMBERG. Thank you.

Mrs. BLACKBURN. And I will yield back, Mr. Chairman.

Mr. SKLAMBERG. We would be glad to get that to you.

Mr. MURPHY. The gentleman yields back, and I now recognize Mr. Waxman.

Mr. DINGELL. Will the gentlewoman yield?

Ms. BLACKBURN. I yield.

Mr. DINGELL. Will you submit for the record the suggestions that you essentially were about to make to my colleague about what it is you need in the way of authority to address the questions that you were just describing?

Mr. SKLAMBERG. We would be glad to, sir.

Mr. DINGELL. I thank the gentlewoman for yielding.

Mr. MURPHY. Thank you. Now Mr. Waxman is recognized for 5 minutes.

Mr. WAXMAN. Thank you very much, Mr. Chairman.

Mr. Sklamberg, Congress has made a number of changes to FDA law in the last year and a half that should help fight counterfeit

drugs. For example, the FDA Safety and Innovation Act increased the maximum prison time to 20 years for knowingly and intentionally selling a counterfeit drug or knowingly and intentionally adulterating a drug such that it has a reasonable probability of causing serious harm or death, and the Drug Quality and Security Act sets up a track-and-trace system that over the next 10 years should make it increasingly difficult for criminals to introduce counterfeit drugs into the drug supply. Can you tell us how useful these new laws have been?

Mr. SKLAMBERG. They have been quite useful, but of course, they don't solve the entire problem. I will take track-and-trace as an example, which I want to thank this committee for its work on. Track-and-trace works when you have folks in the supply chain who want it to work, who want to look and see, is this a legitimate product that I'm dispensing or that I'm getting? What it doesn't do is stop a couple of unscrupulous people or criminals who want to have a transaction together where they are selling a crooked product. So if you have a person outside the legitimate supply chain selling to another person outside the legitimate supply chain administering it to somebody, that is not what track-and-trace is intended for, and track-and-trace wouldn't stop that. The increased penalties in FDASIA, Congressman Waxman, that you mentioned, are useful but there is still a major gap, and this is foreign, unapproved drugs, and they are as dangerous as counterfeits but you can use—in a criminal case—and I used to be a prosecutor, and one of the hard parts of it is, you have to prove what the person did and the mental state. So to get the counterfeit penalties, you have to prove that the person knew it was a counterfeit that they were selling and you have a conspiracy involving maybe dozens of people, hundreds of people, conceivably. We are not going to be able to arrest all of them.

So you may be able to show that, for example, it is a foreign, unapproved drug and not a counterfeit. If you sell a foreign, unapproved drug and the government can't prove fraud, which would often be the case because it is not purporting to be the U.S. drug, it is a foreign, unapproved drug, and a person gets sick and dies, that is a misdemeanor, even with the changes that were made over the last couple of years. If you are selling a dangerous product that causes a death, then the criminal penalty under federal law in that situation would be a misdemeanor.

Now, if there is fraud, the penalties go up under the Food, Drug, and Cosmetic Act. There is also mail fraud, wire fraud, other statutes, but we have that gap.

Mr. WAXMAN. I also mentioned in my opening statement that if you prove an intent to violate the law, which is necessary before you can win a criminal case for drug counterfeiting, then even if we win, the maximum penalty for some violations with potentially life-threatening consequences is only 3 years. Isn't that correct?

Mr. SKLAMBERG. Under the Food, Drug, and Cosmetic Act, for fraud, it would be 3. Specifically for counterfeit, it is higher. But again, counterfeit versus foreign unapproved from a public health consequence, there is really often not much of a difference.

Mr. WAXMAN. So what impact do these weak penalties have on our ability to deter drug counterfeiting?

Mr. SKLAMBERG. They do significantly. I mean, even at the front end. When a case is presented to a federal prosecutor who has 200 other investigations and they have narcotics conspiracies, public corruption, fraud, they are also looking at this. It is not an area of law they have seen before, and if an agent comes to them and says here is a case and they are looking and they will say, well the penalty is 1 year or 3 years, so I can do an investigation, take 2 years, put the other cases in the back of my file cabinet, and as I look at the federal code is, and the federal is Congress's priority for the crime, it is 3 years, the penalty that was in place since 1938. Rationally, that prosecutor is going to look at this and say should I prioritize this, and I am not faulting that prosecutor. That would have been my calculus. And it affects the whole system and kind of what drives the priorities in the whole system.

Mr. WAXMAN. Well, as my colleagues have mentioned, we need your recommendations for what additional tools you need to help prevent these kinds of actions and to discover such actions and to punish these actions, so we will look forward to getting further recommendations from you.

Thank you, Mr. Chairman.

Mr. MURPHY. In anticipating Mr. Dingell's question, details of that to this committee would be most welcome of all those processes Mr. Waxman asked for.

Mr. SKLAMBERG. And my answer is the same: we would be glad to.

Mr. MURPHY. Thank you. I am learning from the master. We only have a few months left of him, so we are all trying to learn from him.

I now recognize the vice chair of the subcommittee, Dr. Burgess, for 5 minutes.

Mr. BURGESS. Thank you, Mr. Chairman.

Mr. Sklamberg, I just really want to underline the point you just made, because on the penalty aspect, there is the deterrent, and then from a prosecutor's perspective, there is the priority, and we are damaging ourselves on both sides. We are not really providing a deterrent to the criminal, and then on the other side, we are not really prioritizing it or getting that impetus to the prosecutor. Did I understand you correctly?

Mr. SKLAMBERG. That is correct, Dr. Burgess.

Mr. BURGESS. And you think that changing that certainly would alter the priority from a priority standpoint at the prosecutorial level?

Mr. SKLAMBERG. It would make it easier for FDA to present those cases to prosecutors, yes.

Mr. BURGESS. Now, I do want to also go back to something that Ms. DeGette was saying on whether or not you have the funding that you need to inspect foreign sites. My understanding with the user fee agreement that was reauthorized in 2012 that we gave you, the FDA, the authority, you go where you need to go, you stay as long as you need to stay. Is my understanding correct?

Mr. SKLAMBERG. That is correct. One thing that we did in the last round of the user fee negotiations is went to a goal of parity of foreign and domestic inspections. So our foreign inspection numbers go up every year, and they are going to move up to get into

line with what the reality is. And of course, in the next round of user fee negotiations, I am sure we will look at what funding would be appropriate at that time.

Mr. BURGESS. And I also presume that during that time you will provide the committee with feedback as to the utility of that flexibility which the law, the committee enabled you to have the last time this was reauthorized.

Mr. SKLAMBERG. Yes, we would do that.

Mr. BURGESS. I will also point out, it was probably prior to your time with the agency, but Mr. Sharfstein came to this committee in 2007 or 2008, and in response to that same question, perhaps asked by another member, his answer was, we have everything we need.

So look, I have been on this committee for 10 years. I understand how this threat has changed, how the globalization of our economy has in fact affected your ability to do your work within our shores. So I appreciate the fact that it is an evolving process, but as Mr. Dingell has pointed out, we need your feedback so that we can help you keep up with the threat as it emerges. No one knew back in 1998 when some of these stories were first being written the degree to which it would evolve today.

Mr. SKLAMBERG. Yes, and that is why when we have the reauthorization of the user fees, I am sure, FDA and the committee will be engaged.

Mr. BURGESS. But don't wait. Let us know along the way.

Now, Ms. Blackburn was talking, and I didn't realize this, you have an agreement with Google about online pharmacies?

Mr. SKLAMBERG. There was, I believe it was in 2011, Google entered into a non-prosecution agreement where they forfeited $500 million, and as part of that, they established a compliance program.

Mr. BURGESS. Well, I don't want to speak out of school, but I just typed in "cheap Viagra" to Google, and you get a lot of sites. Now, the House server won't let me go to any of them, but just so you know, I am not sure that is working all that well. You might want to check it out when you get to a non-House server location.

I do need to ask you this. In 2008, this subcommittee had a big investigation on, it was an active pharmaceutical ingredient in the drug thinner heparin imported from China, and it had been contaminated with a product called hypersulfated chondroitin sulfate, if I recall correctly, and this product that was adulterating the heparin not only didn't thin the blood, it killed the patients. So it was a real troublesome aspect of that contamination. I don't feel like we have ever received the resolution of that that we should have, so can I just ask you today from the FDA's perspective, is this still an open and ongoing investigation or have we just simply said we are never going to get to the bottom of this?

Mr. SKLAMBERG. I would have to get back to you, Dr. Burgess, if I may, on that.

Mr. BURGESS. I wish you would.

Mr. SKLAMBERG. I mean, there is an aspect of it that is open but I want to make sure about that. I know committee counsel has been engaged with FDA on this issue.

Mr. BURGESS. And I would just make the point again that this molecule, hypersulfated chondroitin sulfate, was actually patented in China. I believe this was criminal attempt before the act occurred, and as a consequence, American patients were killed, and from the perspective of a physician, you think of somebody in a dialysis center flushing a line with heparin in a dialysis patient and they died right after that, I mean, that is something they are going to have to live with for the rest of their lives, so this is not a small and inconsequential thing. We make jokes about Viagra. But this was a terribly significant event in the lives of patients and physicians and nurses across this country. I really don't want to see us not resolve this problem.

So Mr. Chairman, I thank you for the time and I will yield back.

Mr. MURPHY. The gentleman yields back. I now recognize Mr. Dingell for 5 minutes.

Mr. DINGELL. Mr. Chairman, I thank you for your courtesy, and I commend you for this hearing. This is a very important hearing, and I think you have conducted it with extraordinary skill. I want to welcome a little later Dr. Prashant Yadav, which is a constituent of mine from the University of Michigan, who will be testifying on another panel. I am sorry I may not be able to be here to hear him.

Now, the Congress has taken some remarkable steps under the leadership of this subcommittee and this committee, giving FDA the authority they need by passing the FDA Safety and Innovation Act, which contained a number of provisions from my Drug Safety Enhancement Act, and most recently the Drug Quality and Security Act, and I think that we can all be proud of what we have done, but as indicated this morning, you pointed out that more can be done.

So answer if you please yes or no. One of the oldest challenges facing this Nation is the globalized nature of our drug supply chain. Commissioner, is it correct that 40 percent of the pharmaceuticals and 80 percent of the active pharmaceutical ingredients are made in foreign countries, yes or no?

Mr. SKLAMBERG. Yes.

Mr. DINGELL. You also have a big problem with some of the raw materials that later go into some of these pharmaceuticals in their finished form, do you not?

Mr. SKLAMBERG. Yes, that is correct.

Mr. DINGELL. You won't have time to answer this, but would you submit to us a brief comment as to whether you have authority to get at those people who manufacture and ship these into the United States and what additional authorities you need. The FDA Safety and Innovation Act gave your agency new authorities such as registration of foreign drug facilities and mandatory detention to help the agency deal with globalized drug supply chain. Is your authority there sufficient and what more is required, if you please, and answer that for the record.

Now, Commissioner, does FDA need additional authorities to keep Americans safe from counterfeit and substandard drugs that are coming in from abroad? Yes or no.

Mr. SKLAMBERG. Additional authorities would help us do the job.

Mr. DINGELL. Would you please define in a written response for inclusion in the record what is required there?

Now, Commissioner, does FDA have the resources it needs to carry out the new authorities granted to the agency in the FDA Safety and Innovation Act? Yes or no.

Mr. SKLAMBERG. We found that additional funding has helped us implement statutes like FDASIA.

Mr. DINGELL. Would you please submit to us what is needed there?

I happen to believe one key reason that counterfeit and substandard drugs are still a public health problem in the United States is the penalties are not sufficient to deter criminals from engaging in this activity. We seem to have an agreement on this. I am wondering if we should make the penalties which we collect be turned over to Food and Drug for additional enforcement. We do that on narcotics. Would this be helpful, and would you submit additional comments on how that would work to assist you with your business?

Mr. SKLAMBERG. We would be glad to.

Mr. DINGELL. Now, Commissioner, the maximum penalty you mentioned for these activities is only $10,000 or 3 years in prison. What should it be, and please define that by relating it to other questions involving narcotics and other events which are essentially similar? Would you submit that for the record?

Mr. SKLAMBERG. We would be glad to.

Mr. DINGELL. Now, Commissioner, is it correct that a Utah man was recently convicted of shipping over $5 million in unapproved drugs but received only a 1-year prison sentence?

Mr. SKLAMBERG. That is correct.

Mr. DINGELL. It seems rather contemptible.

Now, Commissioner, does FDA support strong civil monetary penalties against those charged with misbranding or counterfeiting drugs? Yes or no.

Mr. SKLAMBERG. We have in the past, I believe, but we can get back to you on that.

Mr. DINGELL. I would like to have something on the record. This reminds me of some great lines from Gilbert and Sullivan where the emperor indicated that it was his purpose so sublime to make the punishment fit the crime, and it would seem that this committee might want to do something of that sort today, and with your guidance, I think we can do it.

Mr. Chairman and my colleagues, I thank you. You have been very gracious to me this morning.

Mr. MURPHY. Thank you for also not singing those lines. We appreciate that.

I now recognize Mr. Griffith from Virginia for 5 minutes.

Mr. GRIFFITH. Thank you, Mr. Chairman, and I appreciate a lot of the questions that have been asked today. Let me ask some questions. I agree that we ought to figure out how we need to do this.

In regard to the situation that Mr. Dingell just mentioned in Utah, was the gentleman charged with any other crimes as a part of his scheme?

Mr. SKLAMBERG. I don't recall right now. Maybe I can get back to you if we can go ahead with another question.

Mr. GRIFFITH. That will be fine, because previously you correctly stated that a lot of times there are other charges that can be brought and that those may carry additional time, and so I guess what I would ask you is, is that since law enforcement can bring other wire fraud, mail fraud, whatever other charges, are you seeing that prosecutors are looking at that and raising up the priority on these crimes, and do we need to look at raising the penalties or do we just need to encourage prosecutors to go forward on all fronts as opposed to just one?

Mr. SKLAMBERG. I think what is happening, Congressman Griffith, is that when the case is initially presented to the prosecutor, they are not going to know whether they are going to be able to prove the fraud. So if they prove fraud, mail fraud's maximum penalty is 20 years, wire fraud is 20 years. If I sell you a fake Rolex and mail it to you, I am getting hammered. But they don't know if they're going to be able to prove that, and that is going to require a lengthy, years' long grand jury investigation.

Mr. GRIFFITH. So that is what discourages the prosecutions?

Mr. SKLAMBERG. Up front. Now, they are going to stack the charges the best they can if they prove it.

Mr. GRIFFITH. Sure. Now, obviously you have got a better shot with somebody in Utah of apprehending the individual than you do if they are from some foreign nation. Do you think that there is a better chance of collecting if we raise the penalties or the civil penalties and criminal penalties on the financial side more than the prison time, would that have a greater impact on the foreign imports?

Mr. SKLAMBERG. I think enhancing, for example, asset forfeiture and seizure would make a big effect because we can then take the money, which would have a big effect, deterrence, and also just reducing the upside of engaging in the criminal activity in the first place.

Mr. GRIFFITH. And I would agree that a lot of times that helps law enforcement in other fields and maybe this is one of those areas where we need to agree with Mr. Dingell when he said that perhaps we need to see that the enforcement agency gets at least a portion of those funds back to help them go after other bad actors in this area. I do appreciate that.

Let me ask you this, because you talked earlier about the prioritization of the various crimes by a prosecutor. If we raise these penalties up, at what point do we then deprioritize something else that we may consider important?

Mr. SKLAMBERG. I refer you to the Department of Justice. No, obviously that always is a problem, and to a prosecutor, every case is like their baby. But these are ones, I think because they are not common. Prosecutors or white-collar prosecutors will see mail fraud cases a lot, typical ones. They will see an odometer rollback case much more than they would see a counterfeit drug case. We will present the public health risk and we will convince them, and we are not saying Department of Justice is not cooperative; they are. It is just that the maximum punishments reflect Congress's sense of the priority, and you go into court, you have a trial. We have a case of an unapproved oncology drug. It was a trial, I believe, late last year. The person was convicted of over 20 misdemeanors, and

they were just misdemeanors. And to a rational prosecutor, do you want to spend a couple of years investigating what turned out to be a misdemeanor?

Mr. GRIFFITH. Sure. Let me switch gears, and I know it is not your area of jurisdiction but I would ask you to take the message back. We have been talking about FDA's authority over the drug supply chain, the Drug Quality and Security Act. That also had in it an issue of compounded drugs. Again, I know it is not your jurisdiction but I am continuing to follow the FDA's regulation activities in that area, and I would remind the agency that the DQSA was supposed to preserve the status quo when it comes to compounding drugs for office use and the repackaging of sterile drugs. Unfortunately, we are starting to see some reports that indicate that warning letters are being sent to prohibit these activities by traditional pharmacies, which were going on before we passed the bill and there was kind of an agreement between the House and the Senate that we would leave that as the status quo. So if you could just take it back and just tell them we will keep monitoring this, but I am concerned about that.

Mr. SKLAMBERG. OK.

Mr. GRIFFITH. I appreciate the work you are doing, and this hearing has been great. Thank you for your testimony, and I yield back, Mr. Chairman.

Mr. SKLAMBERG. Thank you, sir.

Mr. MURPHY. I now recognize Mr. Johnson for 5 minutes.

Mr. JOHNSON. Thank you, Mr. Chairman, and gentlemen, thank you for your testimony here today.

A large percentage of the people that I represent in eastern and southeastern Ohio are seniors, and often with limited and fixed incomes. There are many seniors who struggle with the cost of prescription drugs, and I have heard from some individuals who look to purchase drugs from Canada as a way to achieve drastic savings on their prescriptions. But I also have concerns about these practices and how to protect seniors from illegal pharmacies that may be distributing dangerous drugs and playing on their need to save.

So can you clarify the legality of seniors purchasing drugs either in person or online form Canada in order to achieve savings? Is this a legal practice?

Mr. SKLAMBERG. It is not a legal practice.

Mr. JOHNSON. It is not a legal practice?

Mr. SKLAMBERG. It is not legal.

Mr. JOHNSON. It is not legal? OK. Thank you.

Are most Internet pharmacies that purport to be in Canada actually not in Canada or certainly not providing drugs that originated in Canada?

Mr. SKLAMBERG. We found many, many online pharmacies that purport to be Canadian that are not Canadian, and it is a ruse that is used because a lot of vulnerable Americans and people who are very sick, seniors, they will think well, Canada, that is safe, and it turns out it is not Canada, it is someplace like we saw in the videos.

Mr. JOHNSON. Right. OK. Didn't FDA's Operation Bait and Switch survey show that about 85 percent of the online pharmacies were not from Canada? Is that true?

Mr. SKLAMBERG. I don't remember the exact statistic but the number is very high.

Mr. JOHNSON. Can you verify that back to me, please?

Mr. SKLAMBERG. It is correct, 85 percent.

Mr. JOHNSON. OK. Great. I am not a lawyer, but I don't typically ask questions I don't already know the answer to.

Mr. SKLAMBERG. Well, happily I had someone with me who could answer that.

Mr. JOHNSON. Thank you. Last year, the FDA worked with international regulatory and law enforcement agencies to shut down more than 1,600 illegal pharmacy Web sites. Is it true that most of the Web sites represented themselves as Canadian pharmacies claiming that the medicines that they sold were FDA approved or brand-name drugs, which they were not? Is that also true?

Mr. SKLAMBERG. I believe that many of them were. I am not sure if it is the majority. Yes.

Mr. JOHNSON. OK. Thank you.

Mr. MURPHY. Mr. Johnson?

Mr. DINGELL. Will the gentleman yield quickly? And I apologize to him.

This is a very excellent point. Would you submit something for the record so that we have something that would tell us what would assist the gentleman in understanding and help me to understand what is going on? And I will ask unanimous consent that the gentleman get the time back that I have taken from him.

Mr. JOHNSON. My pleasure, Mr. Chairman.

Even in the instance of an online pharmacy actually being in Canada, haven't some of these Internet pharmacies come under criminal investigation?

Mr. SKLAMBERG. Correct.

Mr. JOHNSON. All right. Well, shifting gears here just for a second, let me see if I can get through this next one.

In 2005, five teenage boys from three different States died after ingesting raw DXM powder that they bought in bulk from an online source. All of these tragic deaths were linked to the same Internet supplier operating out of Indianapolis where two men bought the drug in bulk from India, repacked it and sold it over the Internet. Investigators estimated they made $70,000 on sales of the misbranded drug into interstate commerce. This is every parent's worst nightmare. These three incidences have been the subject of scrutiny by this committee in the past when Chairman Upton introduced legislation on the matter in 2009, and I am proud to continue his work on the matter along with my colleague, Mr. Braley, through the introduction of the PACT Act, which would ensure that only legitimate entities registered with the FDA or comparable State agencies can purchase raw, bulk DXM. But there are still questions to be answered.

How did these young men obtain this drug online? How easy is it still for teens to purchase bulk drugs online in order to abuse the substances they get?

Mr. SKLAMBERG. It is very easy to purchase drugs online, whether it be teens or adults, and teens are better at using the Internet than adults.

Mr. JOHNSON. That is true. How prevalent are similar circumstances to the one I just described? How prevalent are they today in your experience and what you guys are seeing?

Mr. SKLAMBERG. We don't have a number specifically on teens versus adults but I would say it would stand to reason that that problem is prevalent.

Mr. JOHNSON. And it is growing.

Mr. SKLAMBERG. As the whole problem is, I would think so.

Mr. JOHNSON. What is being done to protect our Nation's young people and crack down on the illegal online drug sales targeting those who aim to abuse the substances?

Mr. SKLAMBERG. This would be part of our larger effort regarding rogue Internet pharmacies and foreign, unapproved drugs and counterfeit drugs, and obviously we prioritize more vulnerable victims in how we look at cases. So it would be part of that effort and obviously a very important part of it.

Mr. JOHNSON. OK. Thank you, Mr. Chairman, and I yield back.

Mr. MURPHY. Thank you. I now recognize Mr. Long for 5 minutes.

Mr. LONG. Thank you, Mr. Chairman, and thank you all for being here today and for your testimony.

Mr. Sklamberg, we asked you for a lot of things here today, a lot of questions we have of you, but a question I have for you is, if you were going to say the top three things that you need from us, that you need from Congress—now, you rolled your eyes, so I don't know what that means. But what can we do to help this dire situation?

Mr. SKLAMBERG. I wasn't rolling my eyes. I was thinking of——

Mr. LONG. When I first ran for office, my political people said that I did that and they told me not to do that.

Mr. SKLAMBERG. Oh, OK.

Mr. LONG. I still do it.

Mr. SKLAMBERG. I have never won an election nor run for office.

There are a series of things that I think would help us. One is, we talked about increased penalties, we talked about increased authorities.

Mr. LONG. Let me step you on that one. I had to step out of the room for a moment, and I don't know if I missed it or not, but what was the upshot of the video we saw, the gentleman on there that had this huge operation and apparently was induced to come to the United States after 7 months of communication? What was the final upshot of that?

Mr. SKLAMBERG. I don't remember what the ultimate disposition of the case was. He was arrested and sentenced but I don't know what the sentence was exactly. Oh, 87 months' imprisonment.

Mr. LONG. OK. I interrupted you. Number one is larger sentences. Number two?

Mr. SKLAMBERG. Yes. Now, that is one where we were able to prove the crime set at the higher penalties so ones I had mentioned before where we were unable to prove counterfeit drugs or fraud, then you end up with misdemeanors. So I think some of the increased enforcement tools we talked about, asset forfeiture, we talked about seizure, we talked about authority for us to obtain records that would be useful in these cases. I think that for us, we

are working with our foreign regulatory partners to enhance international cooperation, so that is more that FDA is doing, because as this international organized crime activity grows, that is something we have to do.

Mr. LONG. Are we getting more cooperation?

Mr. SKLAMBERG. From certain locations. It is sporadic, and as I had mentioned, I think, to one of your colleagues, international organized crime is clever and so they are going to situate themselves in places that have minimal cooperation with the United States, which makes detection harder and then makes investigation and apprehension and punishment harder on the back end.

Now, there are lots of countries we have very cooperative relationships with and their law enforcement.

Mr. LONG. Let us know what we can do to help you in those instances, if you will.

Mr. SKLAMBERG. Yes, sir.

Mr. LONG. And I would like to yield the balance of my time to my friend, Dr. Burgess, from Texas.

Mr. BURGESS. I thank the gentleman for the time.

Mr. Sklamberg and Mr. Kubiak, a question to both of you, but really an observation. What is the main driver here? It is the ability to make money, and of course, we know people make money in illicit drug trade all the time, but in this instance, you can do a counterfeit drug and no one is shooting at you on the border so in some ways it is a safer occupation for someone who wants to work on the wrong side of the law, and then as you pointed out, the penalties are not all that great.

Prior to the passage of the Medicare Modernization Act in 2003, you did see the news stories of large amounts of seniors getting on buses and going to Canada to shop for their medications. I don't know if you are aware of it, but the Affordable Care Act, which began working one way or another on January 1st, individuals now buying the individual market, a bronze plan, back in my home State of Texas, a deductible is $6,000. So people who have been used to receiving their medications where something is paid for by the insurance company now find themselves on the hook for a big part of that out-of-pocket expense. Some might even argue they are functionally uninsured when it comes to their prescription drug benefit. Are you prepared—what is going to be the natural tendency of someone who needs whatever, Crestor, Lipitor, and now they are having to pay the full out-of-pocket freight or the full freight for the cost of that medication, are they now likely to seek a lower cost on a ready device like their iPad or their laptop?

Mr. KUBIAK. Sir, yes, I think they are likely to seek that. I think the challenge, though, is they need to understand who they are buying it from and——

Mr. BURGESS. I have no quarrel with that, and I don't mean to interrupt you but the time is about to expire. Are you preparing yourself for the fact that there is the possibility that this type of activity may increase and may increase significantly for a population where historically it hasn't been happening?

Mr. KUBIAK. Congressman, I think across the board we have been preparing ourselves for an increase in continued growth unfortunately in this program and this problem over time, and as we

deal with that and deal with these illegal Internet pharmacy sites, we are trying robustly through education and also through enforcement to shut down and close out those opportunities to purchase those that are not secure sites.

Mr. BURGESS. I am just not sure you recognize what is coming your way, and I wanted to warn you what is right over the horizon because people are going to act in their own self-interest when they are faced with those questions.

Thank you, Mr. Chairman. I will yield back.

Mr. MURPHY. The gentleman yields. Yes, Mr. Dingell?

Mr. DINGELL. I ask unanimous consent that the gentleman's time be extended for 1 minute, and I would ask that the gentleman yield to me.

Mr. BURGESS. I knew there was a catch.

Mr. MURPHY. I will tell you what, Mr. Chairman, I have one follow-up question so I will give you a minute and I will give myself a minute.

Mr. DINGELL. I will yield to you, Mr. Chairman. You are more important than I am in this place.

Mr. MURPHY. Well, thank you. Let me start with mine and then I will yield the rest to you.

I want to ask Mr. Kubiak just as a follow-up, are there any legal barriers that constrain you in sharing information with foreign government partners and cooperating with efforts against counterfeit drugs?

Mr. KUBIAK. Sir, collectively, with all the agencies that are represented at the Center, we have quite a broad capability. Individually, each of the agencies has different capabilities to share. So for instance, within Homeland Security investigation, ICE, my parent organizations, we have the broad ability to share information with our customs counterparts around the world through customs mutual assistance agreements, which are outside of the normal mutual legal assistance treaties that normally are required and that Mr. Sklamberg talked about earlier in the day. We do have very broad authority to share, and combined, I think we have those authorities and those capabilities that we need to do that.

I would also suggest just if I may that an increase in the minimum mandatory sentence, an enhancement, if you will, for pharmaceuticals, for those engaged in the sale of illegal or unapproved drugs would be a significant improvement as well. We see kind of across the board that absent that increase in minimum mandatory sentence, an ability to hold those people more accountable that are engaged in the life-threatening activity would greatly enhance our capability to hold people accountable and also be a major deterrent.

Mr. MURPHY. Two things we will have to be addressing. One is the severity of punishment and second is the certainty of punishment.

I will yield a minute to Mr. Dingell

Mr. DINGELL. I thank my friend.

Has there ever been an international conference on this kind of thing so that we could get everybody together so we could all pull in the same direction?

Mr. SKLAMBERG. There have been through a variety of vehicles. The World Health Organization, for example, has been involved in this.

Mr. DINGELL. Would something of this kind be useful again, given the way things are changing?

Mr. SKLAMBERG. There is an established mechanism in the World Health Organization to deal with this issue and some other foreign ones. FDA is pursuing that aggressively.

Mr. DINGELL. All right. My next concern here is the hard fact, and that is, you have difficulty with the funding of your agency. If you could get the funding of your agency to do as it has done by the drug enforcement people where the proceeds of the stuff that is used in this could be seized and utilized for either sale so that you could get revenue or so that you could get other help, would that be of assistance to you in terms of increasing your levels of funding to deal with these kinds of questions?

Mr. SKLAMBERG. I think if I could get back to you on the record for that.

Mr. DINGELL. I would rather have you do that after you have had a chance to think about it.

Mr. Chairman, you have again been most courteous. Thank you.

Mr. MURPHY. The gentleman yields back, and with that, I really want to thank our two distinguished panelists. Mr. Sklamberg and Mr. Kubiak, you have been most helpful in giving us information. We will look forward to getting your follow-up information as soon as you can to this committee so we can take action from there. Thank you.

With that, those two witnesses are dismissed and I would like to ask the next set of witnesses on the second panel to come forward, and while you are coming forward and taking your seat, I will introduce the panelists. Dr. Marcia Crosse is the Director of Health Care at the United States Government Accountability Office. We are also joined by Dr. Prashant Yadav, who is here on behalf of the Institute of Medicine. He is the Director of their Health Care Research Initiative. He is also the director of the William Davidson Institute at the University of Michigan. We would also like to welcome Mr. John Clark, who is the Vice President and the Chief Security Officer of Global Security in the Compliance Division at Pfizer Incorporated, and our other panelist is Mr. Jean-Luc Moreau, the Head of Product Security at Novartis Corporation. Mr. Bruce Longbottom is the Assistant General Counsel at Eli Lilly and Company, and Ms. Elizabeth Jungman is the Director of Drug Safety and Innovation at Pew Charitable Trusts.

So if the witnesses are ready, I will prepare to swear all of you in. You are aware that the committee is holding an investigative hearing, and when doing so has the practice of taking testimony under oath. Do any of you have any objections to testifying under oath? All the witnesses say they do not. The Chair then advises you that under the rules of the House and the rules of the committee, you are entitled to be advised by counsel. Do any of the panelists today desire to be advised by counsel during testimony? And all of the panelists say no. In that case, if you would all please rise and raise your right hand, and I will swear you in.

[Witnesses sworn.]

Mr. MURPHY. So now you are all under oath and subject to the penalties set forth in Title XVIII, section 1001 of the United States Code. You may now each give a 5-minute summary of your written statement.

We will begin with Dr. Crosse for 5 minutes.

TESTIMONY OF MARCIA CROSSE, PH.D., DIRECTOR OF 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, PH.D., ASSISTANT GENERAL COUNSEL, ELI LILLY AND COMPANY; AND ELIZABETH JUNGMAN, J.D., M.P.H., DIRECTOR OF DRUG SAFETY AND INNOVATION, PEW CHARITABLE TRUSTS

TESTIMONY OF MARCIA CROSSE

Ms. CROSSE. Thank you.

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.

As we have just heard, 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, many are criminal enterprises that defraud consumers and deny patients effective treatments. So-called rogue Internet pharmacies often sell counterfeit prescription drugs, sell drugs that have not been approved for sale in the United States, sell drugs that are substandard and have no therapeutic value, and sell drugs that are harmful to consumers. Drugs sold by rogue Internet pharmacies have been found to contain too much, too little, or no active pharmaceutical ingredient, or the wrong active pharmaceutical ingredient. Even worse, these drugs may contain dangerous contaminants such as paint, heavy metals, or poison. Despite the risks, FDA reports that nearly one in four U.S. adults who shop online have purchased prescription drugs from Internet pharmacies.

Although the exact number of rogue Internet pharmacies is unknown and can change daily, one estimate suggests that there are over 36,000 in operation, up from an estimated 34,000 less than a year ago. Most operate from abroad. They illegally ship prescription drugs into the United States, sell drugs without a prescription and make efforts to evade scrutiny by Customs officials. A recent analysis by NABP, the professional organization for the State Boards of Pharmacy, shows that 97 percent of the Internet pharmacies it reviewed were out of compliance with laws or industry standards.

Rogue Internet pharmacies are often complex operations, and federal agencies face substantial challenges investigating and prosecuting those involved. Piecing together these operations can be difficult because they may be composed of thousands of related Web

sites and operators take steps to disguise their identities. The ease with which operators can set up and take down rogue Web sites also makes it difficult for agencies to identify, track, and monitor them because Web sites can be created, modified, or deleted in a matter of minutes.

The global nature of rogue Internet pharmacy operations complicates federal investigations. These Web sites and their operators are often located in countries that are unable or unwilling to aid U.S. agencies, with components of the operations scattered in several countries. If the clerk would show our first figure?

[Slide shown.]

This shows one rogue Internet pharmacy that registered its domain name in Russia, used Web site servers located in China and Brazil, processed payments through a bank in Azerbaijan, and shipped its prescription drugs from India.

Rogue Internet pharmacies use sophisticated marketing methods to appear legitimate. This makes it hard for consumers to differentiate between legitimate and rogue sites. 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. They may also fraudulently display an NABP logo on their Web site despite not having earned the accreditation.

Our second figure, if the clerk would post it, shows a Web site that may appear to consumers to be legitimate but the operators of this site pled guilty to multiple federal offenses including smuggling counterfeit drugs into the United States.

Even when such operations are uncovered, the Department of Justice may not prosecute because of competing priorities and the complexity of these operations. Rogue Internet pharmacy activity clearly violates the Federal Food, Drug and Cosmetic Act, but as we have heard, proving violations can be difficult and violations are subject to relatively light criminal penalties, a maximum of 3 years in jail or a fine of $10,000, or both.

When federal prosecutors do pursue such cases, they often charge operators with violations of other laws such as smuggling, mail fraud, wire fraud, or money laundering since these violations can be less onerous to prove and carry stronger penalties, up to 20 to 30 years in jail and fines up to a million dollars.

In summary, while federal agencies have conducted investigations that have led to convictions, fines and asset seizures, rogue Internet pharmacies continue to provide a convenient mechanism for criminals to sell counterfeit drugs or substandard prescription drugs to U.S. consumers with a low probability of being prosecuted.

Mr. Chairman, this completes my prepared statement. I would be happy to respond to any questions that you or other members of the subcommittee may have.

[The prepared statement of Ms. Crosse follows:]

United States Government Accountability Office

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

GAO-14-386T

GAO Highlights

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

February 27, 2014

INTERNET PHARMACIES

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

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.

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 rogue 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

[1]Counterfeit 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).

[2]We 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.

[3]Both 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.

[4]FDA, "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 rogue 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.[5] 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

[5]GAO, *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.

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 rogue 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.[9] 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]

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

[7]Misbranded 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.

[8]Intellectual 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.

[9]The 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.

[10]GAO, *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.

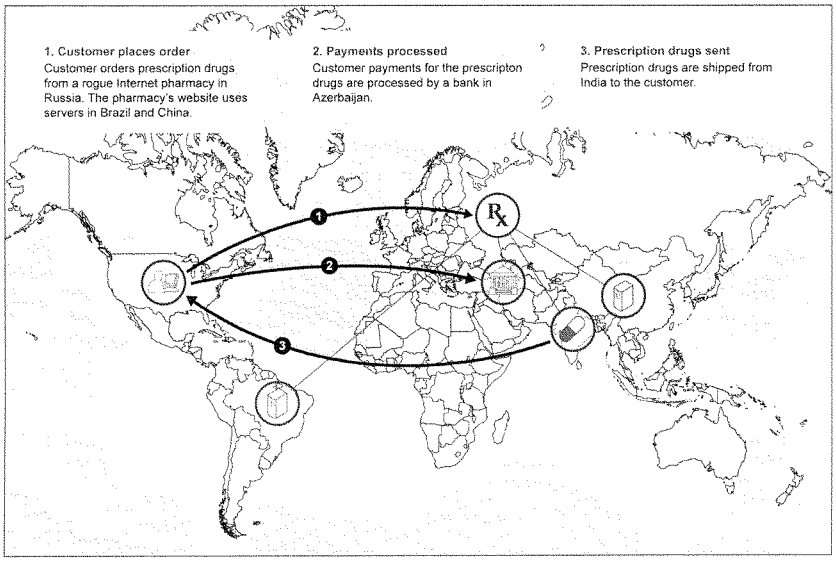
The Complex and Global Nature of Rogue Internet Pharmacies Poses Substantial Challenges for Federal Investigators and Prosecutors

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.

[11]See, e.g., 18 U.S.C. §§ 542, 545.

[12]See GAO-04-820.

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

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]

[13]See, 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

[14]See, 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) rogue, 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.

[15]National 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.

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

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 rogue 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-and-mortar 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]

[16]For 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).

[17]A 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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Mr. MURPHY. Thank you, Doctor.

I now recognize Dr. Yadav. Am I pronouncing that correctly, sir?

Mr. YADAV. Yes.

Mr. MURPHY. Thank you. You are recognized for 5 minutes.

TESTIMONY OF PRASHANT YADAV

Mr. YADAV. Good morning, Mr. Chairman, Ranking Member DeGette and members of the committee, my name is Prashant Yadav. I am the Director of the Health Care Research Initiative at the William Davidson Institute of the University of Michigan, and I served as a member of the Institute of Medicine Committee on understanding the global public health problem of counterfeit, falsified and substandard medicines.

The Food and Drug Administration had commissioned this study in 2011 to advance what at that time was a stymied public discourse on the topic of pharmaceutical crime. After deliberating and hearing public testimony for most of 2012, our committee released our findings and recommendations last year. I was also a member of another committee of the Institute of Medicine, which was on regulatory capacity building in developing countries. This study was also commissioned by the FDA Office of International Programs, and it dealt with questions more broadly of food and drug safety regulations and globalization. I would like to submit for your records copies the two mentioned IOM reports as well as the executive summaries of the two reports and an editorial on this topic. These documents discuss how improving the quality of medicines in this country depends to some extent on better medicine regulation abroad. These reports offer several suggestions as to how different federal agencies and international organizations can work together to improve global drug safety.

In my testimony, I will be using language which is consistent with the IOM report. The members of our committee chose to be clear that we saw two rough categories of dangerous medicines. First, we have falsified drugs, those that carry a false representation of identity or source or both. The other main category is substandard, meaning the medicines that fail to meet our national quality standards. We recognized that often these two categories overlap. But we felt that thinking about these two categories separately helps us characterize the causes of the problems and the solutions for them in a precise manner. We also agreed not to describe the drugs as counterfeit, because we felt this term tends to hold back discussion. Many speakers who use the term "counterfeit" use it to imply something more broad than the narrow legal word "counterfeit." The difference in these two meanings can cause confusion and can alienate generic drug companies, who sometimes view this as hostility to their products hidden in a discussion of counterfeit medicines. So our committee agreed that the problem of trademark infringement was not within our mandate. We attempted to understand the public health problem of poor-quality drugs and we limited our discussions to substandard and falsified, or fake, medicines.

The problem of falsified and fake medicines is undoubtedly the worst in the world's poorest countries, but poses a risk for American patients as well. We are living in what the Economist maga-

zine recently described as a golden age for bad drugs. Different drugs and drug ingredients are made in different parts of the world. Final drug formulations may be packaged and repackaged in different countries many times before reaching the final patient, and supervising these supply chains is a monumental task. The committee recommendations were for the U.S. FDA to share foreign inspections and work towards mutual recognition of inspections done by other stringent regulatory agencies. We reasoned that it is simply not good management to have, for example, Japanese, European, and U.S. inspectors repeating each other's work when so many factories in places like China and India go uninspected.

The key challenge is to identify gaps before product safety emergencies occur. Until recently, the inability to track a package of medicines from the factory to the patient was one such gap. Our committee had asked the Congress to authorize the FDA to establish a mandatory track-and-trace system in the United States. We were concerned that the FDA had received many unfunded mandates over the years, so we would also ask the Congress to allocate the appropriate funds to the agency to ensure the staffing and the technology that is needed does exist. This is consistent with the recommendations of the committee and the new Act, the Drug Quality and Security Act in November is very much in tune with what the committee had recommended. I would like to thank the Representatives here today for your work on that law.

Track-and-trace legislation is going to help but there are still many gaps in the supply chain. One of them is the question of Internet pharmacies. The IOM committee discussed this problem at great length. We reviewed research that states people buy drugs online for different reasons. Some can be described as lifestyle libertarians who believe they should be allowed to self-prescribe, others are bargain hunters who are looking on the Internet to get deals, and the third category are people who are genuinely trying to buy drugs for making sure they can get them with convenience. These customers do not understand the risk of their choices and do not see any better options.

So the committee recommended that the National Association of the Boards of Pharmacy has a program called the Verified Internet Pharmacy Practice Sites, or VIPPS. That program should be strengthened and encouraged. That was one of the strong recommendations from the committee.

One of the key things the committee recommended was to strengthen the wholesale market in the United States. We felt that there are three kinds of wholesalers. There are primary wholesalers, secondary wholesalers and wholesalers who are regional drug wholesalers, and it is easy for wholesalers to obtain licenses in one State and engage in commerce without federal or other States knowing about that.

Mr. MURPHY. I will need you to summarize because you have gone a minute over.

Mr. YADAV. So the committee recommended that FDA should work with State licensing boards and establish a public database to share information on wholesale licenses. This will prevent criminals from licensing in multiple States. On behalf of my colleagues

of the committee, I would like to once again thank the Representatives for including this provision in the DQSA law. We also believe that strengthening the drug wholesale supply chain will set a good example for other countries in the world.

Thank you, Mr. Chairman.

[The prepared statement of Mr. Yadav follows:]

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FALSIFIED AND SUBSTANDARD MEDICINES

Statement of

Prashant Yadav, PhD

Director, Health Care Research Initiative, William Davidson Institute, University of Michigan

and

Member, Committee on Understanding the Global Public Health Implications of Falsified, Substandard, and Counterfeit Medicines
and

Member, Committee on Regulatory Capacity Building in Developing Countries

Board on Global Health
Institute of Medicine
The National Academies

before the

Subcommittee on Oversight and Investigations

Committee on Energy and Commerce

U.S. House of Representatives

February 27, 2014

Good morning, Mr. Chairman, Ranking Member DeGette, and members of the committee. My name is Prashant Yadav. I am the director of the Health Care Research Initiative at the William Davidson Institute of the University of Michigan, and I served as a member of the Institute of Medicine Committee on Understanding the Global Public Health Problem of Counterfeit, Falsified, and Substandard Medicines. The Food and Drug Administration (FDA) commissioned this study in 2011 to advance what was at the time a stymied public discourse on the topic of pharmaceutical crime. After deliberating and hearing public testimony for most of 2012, the committee released our findings and recommendations last year. I also was a member of the Committee on Regulatory Capacity Building in Developing Countries. This study, also commissioned by the FDA Office of International Programs, dealt more broadly with questions of food and drug safety and globalization. I would like to submit for your records copies the IOM reports *Ensuring Safe Foods and Medical Products through Stronger Regulatory Systems Abroad* and *Countering the Problem of Falsified and Substandard Drugs*, as well the executive summaries of both reports and a BMJ editorial about the reports entitled "What to do about unsafe medicines?". These documents discuss how improving the quality of medicines in this country depends to some extent on better medicines regulation abroad. They offer several suggestions as to how different federal agencies and international organizations can work together to improve global drug safety.

In my testimony, I will be using language consistent with that of the report *Countering the Problem of Falsified and Substandard Drugs*. The committee members choose to be clear that we saw two rough categories of dangerous medicines. First, we have the falsified drugs: those that carry a false representation of identity or source or both. The other main category is substandard, meaning medicines that fail to meet national quality standards. We recognized that often these categories overlap. For the purposes of our report, thinking about these two broad groups helped us characterize the causes of the problem and think precisely about solutions. We also agreed not to describe the drugs

as *counterfeit*, because this term tends to hold back discussion. In a narrow, legal sense, a counterfeit drug infringes on a registered trademark. But most speakers who use the term *counterfeit* use it broadly, meaning something that deceives. The difference in these two meanings can cause confusion and alienate generic drug companies, some of whom see hostility to their products hidden in a discussion of *counterfeit medicines*. We accepted the narrow, legal meaning of *counterfeit*. We agreed that the problem of trademark infringement was not within our mandate. In our report, we attempted to understand the public health problem of poor quality drugs. For that reason, we limited our discussion to substandard and falsified (or fake) medicines.

The problem of falsified and substandard medicines is undoubtedly worst in the world's poorest countries, but poses a risk for American patients as well. We are living in what the *Economist* magazine recently described as "a golden age for bad drugs". Different drugs and drug ingredients are made in different parts of the world. Final drug formulations may be packaged and re-packaged in different countries many times before reaching a patient. Supervising these supply chains is a monumental task, and one that increasingly requires international cooperation. In 2011 the IOM report *Ensuring Safe Foods and Medical Products through Stronger Regulatory Systems Abroad* recommended ways for the US FDA to share foreign inspections and work towards mutual recognition of inspections done by other stringent regulatory agencies. We reasoned that it is simply not good management to have, for example, Japanese and American inspectors repeating each other's work, when so many factories in places like China and India go uninspected.

Most Americans have no reason to think about such improvements because our drug safety system usually works. When it fails, there is public outcry. You may remember how, in late 2012 state authorities in Tennessee alerted the CDC of a spike in cases of fungal meningitis. Investigators traced the outbreak to an injectable steroid made under unhygienic conditions at the New England Compounding Pharmacy. The contaminated drug killed 64 people. The hearings that followed the

outbreak brought to light a gap between state and federal regulatory oversight that was at the root of the crisis.

The challenge is to identify such gaps before a product safety emergency. Until recently, the inability to track a package of medicines from the factory to the patient was one such gap. Implementing a national drug tracking system is complicated, but it has been done, notably in Turkey in 2011. Our committee asked Congress to authorize the FDA to establish a mandatory drug track-and-trace system in the United States. We were also concerned that the FDA has received many unfunded mandates over the years, so we asked Congress to allocate the appropriate funds to the agency to ensure the staffing and technology upgrades track-and-trace will require. My colleagues and I were happy to see the president sign the Drug Quality and Security Act in November. This act clarified the FDA's authority over large compounding pharmacies. It also gives the agency the authority to implement a national track and trace system. This is consistent with the recommendations in *Countering the Problem of Falsified and Substandard Drugs*, and on behalf of my colleagues on the committee I would like to thank the representatives here today for your work on that law.

Track-and-trace legislation in the United States is going to help every intermediary on the supply chain have confidence in the quality of medicines. But there are patients who choose to circumvent the regulated supply chain. The internet facilitates this trade. To be clear, the committee saw no fault in regulated online pharmacies. Businesses such as Express Scripts or the e-commerce division of chain pharmacies can provide a valuable service, especially for people in remote areas, or people who are too busy to shop. The challenge is in distinguishing these businesses from criminal enterprises that may be shipping anything from anywhere.

The IOM committee discussed this problem in great length. We reviewed research that says people buy drugs online for different reasons. Some can be described as "lifestyle libertarians" who believe they should be allowed to self-prescribe; they may not approve of medicines regulation at all.

Others are bargain hunters, accustomed to using the internet to shop for deals. They may believe that these websites offer good prices by cutting out the middlemen. The internet marketplace also attracts the poor, the elderly, and the uninsured, people who see few other ways to afford their essential medicines. Some customers at online pharmacies do not understand the risks of their choices; others understand them well, but see no better options.

Navigating the internet drug market is complicated. The internet confuses the cues customers use to judge quality in a store. There is no pharmacist to counsel patients on a website. A site claiming affiliation with a respected chain might be lying. Odds are never on the patient's favor; illicit online pharmacies far outnumber the legal ones. (For example, a 2005 study of 11,000 online drug sellers claiming to be Canadian found that only 214 of them were registered with the Canadian authorities.) As part of their action against pharmaceutical crime, Interpol, an international organization for police cooperation, has organized a series of raids on illegal online pharmacies. Their 2012 raid included regulatory, customs, and police department in over 100 countries, closing over 18,000 sites and leading to 79 arrests. But the success of these operations may seem hollow. Shutting down a website is not satisfying when criminals can simply reopen at a different url.

The National Association of Boards of Pharmacy (called the NAPB) has an online pharmacy accreditation program called the Verified Internet Pharmacy Practice Sites, or VIPPS. To earn accreditation, online pharmacies must comply with state licensing requirements for both the state the head office is in, and all states to which they ship medicines. This means they are required to verify prescriptions, to submit to regular inspections, and to take the same quality assurance steps required on any brick and mortar pharmacy. Accredited pharmacies are allowed to display the VIPPS seal on their website. And, because the seal could be easily copied, the VIPPS website publishes links to both accredited businesses and known fraudulent ones.

Unsurprisingly, these VIPPS-certified businesses do not offer any particular discount over their brick-and-mortar competitors. This may be why even unlicensed internet pharmacies have advocates who believe the stores empower them to avoid artificially inflated medicine prices. They maintain that individual importation improves the competitiveness of the drug market and may drive down pharmaceutical costs in the United States. Our report did not endorse these arguments. We concluded that the VIPPS accreditation system should be widely promoted as a useful tool for patients who need to fill prescriptions over the internet. Some people have suggested that buying medicines online, except from VIPPS accredited sites, be made illegal. But such a law would be un-enforceable, so we did not recommend it. Beyond promoting verified pharmacies, we did not see any novel actions that could better control internet drug sales.

The committee did, however, recommend changes to the medicines wholesale market that could improve the safety of our drug supply. I should start with some background on medicines wholesale. There are three kinds of wholesalers. First, there are the primary wholesalers, who have agreements with the manufacturers. In the United States, McKesson, Cardinal Health, and AmeriSourceBergen control about 90% of the primary wholesale market. We also have several large, regional drug wholesalers. Lastly, there are many thousands of secondary wholesalers. Secondary wholesalers usually have no distribution contracts with manufacturers. They may trade in products other than drugs. And they do not have the same reputations to risk as the major companies.

The distinction between primary and secondary wholesalers is not always clear. Primary wholesalers may, for example, buy medicines from other wholesalers as well as manufacturers. Back-and-forth sales are common among drug wholesalers who need to buy and sell stock to accommodate market demand. That is, when a medicine is scare in one part of the country, they can buy the same medicines from another part of the country that may be flush with it. These markets are constantly fluctuating, and products can change hands many times.

Wholesalers may package and repackage products with every sale. This constant repacking introduces room for fake products, perhaps purchased unknowingly from another intermediary, to gain authentic labels. It also produces a supply of clean packaging that is not always properly destroyed. Because of these risks, and because of the sheer number of transactions in the secondary wholesale market, the committee concluded that secondary wholesale is the weakest point in the American drug distribution system.

Part of the problem is that state pharmacy boards license drug wholesalers, and their standards vary widely. Unscrupulous wholesalers can seek out licensure in states with low standards. Nevertheless, they trade in a national market, buying and selling products in response to national shortages or gluts. We recommended that all drug wholesalers be required to meet NABP accreditation standards. NABP accreditation requires background checks on senior operations, buying, and inventory staff, their supervisors, and anyone owning greater than 10% interest in the company if it is not publically held. The accreditation process also requires a review of wholesaler's record keeping and drug verification practices. Requiring wholesale accreditation of every business would limit the US wholesale market to only vetted firms and make the supply chain less permeable to criminals.

The committee also recommended that the FDA work with state licensing boards to establish a public database to share information on wholesale licenses. Until recently criminals whose wholesale licensure was revoked or suspended in one state could cross the state border and re-open. There was no national database of drugs wholesalers, so the authorities would be none the wiser. Starting the first of next year, the Drug Security and Supply Chain Act will require that all drug wholesalers to report crucial information to a central database. This includes all the states in which they hold license, all names under which they do business, the business contact information, and any disciplinary action against them including suspension or revocation of license. Failing to report the necessary information

promptly can result in suspension or revocation of license. On behalf of my colleagues on the IOM committee, I would like to thank the representatives for including this provision in the law.

We also believe that changes to the drug wholesale system in the United States could help build momentum for stronger wholesale controls in other parts of the world. Ours is not the only country with a chaotic drug wholesale market. My colleagues in developing countries deal with vastly more fragmented systems, and in their frustration with it, sometimes point out that even in the United States we have a hard time managing this step in the supply chain. By strengthening controls on our wholesale system, we can show leadership in taking the necessary steps to improve the market.

Because everywhere in the world legislators like you have the same questions: "what percent of our drug supply is compromised?" and "what drugs are the targets?" There is no good answer to those questions. One of our main conclusions was that this problem is hard to measure. Medicines are for sick people. Deaths from falsified and substandard drugs may appear to be the natural progression of an underlying disease. This is most true in parts of the world with weak medicines regulatory systems, limited surveillance of the drug market, and high all-cause mortality. These are the places that bear a disproportionate burden of the fake drug trade; places where untimely deaths are a sad, but unsurprising, part of life.

So deaths from fake drugs go largely uncounted, to say nothing of sickness, or time and money wasted in using them. As part of the dissemination of this report, the Institute of Medicine commissioned an analysis to estimate the excess deaths we can attribute to falsified and substandard antimalarials. The statisticians relied on a pooled analysis that scholars from the NIH Fogarty Center published in *Lancet* in 2012. They found that about 35% of antimalarial drugs in sub-Saharan Africa and Southeast Asia fail quality testing. Drawing on this figure, as well as information about the case-fatality of untreated malaria and the proportion of childhood fevers incorrectly treated with malaria medicine, the statisticians estimated that in sub-Saharan Africa alone fake antimalarials kill about 96,000 children

under five every year. I want to be clear that those 96,000 excess deaths should not, strictly speaking, be described as malaria deaths, but deaths resulting from fake malaria medicine. And I should also emphasize that those 96,000 excess deaths come from only one category of drug, for one disease. We don't have the proper information to make similar estimates for other diseases. But there is every reason to believe that the drugs used to treat pneumonia, diarrhea, and other routine infections of childhood are of also of uneven quality with sometimes deadly consequences.

Compared to most other medicines, we have a relatively good understanding of the fake antimalarials market, partly because the threat of drug resistance leads scientists to monitor antimalarial quality with some vigilance. For other classes of drugs the picture is less clear. The first step in a reliable drug quality survey is choosing a representative sample from the market. In poor countries, the drug market is chaotic; people buy medicine in all kinds of street markets and shops, not just from licensed drug stores. Monitoring these markets is the responsibility of the drug regulatory authority. Quality testing requires expensive equipment, trained analysts, and perhaps most of all, the ability to act when a dangerous product is found. These are not features of medicines regulatory systems in many developing countries.

Ultimately, the national regulatory authority assures the safety of the drug supply. Our report asked international donors to support the development of stronger regulatory agencies in low- and middle-income countries. This recommendation has special resonance for the United States. As a country, we have invested heavily in global health over the last twenty years, and the world is a measurably better place for it. Child and maternal mortality have dropped by almost 50% since 1990. Poorly made and fake medicines threaten this progress and invite diminishing returns on the American taxpayer's investment in global health.

The committee saw a role for development finance organizations in improving the quality of medicines. Running a modern pharmaceutical factory to international standards is expensive, especially

in developing countries with infrastructure problems. Manufacturing equipment must be bought on foreign markets with hard currency, currency that banks in these countries may not have or be willing to lend. These firms are often obliged to absorb their customer's debts, further reducing their working capital. In developed countries, businesses mortgage their assets to raise money, but mortgage laws tend to disallow this in developing countries. After development finance provides some initial capital investments, governments could take on manageable roles. For example, they could encourage good manufacturing through partnerships with foreign firms.

The problem remains that once drugs are circulating in poor countries, routine testing is difficult. Inspectors need sturdy, portable field assays that they can bring with them to remote places for random testing. The Global Pharma Health Fund (a charitable organization funded by Merck, Germany) developed a widely used portable analysis kit called Minilab. Minilab includes all the solvents and reagents needed for a range of basic drug quality analyses. US Pharmacopeia, USAID, the WHO, and various other organizations distribute these kits in their projects. While these kits are useful, there is always room for new, innovative drug testing technologies. The committee concluded that public funding could direct academic research to this important problem. The National Institute of Standards and Technology has the technical depth in physical and material science to manage such research. We suggested they use a Small Business Innovation Research awards (SBIRs) to direct scientists and engineers to develop durable field detection technologies for drug testing in developing countries.

Mr. Chairman, that concludes my testimony. Thank you and the members of your committee for the opportunity to participate in the hearing.

Mr. MURPHY. Thank you.

Mr. Clark, you are recognized for 5 minutes.

TESTIMONY OF JOHN P. CLARK

Mr. CLARK. Chairman Murphy, Ranking Member DeGette, members of the subcommittee, it is a pleasure to appear before you today to discuss an issue of great importance, the threat that counterfeit medicines pose to the health and safety of patients in the United States and around the world.

My name is John Clark, and I am the Chief Security Officer for Pfizer, Inc., and Vice President of its Global Security Team. Pfizer is a diversified global health care company and one of the world's largest biopharmaceutical companies. Our core business is the discovery, development and marketing of innovative pharmaceuticals for human health, and we are committed to ensuring the integrity of those products when they reach the market.

I am responsible for ensuring that programs are in place to protect Pfizer's personnel, real and intellectual property, reputation and, most importantly, the integrity of its medicines. Prior to joining Pfizer in 2008, I served as Deputy Assistant Secretary at Immigration and Customs Enforcement, responsible for the overall management and coordination of the agency's operations. During my more than 25 years at ICE and its predecessor agency, U.S. Customs, I held a variety of investigative, management and executive positions.

A significant aspect of my job at Pfizer is to mitigate the threat that counterfeit medicines pose to the health and safety of patients who rely upon Pfizer medicines to live healthier and happier lives. Counterfeit medicines pose that threat because of the conditions under which they are manufactured in unlicensed and unregulated sites, frequently under unsanitary conditions, and the lack of regulation of their contents. In many instances, they contain none of the active pharmaceutical ingredient found in the authentic medicine, or an incorrect dosage, depriving the patient of the therapeutic benefit of the medicines prescribed by their physicians. In others, they may contain toxic ingredients such as heavy metals, arsenic, pesticides, rat poison, brick dust, floor wax, leaded highway paint, and even sheetrock or wallboard, all of which we found in counterfeits.

Counterfeit medicines are a global problem, one from which no region, country, therapeutic area or pharma company is immune.

While the true scope of the counterfeit problem is hard to estimate, we can provide some metrics based on the seizures reported to us by enforcement authorities and confirmed by our labs. In reviewing those internal metrics to prepare for today's hearing, I was struck by how significantly the landscape had changed since November 2011 when I appeared before the House Judiciary Committee just about 2 years ago now.

Since November 2011, authorities have reported to us the seizure of more than 55 million doses of suspicious Pfizer medicines. Twenty-eight percent of those seizures—15.5 million dosages—were confirmed as counterfeit medicines, and we differentiate—we are very, very conservative in our statistics, and if we haven't confirmed, it

is just reported, we don't count it as a statistic. So we are usually underreporting so we don't get accused of exaggerating.

The number of Pfizer medicines targeted by counterfeiters has increased by 36 percent, from 50 to 68 different Pfizer medicines now. Counterfeit Pfizer medicines have been confirmed in six new countries—Armenia, Cameroon, Jamaica, Kosovo, Maldives, and Saint Lucia—bringing the total to 107 countries in which counterfeit Pfizer medicines have been seized by authorities. Counterfeit versions of 26 Pfizer medicines have been confirmed in the legitimate supply chains of 60 countries, an increase from 22 medicines in 53 countries in November of 2011.

Seizures recorded during 2013 reveal that while Viagra, a treatment for erectile dysfunction, remains our most targeted medicine for counterfeiters, other medicines have attracted increasing attention with seizures of each of the top five exceeding 1 million doses. The seizure of almost 3.6 million counterfeit doses of Viagra represented just 34 percent of the overall confirmed seizures of Pfizer medicines in 2013, down from 89 percent in 2012.

For the first time, Lipitor, a treatment for cholesterol, came a close second, with the seizure of almost 3.1 million tablets, representing 29 percent of all confirmed dosages seized.

Closing out the top 5 most counterfeited Pfizer medicines last year were Xanax, 1.3 million, Ponstan, 1.1 million, and Centrum, just over 1 million, and again, these are relatively low probably compared to what was out there but just the ones we could confirm.

The increased counterfeiting of Xanax is likely linked to its popularity, particularly on college campuses, as a party drug often used to decrease anxiety and insomnia. Additionally, Xanax appears to be preferred by individuals taking crystal meth. Counterfeit Xanax seizures in 2013 included those seized from a factory in Texas where 1,000 counterfeit Xanax tablets and tooling were seized by the Drug Enforcement Administration.

Despite increased breaches in the legitimate supply chain, the major threat to U.S. patients is the Internet and the many professional-looking Web sites that promise safe, FDA-approved branded medicines from countries such as Canada and the U.K. In 2006, Pfizer Global Security launched a robust Internet program to identify and disrupt rogue online pharmacies dispensing Pfizer medicines to unsuspecting patients. Although that program resulted in a takedown of several rogue OLPs and arrests, it was in essence a whack-a-mole approach. Recognizing the limitations of that strategy, we sought a broader and more permanent remedy.

Along these lines, in 2013 we partnered with Microsoft in an innovative OLP disruption program that attacked the affiliate networks where they were most vulnerable by simultaneously disabling domains to disrupt traffic to the sites and eliminating their ability to process credit card payments for orders placed. This new approach has proven much more effective, evidenced by the disruption of two affiliate networks and the removal of more than 3,300 rogue OLPs from the Internet just last year.

To protect unsuspecting patients from the risk of obtaining counterfeit medicines online, we have extended our Internet monitoring program to Craigslist and Facebook along with other classified-ad-

vertising Web sites and social media outlets. As a result of those efforts, we have identified several individuals offering Viagra on Craigslist. Our test purchases confirmed that these individuals are selling counterfeits. Subsequent referral of these incidents to local law enforcement resulted in the arrest of several sellers including a Maryland housewife. The social-network monitoring also identified several drop shippers of rogue OLPs who use their access of counterfeit medicines to advertise independently in Craigslist. One such referral to police in Toronto resulted in the arrest of six Craigslist sellers.

Mr. MURPHY. Mr. Clark, I have to ask you to wind up.

Mr. CLARK. That is it. I will be glad to take questions.

[The prepared statement of Mr. Clark follows:]

Testimony of John P Clark
Chief Security Officer, Pfizer Inc, and Vice President, Global Security
Committee on Energy and Commerce
Subcommittee on Oversight and Investigations

February 27, 2014

Chairman Murphy, Ranking Member DeGette, and members of the Subcommittee. It is a pleasure to appear before you today to discuss an issue of great importance – the threat that counterfeit medicines pose to the health and safety of patients in the United States and around the world.

My name is John Clark, and I am the Chief Security Officer for Pfizer Inc, and Vice President of its Global Security Team. Pfizer is a diversified, global health care company and one of the world's largest biopharmaceutical companies. Our core business is the discovery, development, and marketing of innovative pharmaceuticals for human health, and we are committed to ensuring the integrity of those products when they reach the market. I am responsible for ensuring that programs are in place to protect Pfizer's personnel, real and intellectual property, reputation, and the integrity of its medicines.

Prior to joining Pfizer in 2008, I served as Deputy Assistant Secretary at Immigration and Customs Enforcement, responsible for the overall management and coordination of the agency's operation, as well as the Assistant Secretary's principal representative to the Department of Homeland Security and to the law enforcement and intelligence communities. During my more than 25 years in ICE and its predecessor agency, U.S. Customs, I held a variety of investigative, management and executive positions.

Threat to Patient Health and Safety

A significant aspect of my job is to mitigate the threat that counterfeit medicines pose to the health and safety of patients who rely on Pfizer medicines to live healthier and happier lives. Counterfeit medicines pose that threat because of the conditions under which they are manufactured – in unlicensed and unregulated sites, frequently under unsanitary conditions – and the lack of regulation of their contents. In many instances, they contain none of the active pharmaceutical ingredient (API) found in the authentic medicine, or an incorrect dosage, depriving patients of the therapeutic benefit of the medicines prescribed by their physicians. In others, they may contain toxic ingredients such as heavy metals, arsenic, pesticides, rat poison, brick dust, floor wax, leaded highway paint and even sheetrock or wallboard.

Counterfeit medicines are a global problem; one from which no region, country, therapeutic area or biopharma company is immune.

The Changing Landscape

While the true scope of the counterfeit problem is hard to estimate, we can provide some metrics based on the seizures reported to us by enforcement authorities and confirmed by our laboratories.

In reviewing those internal metrics to prepare for today's hearing, I was struck by how significantly the landscape had changed since November 2011, when I appeared before the House Judiciary Committee.

Since then:

- Authorities reported to us the seizure of more than 55 million doses of "suspicious" medicines. 28.2% of those seizures – 15.5 million doses – were confirmed as counterfeit versions of Pfizer medicines.
- The number of Pfizer medicines targeted by counterfeiters has increased by 36%, from 50 to 68.
- Counterfeit Pfizer medicines have been confirmed in six new countries – Armenia, Cameroon, Jamaica, Kosovo, Maldives and Saint Lucia – bringing the total to 107.
- Counterfeit versions of 26 Pfizer medicines have been confirmed in the legitimate supply chains of 60 countries, an increase from 22 medicines in 53 countries.

Seizures recorded during 2013 reveal that while Viagra, a treatment for erectile dysfunction, remains the most targeted, other medicines have attracted significant attention by those who counterfeit our medicines, with seizures of each of the top five exceeding 1 million doses:

- With the seizure of almost 3.6 million counterfeit doses, Viagra remained number one, although the percentage of total seizures dropped precipitously to 34.1%, down from 89% in 2012.
- For the first time, Lipitor, a treatment for high cholesterol, came a close second, with the seizure of almost 3.1M tablets, 29.4% of the confirmed counterfeit doses seized.
- Closing out the top 5 were Xanax (almost 1.3M), Ponstan (more than 1.1M) and Centrum (more than 1M).

This increased counterfeiting of Xanax is likely linked to its popularity, particularly on college campuses, as a "party drug" often used to decrease anxiety and insomnia. Additionally, Xanax appears to be preferred by individuals taking Crystal meth, a very pure form of methamphetamine that can be smoked. Because of its potential for abuse, the U.S. Drug Enforcement Agency (DEA) has classified Xanax as a controlled substance requiring a doctor's prescription. The Xanax seizures included 1,000 counterfeit tablets from a factory in Texas from which counterfeit tablets and tooling were seized by authorities.

Pfizer's Program to Mitigate that Threat

Because counterfeit medicines are first and foremost a matter of patient health and safety, we have implemented an aggressive anti-counterfeiting campaign to detect and disrupt major manufacturers and distributors of counterfeit Pfizer medicines. By attacking counterfeits at or near their source, we protect the global market. From 2004 through the end of 2013, our efforts have prevented more than 168.4 million doses of counterfeit Pfizer medicines – more than 96.3 million finished doses and enough API to manufacture another 72.1 million – from reaching patients around the world. And, because those who counterfeit our medicines have no "brand loyalty," raids by law enforcement authorities based on evidence we have provided have also resulted in seizures of millions of doses of counterfeits marketed by other major pharmaceutical companies.

I attribute the success of our program to our talent – colleagues placed strategically around the world with extensive law enforcement experience who know how to initiate and develop cases – and the effective partnerships we have forged with enforcement authorities around the world. We not only refer the results of our investigations, but also provide support as required in investigations and test –with no cost to the government– suspected counterfeit Pfizer medicines to determine their authenticity.

We also provide training to enforcement authorities to raise awareness to the counterfeiting problem and enhance their ability to distinguish counterfeit from authentic Pfizer medicines. As of December 31, 2013, we have provided training to authorities from 140 countries, often in conjunction with programs sponsored by the U.S. Patent and Trade Office (PTO) and the World Customs Organization (WCO). In some instances, we have sponsored regional conferences to facilitate collaboration between authorities in the regions, and work with them to develop actionable plans of action to address the problem.

In the U.S., we work closely with ICE, the FBI and the Food and Drug Administration (FDA) on their investigations, and with CBP to improve their ability to prevent counterfeit Pfizer medicines from reaching U.S. patients.

Protecting Patients from the Online Threat

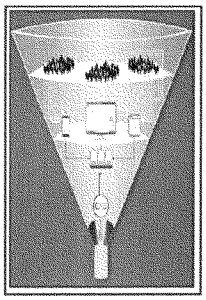
Despite increased breaches in the legitimate supply chain, the major threat to U.S. patients is the Internet and the many professional looking websites that promise safe, FDA-approved, branded medicines from countries such as Canada or the UK.

Unsuspecting patients are easily lured by the ease with which they can order their medicines online, often without the need to consult a doctor or provide a valid prescription. They do not realize that many of those sites have failed to disclose the true source of the products they dispense or even where they – the "dispensing" online pharmacy are located. In such instances, the WHO has estimated that patients have more than a 50% chance of receiving a counterfeit medicine.

It is possible for U.S. patients to buy their medicines safely online through pharmacies that have been accredited by the National Association of Boards of Pharmacies (NABP) as complying with licensing and inspection requirements. Those pharmacies, designated as VIPPS (Verified Internet Pharmacy Practice Sites), represent only a small percentage of online pharmacies. In a report issued in April 2013, the NABP found that, of the more than 10,000 websites it analyzed, almost 97% were "out of compliance with pharmacy laws and practice standards established in the U.S., and many other developed countries, to protect public health."

OLP Disruption Program

In 2006, we launched a robust Internet Program to identify and disrupt rogue online pharmacies (OLPs) that dispensed counterfeit Pfizer medicines to unsuspecting patients. Although that program resulted in the take-down of several OLPs, and the arrest and disgorging of profits from those behind some of those sites, it was in essence a "Whack-a-Mole" approach. Recognizing the limitations of our more traditional investigative strategies, we sought a broader and more permanent remedy.



The program disrupts networks at their choke points.

To permanently disrupt their business model, we partnered with Microsoft, in an innovative OLP Disruption Program that attacked the affiliate networks where they were vulnerable by simultaneously disabling domains to disrupt traffic to the sites, and eliminating their ability to process credit card payments for orders placed. The effectiveness of such systemic takedowns was demonstrated last year when, with the disruption of two affiliate networks, we took down more than 3,300 rogue OLPs.

Social Media

To protect unsuspecting patients from the risk of obtaining counterfeit medicines online, we have extended our internet monitoring program to Craigslist and Facebook along with other classified advertising websites and social media outlets.

Through those monitoring efforts, we identified several individuals offering Viagra on **Craigslist.** When test purchases confirm that the medicine dispensed are counterfeit, referrals are made to local law enforcement. Such referrals to U.S. authorities have resulted in the arrests of several sellers, including a Maryland housewife, as well as those who function as drop-shippers for rogue OLPS but advertise independently on Craigslist. More recently, a referral to police in Toronto resulted in the arrest of six sellers as part of Project PACE (Partners Against Counterfeiting Everywhere).

Facebook, the world's most popular social networking site, is an attractive marketing platform, permitting distributors to market their products directly to consumers. While such ads increasingly involve illicit products, including counterfeit medicines, obvious misspellings of the names of products or the use of images rather than text, make it more difficult to search and locate sellers. In May 2013, our monitoring efforts identified a page offering various Pfizer medicines including Ativan, Xanax and Viagra. Following an investigation in our APAC region the matter was referred to authorities in the Philippines, who raided a warehouse from which they seized more than 144,000 doses of counterfeit Pfizer medicines, including Centrum, Lipitor, Norvasc and Viagra.

Case Study: Philippine-Based Call Center Targeting U.S. Patients

The take-down of the 724 Care Inc, a call center in Cebu City, Philippines, is an excellent example of how easily patients can be deceived, and the risks to which they are exposed, when ordering medicines online. It also demonstrates the collaboration at the core of our fight against counterfeit medicines, both with law enforcements authorities around the world and among the teams that comprise Global Security.

The 724 call center employed as many as 200 agents to call patients in the U.S., UK and Australia, encouraging them to refill orders for Viagra and other ED medicines. The scripted sales pitch was convincing, but the medicines dispensed to patients were either counterfeit or unapproved generics. Agents were expected to generate $800 in sales each day.

When authorities raided the 724 office in July, 2012, they expected to find a room filled with computers on which incriminating data was stored. Instead, they discovered that all sales data was strategically stored in Google's "Cloud" - beyond the immediate reach of local law enforcement. While the call center was based in the Philippines, leveraging the low-cost manpower that an emerging market can provide, it relied on German IT technicians, Israeli trainers, and sourced its products from India and China.

Special agents with U.S. Immigration and Customs Enforcement (ICE), working closely with local authorities, contacted Google to "freeze" the data, ensuring its availability to enhance evidence already amassed against 724 and its principals through a lengthy undercover investigation in which Global Security effectively assisted. Within Global Security (GS) there was also a coordinated effort between the APAC, Americas and Intelligence teams.

- Philippine authorities, through an undercover operative working at the call center, received detailed information about its operations, including the script used to convince patients that it was safe to order medicines from them.
- A consultant engaged by GS APAC "friended" a call center agent via Facebook and, when asked for a referral to a U.S. patient, introduced him to a consultant based in the U.S.
- The U.S.-based consultant placed two orders with the call center, each of which was filled with counterfeit 100mg tablets that were sub potent, containing only 30% of the label claim.

Through further investigation we linked the call center to approximately 70 online pharmacies as well as to prior test purchases as far back as 2008, in which orders had been filled with counterfeit Viagra.

Case Study: Online Sales Linked to Japanese Organized Crime

Based on a referral from Global Security, Japanese authorities dismantled a global network – with members in Japan, Korea and the U.S. – that dispensed counterfeit Viagra, sourced from China, to patients in Japan and Thailand. The final blow to the criminal enterprise came in November 2012, when Kanagawa Police arrested eight members of the criminal enterprise, including two high-ranking members of the Yakuza, a transnational organized crime syndicate based in Japan.

The investigation began in March 2011, when GS initiated an investigation into the LIFE ONE online pharmacy, identified as dispensing counterfeit Viagra in an Internet Market Survey conducted in Japan. Samples of Viagra purchased during the GS investigation were confirmed as counterfeit, with amounts of the active pharmaceutical ingredient ranging from sub-potent as low as 57% of label claim, to super-potent as high as 207% of label claim, more than twice the maximum approved dosage. After identifying additional websites and several members of the network, GS referred the matter to the Kanagawa Prefectural Police.

In November 2011, after police surveillance confirmed the information we provided, police raided several locations, from which they seized counterfeit Viagra tablets and business records, and made two arrests. The records seized in those raids provided authorities with valuable information including the names of the ringleaders – two Japanese nationals based in California – who brought the counterfeits from China to the U.S. by courier and then shipped them to Japan.

GS was instrumental in gaining the cooperation of the ICE Attaché in Tokyo to facilitate the arrests of those members based in the U.S. It was evidence developed as a result of that U.S.–Japan collaboration that led to a second round of raids in November 2012. In addition to the two Yakuza members, those raids resulted in the arrests of a Korean national, who served as a courier. Based on its analysis of records seized, authorities have estimated sales for the criminal enterprise of at least $5.9 million (U.S.D).

Case Study: Counterfeiting Network with Links to Yakusa Disrupted

Authorities in Osaka disrupted a counterfeiting network with links to the Yamaguchi Gumi, the largest Yakuza group in Japan, which brings in billions of dollars a year through counterfeiting, Internet pornography, extortion and other illegal activities. Global Security provided authorities with information concerning a group that shipped counterfeits, sourced from China, to dealers in Japan and Korea. Police analysis of the names and phone numbers linked the Osaka dealers to that same group.

In raids conducted in late-September 2013, authorities seized counterfeit Viagra and counterfeit DVDs, and made six arrests, including two members of the Yamaguchi Gumi. According to authorities, involvement of Yakuza increased both the urgency and danger of the raids, but provided an opportune moment to round up the Osaka group and disrupt their operation.

Statements made following the arrests demonstrate the effectiveness of our efforts to disrupt the online sale of counterfeit medicines. According to the defendants, they avoided the Internet and resorted to more "primitive" methods to sell their products – mail, fax and phone – because "Pfizer was actively hunting down websites."

Case Study: Collaboration Topples Global Distribution Network

Sheikh Waseem Ul Haq (Waseem) first came to our attention in APAC through a website on which he offered to sell Viagra and other Pfizer medicines. Test purchases were made. Lab analysis confirmed the Viagra was counterfeit. In subsequent meetings with Waseem and his partner, our APAC consultant earned their trust and gained a great deal of information about their operation, including their ability to ship counterfeits to the UK and the U.S.

Waseem disclosed that he had offices in the UK and agreed to have an order delivered to a UK-based associate, in actuality another GS consultant. After receiving that shipment, the EMEA consultant developed a relationship with Waseem's UK distributor, "Mrs. Ali," that led to her arrest in November 2006, and the seizure of more than 100,000 doses of illegal and counterfeit medicines, as well as narcotics, forged passports and drivers' licenses, and a credit card cloning machine. When questioned by the authorities, Mrs. Ali identified Waseem as her source for the counterfeit medicines and provided additional information concerning the criminal enterprise.

Waseem came to the attention of U.S. authorities as the result of an investigation into a death, in January 2009, attributed to an overdose of controlled substances. Authorities found more than 17,000 doses of medicines in Chinese and Urdu (Pakistani) packaging in the deceased's apartment. A search of his computer revealed his Pakistani source to be Waseem, operating as Waseem Enterprises and Harry's Enterprises. The FBI launched an undercover investigation, and made several controlled buys from him.

During the course of its investigation, the FBI became aware of Mrs. Ali, her connection with Waseem, and the role that Pfizer had played in the events leading to her arrest and conviction. To facilitate the FBI investigation, GS shared the evidence it had gathered against Waseem in Pakistan and the UK, including statements by his partner that helped establish his knowledge that his criminal enterprise was exporting counterfeit medicines to the U.S.

The tentacles of Wasseem's criminal enterprise spread around the world, posing a global threat to those patients who unknowingly received the counterfeit medicines it dispensed. Its takedown by U.S. authorities in late 2012 is a tribute to the coordination of well-executed investigations in each of our regions, demonstrating how effectively our investigative capabilities match the global reach of those who manufacture and distribute counterfeit versions of our medicines.

Case Study: Sophisticated Global Operation Disrupted

Armed with information from a four-year investigation by Global Security, Chinese authorities raided the factory and home of Dr. Qifa Shen, a major international manufacturer and distributor of counterfeit medicines, including Metakelfin, an anti-malarial intended primarily for pregnant women. The raid resulted in the seizure of two million counterfeit tablets, the arrest of Dr. Shen and two other suspects, and the shutdown of a vast counterfeiting operation that jeopardized the health of patients on three continents by delivering dangerous counterfeit medicines to markets in China, Africa and the United States.

The raid by officers from NanHai FoShan PSB took place just as Shen was completing a production run and preparing to ship his counterfeits. Among the millions of counterfeits seized were 84,500 doses of counterfeit Metakelfin. Substantial quantities of ingredients, heavy machinery and other equipment used in the manufacturing process were seized, as well as counterfeit packaging for medicines of several major pharma companies.

Previous GS investigations identified a Kenya-based crime group, responsible for distributing counterfeit Metakelfin, as one of Shen's customers. Counterfeit versions of Metakelfin have been confirmed in the legitimate supply chains not only of Kenya, but also in Tanzania and Uganda. Chemical analysis found that some contained none of Metakelfin's active ingredients, placing the lives of both mother and child at risk; others contained sub-potent levels, creating therapeutic failure and the risk of drug-resistant strains of the disease.

In addition to the counterfeits seized, Shen was known to provide substantial amounts of Panadol to criminal networks for sale in the United States.

Guangdong provincial authorities believe the raid has neutralized a sophisticated criminal organization responsible for manufacturing and distributing counterfeit medicine to the Chinese domestic market and overseas.

What More Can We Do?

We have seen progress in the fight against counterfeit medicines, but much more needs to be done. In some countries, pharmaceutical counterfeiting is not a crime; in others it has only minimal sanctions. Lax enforcement of laws that do exist is yet another problem.

Pharmaceutical counterfeiting is a high profit criminal activity that carries a low risk to the criminal which is why it has attracted drug traffickers, firearm smugglers and even terrorists. One of the principal players in the 2003 Lipitor breach here in the U.S. was a convicted cocaine trafficker. In 2006, the U.S. Attorney for the Eastern District of Michigan announced the indictment of 19 people who gave a portion of their profits from the sale of counterfeit Viagra to Hezbollah.

Those who counterfeit medicines seem confident that even if they get caught, they will get a mere slap on the wrist. Decisions on charges filed and to which pleas of guilty are accepted should leverage the newly enhanced maximum sentences approved under the Food and Drug Administration Safety and Innovation Act to ensure that the punishment imposed fits the crime committed against patient health and safety. Permitting Andrew Strempler, the president of RxNorth pharmacy, to plead to wire fraud limited his sentence to four years, certainly not reflective of the risk to patient safety his network – which advertised safe and effective medicines but delivered dangerous fakes from China – posed to patients in the U.S. and around the world.

Recognizing the inherent risk that any counterfeit medicine poses to patients, we must streamline CBP's procedures to facilitate the ability of rights holders to confirm or disprove the authenticity of suspected counterfeit medicines. Expedited procedures must also be put in place to shutdown "rogue" websites dispensing counterfeit medicines to U.S. patients.

Conclusion

Thank you for this opportunity to express my concerns. For Pfizer, pharmaceutical counterfeiting is first and foremost an issue of patient health and safety. We look forward to working with you to ensure the health and safety of all U.S. patients through the enactment and enforcement of appropriate legislation and regulations.

Mr. MURPHY. Thank you. I have to step out for a while, and Dr. Burgess will take over, but I just want to ask one clarifying question, Mr. Clark, before I go. If you compare money counterfeiting to electronic counterfeiting to drug counterfeiting, tell me about the different ratios and profitability.

Mr. CLARK. We had 3 years ago seen German customs refer to a study from the University of Bonn that did just that. For a $1,000 base investment by a counterfeiter, they compared what they estimated would be the return on investment. They went through several levels of different commodities. I think cash was the lowest. For $1,000 invested, they estimated that there would be a $5,000 return on investment for counterfeiting cash. I think credit cards were second with $10,000 return. The second highest level commodity counterfeited for return on investment was electronics. They estimated for $1,000 investment, the return would be $100,000. The highest on that list by the University of Bonn was pharmaceutical products. For $1,000 invested, they estimated that the return on investment would be $500,000.

Mr. MURPHY. Thank you, incredible. I appreciate that.

Mr. Moreau, you are recognized for 5 minutes.

TESTIMONY OF JEAN-LUC MOREAU

Mr. MOREAU. Mr. Chairman and members of the subcommittee, my name is Jean-Luc Moreau and I am the global head of product security at Novartis International. My primary responsibility is to protect the company, its products, and most importantly, the people who rely on Novartis medicines from counterfeits.

Modern counterfeiting is an industrial global business which in 2010 generated an estimated $75 billion for organized crime. In 2002, the Pharmaceutical Security Institute recorded 196 product incidents worldwide. In 2012, the same Pharmaceutical Security Institute recorded 2,018 cases representing a 10-fold increase in only one decade.

Counterfeit drugs are most of the time extremely dangerous. For example, the World Trade Organization has estimated that counterfeit antimalarial drugs kill 100,000 Africans annually. My own experience tells me that this number is basically underestimated.

Counterfeit drugs are generally indistinguishable from the genuine drugs. Some examples are displayed on the monitors. Russian counterfeiters have gone so far as to add holograms to the packaging of their fake drugs which say "protected against counterfeit."

Counterfeit drugs are made in clandestine facilities which are downright filthy. As the pictures on the monitor show, Novartis products are made in state-of-the-art facilities. By contrast, as the pictures on the screen demonstrate, counterfeiters manufacture their illicit products in decrepit conditions. Counterfeiting operations generally ship and/or store their fake products in unsanitary and improper conditions, more examples on the screen.

Counterfeiting today is frequently highly organized, transnational, and businesslike. Counterfeiters operate industrial production facilities with the capacity to saturate markets with fake products. They target low-volume, high-specialty medicines, as well as high-volume, low-margin products as over-the-counter drugs or generics. They reach people directly through the Internet

or illicit retailers or they infiltrate legitimate supply chains, as in many countries.

The scope of sophistication of this modern counterfeiting is clearly illustrated by the two following examples. The first example, in May 2006, customs officers at London Heathrow seized a shipment from Dubai en route to the Bahamas which contained thousands of packs of eight confirmed counterfeit drugs from seven pharmaceutical companies, including more than 3,000 packs of a counterfeit Novartis medicine for hypertension. The counterfeit product had been manufactured in China, transported by road to Hong Kong, flown to Dubai while they were stored in a duty-free warehouse before being shipped to the Bahamas via the U.K. In the Bahamas, an illicit fulfillment center established by Rx North, an Internet drug Web site, process orders placed on the Internet by American and Canadian patients. The fake products were shipped directly to the Bahamas to customers in the U.S. and Canada.

The second example, Novartis manufactures Coartem, which is a breakthrough drug for malaria. Novartis has made over 500 million Coartem treatments available without profit in malaria-endemic countries through programs such as the U.S. President's Malaria Initiative and the Global Fund to Fight AIDS, Tuberculosis, and Malaria.

In March 2010, I organized a market survey in three Nigeria basin countries, Cameroon, Nigeria, and Benin, which concluded that around 25 percent of our Coartem donated to Eastern African countries was being stolen and shipped 5,000 miles away to Western Africa where it was sold on the street not for free but for an average of $5 per treatment.

This large-scale diversion scheme created a mass-market for Coartem which attracted an extensive counterfeiting operation. In July 2012, a container ship from Guangzhou, China, to Luanda in Angola was seized by customs officers. It contained Hi-fi speakers hiding 1.5 million treatments of fake Coartem. Subsequent investigations in Western Africa confirmed that this counterfeit version of Coartem contained nothing but flour, cornstarch, dextrose, and an industrial colorant. There is no question in my mind that the Coartem diversion and counterfeiting schemes are grievously undercut efforts to eradicate malaria and have led directly to the deaths of hundreds of thousands of Africans.

The United States and other countries should develop comprehensibility of criminal laws to confront counterfeiting, impose stiffer sanctions for pharmaceutical crimes, and make the commitment to vigorously enforce those laws.

Thank you.

[The prepared statement of Mr. Moreau follows:]

STATEMENT OF
JEAN-LUC MOREAU
GLOBAL HEAD PRODUCT SECURITY
NOVARTIS INTERNATIONAL AG

before the

Subcommittee on Oversight and Investigations
House Energy and Commerce Committee
February 27, 2014

"Counterfeit Drugs: Fighting Illegal Supply Chains"

My name is Jean-Luc Moreau and I am the Global Head of Product Security for Novartis International AG. I am a French National and former Senior Officer and veteran with 25 years' experience in the French military. My overarching responsibility at Novartis is to protect the company, its products, and, most importantly, the individuals who rely on Novartis' medicines from counterfeit, substandard, adulterated, or expired medications. To this end, I coordinate the Group Brand Integrity Program which embraces all of Novartis' functions and divisions. I also manage a Group Product Security Steering Committee and a team which specializes in detecting and investigating counterfeiting and other product security incidents in the 140 countries in which Novartis currently does business. My many years of personal experience in this arena affirm the following well-documented facts:

- Drug counterfeiting is a pervasive and rapidly expanding global problem engineered by increasingly sophisticated and resourceful criminal enterprises.

- The products peddled by these illicit operations are fakes, produced, labeled, and packaged to mislead patients, health care givers, and others in the legitimate distribution chain into believing that the drugs are genuine.
- Pharmaceutical counterfeiting causes very real and serious harm to public health and safety: patients who need medicines to treat diseases, relieve pain, or save their lives don't get them; public confidence in drug manufacturers, pharmaceutical therapies, and health care delivery systems is eroded; patients who take products adulterated with dangerous impurities may be injured or die; and drug resistance is accelerated.
- The proliferation of drug counterfeiting operations is facilitated by a multiplicity of factors including, inter alia: countless unregulated Internet pharmacies which make fake products easily available anywhere on the globe; the absence of strong and qualified regulatory agencies in many countries; minimal risks of prosecution and relatively low penalties (even in the United States); and the lack of effective import/export controls.

Novartis Has a Compelling interest
In Preventing Drug Counterfeiting

Novartis is a multinational research-based health care business with its corporate global headquarters in Basel, Switzerland and U.S. headquarters in East Hanover, New Jersey. Novartis has approximately 135,000 employees worldwide, 27,000 of whom are located in the United States. In 2013 alone, Novartis invested $9.9 billion in the research and development of new

pharmaceutical therapies. Across all of its divisions, Novartis' product line includes drugs, vaccines, devices, and surgical appliances to treat conditions such as cancer, multiple sclerosis, diabetes, hypertension, Alzheimer's disease, high cholesterol, epilepsy, organ rejection in transplants, and eye and vision care. All in all, Novartis manufactures and markets an extensive line of products across its diverse health care portfolio including innovative pharmaceuticals, eye care products, generics, consumer health products, vaccines, and diagnostic tools that are made available in 140 countries. Unfortunately, many of these products have been the target of pharmaceutical crime such as counterfeiting and diversion including Glivec (cancer), Exelon (Alzheimer's), Diovan (high blood pressure), Neoral (immunosuppressant for organ transplants), Zometa (bone cancer), Femara (breast cancer), Optalidon (pain), and Coartem (malaria).

Novartis attaches an extremely high priority to ensuring that patients using Novartis products, and the physicians who prescribe them, have complete confidence that its drugs are safe and effective. If patient and prescriber trust in Novartis products is compromised, patients will not take medicines that can ease their pain, treat their diseases, or save their lives. In addition, the reputation of the company will suffer and its ability to spend billions of dollars on researching and developing new therapies will be jeopardized. For these reasons, Novartis has dedicated considerable manpower and financial resources to combating drug counterfeiting on a global scale. Novartis works closely with law enforcement and health authorities in numerous countries to investigate and suppress the counterfeiting of its products and to ensure that drugs purchased from Internet pharmacies are authentic, safe and effective.

Pharmaceutical Counterfeiting
Is Pervasive and Pernicious

Counterfeiting is an enormous global business which will grow rapidly if left unchecked. It has been estimated that in 2010, activities related to counterfeit drugs generated revenue of $75 billion and that an annual rate of growth of 20 percent in such revenue is not unrealistic.

Experts on drug counterfeiting believe that 1 percent of the drugs in the developed world, including the U.S. and Europe, are fake. In developing countries, between 10 and 50 percent are thought to be counterfeit. In some underdeveloped countries, fake products could comprise as much as 70 percent of the drug supply. According to the Pharmaceutical Security Institute, there were 1,664 new counterfeiting incidents reported in 2012, a 2.2 percent increase over the prior year. During this period, there were 483 counterfeiting incidents involving 207 different pharmaceutical products which impacted the legitimate supply chain in 47 separate countries.

The pernicious impact of counterfeit pharmaceuticals must not be measured exclusively by statistics because the toll on human life is staggering. For example, the World Trade Organization has estimated that counterfeit anti-malaria drugs kill 100,000 Africans annually. More generally, 700,000 deaths a year have been attributed to counterfeit drugs. Although it is impossible to estimate the number of individuals whose health was jeopardized because they took a counterfeit drug, the number could easily be in the millions.

A counterfeit drug may be defective for many reasons. The drug may contain no active pharmaceutical ingredient ("API"), too little or too much API, or the wrong API. It may be

adulterated and contain dangerous impurities. The products may be expired and relabeled to reflect a new expiry date and/or they may have incorrect or misleading labeling. Counterfeiters have developed the capability to produce fake products and package them in ways which make them virtually indistinguishable from the genuine drug. See Attachments 1, 2, and 3. Counterfeiters are also adept at evading technological solutions to pharmaceutical crime. For example, Russian counterfeiters went so far as to add holograms to the packaging for their fake products. The hologram carried the statement: "Protected against counterfeits". See Attachment 4.

Counterfeit drugs are frequently made in substandard facilities most of which are downright filthy. Novartis manufactures its pharmaceuticals in state-of-the-art facilities which comply with FDA good manufacturing practices. See Attachments 5 and 6. By contrast, counterfeiters produce their illicit products in decrepit conditions. See Attachments 7, 8, 9, and 10. Counterfeiting operations ship and/or store their fake products under unsanitary and inappropriate conditions. See Attachments 11, 12, 13, and 14. Drugs not stored and shipped under proper conditions can lose their potency or become totally useless, if not harmful.

Modern Drug Counterfeiting Operations Are Often Highly Sophisticated

Pharmaceutical counterfeiting in today's world is often highly organized, transnational, and industrialized. Drug counterfeiters are aggressive, diversified, and utilize highly detailed and flexible business strategies. They have the capability to target low volume/high margin products in the oncology, cardiovascular, and neurosciences fields as well as high volume/low margin products such as over-the-counter drugs, generic medicines, and vaccines. The

operations can reach patients directly through the Internet or street dealers in Africa and elsewhere. They have the capacity to infiltrate legitimate supply chains as they have in the Middle East, Latin America, Southeast Asia, and Sub-Saharan Africa. Counterfeiters operate illicit and unregulated industrial production facilities, many of which have the capacity to flood markets with fake products.

Counterfeiting syndicates operate business models parallel to the legitimate supply chain with geographically diverse manufacturing facilities, logistics hubs, and sales personnel all under the direct control of the counterfeiters. The depth, breadth, and sophistication of modern drug counterfeiting operations are clearly illustrated by the following three examples.

Rx North

In May 2006, Customs officers at London Heathrow Airport in the United Kingdom seized a shipment from Dubai, en-route to the Bahamas which contained several thousand packs of eight confirmed counterfeit pharmaceutical products from seven companies, including more than 3000 packets of a counterfeit Novartis medicine for hypertension. See Attachment 15. The counterfeit products had been manufactured in China, transported by road to Hong Kong, flown to Dubai where they were stored in a duty free warehouse before being shipped to the Bahamas via the UK. Based on information provided by the pharmaceutical industry, local authorities in the Bahamas executed a search warrant at the destination address where additional counterfeit drugs were seized, including more of the counterfeit Novartis hypertension drug as well as a fake Novartis treatment for Alzheimer's.

The counterfeiting facility in the Bahamas was a fulfilment center established by Rx North, an Internet drug website. The facility processed orders placed on the Internet by American and Canadian patients and shipped pre-addressed orders for Rx North to mail forwarders based in the UK and the Netherlands Antilles. The products were then shipped from the UK or Netherlands Antilles direct to individual customers in the United States and Canada. These routes were used in order to reduce suspicion and avoid Customs inspections.

In August 2006, the Food and Drug Administration issued a warning to consumers not to buy or use prescription drugs from certain websites, including Rx North. In September 2006, RxNorth.com informed prospective customers that responsibility for order fulfilment would be transferred to Canadadrugs.com. Canadadrugs.com had previously been implicated in incidents of counterfeit pharmaceutical products and later became the center of another international counterfeit drug scandal, mainly affecting U.S. patients.

Following investigations in all of the countries impacted by Rx North, a Dubai-based trading company general manager and three co-defendants were convicted in the United Arab Emirates and imprisoned for terms ranging from one to eight years. Two men in the UK were also prosecuted and convicted for their roles in the RxNorth operation. Andrew Strempler, a Canadian citizen, pleaded guilty in the Southern District of Florida for his role in a scheme to defraud consumers purchasing pharmaceuticals online through his ownership of Rx North. In January 2013, he was sentenced to 4 years in prison and also ordered to pay a forfeiture of

$300,000 and a fine of $25,000. He was also ordered to pay restitution to the companies whose products he counterfeited.

Middle East Network

A counterfeiting enterprise in the Middle East operated a network which encompassed China, Syria, Iraq, Jordan, Occupied Palestinian Territories, and Egypt. See Attachment 16. In 2003, Jordanian nationals registered a company specializing in "garments, electronics and international economic consultancy" in Shenzen, Guangdong Province in China. The organization then opened two distribution hubs--one at the point where the Iraqi border meets Syria and Jordan and the other in the United Arab Emirates. The Syrian/Jordanian hub focused on distributing counterfeit life-saving drugs to supply Iraqi demand while the UAE hub specialized in distributing fake lifestyle drugs in Gulf countries. The counterfeit Novartis products distributed by this network across the Middle East included treatments for hypertension, leukemia, breast cancer, and Alzheimer's.

In 2007, Jordanian authorities conducted a series of successful raids against the organization in Amman. Soon after, the leader of the group, who had escaped a raid on his facilities in Amman, moved to Egypt and set up a third hub in Cairo. In 2008, Chinese authorities arrested and prosecuted three Jordanians linked to this syndicate, while other members of the same group were being arrested and prosecuted in the Occupied Palestinian Territories. The Jordanian who escaped from Amman to open the Egyptian hub was arrested in Cairo and the business closed down by authorities in April 2009. In May of the same year, a clandestine

counterfeit drug manufacturing site was discovered by authorities in Damascus, Syria. The facility was equipped with modern industrial Chinese-made machinery and professional printers. Over 60 suspects were arrested and several tons of bulk blister packs, vials, folding boxes, newly printed leaflets, and barrels of unknown chemical substances were seized.

In this case, nearly 100 members of the criminal counterfeiting group were arrested between 2007 and 2009. Businesses owned in China and in the Middle East provided the network with legitimacy and the means to transfer money as well export and import products. The counterfeit manufacturing facility in Damascus allowed the network to continue its illicit trade unhindered, despite Chinese authorities disrupting their operations in Shenzen. The international spread of this organization – which profited from the porous borders of the Iraqi warzone and generated opportunity in a politically tense region--made enforcement actions lengthy and difficult. Nevertheless, Novartis played a key role in investigation by providing information and encouraging law enforcement and security agencies in the affected countries to take action.

Counterfeit Antimalarial Treatment

Novartis manufactures a breakthrough drug, Coartem, for the treatment of multi-drug resistant malaria. It was the first ACT (artemisinin combined therapy) added to the World Health Organization's Essential Medicines list (40 percent of the world's population is at risk of contracting malaria with children and pregnant women being the most vulnerable.). Coartem is a highly-effective 3 day malaria treatment with cure rates of over 96% and holds the potential

for helping to eradicate the disease. In 2001, Novartis signed a memorandum of understanding with the WHO to make Coartem available at cost (i.e., without profit) in malaria-endemic countries. Novartis has provided over 500 million Coartem treatments since that time. Novartis manufactures two presentations of this treatment – the only difference between them is the packaging. One is for private sale and is manufactured in China. The other is sold at cost to international aid agencies and donation funds, including the U.S. President's Malaria Initiative and the Global Fund to Fight Aids, Tuberculosis and Malaria. This public version is manufactured in the U.S. and distributed for free all-over the malaria burden zone, particularly in Sub-Saharan Africa.

In 2009, multiple diversion incidents were reported in Guinea, Malawi, Nigeria, Cameroon, Ivory Coast, and the Democratic Republic of Congo. Put simply, the treatments donated to Eastern African countries were being stolen and sent to Western and Central African countries where they were made readily available for sale to patients at street markets – not for free but at the price of $6.00 to $8.00 per treatment. In March 2010, Ministry of Health officials in charge of the National Malaria Program of Uganda were sent to prison for corruption and diversion -- they were syphoning the donated treatments --essentially stealing millions of dollars of international aid from the malaria stricken population. Novartis found that up to 24% of its deliveries to Eastern African countries were being diverted elsewhere. Novartis continues to work very closely with PMI, The Global Fund and the WHO to support investigations into these thefts.

This large-scale systemic, organized, transcontinental enterprise made the diverted malaria drugs a valuable commodity rendering them an attractive prospect for counterfeiters. In July 2012, a container shipped from Guangzhou in Guangdong Province, China to Luanda in Angola was seized by Customs officers. The shipment contained Hi-Fi speakers containing a total of 1.4 million fake treatments. See Attachments 17, 18. Subsequent investigations in Western Africa confirmed that the counterfeit version of Coartem – a placebo containing nothing but flour, corn starch, dextrose and an industrial colorant - had flooded markets across the region. See Attachment 19. In terms of volumes seized, scale, and direct substantiated risk for patients, this case is the biggest single seizure of fake pharmaceuticals ever recorded by the Pharmaceutical Security Institute.

An established African diaspora in Guangzhou, China, has set up a complex structure of export and import companies with associated sister companies in recipient countries in Africa. The China-based group arranges the manufacture of the fake drugs (not only the Novartis product) with local facilities and as well as the shipping for the fake medicines under covering loads to Africa. Close tribal networks in Africa ensure the passage of counterfeit product upon arrival and distribution to illicit street retailers.

The industrial-scale counterfeiting of the antimalarial, Coartem, originally intended to reach sick patients at no cost to them, is killing thousands of innocent patients and severely damaging hopes of eradicating malaria. In some countries, the counterfeit treatment is more readily available than the genuine. The non-profit treatment has been mutated into a lucrative money-making scheme by criminal networks that operate with impunity because the

local operating environments are corrupted and permissive and the target population is many and widespread.

Conclusion

It is beyond quibble that drug counterfeiters present a grievous threat to public health and safety on a global basis. Their ingenuity and sophisticated, large-scale operations generate sizeable profits which come at the expense of those who rely on medicines to treat disease, ease pain, and prevent death. In an effort to help thwart counterfeiters and other pharmaceutical crime, Novartis, along with many other companies and interested parties, worked with Congress to ensure that effective track and trace provisions were included in the Food and Drug Administration Safety and Innovation Act ("FDASIA"). Track and trace requirements along with other anti-counterfeiting efforts by the industry hold the promise of helping to prevent fake drugs from entering legitimate drug supply chains. Unfortunately, such mechanisms are likely to be ineffective in stopping counterfeiters who supply their product through illicit channels such as Internet websites, street vendors or pharmacists, hospitals and doctors who are willing to participate in the counterfeiting schemes. Novartis believes that the United States must seize the momentum created by FDASIA and take further steps to combat counterfeiting. Much stiffer penalties for pharmaceutical crimes should be put in place in the U.S. and other countries—and each government must make the commitment to aggressive enforcement of anti-counterfeiting laws. Efforts are also urgently needed to increase international awareness of the threats posed by drug counterfeiting in the hope that other countries will develop regulatory schemata and enforcement tools to effectively confront the

well-resourced criminal counterfeiting networks. As for Novartis, it will continue to dedicate substantial corporate resources to detecting and deterring drug counterfeiting.

Mr. BURGESS [presiding]. Mr. Longbottom, you are recognized for 5 minutes.

STATEMENT OF BRUCE LONGBOTTOM

Mr. LONGBOTTOM. Good morning, Mr. Chairman, Madam Ranking Chairman, and members of the subcommittee. My name is Bruce Longbottom. I am assistant general counsel for trademarks at Eli Lilly and Company. We are a global pharmaceutical manufacturing company based in Indianapolis. And like my colleagues here, our company also invests heavily to research, develop, and produce safe and effective medicines which treat many diseases and save lives.

First, let me thank the chairman, ranking member, and members of the subcommittee for your focus on this important issue and for inviting Eli Lilly to testify today about fighting counterfeit drugs and illegal supply chains. We do appreciate the attention you are devoting to investigate the problem of counterfeit medicines, which pose an ongoing risk to patient safety. And this threat of counterfeit medicines is an issue that is near and dear to Lilly and to also the heart of our CEO Dr. John Lechleiter, who has spoken on this on several occasions.

At Lilly, like the other companies here, we have seen counterfeit copies of our own branded medicines around the world and we have seen counterfeiters target a range of medicines from our medicines for mental illness to our medicines for cancer as well. Some of the medicines that are fake may contain over amounts and excess amounts of the API, the active pharmaceutical ingredients, or perhaps contain the wrong APIs or none at all. Some counterfeit drugs contain toxic dangerous ingredients, and we are not alone in this experience, again, as heard already today. We view this as a global health threat that we must work diligently to solve with others in partnership.

We would like to congratulate this committee for its hard work in passing the Drug Quality Security Act of 2013, or DQSA. That new law's establishment of a track-and-trace system for pharmaceuticals will serve greatly to close gaps in the supply chain for prescription drugs in the traditional supply chain, which is from the legitimate manufacturer to the wholesaler to the pharmacies and then to patients.

But while DQSA establishes important requirements for good guys, I believe today's hearing is to look at the bad guys. And as such, I will focus my remarks today on the most common way that counterfeit drugs reach U.S. patient, and that is of course through the Internet, a topic already mentioned several times today and rightfully so I would add.

Obviously, more and more of us are becoming more comfortable with purchasing products online. We are very easily doing that, and e-commerce is projected to grow at over 10 percent every year. And as more and more Americans do look online for their medicines, and there have been some examples even in this hearing this morning of looking online for medicines, what are we finding? Forty to fifty thousand active illegal online drug sellers, and 97 percent, according to the National Association of Boards of Pharmacy do not meet pharmacy and drug safety standards. So tens of

thousands of fake online pharmacies put patients at risk. Now, is that OK? Of course not. I think no one here is satisfied with that. We don't want to stay at that position.

When we interact with a pharmacy, what should we be expecting as we go to a pharmacy whether in the real world or online? I think there are two basic things. One is a drug approved by the FDA and the second is a pharmacist who has been licensed by their state pharmacy board. So that prescription medicine has been blessed by the FDA and that pharmacist has been blessed by the state licensing authority. And I would like to coin the term if I could the sanctity of the pharmacy. I think that is the standard that we should work towards whether in the real world or online.

With regard to the online world, there is no one easy bullet to take care of the problem. There is no one easy solution. There are several elements that are critical to adding towards that solution and there are more details in my submitted written materials, but just at the very high level, some of those themes are patient education, stronger laws, more aggressive enforcement of existing laws, and also voluntary cooperation by Internet-based companies.

Now, just as the DQSA used one tool primarily to tighten defenses in the brick-and-mortar supply chain, and that tool was of course serialization, I believe there are one or more tools that could also be used to tighten the illegitimate supply chain, the online supply chain. And one of those tools I would like to mention is delisting. That is a tool that could be used to exclude these bad illegal rogue online pharmacies from natural search results found using search engines. In other words, if a Web site selling medicines did not sell only FDA-approved drugs or did not provide those services using a state licensed pharmacist, you would not find that Web site in the search results after it was delisted. The online pharmacy would still be on the Internet, probably hosted in a foreign country, but would not be found by the patient in the U.S. doing an Internet search.

If natural search results were cleaned up in this way, that would be the Internet equivalent, I believe, of what the DQSA has done to tighten the traditional supply chain.

And there are other tools that could be discussed as well. Search optimization for the NABP-approved pharmacies may be another helpful tool to boost those in the search rankings.

The Internet is here to stay. The number of fake online pharmacies is growing, and Eli Lilly and Company stands committed to patient safety in both the brick-and-mortar pharmacies and the Internet-based pharmacies, and I very much appreciate the opportunity to speak with you today and I am happy to answer any questions.

Thank you.

[The prepared statement of Mr. Longbottom follows:]

House Energy and Commerce Committee
Subcommittee on Oversight and Investigations
Hearing on "Counterfeit Drugs: Fighting Illegal Supply Chains"
February 27, 2014

One Page Summary - Testimony of Bruce Longbottom, Eli Lilly and Company

- Lilly has seen our own brand medicines counterfeited around the world, and we have seen counterfeiters target a range of therapies, from our medicines for mental illness to our medicines for cancer. Counterfeit medicines are a growing problem that is not limited to innovative products or any particular categories of medicine.

- The most common way that counterfeit medicines enter the United States and reach U.S. patients is through the Internet (illegitimate online "pharmacies" or B2C and B2B sellers that facilitate sales/shipments).

- There are approximately 40,000 to 50,000 active online drug sellers operating globally. The vast majority – nearly 97% according to the National Association of Boards of Pharmacy – is operating illegally by failing to comply with pharmacy and patient safety laws and standards. There are tens of thousands of fake online pharmacies that put patients at risk.

- According to FDA, 23% of adult Internet consumers surveyed bought medicine online in 2012.[1] And an estimated 36 million Americans have frighteningly done so without a doctor's prescription. The Internet has become a more significant part of our everyday lives and shopping habits; it is critical that our public policy and laws evolve along with our technology.

- **Combating counterfeit drugs in the United States and internationally requires a robust strategy to combat their sales on the Internet.** The strategy – which includes Governmental Accountability Office findings (GAO) dating back to 2005[2]– will require: 1) better public education; 2) stronger laws; 3) improved enforcement of our existing laws; and 4) voluntary cooperation and adoption of best practices by Internet commerce companies.

- Many will argue that policies and laws should not change to deal with the problem online, but as with serialization, it is possible and must be done to protect the sanctity of the pharmacy and the quality and integrity of the U.S. drug supply.

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[1] FDA BeSafeRx: http://www.fda.gov/downloads/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/BuyingMedicinesOvertheInternet/BeSafeRxKnowYourOnlinePharmacy/UCM318643.pdf
[2] GAO: http://www.gao.gov/products/GAO-05-372

House Energy and Commerce Committee
Subcommittee on Oversight and Investigations
Hearing on "Counterfeit Drugs: Fighting Illegal Supply Chains"
February 27, 2014

Testimony of Bruce Longbottom, Eli Lilly and Company

Good morning, Mr. Chairman and members of the subcommittee. I am Bruce Longbottom, Assistant General Counsel for Trademarks for Eli Lilly and Company, which is a global pharmaceutical company. Lilly invests heavily to research, develop and manufacture safe and effective pharmaceutical medicines, which treat many diseases and save lives.

First let me thank the Chairman, Ranking Member, and members of the subcommittee for their focus on this important issue and for inviting Eli Lilly to - testify about "Fighting Counterfeit Drugs and Illegal Supply Chains." We appreciate the attention you are devoting to investigate the problem of counterfeit medicines, which pose an ongoing risk to patient health and safety. The threat of counterfeit medicines is an issue that is near and dear to Lilly and, most importantly, to the patients that depend on the integrity of the Lilly brand.

Lilly has seen our own brand medicines counterfeited around the world, and we have seen counterfeiters target a range of therapies, from our medicines for mental illness to our medicines for cancer. One of the world's most commonly

counterfeited products is medicine for erectile dysfunction or ED. Lilly has seen enormous quantities of counterfeit ED medicine circulating the world, and it is telling of the expansive criminal network of pharmaceutical counterfeiters. Some product will contain dangerously high levels of Active Pharmaceutical Ingredients (API), some might contain the wrong APIs, or none. Some counterfeit drugs contain dangerous toxic ingredients. Lilly is not alone in this experience. Counterfeit medicines are a growing problem that is not limited to innovative products or particular categories of medicine. Authorities around the world can attest that there are counterfeit versions of branded, generic, and even over-the-counter medicine. Criminals can profit readily from trade in counterfeit medicines, as it offers lower risks and higher rewards than other criminal activity. In countries plagued with disease, public reports indicate there may be huge quantities of counterfeit vaccines and antibiotics. As such, Lilly has come to view this issue as a global health threat, and one that we must diligently work to combat in partnership with others.

In that spirit, Lilly would like to thank and applaud the Energy and Commerce Committee for its hard work last year to pass the Drug Quality Security Act of 2013

(DQSA). That new law's establishment of a national pharmaceutical track-and-trace system is a critical and necessary step for ensuring the integrity of the U.S. drug supply, and it helps to establish a model internationally. That system will serve to close gaps in the supply chain for prescription medicines in the traditional distribution model – those traveling from legitimate manufacturers to wholesale distributors to pharmacies to patients. But while DQSA establishes important requirements for the good guys, the focus of today's hearing is on the bad guys: the illegal supply chain. As such, I will to focus my remarks today on the most common way that counterfeit medicines enter the United States and reach our patients: through the Internet.

As most of us obtain our medicines at a local brick-and-mortar pharmacy, the new DQSA is great added protection for us. However, there is also a newer, less traditional distribution model that also delivers prescription medicines to patients – it is called the Internet. More and more of us are becoming very comfortable with using the Internet not just for accessing information, but also for purchasing all sorts of products. Indeed, ecommerce is projected to grow 10% year over year[3]. It is very

[3] CPC Strategies: http://www.cpcstrategy.com/blog/2013/08/ecommerce-infographic/

easy to shop online. This is also true in the area of healthcare and medicine. According to FDA, 23% of adult Internet consumers surveyed bought medicine online in 2012.[4] And an estimated 36 million Americans have frighteningly done so without a doctor's prescription. The latter statistic is from study by The Partnership at Drugfree.org in 2010, so that number is likely much higher now.

As more and more Americans look online for their medicines, whether those medicines have been prescribed by doctors or have been self-prescribed (which of course invites other significant problems, including drug abuse), what do they find? Today, according to LegitScript, there are approximately 40,000 to 50,000 active online drug sellers operating globally. But the vast majority – nearly 97% according to the National Association of Boards of Pharmacy -- is operating illegally by failing to comply with pharmacy and patient safety laws and standards – such as requiring only FDA-approved medicines and state-licensed pharmacists. This means there are tens of thousands of fake online pharmacies that put patients at risk!

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[4] FDA BeSafeRx:
http://www.fda.gov/downloads/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/BuyingMedicinesOvertheInternet/BeSafeRxKnowYourOnlinePharmacy/UCM318643.pdf

Is this OK? Of course not. Whether we walk up to a counter and present our prescription to a pharmacist, or we find a website, select a medicine, submit a prescription, and click our mouse to trigger shipment of a life-saving drug – in either case the pharmacy must follow the laws put in place to protect patients. In short, just like the brick-and-mortar supply chain will be made secure under DQSA, the Internet supply chain should be secure. How secure?

A pharmacy is, in a sense, set apart from other locations where products or services are being offered to the public. In particular, when we interact with a pharmacy, we should expect two things:

1. Prescription drugs that have been approved by the FDA, and
2. Those drugs being dispensed by a pharmacist who has been licensed by the state board of pharmacy; often representing the 'last stop' for warnings to patients about contraindications – or the medically-harmful combination of therapies.

In other words, the prescription medicines have been issued a "gold seal of approval" by the FDA and the person dispensing the medicine has been issued a "gold seal of approval" by the state licensing authority. That is the maximum potential of the FDA-approved pharmacy. That is what we should all expect from

every pharmacy, whether online or real world. And so, as you examine this problem and how to fight it, we must think about how to protect the integrity of accredited pharmacies as they exist in the online world.

There is of course no silver bullet, no one solution to the problem found when the Internet and prescription medicines intersect, especially given the global nature of the Internet. But there are several elements to the solution, and as the Internet becomes an even more prominent part of our everyday lives, it is critical that our public policies adapt and evolve with it.

- Part of the solution is patient education. The average person needs to understand the risk they take by purchasing drugs from an unknown source on the Internet. Initiatives like FDA's BeSafeRx campaign launched in 2012, the online public service announcements run by the Center for Safe Internet Pharmacies (CSIP) and the Alliance for Safe Online Pharmacies (ASOP) in 2013, and the potential new dot-pharmacy top-level domain applied for by the National Association of Boards of Pharmacy (NABP) are just three examples of critical work being done by stakeholders to educate consumers. I am happy to share more information about

any of these initiatives in subsequent interaction with the subcommittee staff. Still, education can only go so far, and more must be done.

- Another part of the solution is to have stronger laws. As passed by this Committee, the Food and Drug Administration Safety and Innovation Act of 2012 (FDASIA) expanded existing penalties for drug counterfeiting by increasing the maximum penalties from a possible $2,000,000 fine and 10 years imprisonment to maximum penalties of $5,000,000 and 20 years imprisonment. The Act also added a criminal offense for knowingly and intentionally adulterating a drug with a reasonable probability of causing serious adverse health consequences or death. This too is a good start, but all too often the laws don't keep up with criminals' practices – especially on the Internet – so we thank Congress for remaining vigilant in looking for new ways to close legal loopholes.
- Another part of the solution is more aggressive enforcement of existing laws. Although the July 2013 GAO report on Internet pharmacies outlined a variety of law enforcement challenges - including that most illegal sites operate abroad and operate through complex global organizations which disguise their identities – nevertheless law enforcement actions can be effective and are a necessary deterrent to criminal activity online. I want to take the opportunity to recognize and

express Lilly's appreciation for the good work that has been done by U.S. government agencies, including by FDA/OCI, CBP, and HSI. Their hard work and attention to this issue has a meaningful impact, and it must continue. For example, in June 2013 the US Government collaborated with nearly 100 countries on Operation Pangea VI. According to the FDA, this Operation resulted in the elimination of 1,677 websites selling illegal prescription drugs, and dangerous drugs valued at $41 million were seized. Without CBP's excellent work and international cooperation, there would be even more illegal product in circulation today, finding its way to people in need of treatment. Coordinated international enforcements like this are critical. Ideally, they would be done throughout the year. They can serve as a more effective deterrent if they are systematic and ongoing campaigns.

- Last, but definitely not least, part of the solution is voluntary cooperation by Internet-based companies. According to LegitScript, the number of advertisements for illegal drugs and pharmacies found on major search engines like Google and Bing [Microsoft] has declined by more than 99.9% percent since 2010. The Center for Safe Internet Pharmacies (CSIP), of which Google and Microsoft are members along with 11 other Internet commerce and payment companies,[5] provides a way for

[5] CSIP: http://www.safemedsonline.org/who-we-are/members/

these ecommerce stakeholders to be part of the solution too by developing voluntary best practices, collaborating with law enforcement, and - as mentioned earlier - helping to educate consumers about the threat of illegal online drug sellers. These companies can help to transform the Internet landscape when it comes to online pharmacies by adopting model voluntary practices and holding them up as an example for the rest of the world. And our government, along with other governments, can help to encourage their adoption internationally.

I am sure you are well aware that the there is one primary tool in the Drug Quality Security Act used to tighten defenses against counterfeit and illegal drugs reaching patients in brick-and-mortar pharmacies: that tool is serialization. Likewise, there is also one primary tool that could be used to tighten defenses against counterfeit and illegal drugs reaching patients from online pharmacies - that tool is delisting. That tool could be used to exclude "bad" online pharmacies (those that fail to comply with the standards mentioned above to which we hold an actual physical pharmacy) from natural search results found using search engines. In other words, if a website selling medicines did **not** sell only FDA-approved drugs or did **not** provide those services using a state-licensed pharmacist, after delisting you would **not** find that

website in the search results. The online pharmacy would still be available on the Internet, no doubt hosted in another country, but it would not be found by the patient in the U.S. who is doing an Internet search for his or her medication. If natural search results were cleaned up in this way, that would be the Internet equivalent of what DQSA is doing to tighten the traditional supply chain. The supply chain for counterfeit drugs is long, complex and stretches far around the globe. De-listing "bad" online pharmacies from natural search results would effectively serve to break that chain before it reaches U.S. patients.

Finally, whenever increased oversight of the Internet is discussed, objections are raised such as (1) it's censorship, (2) it'll hurt innovation, or (3) it's futile because the Internet is just too big. In the case of pharmaceuticals, these objections are not correct and they do a disservice to public health and safety. Our existing laws and regulations were put in place as a safety net to protect patients, and now the Internet has ripped a large hole in that safety net which needs to be patched. I have brought with me today a document summarizing media reports of patients harmed by illegal online drug sales, which I request to have submitted for the record along

with my testimony. It demonstrates how very real this issue is, how it has impacted real lives. And these are the cases that have been reported. Some are never known. The Internet is here to stay. The number of fake online "pharmacies" is growing. The question is: what are we going to do about it? We have to do something. This is an area where the pharmaceutical industry and major Internet commerce companies agree, as told by the public commitments and statements of the Center for Safe Internet Pharmacies (CSIP), which includes Google, Microsoft, GoDaddy, Visa and PayPal as its members: the growth of illegitimate online drugs sellers is a big problem and we have to work together to protect people and do something about it. Lilly stands committed to this goal of patient safety in both brick-and-mortar and Internet-based pharmacies, and we appreciate the opportunity to testify before the Subcommittee today to advance that goal.

I look forward to your questions. If I can't answer them now, I will talk with others at Lilly and get right back to you.

Thank you.

Mr. BURGESS. Ms. Jungman, you are recognized for 5 minutes.

STATEMENT OF ELIZABETH JUNGMAN

Ms. JUNGMAN. Thank you. Chairman Murphy, Ranking Member DeGette, and members of the subcommittee, thank you for the opportunity to present testimony. My name is Elizabeth Jungman. I direct drug safety and innovation work at The Pew Charitable Trusts.

Mr. BURGESS. May I ask, is your mike on?

Ms. JUNGMAN. Pardon me. My name is Elizabeth Jungman. I direct drug safety and innovation work at The Pew Charitable Trust, which is an independent, nonpartisan research and policy organization dedicated to serving the public.

Counterfeit drugs are far more than an intellectual property problem; they are a public health problem with real human costs. Counterfeit and other unsafe drugs have entered our drug supply numerous times over the past few decades. Three recent incidents of fake cancer drugs are one example. My testimony for the record and our Web site have others.

I am grateful to Congress for recently enacted two import laws that have been discussed by other panelists, Title VII of the FDA Safety and Innovation Act, which focused on upstream supply chain security; and Title II of the Drug Quality and Security Act, which laid the groundwork for tightening the downstream drug distribution system.

My testimony today will focus on next steps, how policymakers and stakeholders can make full use of these new tools.

Meaningful penalties for drug counterfeiting and diversion are important, but the best way to prevent unsafe products from reaching patients is a tightly closed distribution system. So that is my focus today.By passing the Drug Quality and Security Act last year, Congress created a national serialization and traceability system that will fundamentally change drug distribution in this country.

Beginning in late 2017, each package of prescription drugs will bear a unique serial number enabling it to be verified and eventually allowing for its distribution history to be traced. The DQSA contains some requirements for companies in the supply chain to check serial numbers but in most cases only when there is an existing belief that the product is suspect.

A more powerful use of serial numbers would be as a routine proactive check. Counterfeiters can be sophisticated but falsifying a serial number is much harder if that number is routinely checked against a manufacturer's database. Pharmacists, physicians, payers, and border agents could use this important new tool to help stop fake products from reaching patients.

It is important to underscore that the risks go beyond counterfeit drugs. In 2009, thieves stole a tractor-trailer containing at least 120,000 vials of insulin, an injectable drug that must be refrigerated. After several months, the stolen drugs were sold to chain drugstores. We don't know how many patients received compromised medicines, but only a small percent of the drugs were

ever recovered. Regular checking could have identified them immediately.

Verification should become routine in pharmacies. To achieve that, the system must be designed to ensure that verification is practical and efficient. Waivers of the DQSA's requirements should be rare lest we exempt businesses like the pharmacist in Chicago indicted last year for substituting Chinese counterfeits for legitimate products.

Patients can also make use of this new tool. Doctors who purchased a counterfeit cancer drug last year may not have known that it was fake. While the DQSA does not require physicians to check serials, patients deserve this safety check. Physician societies and payers should consider the potential for authentication to protect patients.

Proactive verification of serial numbers is not without precedent. Other countries like Turkey and Italy already use it to protect their citizens and to prevent fraud. The U.S. is behind the curve in this case, but our law creates the tools necessary for similarly robust protections if Congress, regulators, and payers take action to encourage them.

Payers can also explore the use of serial numbers as a condition of reimbursement both to ensure product legitimacy and to reduce fraud. Large-scale fraud against government programs is well-documented yet preventable through serial checks. To be fully effective, such an approach would require another system element not explicitly contemplated by the DQSA: decommissioning serial numbers so that they cannot be reused.

Serial numbers could also be used by agents at the border. Spot-checks of incoming products could help determine legitimacy, and this will complement the progress in regulating drug imports that was made in the 2012 FDA Safety and Innovation Act.

The DQSA requires in 10 years an electric interoperable system for tracing each unit of medicine. There is an opportunity now to build in strong features that will allow for more comprehensive automated use in the future. But stakeholders do not have to wait 10 years to begin using the DQSA. Starting next year, FDA will stand up a public database of licensed wholesalers, and all stakeholders will pass pedigree information. So long before the law is fully implemented, dispensers can check to ensure that their sources are legitimate.

The DQSA and the FDA Safety and Innovation Act are important steps in securing our pharmaceutical supply chain, but alone they will not solve the problem. Congress, regulators, border agents, and supply chain stakeholders can help create a safer drug supply by supporting robust and implementation of these laws and full use of the tools that they provide.

Thank you.

[The prepared statement of Ms. Jungman follows:]

Testimony before the

Committee on Energy and Commerce, Subcommittee on Oversight and Investigations

United States House of Representatives

February 27, 2014

Elizabeth Jungman, Director, Drug Safety and Innovation

The Pew Charitable Trusts

Chairman Murphy, Ranking Member DeGette, and members of the Oversight and Investigations Subcommittee, thank you for holding this hearing and for the opportunity to present testimony. My name is Elizabeth Jungman; I direct drug safety and innovation work at The Pew Charitable Trusts. Pew is an independent, nonpartisan research and policy organization dedicated to serving the public. We have a longstanding focus on the safety of the prescription drug supply chain.

Counterfeit drugs are far more than an intellectual property problem; they are a public health problem with real human costs. Counterfeit and other unsafe or illegitimate drugs have entered the U.S. drug supply numerous times over the past few decades. We have likely all heard of the recent example of patients exposed to counterfeit Avastin, and I have attached other examples to my testimony.

I am grateful to Congress for enacting two important recent laws to help secure the drug supply: Title VII of the FDA Safety and Innovation Act, which focused on "upstream" supply chain security, and Title II of the Drug Quality and Security Act (DQSA), which laid the groundwork for tightening the "downstream" drug distribution system.

My testimony today will focus on next steps, and particularly on the potential for policymakers and supply chain stakeholders to make full use of these tools and to go beyond statutory requirements to create even more robust protections.

We recognize the importance of better enforcement tools, including meaningful penalties, in deterring criminal behavior. Pew called for higher penalties in 2011, and we applaud the recent efforts of Congress and the Sentencing Commission to make drug counterfeiting and theft more

costly for those who undertake it. We acknowledge that there is likely still more to be done to ensure that prosecutors have the tools they need to protect our drug supply. However, the best way to prevent unsafe products from reaching patients is a tightly closed distribution system, and this is my focus today.

Use of drug serialization

In passing the Drug Quality and Security Act last year, Congress created a national serialization and traceability system for medicines sold in the United States. This will fundamentally change the distribution system for drugs in this country.

Beginning in late 2017, each package of prescription drugs will be given a unique serial number enabling it to be verified, and, eventually, allowing for its distribution history to be traced. The DQSA contains some requirements for companies in the supply chain to make use of these serial numbers, but in most cases only when there is an existing belief that a product is suspect.

An even more powerful use of serial numbers would be to use them as a proactive check to identify illegitimate product that otherwise might pass unnoticed into the drug supply chain. Pharmacists, physicians, payers, and border agents could use this important new tool to help stop fake products from reaching patients. Drug counterfeiters are capable of copying sophisticated packaging, and will be able to imitate the new serial numbers and barcodes required by the DQSA. Faking or copying a serial number is much harder, however, if that number is routinely verified against the manufacturer's database. For instance, a system could flag if the same serial number was checked repeatedly in different locations.

It is important to underscore that the risks go beyond counterfeit drugs. In 2009, for example, thieves stole a tractor-trailer containing at least 120,000 vials of insulin—an injectable drug that must be refrigerated. This stolen drug disappeared for months before being identified on the shelves of chain drugstores in Texas, Georgia, and Kentucky. No patient deserves to receive a prescription medicine that was handled by criminals, but only a tiny proportion of the stolen drugs was ever found.[1,2] The lot number of the stolen drug was known: routine checking could have identified it immediately.

Verification should become routine in pharmacies. To achieve this, the system must be designed to ensure that verification is practical and efficient. Waivers of DQSA's requirements should be rare, lest we exempt businesses like the pharmacist in Chicago who was indicted last year for substituting Chinese counterfeits for legitimate products.[3]

Physicians can also make use of serial numbers. Doctors who purchased counterfeit cancer drugs last year may not have known they were fake. While the DQSA does not require it, routine verification should become the norm. This is a safety check patients deserve. Both physician societies and payers should consider the potential of this tool to protect patients.

Proactive verification of serial numbers is not without precedent—it is already in place or being implemented in several countries. For example, Italy and Turkey require pharmacy authentication of serialized medicines in order to protect their citizens and prevent fraud. Additional countries such as China and Brazil are advancing similar requirements.[4,5] The United States is, unfortunately, behind the curve in this case: Our law requires only minimal verification for pharmacies, but it does give them the tools to make these checks if they choose to, or if Congress, regulators, or payers encourage them to.

Payers could also explore the use of serial numbers as a condition of reimbursement, both to ensure product legitimacy and to reduce fraud. The potential losses to payers from counterfeit, stolen and diverted products are significant.

Two years ago, the U.S. Attorney for the Southern District of New York charged 48 individuals in a large-scale diversion scheme in which criminals bought patients' prescription drugs, including medicines for HIV, schizophrenia, and asthma, and sold them back into distribution through licensed pharmaceutical wholesalers and pharmacies. Not only were patients at risk, but the Medicaid program was defrauded of $500 million.[6] Similar schemes in other states are well documented, including one in Tennessee in January of 2013.[7]

This massive criminal recycling of government-subsidized drugs could have been prevented by a serial number that was proactively verified. This, however, raises the importance of another system element not explicitly required in the DQSA: serial number "decommissioning." If a serial number was retired after drugs reached the pharmacy the first time it would have been caught on its second trip around, after criminals bought it from a patient and resold it. Without proactive checking, and some form of serial number retirement, even a real serial number could be sold many times over without detection. As the FDA and stakeholders build the new verification system, and as Congress oversees that effort, they should consider allowing for features like decommissioning that, while not explicitly required by the law, would be useful in preventing patient harm and taxpayer fraud. Even if serial numbers are not initially decommissioned, the architecture of the system should be built to allow for this possibility at a later date.

Serial numbers could also be used at the border. An estimated 80% of drug ingredients and 40% of finished drugs used by Americans are manufactured overseas, so our border agents play a critical role in facilitating the import of legitimate medicines, and keeping counterfeits out. Once drugs sold in the United States are required to bear serial numbers beginning late 2017, agents could spot-check serial numbers when warranted to determine product legitimacy. This use of serials would complement the progress in regulating drug imports made in the 2012 FDA Safety and Innovation Act, including new controls at the border (such as the power to refuse an imported drug if the plant making it did not allow an FDA inspection, and the ability for FDA to require electronic submission of certain compliance information as a condition of granting entrance), an updated inspection framework, and new resources for this important work.

Use of new traceability tools

The DQSA requires that, in ten years' time, manufacturers, repackagers, wholesalers, and pharmacies participate in an electronic, interoperable system that permits the tracing of each unique package of medicine in distribution. However, the law does not specify precisely how this system will function. Consequently, there is an opportunity to create a system that will be a stronger defense against the insertion of unsafe drugs into the legitimate distribution chain.

As FDA and stakeholders set up the new system, they should build it to enable automatic verification of each transaction between partners in the drug supply chain. If an unauthorized entity attempted to participate, or if the product sold did not have a verifiable transaction history, the system should quickly flag the inconsistency and allow legitimate actors to avoid purchasing an illegitimate product. Automatic verification is not required by the DQSA, but establishing the system architecture to include automated checks would protect every member of the supply chain from the business risks that come with counterfeit products, and it would protect patients.

Stakeholders do not have to wait until the fully interoperable system is in place, or even until product is serialized, to begin using DQSA tools to better secure the supply chain. In anticipation of the fully interoperable electronic system, doctors, pharmacists, and others can take advantage of other tools in the DQSA to ensure they are buying good products. For example, the DQSA will establish a public database of licensed wholesalers so that when a doctor is offered a too-good-to-be-true price on a product like Avastin, he or she could check out the wholesaler offering that deal. The DQSA also requires, for the first 10 years, that trading partners pass transaction histories; a pharmacy could check this documentation to provide assurance that the source is legitimate, particularly in situations, such as when buying a drug in short supply, where the incentives for fraud are high. We don't have to wait 10 years to start taking advantage of the DQSA – these are steps stakeholders can take next year to improve the integrity of our supply chain.

Conclusion

The DQSA and the FDA Safety & Innovation Act are important steps in securing our pharmaceutical supply chain, but, alone, they will not solve the problem. Congress, regulators, border agents and supply chain stakeholders can help create a safer drug supply by supporting robust implementation of these laws, and full use of the tools they provide.

REFERENCES

[1] Ciolek, Michelle M., Special Agent, Office of Criminal Investigations, U.S. Food and Drug Administration. Affidavit in support of search warrant. July 21, 2009. USA v. Altec Medical Inc and RX healthcare Inc. Document number: 8:09-cr-00814-WMC

[2] U.S. Food and Drug Administration. "Update to FDA Alert about Stolen insulin". August 26, 2009. http://www.fda.gov/ForConsumers/Consumerupdates/ucm180320.htm

[3] U.S. Food and Drug Administration, Office of Criminal Investigations. "April 18, 2013: Suspended North Side Pharmacist Indicted for Allegedly Smuggling and Trafficking Counterfeit Viagra". U.S. Department of Justice Press Release, April 18, 2013. http://www.fda.gov/ICECI/CriminalInvestigations/ucm349021.htm. Accessed February 24, 2014.

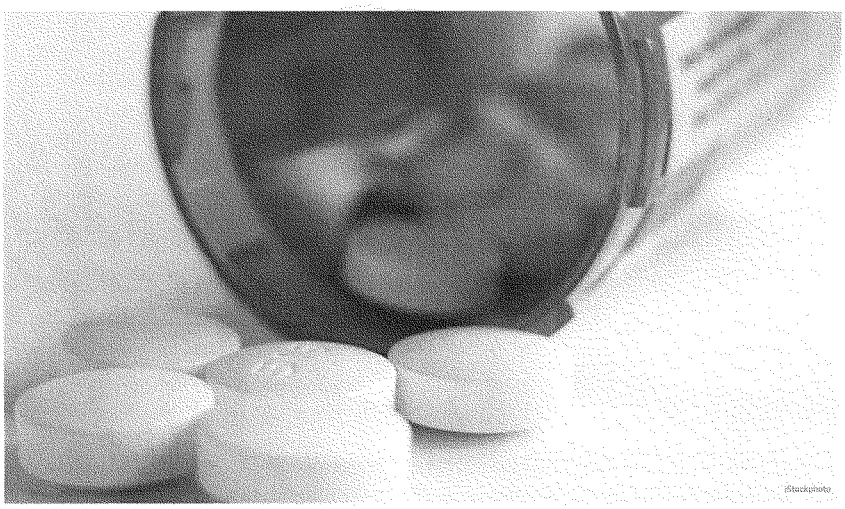
[4] Basta, Nicholas. "Serialization systems are going into operation around the world, but cross-industry collaboration awaits new legislation," Product Security Report, August 27, 2012 http://www.pharmaceuticalcommerce.com/index.php?pg=special_report&articleid=26610&keyword=2012%20product%20report-serialization-RxTEC.

[5] Turkish Ministry of Health. "G.D. of Pharmaceuticals and Pharmacies Guidance on Implementation of Identification and Barcoding of Medicinal Products for Human Use, Version 1.2" Ankara, 2009. http://www.clinicaltrial-storage.com/index.php/regulations-in-turkey-menu/89-turkish-drugs-barcode-guidance-v1-2

[6] United States Attorney's Office, Southern District of New York. Manhattan U.S. Attorney Announces Charges Against 48 Individuals in Massive Medicaid Fraud Scheme Involving the Diversion and Trafficking of Prescription Drugs. July 17, 2012. http://www.justice.gov/usao/nys/pressreleases/july12/prescriptiondrugs.html Accessed July 20, 2012

[7] United States Attorney's Office for the Middle District of Tennessee. "Three Individuals Indicted For Prescription Drug Diversion Conspiracy". January 24, 2013. http://www.justice.gov/usao/tnm/pressReleases/2013/1-24-13A.html

A brief from THE PEW CHARITABLE TRUSTS | Feb 2014



Case Studies: How Unsafe Drugs Can Reach Patients

The following case studies illustrate breaches to the pharmaceutical supply chain—the route a drug travels from its raw-material origins to the delivery of a finished medicine. These examples, many of which are summarized in the Pew report *After Heparin: Protecting Consumers From the Risks of Substandard and Counterfeit Drugs*, demonstrate the different ways that contaminated, fake, or otherwise unsafe medicine can reach patients. They also underscore the need for reform.

Eighty percent of the active and bulk chemical ingredients in U.S. drugs originate overseas, according to estimates by the Food and Drug Administration (FDA).[1] The increasingly global and outsourced production of drugs creates vulnerabilities in the pharmaceutical supply system that can put patients' lives at risk without sufficient oversight by industry and regulators.

Once a finished drug enters distribution, it can pass through many hands before reaching a pharmacy, thereby creating opportunities for criminals to insert illegitimate products into the supply chain. Stolen and counterfeit medicines have made it onto pharmacy shelves or reached patients numerous times over the past decade.

Previously dispensed drugs, held under unknown conditions, were illegally resold to patients at U.S. pharmacies, costing the New York Medicaid program $500 million.

In 2012, the U.S. attorney for southern New York uncovered a massive criminal ring of drug diversion and relabeling that cost the state Medicaid program more than $500 million and put unknown numbers of patients at risk from compromised medicines.[2]

"Collectors" purchased the drugs from patients and sold the medicines back into distribution through pharmaceutical wholesalers, allowing them to eventually reach pharmacies. The unsuspecting patients who received these recycled drugs were exposed to medicines that may have expired or been contaminated.[3]

The practice of diverting and reintroducing pharmaceutical product for profit is not new. Similar schemes in other states are well documented. In 2013, for example, three people were indicted in a Tennessee court for allegedly buying medicines that had been collected from patients and then reselling the drugs to pharmacies as legitimate products.[4]

Counterfeit cancer medicines were distributed in the United States.

Twice in 2012 and once in 2013, FDA announced that counterfeit cancer medicines had been found in the United States. The fake drugs contained none of the active ingredient necessary to treat the disease.[5]

According to FDA, the counterfeit drugs came from foreign suppliers that were providing medicines to U.S. medical practices using illegal channels that were approved for use in other countries such as Turkey, but not the United States.[6] FDA notified more than 100 doctors in 33 states that they had purchased illegal prescription drugs from foreign or unlicensed suppliers.[7]

An adulterated blood thinner harmed patients in the United States.

In early 2008, the U.S. Centers for Disease Control and Prevention began investigating an outbreak of allergic-type reactions in patients undergoing dialysis. Most of these patients had received intravenous heparin, a widely used blood thinner manufactured by Baxter Healthcare.[8] Further investigation revealed that an adulterant with toxic effects, oversulfated chondroitin sulfate (OSCS), had been introduced during heparin's manufacture in China.[9] The chemical structure of OSCS so closely mimicked heparin that it passed standard tests.[10]

Dozens of Americans suffered adverse reactions, including death.[11] Investigations into this tragedy have revealed a number of systemic failures, including inadequate oversight and supply chain management by both regulators and industry. Heparin's complex production chain was left vulnerable to abuse by perpetrators who have not been identified.

2

Manufacturing quality and safety problems at an India-based generics company led FDA to ban imports of more than 30 drugs produced there.

Ranbaxy is one of the largest worldwide producers of generic medicines. Its products filled 52 million U.S. prescriptions in 2007.[12]

In 2008, in-depth plant inspections by FDA resulted in allegations of numerous safety and quality issues.[13] According to the agency, Ranbaxy exposed products to potential cross-contamination by penicillin and failed to adequately investigate sterility failures.[14] A Department of Justice subpoena motion stated that Ranbaxy also used active pharmaceutical ingredients made at sites not approved by FDA.[15]

In 2008, the agency suspended importation of more than 30 Ranbaxy products, including drugs for epilepsy, diabetes, and allergies.[16] It again suspended importation of products made at a Ranbaxy plant in 2014. FDA believes that increasing its on-the-ground presence in countries such as India could strengthen its oversight of imported drugs.[17]

A pharmaceutical broker falsely labels medicines imported into the United States to conceal unapproved manufacturing plants.

In the late 1980s and early 1990s, drug broker Flavine International Inc. bought cheap materials from Chinese plants that were not approved by FDA. Flavine falsely labeled the products as active ingredients from Long March Pharmaceutical, an FDA-approved facility.[18] The drugs, which included bulk shipments of the antibiotic gentamicin, were sold to U.S. manufacturers, which eventually recalled gentamicin products from the market.[19] In 1997, Flavine was fined, and its owner was sentenced to two years in prison.[20]

This case underscores the importance of manufacturer scrutiny of brokers and suppliers to verify that all drug production is actually occurring at the declared sites and that sufficient quality assurance systems are in place.

A major foreign manufacturer of antibiotics for the U.S. market admitted that it did not follow approved manufacturing standards.

In the 1990s, the Italian pharmaceutical manufacturer Biochimica Opos, then a wholly owned subsidiary of the French drug company Roussel-Uclaf, falsified records to conceal its use of undisclosed manufacturing sites in Italy, France, and Romania to produce the antibiotic cefaclor. The company ultimately recalled this and other products and withdrew its approved marketing applications.[21]

In 2001, Roussel-Uclaf's successor, Aventis Pharma A.G., pleaded guilty to multiple felony charges and was ordered to forfeit $10 million in proceeds and pay a $23 million criminal fine to the U.S. government. The case represented the first time a foreign corporation making a drug product entirely outside the United States received a criminal punishment for defrauding FDA.[22] As drug manufacturing becomes increasingly globalized, such international collaboration is essential for improving oversight and identifying wrongdoing.

Cough medicine in Panama is mixed with an industrial solvent falsely labeled as sweetener.

In Panama, 78 people died in 2006 after taking a cough medicine that the government had unknowingly mixed with toxic syrup originating in China. Diethylene glycol (DEG), an industrial solvent often used in antifreeze formulations, had been labeled as glycerin, which is commonly used to make syrup formulations of medicines.[23] The material passed through brokers in China and Europe, receiving new labels along the way, before finally reaching Panama.[24] Product testing by the brokers was either insufficient or nonexistent. The Panamanian government ultimately distributed 60,000 units of medicine mixed with DEG to patients.[25]

False labeling masked the source of the problem from officials; as a result, the cause of patient deaths was not identified for more than a month after initial distribution of the adulterated medicine.[26]

Insulin known to be stolen was discovered on pharmacy shelves.

In 2009, thieves in North Carolina stole a truck containing more than 120,000 vials of Levemir insulin made by Novo Nordisk.[27] According to an FDA affidavit, the temperature-sensitive medicine was illicitly sold back into distribution through wholesalers and eventually reached medical centers in Texas, Georgia, and Kentucky.[28] Diabetic patients received the stolen goods, and some reported poor blood sugar control.[29] In this case, according to the same affidavit, wholesaler documentation of the insulin's origins (the drug's "pedigree") indicated it was purchased from a national distribution company Feb. 7, 2009, a day after the medicine was reported stolen.[30]

State requirements for drug pedigrees and drug wholesaler licensure vary. Most pedigrees are paper and thus easily falsified. A national system to track and authenticate drugs would improve distribution security.

A counterfeit injectable anemia drug was sold into legitimate distribution in the United States, resulting in subtherapeutic dosing and severe side effects for patients.

In 2002, criminals in Florida relabeled up to 110,000 bottles of low-dose Epogen, an anemia drug, to create counterfeit high-dose Epogen and Procrit.[31] The counterfeit drugs passed through several registered and unregistered intermediaries before a portion was allegedly sold to a national wholesaler.[32] As a result, patients received insufficient levels of life-preserving therapy and suffered painful side effects.[33]

The relabeling of low-dose Epogen to resemble a stronger product yielded an estimated $46 million in profits. FDA recovered less than 10 percent of the counterfeit medicine; more than 90,000 vials may have reached patients. This illustrates the potential for counterfeit drugs from domestic sources to enter the U.S. supply chain.[34]

Endnotes

1 U.S. Government Accountability Office, Food and Drug Administration: Improvements Needed in the Foreign Drug Inspection Program (Publication No. GAO/HEHS-98-21, March 1998), http://www.gao.gov/assets/230/225564.pdf.

2 Federal Bureau of Investigation, "Manhattan U.S. Attorney Announces Charges Against 48 Individuals in Massive Medicaid Fraud Scheme Involving the Diversion and Trafficking of Prescription Drugs," news release (July 17, 2012), http://www.fbi.gov/newyork/press-releases/2012/manhattan-u.s.-attorney-announces-charges-against-48-individuals-in-massive-medicaid-fraud-scheme-involving-the-diversion-and-trafficking-of-prescription-drugs.

3 U.S. Attorney's Office, Middle District of Tennessee, "Three Individuals Indicted for Prescription Drug Diversion Conspiracy" (Jan. 24, 2013), http://www.justice.gov/usao/tnm/pressReleases/2013/1-24-13A.html.

4 U.S. Attorney's Office, Southern District of Florida, "Boca Raton Man and New Jersey Man Sentenced in $7 Million Human Growth Hormone and Tax Scheme," news release (July 31, 2008), http://www.justice.gov/tax/usaopress/2008/txdv08_080731-01.pdf.

5 U.S. Food and Drug Administration, "Avastin (bevacizumab): Counterfeit Product - FDA Issues Letters to 19 Medical Practices," http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm291968.htm.

6 U.S. Food and Drug Administration. "Avastin (bevacizumab)."

U.S. Food and Drug Administration. "Another counterfeit cancer medicine found in U.S.: Illegal practice puts patients at risk," http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/ucm298047.htm.

U.S. Food and Drug Administration. "Health Care Provider Alert: Another Counterfeit Cancer Medicine Found in United States," http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/CounterfeitMedicine/ucm338283.htm.

7 U.S. Food and Drug Administration. "Letters to Doctors About Risks of Purchasing Medications From Foreign or Unlicensed Suppliers," http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/ucm299920.htm.

8 U.S. Centers for Disease Control and Prevention, "Acute Allergic-Type Reactions Among Patients Undergoing Hemodialysis: Multiple States, 2007-2008," Morbidity and Mortality Weekly Report (Feb. 1, 2008), http://www.cdc.gov/mmwr/preview/mmwrhtml/mm57e201a1.htm.

9 Takashi Kei Kishimoto et al., "Contaminated Heparin Associated With Adverse Clinical Events and Activation of the Contact System," New England Journal of Medicine (June 5, 2008) 358: 2457-67.

Steve Usdin, "The Heparin Story," International Journal of Risk and Safety in Medicine (2009) 21: 99-103.

10 Robert L. Parkinson, CEO of Baxter International, testimony before the U.S. House Energy and Commerce Committee, Subcommittee on Oversight and Investigations, 110th Congress, April 29, 2008.

11 U.S. Government Accountability Office, Food and Drug Administration: Response to Heparin Contamination Helped Protect Public Health; Controls That Were Needed for Working With External Entities Were Recently Added (October 2010, Publication No. GAO-11-95), http://www.gao.gov/assets/320/311879.pdf.

12 Justin Blum, "U.S. Approves Ranbaxy Drugs Despite Questions," Bloomberg, Aug. 13, 2008, http://www.livemint.com/Companies/55vu4OytuG7ALE2wjgxWwO/US-approves-Ranbaxy-drugs-despite-questions.html.

13 U.S. Food and Drug Administration, "Transcript of Media Briefing on Ranbaxy Labs (Sept. 17, 2008), http://www.fda.gov/downloads/NewsEvents/Newsroom/MediaTranscripts/ucm121266.pdf.

14 U.S. Food and Drug Administration, "Warning Letter" (WL: 320-08-03, Sept. 16, 2008) to Malvinder Singh, CEO and managing director of Ranbaxy Laboratories Ltd. http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2008/ucm1048134.htm.

15 Motion to Enforce Subpoenas and Points and Authorities. United States of America, petitioner, v. Ranbaxy Inc. and Parexel Consulting, respondents. U.S. District Court for the District of Maryland, Southern Division (July 3, 2008).

16 Food and Drug Administration, "FDA Issues Warning Letters to Ranbaxy Laboratories Ltd., and an Import Alert for Drugs From Two Ranbaxy Plants in India," news release (Sept. 16, 2008), http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2008/ucm116949.htm.

List of Drugs Manufactured at the Dewas and Paonta Sahib Facilities of Ranbaxy Laboratories Ltd. (revised Sept. 24, 2008), http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/ucm118441.htm.

17 U.S. Food and Drug Administration, Consumer Health Information. "FDA Beyond Our Borders" (Dec. 9, 2008), http://www.fda.gov/downloads/ForConsumers/ConsumerUpdates/ucm103044.pdf.

18 John Henkel, "Probe Proves Effective Against Antibiotic Smuggling Scheme," FDA Consumer (January-February 1998), http://permanent.access.gpo.gov/lps1609/www.fda.gov/fdac/departs/1998/198_irs.html.

19 Cheryl A. Thompson, "FDA Admits to Lacking Control Over Counterfeit Drug Imports," American Journal of Health-System Pharmacy (June 9, 2000), http://www.ashp.org/import/news/HealthSystemPharmacyNews/newsarticle.aspx?id=135.

20 U.S. Department of Justice, "New Jersey Drug Firm and Owner Sentenced and Fined in Illegal Pharmaceutical and Money Laundering Scheme," news release (April 10, 1997), http://www.justice.gov/opa/pr/1997/April97/146civ.htm.

21 Carol Lewis, "FDA Investigators' Reports—January-February 2002," FDA Consumer (Jan. 4, 2002).

22 U.S. Food and Drug Administration, Office of Criminal Investigation, "The Enforcement Story: Fiscal Year 2001," http://www.fda.gov/ICECI/EnforcementActions/EnforcementStory/EnforcementStoryArchive/ucm090830.htm.

23 E. Danielle Rentz et al., "Outbreak of Acute Renal Failure in Panama in 2006: A Case-Control Study," Bulletin of the World Health Organization (2008) 86:749-756, http://www.who.int/bulletin/volumes/86/10/07-049965.pdf?ua=1.

24 J.G. Schier et al., "Medication-Associated Diethylene Glycol Mass Poisoning: A Review and Discussion on the Origin of Contamination," Journal of Public Health Policy (2009) 30: 127-43.

25 Rentz, "Outbreak of acute renal failure."

26 Rentz, "Outbreak of acute renal failure."

27 U.S. Food and Drug Administration, "Update to FDA Alert About Stolen Insulin" (Aug. 26, 2009), http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm180320.htm.

Michelle M. Ciolek, special agent, Office of Criminal Investigations, U.S. Food and Drug Administration, "Affidavit in Support of Search Warrant," USA v. Altec Medical Inc and RX Healthcare Inc. (July 21, 2009), Document number: 8:09-cr-00814-WMC.

28 Ciolek, affidavit.

29 U.S. Food and Drug Administration, "Update to FDA Alert about Stolen Insulin."

30 Ciolek, affidavit.

31 Cheryl A. Thompson, "Counterfeit Drugs Arise From Various Sources; Wholesalers Blamed for Promoting Drug Diversion," American Journal of Health-System Pharmacy (Aug. 1, 2003), 60.

32 Katherine Eban, testimony at hearing on "Sick Crime: Counterfeit Drugs in the United States" before the U.S. House Committee on Criminal Justice, Drug Policy, and Human Resources, 109th Congress, Nov. 1, 2005.

Donna Young, "Counterfeit Drug Lawsuit Points Finger at Wholesaler, Pharmacy," American Journal of Health-System Pharmacy (Oct. 1, 2004).

33 Kevin Fagan, testimony at hearing on "Sick Crime: Counterfeit Drugs in the United States" before the U.S. House Committee on Criminal Justice, Drug Policy, and Human Resources, 109th Congress, Nov. 1, 2005.

James M. Butler, testimony at hearing on "Sick Crime: Counterfeit Drugs in the United States" before the U.S. House Committee on Criminal Justice, Drug Policy, and Human Resources, 109th Congress, Nov. 1, 2005.

34 Thompson, "Counterfeit Drugs Arise."

Contact: Sarah Carroll, communications
Email: scarroll@pewtrusts.org
Project website: pewhealth.org/drugsafety

The Pew Charitable Trusts is driven by the power of knowledge to solve today's most challenging problems. Pew applies a rigorous, analytical approach to improve public policy, inform the public, and stimulate civic life.

Mr. BURGESS. Thank you. And I thank the witnesses, each and every one of you, for your testimony. And we will now move to questions. Each Member will be recognized for 5 minutes. I will begin.

Dr. Crosse and Dr. Yadav, I appreciated your testimony. You heard my questions to the FDA and to ICE. I mean cost is a big driver here and people are looking at pharmacy bills that they may never have seen before. I feel that right over the horizon this problem is going to crescendo in size.

One of you referenced people who go online because they are bargain hunters or they are self-prescribing. Self-prescribing means they are avoiding a doctor visit to get a prescription. So basically cost is the driver there. Has there been any study on, say, one of the popular proton pump inhibitors for acid reflux disease went over-the-counter. Did you see a drop-off in Internet activity with the purchase of other brands that remained on patent and were therefore more expensive? Was cost reflective in the Internet activity?

Ms. CROSSE. I am not aware of any studies that have directly addressed that. We certainly do know that activity has increased across time in general and the number of sites I think reflects that. Internet purchases originally were focused more in the so-called lifestyle drugs. That has moved increasingly into individuals seeking to save money on their blood pressure medicine or whatever other medications they may regularly be on. But I don't know of studies that specifically looked at that change when something goes from prescription to over-the-counter.

Mr. BURGESS. And, Dr. Yadav, did the Institute of Medicine do any of that sort of investigative work?

Mr. YADAV. So the short answer is no. I think we looked at various studies and I think we will submit to the committee some of the findings which show which type of categories were being purchased more, what kinds of factors and root causes were leading to that. But there was no study which showed how does this change when the product goes from being prescription to over-the-counter.

Mr. BURGESS. Do any of our representatives from the industry have any experience with that?

Well, Mr. Clark, I just noticed on your Web site some of the things you have in the pipeline, the Phase III and Phase II drugs, I mean some pretty exciting stuff already on the horizon, PCSK9 for lipid control. Is the development of those products in any way going to be impacted by the fact that the diversionary activities that you described are going on? Is that going to have a direct effect on your research and development side?

Mr. CLARK. It could and it is one of the worries we have had in rolling out just last year some of the newer medicines. They need a track record to build up success and to prove to the world how good they are. We went out ahead of several them to start checking the Internet and the B2B sites to see if in terms of Eloquest, Xeljanz, a few others that were coming out, worried that if competed with by counterfeits and there are reports of they don't work because of the counterfeit effect, it could indeed actually the reputation of the medicine themselves and stuff. Fortunately, the ones

we have been looking at so far haven't had that much competition on the Internet.

Mr. BURGESS. How about for any of you does it affect your R&D budget, the fact that you are obviously losing sales?

Mr. CLARK. I can speak for my shop. We have never been held to task by the company for return on investment for sales. It is a reputational thing, which obviously has a collateral sales impact, but it is really a patient health and safety issue for us.

Mr. MOREAU. The very same at Novartis.

Mr. BURGESS. And, Mr. Moreau, your description of the antimalarial drug, I mean the United States taxpayers spent a lot of money in the PEPFAR program to buy the drug to prevent the disease to save the children in other countries and human tragedy because of the counterfeit drugs making it into the pipeline and the American taxpayers being ripped off. This is something that just absolutely has to be stopped and we certainly appreciate your vigilance to that and we will welcome your input back to the committee.

Mr. MOREAU. Yes, Congressman. On a more positive note, I just want to inform the committee that we have been working, we are still working very closely with federal agents attached to USAID on this case, and there are reasons to believe that the criminal gang responsible for this counterfeiting operation will one day or another be arrested in China.

Mr. BURGESS. All right. Very well. And, Mr. Longbottom, you heard my description of the little research project I did here on the committee dais where I put into a search engine a name of a cheap pharmaceutical project. I got a lot of results, a lot of hits. And then you talked about delisting and in fact are those types of activities actually in process where you are working with the search engines to try to minimize this?

Mr. MOREAU. We are currently developing a web monitoring program, especially here in the states and with the plan to liaise directly with authorities and exchange information and intelligence.

Mr. BURGESS. All right. Thank you.

Mr. LONGBOTTOM. Mr. Chairman, may I answer your question?

Mr. BURGESS. Sure.

Mr. LONGBOTTOM. Thank you. Yes, we are not currently working on those tools but I do know that the Center for Safe Internet Pharmacies, or CSIP, referred to earlier by another committee member, is at work to develop proposals to work together, and those are the e-commerce companies, the search engines, the payment card companies, the domain name registrars. So it might come out of that group. But wouldn't it have been nice if had you done the search, the first 35 results would have been the NABP-certified——

Mr. BURGESS. Yes, sir.

Mr. LONGBOTTOM [continuing]. Online pharmacies? I think that is where we really want to move to. I would love to see that for my family members going online, constituents as well. I think that is where we are headed.

Mr. BURGESS. Absolutely. My time is expired. I recognize the ranking member for 5 minutes.

Ms. DEGETTE. Thank you very much, Mr. Chairman.

And I want to thank all of you for coming here today and working collaboratively with us to try to resolve this very difficult and international problem.

I am concerned because we recognize this issue of counterfeit drugs. We have been trying to work on it assiduously with the track-and-trace legislation, with the FDA, giving more resources with all of the private companies giving more resources.

But yet, according to the testimony that I am hearing from all the witnesses today, the prevalence of these counterfeit drugs, particularly on the Internet, just continues to grow and to get more sophisticated. And so what I would like to examine in just this short period of time I have is what we can really do to try to bend this curve and to solve the situation.

So I would like to start with you, Dr. Crosse. You testified, as did the others on the last panel, that the sentences are really ridiculously low for these federal offenses, and I agree with that. I think the sentences need to be increased, but I am trying to figure out, and this is what I was talking to the chairman about, is how much is increasing sentences really going to prevent this kind of conduct, especially as Mr. Moreau and Mr. Longbottom and others have testified. Some of these people are renegade gangs in foreign countries.

And so one thing I want to ask you, did the GAO find that these prosecutors who were able to prosecute people under other statutes, money laundering, wiretap, et cetera, would there have been more prosecutions and more convictions if they had been able to get felony convictions and higher sentences?

Ms. CROSSE. We did hear from prosecutors that increasing the penalties or clarifying what was required to be the threshold for criminal activity might make this a higher priority among all of the competing cases——

Ms. DEGETTE. OK.

Ms. CROSSE [continuing]. That they have. If they are having to pick something that is really difficult and that carries low penalties, it has a lower priority.

Ms. DEGETTE. And so even though they have these other statutes they could charge them, this would help?

Ms. CROSSE. Right. They indicated that it would be helpful.

Ms. DEGETTE. OK. But it alone would not help? We are going to need to do other things, right?

Ms. CROSSE. That is correct.

Ms. DEGETTE. OK. And what would some of those other things be?

Ms. CROSSE. Well, there have been a number of settlements that have been undertaken to get at some of the service providers to these Internet sites. The Google settlement was mentioned earlier. All that did though was remove the sponsored links at the top——

Ms. DEGETTE. Right.

Ms. CROSSE [continuing]. Of the page. That doesn't eliminate those.

Ms. DEGETTE. So Internet vigilance like Mr. Longbottom and others have been talking about would be helpful?

Ms. CROSSE. That can be helpful. Also the NABP is engaged——

Ms. DEGETTE. Yes.

Ms. CROSSE [continuing]. In getting a top-level domain name, a .pharmacy, where there would be controls in place on which Web sites could have a .pharmacy extension as opposed to a .com. That would require educating consumers to go to those links and not others.

Ms. DEGETTE. And let's follow up on that, educating consumers. Mr. Clark, I was actually talking to you yesterday about this. It seems to me one of the real keys is educating consumers that they shouldn't be going on these Web sites. Can you describe for me what kinds of efforts the industry is taking to do that consumer education?

Mr. CLARK. Sure. I know from our experience and my colleagues have done similarly, we are always working with media to try and highlight issues, whether it is a case or just background information, speaking at conferences. We do a lot of training of law enforcement along the same lines to educate them because I think it is not only just the consumers. First and foremost it is the medical community. I mean it is astounding how doctors and nurses aren't so familiar with this and law enforcement as well. So there is a huge outreach by most of the companies to try and get to all of the constituents within those sectors and stuff to try and raise awareness because——

Ms. DEGETTE. And, I am sorry, are you also working with the various federal agencies to increase this education?

Mr. CLARK. Absolutely.

Ms. DEGETTE. The FDA and the—OK.

Now, I wanted to ask you, Ms. Jungman. By the way, I am the co-chair of the Diabetes Caucus, so I was horrified to hear your insulin example. And what you really focused on is what more can we do? Does Congress need to do anything to help improve this serial number issue? Because that sounded like a very intriguing and relatively successful way to help to identify these counterfeit drugs.

Ms. JUNGMAN. I think that Congress definitely could have a role here. I think oversight as the system is implemented both to ensure that all stakeholders are fully participating but also to be sure that as a system, architecture is built up. There are ways that the system could be built that are more robust or just barebones, and I think congressional oversight could play a real role in ensuring that it is built to have the functionality that would allow for serial checking in a way that is automatic and simple for people to use.

Ms. DEGETTE. Thank you.

Thank you very much, Mr. Chairman. And if you can help convey with me to Mr. Murphy that we should continue this oversight, I think that would be great.

Mr. BURGESS. I thank the gentlelady.

I would be willing to go for one supplemental question if you were.

Ms. DEGETTE. OK. One.

Mr. BURGESS. Well, it just so happens I have one. Has the Ryan Haight Act been effective in reducing the number of Internet pharmacies selling controlled substances, Dr. Crosse?

Ms. CROSSE. DEA tells us that it has been effective in reducing the number of domestically located Web sites selling controlled substances. However, they haven't been doing a lot of looking overseas.

They have had a small sample of Web sites that they looked at and ordered controlled substances, and 40 percent of the Web sites where they placed those orders actually provided them with controlled substances. They tell us, though, that they are more likely to be schedule III or schedule IV, drugs like Vicodin or Xanax, rather than oxycodone, which is a schedule II substance. So they do believe it has been effective in pushing the activity offshore.

Mr. BURGESS. I recognize the ranking member for an additional question.

Ms. DEGETTE. I am fine. I just want to thank the panel.

Mr. BURGESS. And to be bipartisan I would join in that thanks for all the witnesses, all the members who participated in today's hearing. I remind Members they have 10 business days to submit questions for the record and I ask all the witnesses to agree to respond promptly to written questions.

With that, the subcommittee shall stand adjourned. Thank you.

[Whereupon, at 12:30 p.m., the subcommittee was adjourned.]

[Material submitted for inclusion in the record follows:]

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

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[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

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[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

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[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 report[20] 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

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[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.

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[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).

FRED UPTON, MICHIGAN
CHAIRMAN

HENRY A. WAXMAN, CALIFORNIA
RANKING MEMBER

ONE HUNDRED THIRTEENTH CONGRESS

Congress of the United States
House of Representatives
COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515–6115
Majority (202) 225-2927
Minority (202) 225-3641

March 14, 2014

Mr. Howard Sklamberg
Deputy Commissioner for Global Regulatory Operations and Policy
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Mr. Sklamberg:

Thank you for appearing before the Subcommittee on Oversight and Investigations on Thursday, February 27, 2014, to testify at the hearing entitled "Counterfeit Drugs: Fighting Illegal Supply Chains."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

Also attached are Member requests made during the hearing. The format of your responses to these requests should follow the same format as your responses to the additional questions for the record.

To facilitate the printing of the hearing record, please respond to these questions and requests with a transmittal letter by the close of business on Friday, March 28, 2014. Your responses should be mailed to Brittany Havens, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, D.C. 20515 and e-mailed in Word format to brittany.havens@mail.house.gov.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,

Tim Murphy

Tim Murphy
Chairman
Subcommittee on Oversight and Investigations

cc: Diana DeGette, Ranking Member, Subcommittee on Oversight and Investigations

Attachments

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

The Honorable Tim Murphy
Chairman
Subcommittee on Oversight and Investigations
Committee on Energy and Commerce
House of Representatives
Washington, D.C. 20515-6115

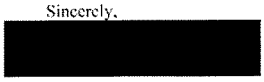
APR 13 2015

Dear Mr. Chairman:

Thank you for providing the Food and Drug Administration (FDA or the Agency) with the opportunity to testify at the February 27, 2014, hearing entitled "Counterfeit Drugs: Fighting Illegal Supply Chains," before the Subcommittee on Oversight and Investigations, Committee on Energy and Commerce. This is a partial response for the record to questions posed by you, in a letter we received on March 14, 2014.

If you have further questions, please let us know.

Sincerely,



Thomas A. Kraus
Associate Commissioner
for Legislation

cc: The Honorable Diana DeGette
Ranking Member
Subcommittee on Oversight and Investigations

We have restated each of your questions below in bold, followed by FDA's responses.

The Honorable Tim Murphy

1. **Please describe the difficulties in prosecuting counterfeit drug crimes under current Federal law. For example, what are the difficulties in proving that a defendant knew the drugs were counterfeit?**

   In many counterfeit drug investigations, the counterfeit drug is manufactured in a foreign location. Because of the difficulties in locating the actual counterfeiters, FDA's ability to prosecute those who facilitate the distribution of counterfeit drugs by turning a blind eye to the source of their drugs is critical to the Agency's success in combating the counterfeit drug problem. However, as a practical matter, it is often difficult to prove that criminals who acted as purveyors, rather than manufacturers, of counterfeit drugs knew that the drugs were counterfeit. Counterfeit drugs are, by definition, represented to be the genuine product and are often visually indistinguishable from genuine product. In fact, the profit from drug counterfeiting depends on selling the product as if it were the legitimate drug. Therefore, unless the defendant was involved with the manufacture of the counterfeit product, it can be difficult to prove beyond a reasonable doubt that the defendant had actual knowledge that a particular drug was counterfeit.

2. **Please explain if it would be easier for Federal prosecutors to prove that a defendant knew the drugs were unapproved rather than proving the defendant knew that the drugs were counterfeit?**

   We believe that it would be easier to prove a defendant's knowledge that drugs were not FDA-approved (i.e., unapproved) than it would be to prove a defendant's knowledge that a drug is counterfeit. Counterfeit drugs are intended to masquerade as the genuine drug product; their counterfeit nature is concealed and difficult to detect without testing or close examination. Certain unapproved drugs, on the other hand, are more easily identified. For example, those products manufactured for a foreign market often bear labels that are in a foreign language or easily distinguishable from the FDA-approved label. Unlike counterfeit drugs, the unapproved nature of a drug is often readily apparent by visual inspection.

3. **Are existing penalties for counterfeit and foreign unapproved drugs substantially lower than the penalties for violations relating to intellectual property or economic loss? If so, what are some examples?**

   Generally, the existing maximum penalty for counterfeit and foreign unapproved drug violations of the Federal Food, Drug, and Cosmetic Act (FD&C Act or the Act) is one year in prison. The maximum penalty increases to three years in prison if the Government can prove beyond a reasonable doubt that the offense was committed with intent to defraud or mislead. These maximum penalties are significantly lower

than the maximum penalty for most other serious Federal offenses. For example, the maximum penalty for health care fraud is 10 years generally; 20 years if the offense results in serious bodily injury; and life if the offense results in death. The maximum penalty for mail fraud, wire fraud, and smuggling is 20 years in prison. The maximum penalty for securities and commodities fraud is 25 years and for bank fraud, 30 years.

4. **Would increasing penalties for counterfeit drug and foreign unapproved drug violations to the same level for other comparable criminal violations deter criminal actors?**

We believe that stronger penalties would have a deterrent effect. The relatively low maximum penalties currently provide little punishment or deterrence, especially viewed in relation to the huge profits offenders can reap from selling drugs in violation of the FD&C Act. The harm caused by these violative products is not merely financial; consumers who use counterfeit or unapproved drugs may suffer harm, or even die, because they did not receive recognized, effective therapies or because the products contain dangerous substances. The distribution of counterfeit and unapproved drugs is almost always an economically motivated crime, and the offenders may perceive that the potential profits outweigh possible punishment. Increasing the potential penalties, both in terms of prison time and monetary penalties, would help to deter those who believe that the risks of engaging in this conduct are minimal, especially in comparison to the perceived gains. What's more, while it is critical to use all available tools, including general criminal statutes such as mail fraud, wire fraud, or smuggling, to prosecute the distribution of counterfeit and unapproved drugs, it is also important to note that these general statutes do not encompass the full range of specific conduct that violates the FD&C Act, nor are they meant to do so. It is also important to consider which elements of criminal violations can be proven. Having appropriate penalties for violations of the FD&C Act can reflect the specific harm that may come from those violations the priority that the Government should place on prosecuting such conduct.

a) **GAO has stated that agencies and U.S. Attorneys' Offices may not pursue cases because they believe the penalties will not meet minimum thresholds established to prioritize cases. Would increasing penalties for counterfeit and foreign unapproved drug violations lead to more of these cases being investigated and prosecuted?**

While we believe that stronger penalties may increase the likelihood that more counterfeit and foreign unapproved drug cases could be prosecuted by the Department of Justice (DOJ), DOJ itself is in the best position to answer this question.

b) **To what extent has FDA observed that comparatively low penalties fail to deter criminals from trafficking in counterfeit or foreign unapproved drugs? Please explain whether FDA believes that existing offenses and**

penalties deter counterfeit or unapproved drug traffickers from repeating the same behavior.

We do not believe that the existing penalties under the FD&C Act provide sufficient deterrence, given the high-profit incentives. We also note that to prove a felony under the Act, we must prove that the offense was committed with the specific intent to defraud or mislead. This means that the Government must prove more than just knowledge that the drugs were unapproved or counterfeit. The Government must prove that the defendant acted with a specific intent to defraud or mislead. This high burden of proof, in combination with relatively low penalties, poses challenges to successful prosecution of offenders. What's more, while it is critical to use all available tools, including general criminal statutes such as mail fraud, wire fraud, or smuggling, to prosecute the distribution of counterfeit and unapproved drugs, it is also important to note that these general statutes do not encompass the full range of specific conduct that violates the FD&C Act, nor are they meant to do so. It is also important to consider which elements of criminal violations can be proven. Having appropriate penalties for violations of the FD&C Act can reflect the specific harm that may come from those violations the priority that the Government should place on prosecuting such conduct.

5. **Would criminal actors be deterred from manufacturing and selling counterfeit and foreign unapproved drugs if they were subject to forfeiting the proceeds of their illegal activities? Please explain to what extent providing forfeiture authority under the Federal Food Drug and Cosmetic Act would help with cases where Federal authorities were not able to get at the individual due to difficulties with foreign investigations.**

Providing clear asset forfeiture authority under the FD&C Act would help eliminate the financial motivation behind criminal violations of the Act by depriving offenders of the proceeds of their crimes. The proposed remedy would serve as an important and effective deterrent.

Civil asset forfeiture authority is particularly critical to FDA's effort to protect the global supply chain and combat the increasing number of offenders who operate from foreign locations and import counterfeit and unapproved drugs into the United States. Because these offenders are not in the United States, prosecuting them is time-consuming and sometimes impossible due to foreign legal requirements and the refusal of some countries to extradite. The proposed civil forfeiture authority would enable FDA to seize and forfeit proceeds of these offenses under some circumstances, even when the criminal offender cannot be prosecuted. This ability would serve as a significant disincentive to offenders, who otherwise could continue to operate from their foreign locations with impunity and profit, from selling harmful products to American consumers.

For example, FDA could conduct an investigation that identifies an individual in a foreign location operating a website that offers counterfeit or other substandard drugs for sale to customers in the United States in violation of the FD&C Act. FDA might not be able to prosecute the offender because of the lack of an extradition treaty between the foreign country and the United States. However, through an investigation of the offender's financial transactions, FDA might identify funds in bank accounts and other assets, in the United States and elsewhere, which are the proceeds of or are traceable to the proceeds of the FD&C Act violations. With clear asset forfeiture authority, FDA could seek judicial forfeiture of those proceeds, even though FDA might not be able to prosecute the individual offender.

6. **Please describe the difficulties FDA has encountered when trying to gather information for counterfeit/foreign unapproved or rogue Internet pharmacy cases. To what extent would administrative subpoenas strengthen investigations and prosecutions of counterfeit and foreign unapproved drug cases?**

Currently, FDA does not have the authority to issue administrative subpoenas in connection with criminal investigations. To obtain records needed to pursue a criminal investigation, FDA typically must request, through DOJ, that a grand jury subpoena be issued for records. The need to use grand jury subpoenas to compel the production of records can be detrimental to FDA's public health mission and is an inefficient use of Government resources.

First, information obtained via a grand jury subpoena is subject to broad secrecy requirements. Rule 6(e) of the Federal Rules of Criminal Procedure imposes strict rules against disclosure of grand jury matters. In some cases, these secrecy requirements have prevented FDA's Office of Criminal Investigations from disclosing pertinent information to other divisions of FDA and to other public health and law enforcement agencies, even when the information pertains to ongoing conduct that poses a risk to the public health.

Grand jury subpoenas are issued by Assistant United States Attorneys (AUSAs), who typically carry a significant case load and must balance many competing law-enforcement priorities. Many other agencies have administrative subpoena authority for criminal investigations, and as a result may have more complete information by the time they bring a case to an AUSA.[1] The need to consult AUSAs for grand jury

[1] Examples of law enforcement agencies that are authorized to use administrative subpoenas in criminal investigations include: all Inspectors General (5 U.S.C. App. (III) 6), United States Postal Inspection Service (18 U.S.C. § 3061), Internal Revenue Service (26 U.S.C. § 7602), Immigration and Customs Enforcement (19 U.S.C. § 1509, 21 U.S.C. § 967, 50 U.S.C. § 1701 and 8 U.S.C. § 1225(d)(4)), Drug Enforcement Administration (21 U.S.C. § 876), Department of Labor (29 U.S.C. § 1134(c)), Small Business Administration (15 U.S.C. § 634(b)), United States Secret Service (18 U.S.C. § 3486(a)(1)(A)(ii)), Nuclear Regulatory Commission (42 U.S.C. § 2201(c)), Bureau of Alcohol, Tobacco, Firearms and Explosives (15 U.S.C.§ 49 and 27 U.S.C. §202(g)), and Federal Bureau of Investigation (21 U.S.C. § 876; 18 U.S.C. § 3486). In addition, the Department of Justice, through the United States Attorneys, is authorized to issue administrative subpoenas for investigations of Federal health care offenses, RICO, and Foreign Corrupt Practices Act.

subpoenas can, in some cases, cause delays, giving offenders time to alter or destroy critical evidence, move locations, or change their criminal behavior in an effort to escape prosecution. Because trafficking in counterfeit or unapproved drugs often involves distribution from abroad into many different judicial districts, there may be multiple districts in which grand jury subpoenas might be issued. Currently, FDA is not always able to fully develop a criminal case or identify districts in which criminal prosecution is most likely appropriate before presenting the case to a United States Attorney's Office. Therefore, an AUSA may be reluctant to open a criminal case and issue a grand jury subpoena, if the evidence FDA has been able to gather contains little to indicate that the target is either located in or distributing significant quantities into the AUSA's district.

7. **Does FDA have the authority to bring cases against Internet pharmacies that merely require users to fill out a survey rather than requiring an actual prescription?**

Under section 503(b) of the FD&C Act, FDA has legal authority to take action against the sale or dispensing of a prescription drug without a prescription (21 U.S.C. § 353(b)(1)). Nevertheless, Internet pharmacies have prescribed drugs to U.S. citizens based solely on their answers to online surveys without any other information. Due to the absence of a definition of "valid prescription," FDA's authority to take action in such circumstances is subject to challenge.

a) **GAO cited a DOJ official as saying that prosecuting Internet pharmacies for dispensing drugs without a prescription is difficult due to having to determine which state laws best match the circumstances of each case. Would extending the Ryan Haight Act's definition of "valid prescription" (and telemedicine exemption) to the FFDCA to apply to drugs not containing controlled substances help solve this problem?**

Extending the Ryan Haight Act's definition of "valid prescription" to non-controlled prescription drugs would help standardize what constitutes a valid prescription. This legislative change was included as one of the recommendations of the March 2011 Report to the Vice President of the United States and to Congress of the Counterfeit Pharmaceutical Inter-Agency Working Group.[2] Currently, states have different definitions of what constitutes a valid prescription. Internet pharmacies typically operate across state lines. The pharmacy may be in one state (or overseas), the doctor who issues the prescription may be in another state, and the customer may be located in a third state. In such cases, it is not clear which state law applies. A Federal definition of what constitutes a "valid prescription" for non-controlled prescription drugs would provide clarity in Internet pharmacy investigations, where there is a question as to whether the drugs are being dispensed pursuant to a valid prescription, and it is not clear which state law applies.

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[2] See pages 15-16 of the Report, available at
https://www.whitehouse.gov/sites/default/files/omb/IPEC/Pharma_Report_Final.pdf.

b) **GAO has said that there are over 36,000 active rogue Internet pharmacies. For online pharmacies offering controlled substances, the Ryan Haight Act requires them to disclose on their website which states they are licensed in, their pharmacists' credentials, and contact information such as a name, address, telephone number and email address. Would extending the Ryan Haight Act's requirement so that all online pharmacies provide this information, not just ones selling controlled substances, help address the problem of rogue Internet pharmacies selling counterfeit or unapproved prescription drugs that are not controlled substances?**

The online pharmacy disclosure requirements embodied in the Ryan Haight Act have strengthened the Government's ability to take enforcement actions against rogue online pharmacies engaged in the marketing and distribution of controlled substances. We would be happy to work with the Committee going forward on exploring potential avenues to address the issues posed by rogue online pharmacies, including, but not limited to, extending the Ryan Haight Act's disclosure requirements to all online pharmacies, defining what constitutes a "valid prescription" under the FD&C Act; a requirement that Internet pharmacies disclose their locations, pharmacist in charge, contact information, and other salient contact information, for transparency and accountability and so that consumers can contact the pharmacy if there is a problem; a requirement that Internet pharmacies have to notify FDA that they are selling prescription drugs to U.S. consumers and what state(s) they are licensed in, providing FDA with information about which entities are selling prescription drugs online; a requirement that the online pharmacy be located within the United States, facilitating jurisdiction, oversight, and prosecution; and a requirement that Internet pharmacies comply with state licensing and registration laws.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

The Honorable Tim Murphy
Chairman
Subcommittee on Oversight and Investigations
Committee on Energy and Commerce
House of Representatives
Washington, D.C. 20515-6115

JUL 17 2015

Dear Mr. Chairman:

Thank you for providing the Food and Drug Administration (FDA or the Agency) with the opportunity to testify at the February 27, 2014, hearing entitled "Counterfeit Drugs: Fighting Illegal Supply Chains," before the Subcommittee on Oversight and Investigations, Committee on Energy and Commerce. We provided a partial response on April 13, 2015. This letter is our final response.

If you have further questions, please let us know.

Sincerely,

[redacted]

Thomas A. Kraus
Associate Commissioner
for Legislation

Enclosure

cc: The Honorable Diana DeGette
Ranking Member
Subcommittee on Oversight and Investigations

Attachment 2 – Member Requests for the Record

The Honorable Tim Murphy

1. **Please provide the Committee with detailed recommendations for what additional tools you need to help prevent, discover and punish these criminal actions.**

   The following tools would significantly aid FDA's ability to combat rogue Internet pharmacies.

   (1) Providing FDA with civil and criminal forfeiture authority under the Federal Food, Drug, and Cosmetic Act (FD&C Act).
   (2) Administrative Subpoena authority for criminal investigations.
   (3) Increasing the statutory maximum penalties for drug offenses under the FD&C Act.
   (4) Extending the Ryan Haight Act definition of "valid prescription" to non-controlled prescription drugs regulated under the FD&C Act.

The Honorable Marsha Blackburn

1. **During your testimony you said that twelve companies have already applied to FDA's security supply chain pilot project.**

   (a) **What countries are these companies located in?**

Sixteen firms applied to the Secure Supply Chain Pilot Program, and FDA accepted 13 to participate. The participants all have headquarters in the United States; however, each supply chain has a manufacturer located in a foreign country. These countries are: India, Japan, China, Belgium, Italy, UK, France, Czech Republic, Switzerland, Israel, and Sweden.

   (b) **Please explain the successes that you have had in analyzing the project, how you are equating the variables, and what you see as your deliverables from the project as we move forward.**

The pilot program has been operational since February 5, 2014. It is too soon to determine the successes. FDA is in the process of addressing issues specific to each supply chain. FDA is establishing a performance baseline in order to evaluate the pilot program and identifying process improvements and lessons learned. FDA hopes to understand better how firms transmit imports data upon the submission of an imports entry and what improvements can be made both by FDA and firms to gain greater compliance with FDA requirements for imported drugs.

The Honorable Michael C. Burgess

1. **From FDA's perspective, is the heparin contamination still an open and ongoing investigation? Please explain.**

The primary criminal investigation was closed by FDA on January 20, 2010. There is, however, an open and ongoing related investigation into the contaminated heparin.

The Honorable Morgan Griffith

1. **Was the gentleman in Utah who was recently convicted of shipping over $5 million in unapproved drugs but only received a 1-year prison sentence charged with any other crimes as part of his scheme?**

In the case referenced, *United States v. Michael Lawrence O'Donnell* (2:11-cr-00556-DN, District of Utah), the original indictment charged 12 counts of mail fraud and 13 counts of engaging in wholesale distribution of prescription drugs without a license. Mr. O'Donnell pleaded guilty to one count related to the unlicensed wholesale distribution of prescription drugs.

The Honorable Billy Long

1. **During the hearing you discussed the difficulties of detecting, investigating, apprehending, and punishing those involved in international organized crime. Please explain what Congress can do to help you better navigate the international organized crime problem.**

   The following recommendations would significantly aid FDA's ability to combat rogue internet pharmacies.

   (1) Providing FDA with civil and criminal forfeiture authority under the FD&C Act.

   (2) Administrative Subpoena authority for criminal investigations.

   (3) Increasing the statutory maximum penalties for drug offenses under the FD&C Act.

   (4) Extending the Ryan Haight Act definition of "valid prescription" to non-controlled prescription drugs regulated under the FD&C Act.

The Honorable John Dingell

1. **Are the bottles that you referenced in the lighter fluid slide, displayed during your testimony, glass or plastic medicine bottles?**

The bottles were plastic medicine bottles.

2. **Please submit any changes that you recommend we make with regards to improving the efforts of the Office of Drug Supply, Integrity and Recalls.**

The Office of Drug Security, Integrity and Response (ODSIR) is currently handling drug supply chain security issues through the Division of Supply Chain Integrity and imports, exports,

recalls, and shortages issues through the Division of Imports Exports and Recalls. Within these program areas, ODSIR handles many important Agency functions, including, but not limited to, implementing important Food and Drug Administration Safety and Innovation Act (FDASIA) and Drug Supply Chain Security Act provisions that will improve the security of our nation's drug supply; combating counterfeit, substandard, and otherwise unapproved drugs sold to U.S. consumers at retail and over the Internet; facilitating the removal of adulterated and/or misbranded products from the market; notifying the public about counterfeit, substandard, and otherwise unapproved drugs; and working to prevent the importation of adulterated, misbranded, and unapproved drugs. Additionally, ODSIR is responsible for identifying and coordinating compliance activities related to significant public health threats related both to supply chain security and others. ODSIR's new role in responding to public health incidents is the reason the office was renamed ODSIR (formerly Recalls). The divisions within ODSIR are linked by subject matter and deal with an array of responsibilities and issues. We handle these responsibilities effectively and with limited staff and resources.

3. **Please submit to the Committee any suggestions that you have regarding what it is you need in the way of authority to address the questions regarding information sharing with Internet service providers needed in rogue Internet pharmacy investigations that you described during the hearing.**

In an effort to receive timely information from Internet service providers, FDA is in need of administrative subpoena authority for criminal investigations involving the Internet. Currently, FDA must obtain a grand jury subpoena, through the Department of Justice, to obtain such information. The need to consult with the Department of Justice for grand jury subpoenas can in some cases cause delay.

4. **Please submit to the Committee whether you have authority to go after the people who manufacture and ship imported pharmaceuticals into the United States and what additional authorities you would need to do so.**

The illegal importation of adulterated products that are counterfeit or have hidden and potentially dangerous, undeclared active pharmaceutical ingredients can pose dangerous risks to American consumers. In an effort to keep Americans safe, FDA proposes a change be made in section 306 of the FD&C Act to extend the authority to debar importers of food under limited circumstances to drug importers as well. Currently, FDA can debar food importers for a limited time for certain criminal conduct related to the importation of food or where the importer demonstrates a pattern of importing food that poses a substantial hazard. We propose that this authority be extended to drug importers and those offering drugs for import. This authority would provide an administrative remedy and useful tool to address dangerous illegal importation where it is currently impractical to pursue injunctions in Federal court.

Under the FD&C Act, FDA has the authority to pursue persons who import adulterated, misbranded, or unapproved new drugs into the United States from foreign sources. In many cases, FDA's ability to exercise this authority is limited by the challenges of criminally investigating conduct that occurred largely in foreign locations and of extraditing offenders to

stand trial in the United States. We further refer to additional authorities mentioned in other responses.

Despite our extraterritorial jurisdiction, FDA does not often have the authority to "go after" people who manufacture and ship pharmaceuticals to the United States. For various reasons, including claims of lack of knowledge about shipment of the product to the United States, foreign firms are often insulated from liability. Typically, our approach is to take action against the foreign product. This approach could be enhanced by enforcement tools that would allow FDA to cause a loss to the person who violates the law. The Agency currently uses the authorities under 21 U.S.C. 381 to administratively refuse entries of drugs that appear to be, among other violations, adulterated, misbranded, or unapproved.

5. **The FDA Safety and Innovation Act gave your agency new authorities such as registration of foreign drug facilities and mandatory detention to help the agency deal with the globalized drug supply chain. Is your authority sufficient? If not, what more is required?**

FDA is currently engaged in the process of implementing FDASIA Title VII. FDA does not yet have sufficient data to assess the impact of the newly granted authorities on improvement in the integrity of the drug supply chain, especially in light of evolving risks. If additional needed authorities are identified, FDA will work with Congress as appropriate.

The FDASIA authorities are valuable, but additional authorities would be very helpful in protecting the public health. In particular, FDA could benefit from the following: Subpoena authority; seizure authority; asset forfeiture authority; remove Interstate commerce elements from the FD&C Act and PHS Act; and increased civil and criminal penalties.

6. **Please elaborate on what additional authorities FDA needs to keep Americans safe from counterfeit and substandard drugs that are coming from abroad.**

FDASIA provided FDA with many new authorities that will help FDA keep Americans safe from counterfeit and substandard drugs coming from abroad. Specifically related to the importation process, section 708 provides FDA the authority to destroy FDA-refused drug products under a certain value threshold; section 713 provides FDA the authority to mandate certain reporting requirements at the time of entry; and section 714 requires commercial importers of pharmaceuticals to register with FDA. These authorities provide FDA better access to pharmaceutical supply chain information, which allows us better opportunity to block the importation of illegitimate pharmaceutical importations and to facilitate compliant trade. The destruction authority enables FDA to better ensure these illegitimate shipments will not return to the United States through other channels.

The regulations and guidance documents for these FDASIA sections are progressing; it would be advisable to implement these authorities and gauge their impact before requesting new and additional authorities, such as:

(a) The authority to use rapid-detection technologies to authorize FDA to seize and destroy counterfeit and substandard drugs from repeat offenders, without a hearing and without burden to U.S. Customs and Border Protection.
(b) Public cease-and-desist orders that require a response from the foreign government regulating the exportation of the counterfeit or substandard drug.
(c) Clear authority to take civil and criminal action against people and entities that facilitate the sale of counterfeit, substandard, and otherwise unlawful drug products over the Internet, including against third-party platforms and credit card companies that process the transactions.

7. **Please provide a written response explaining what resources FDA needs to carry out the new authorities granted to the agency in the FDA Safety and Innovation Act.**

FDA is currently engaged in implementing FDASIA Title VII. FDA does not yet have sufficient data to assess the resources needed to fully implement these new authorities.

8. **Please submit your comments on if and how it would be helpful to take the penalties that we collect and turn them over to the FDA for additional enforcement, like we already do for narcotics.**

For policy reasons, FDA does not believe that it would be appropriate for the Agency to benefit directly from the forfeiture of proceeds or other facilitating property. In some cases, other Federal agencies are able to obtain reimbursement of their investigative costs and expenses from the penalties, such as fines and restitution that are collected from criminal offenders.[1] A similar provision to enable FDA to receive reimbursement for its investigative costs from criminal offenders would be helpful to increase available resources to address the problem of counterfeit and unapproved drugs.

FDA, through its Office of Criminal Investigations (OCI), is currently a member of the Department of Justice's Asset Forfeiture Fund (the Fund). Proceeds of forfeitures in cases brought to the Department of Justice by FDA are deposited into the Fund. In accordance with the policies of the Fund, OCI may seek withdrawal from the Fund to assist ongoing investigations with the identification and removal of criminally derived assets.

9. **The maximum penalty you mentioned in your testimony for these activities is only $10,000 or 3 years in prison. What does FDA believe is the appropriate maximum penalty? Please define that by relating it to other questions involving narcotics and other events that are similar.**

The maximum prison sentence for most FD&C Act offenses is three years in prison. We believe that a more appropriate penalty scheme would provide for a maximum of 10 years in prison for each offense, with an increase to a maximum of 20 years, if the offense results in serious bodily injury, and life in prison, if the offense results in death. These suggested statutory maximum sentences are modeled after, and commensurate with, the sentencing schemes for other Federal

[1] For example, the Inspector General of the Department of Health and Human Services is authorized to receive reimbursement for the costs of conducting investigations in certain circumstances (see 42 U.S.C. 1320a-7c(b)).

offenses with public-health significance. For example, the maximum penalty for tampering or attempting to tamper with a consumer product is 10 years, 20 years if the offense causes serious bodily injury, and life in prison if death results (see 18 U.S.C. § 1365(a). Similarly, the maximum penalty for health care fraud is 10 years, 20 years if the violation results in serious bodily injury, and life in prison if the offense results in death (see 18 U.S.C. § 1347).

Although the maximum fine provided for in the FD&C Act for a felony offense is $10,000, the actual maximum fine is governed by 18 U.S.C. § 3571, which provides for significantly higher maximum fines commensurate with other Federal offenses. We believe that the maximum fines provided for in 18 U.S.C. § 3571 are sufficient.

10. **Does FDA support strong civil monetary penalties against those charged with misbranding or counterfeiting drugs? Please explain.**

As noted previously, FDA's ability to combat misbranding or counterfeiting would be enhanced by clear authority to take civil and criminal action against persons and entities that facilitate the sale of counterfeit, substandard, and otherwise unlawful drug products over the Internet, including against third-party platforms and credit card companies that process the transactions. This would include strong civil monetary penalties.

11. **Last year, the FDA worked with international regulatory and law enforcement agencies to shut down more than 1,600 illegal pharmacy Web sites. During the hearing you agreed that most of those websites claimed to be Canadian pharmacies and the medicines that they were selling were FDA approved or brand-name drugs, which they were not. Please further explain how many of the 1,600 sites claimed to be Canadian.**

All of the 1,600 websites used templates claiming to be Canadian Pharmacies or would otherwise attempt to lead the consumer to believe they were Canadian. They branded themselves as follows:

(a) Canadian Health & Care Mall
(b) Canadian Family Pharmacy
(c) Canadian Neighbor Pharmacy
(d) Canadian Pharmacy
(e) My Canadian Pharmacy LTD
(f) Pharmacy Express
(g) Toronto Drug Store

12. **During the hearing, you mentioned that you have difficulty with the funding of your agency. If you could get the funding of your agency to do as it has been done by the drug enforcement people, where the proceeds of these crimes could be seized and utilized for sale so that you could get revenue or so that you could get otherhelp, would that be of assistance to you in terms of increasing your levels of funding to deal with these problems?**

As stated above, FDA, through its OCI, is currently a member of the Department of Justice's Asset Forfeiture Fund (the Fund) and is able to use money from the Fund to further its criminal investigations in accordance with Department of Justice policy. A similar provision to that used by HHS, as described above, whereby FDA could obtain reimbursement of investigative costs and expenses from penalties, such as fines and restitution, would help in increasing available resources to address the problem of counterfeit, unapproved, and substandard drugs.

FRED UPTON, MICHIGAN
CHAIRMAN

HENRY A. WAXMAN, CALIFORNIA
RANKING MEMBER

ONE HUNDRED THIRTEENTH CONGRESS

Congress of the United States
House of Representatives
COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515–6115
Majority (202) 225-2927
Minority (202) 225-3641

March 14, 2014

Dr. Prashant Yadav
On behalf of The Institute of Medicine
Director, Health Care Research Initiative
William Davidson Institute
University of Michigan
724 East University Avenue
Ann Arbor, MI 48109

Dear Dr. Yadav:

Thank you for appearing before the Subcommittee on Oversight and Investigations on Thursday, February 27, 2014, to testify at the hearing entitled "Counterfeit Drugs: Fighting Illegal Supply Chains."

During the hearing, Members asked you to provide additional information for the record. The request for information is attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

To facilitate the printing of the hearing record, please respond to these questions with a transmittal letter by the close of business on Friday, March 28, 2014. Your responses should be mailed to Brittany Havens, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, D.C. 20515 and e-mailed in Word format to brittany.havens@mail.house.gov.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,

Tim Murphy

Tim Murphy
Chairman
Subcommittee on Oversight and Investigations

cc: Diana DeGette, Ranking Member, Subcommittee on Oversight and Investigations

Attachments

March 28, 2014

The Honorable Tim Murphy
Chairman
Subcommittee on Oversight and Investigations
Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, DC 20515-6115

Dear Chairman Murphy:

I appreciate the opportunity to testify before your Subcommittee on "Counterfeit Drugs: Fighting Illegal Supply Chains."

The following question was asked in follow-up to the hearing, and my response is included as well as referenced materials.

The Honorable Michael C Burgess

1. **During the hearing when we discussed the reflection of cost in internet activity with the purchase of other brands that remained on patent and were therefore more expensive, you offered to provide the Committee with the findings of various studies that show which type of categories were being purchased more and what kinds of factors and root causes were leading to that. Please provide those findings to the Committee.**

I thank Congressman Burgess for his question and hope this response provides useful information on the nature of online pharmaceutical activity in the United States.

The Institute of Medicine report does not discuss the relationship between the price of patented drugs and internet sales. A 2006 study published by the Frasier Institute, however, estimated that 60% of the top-selling cross-border drugs bought online by Americans from Canada between 2004 and 2005 were brand-name products. The other 40% were generic drugs. The study also reported that more than half of Canadian internet pharmacy sales were for top-selling brand-name prescription drugs consumed primarily by seniors. This study (Skinner, 2006) was not referenced by the IOM committee, but a copy is attached.

It is difficult to comment on the proportions of types of drugs purchased online. Most online drug sellers are illegal which makes it difficult to track and precisely measure their activity. It is clear, however, that patients attempt to purchase all types of drugs online. People often think of patients as turning to online pharmacies for lifestyle drugs, such as Viagra. Americans are also purchasing drugs for more serious medical conditions, including asthma, arthritis, cholesterol, diabetes, Parkinson's disease, and cancer. While somewhat dated, Fox (2004) reported that three-quarters of those who purchased prescription drugs online, purchased a drug for a chronic medical condition. One quarter purchased them for other purposes, such as weight loss or sexual performance. A study by researchers at the University of California San Diego, which analyzed the web traffic of a major fake online pharmacy, found that Americans purchase non-lifestyle drugs a third of the time (Kanich, et al, 2011). The IOM committee did not reference these studies, but both are attached.

The report does discuss the factors which encourage patients to purchase drugs over the internet. Many American shoppers believe that internet pharmacies sell cheaper drugs. This is particularly attractive to the elderly or uninsured patients who might not otherwise be able to afford their medicines. Patients are also motivated by convenience, access, addiction, or a desire to self-prescribe without a physician's advice. Studies demonstrating these motivations, all referenced in the IOM report, are attached (Baert and De Spiegeleer, 2010; Crawford, 2003; Levaggi et al., 2012).

The studies referenced above and attached include:

- Baert, B., and B. De Spiegeleer. 2010. Quality analytics of internet pharmaceuticals. *Analytical and Bioanalytical Chemistry* 398(1):125-136

- Crawford, S. Y. 2003. Internet pharmacy: Issues of access, quality, costs, and regulation. *Journal of Medical Systems* 27(1):57-65.

- Fox, Susannah. 2004. *Prescription drugs online*. Pew Internet & American Life Project. Washington, DC. http://web.pewinternet.org/~/media//Files/Reports/2004/PIP_Prescription_Drugs_Online.pdf.pdf

- Kanich, C., N. Weavery, D. McCoy, T. Halvorson, C. Kreibichy, K. Levchenko, V. Paxson, G. M. Voelker, and S. Savage. 2011. *Show me the money: Characterizing spam-advertised revenue*. Paper presented at Proceedings of the 20th USENIX conference on Security, San Francisco, CA.

- Levaggi, R., C. Marcantoni, L. Filippucci, and U. Gelatti. 2012. Not a good buy: Value for money of prescription drugs sold on the internet. *Health policy (Amsterdam, Netherlands)* 106(3): 241-245.

- Skinner, Brett. 2006. *Price Controls, Patents, and Cross-Border Internet Pharmacies Risks to Canada's Drug Supply and International Trading Relations*. The Fraser Institute. Vancouver, Canada.

I hope this information will be helpful to Congressman Burgess and the Committee.

Sincerely,

Prashant Yadav
Member, IOM Committee on Understanding the Global Public Health Implications of Counterfeit, Falsified and Substandard Drugs (February 2012-February 2013)

cc: Diana DeGette, Ranking Member, Subcommittee on Oversight and Investigations

Attachments

[The attachment to Mr. Yadav's response has been retained in committee files and can be found at: *http://docs.house.gov/meetings/if/if02/20140227/101804/hhrg-113-if02-wstate-yadavp-20140227-sd003.pdf*.

FRED UPTON, MICHIGAN
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WASHINGTON, DC 20515–6115
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Minority (202) 225-3641

March 14, 2014

Mr. John P. Clark
Vice President and Chief Security Officer
Global Security, Compliance Division
Pfizer Inc.
235 East 42nd Street
New York, NY 10017

Dear Mr. Clark:

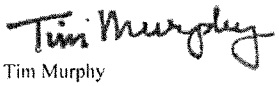
Thank you for appearing before the Subcommittee on Oversight and Investigations on Thursday, February 27, 2014, to testify at the hearing entitled "Counterfeit Drugs: Fighting Illegal Supply Chains."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

To facilitate the printing of the hearing record, please respond to these questions with a transmittal letter by the close of business on Friday, March 28, 2014. Your responses should be mailed to Brittany Havens, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, D.C. 20515 and e-mailed in Word format to brittany.havens@mail.house.gov.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,



Tim Murphy
Chairman
Subcommittee on Oversight and Investigations

cc: Diana DeGette, Ranking Member, Subcommittee on Oversight and Investigations

Attachments

Pfizer Inc
235 E. 42nd Street
New York, NY 10017-5755
USA

John Clark
Chief Security Officer, Pfizer
Vice President, Global Security

March 28, 2014

The Honorable Tim Murphy
Chairman
Subcommittee on Oversight & Investigations
Committee on Energy & Commerce
2125 Rayburn House Office Building
Washington DC, 20515

Dear Chairman Murphy,

Thank you for this opportunity to expand upon my recent testimony before the Subcommittee on Oversight and Investigations as part of its hearing on *Counterfeit Drugs: Fighting Illegal Supply Chains*. For Pfizer, as for the members of your Committee, counterfeit medicines are first and foremost a matter of patient health and safety.

My responses to the three additional questions for the record posed by The Honorable Renee Ellmers are as follows:

1. Mr. Clark, given your experience in law enforcement and now at Pfizer, what additional tools could Congress and/or the Administration provide to help combat this threat to patient safety?

   Current regulations and procedures impede the ability of rights holders to assist Customs and Border Protection (CBP) in determining whether goods being imported into the U.S. are authentic or counterfeit. Congress could enhance the ability of rights holders, such as Pfizer, to prevent counterfeit medicines from reaching patients in the U.S. by passage of the Customs Authorization Act or other legislation that would permit CBP to provide rights holders with unredacted photographs or samples of goods and/or packaging to facilitate their authentication.

   Historically, IPR holders had provided invaluable assistance to CBP by authenticating suspect merchandise before it entered the stream of commerce in the U.S. In 2008, however, CBP advised its personnel that disclosing certain "identifying information" – including serial numbers, batch/lot numbers and barcode clearly visible on the packaging – to rights holder was a violation of the Trade Secrets Act, a criminal misdemeanor. The failure to disclose such information to rights holders, such as Pfizer, impedes their ability to determine the authenticity of "suspect" articles.

   Interim CBP Regulations, introduced in 2012 purportedly to address this problem, failed to do so, providing rights holders access to redacted images only after a delay of seven days to afford the importer an opportunity to demonstrate that the suspect articles were not counterfeit.

The Customs Reauthorization Act would amend the Tariff Act of 1930, providing rights holders with immediate access to unredacted images and samples of the suspect merchandise.

Additional information from CBP on the source of goods detained and seized would also facilitate our ability to initiate pro-active investigations to disrupt counterfeits at or near their source, more effectively protecting patients in the US and around the world.

2. Mr. Clark, I have a Pfizer vaccine manufacturing facility in my district and as a former health care provider I recognize the importance of vaccination in preventing serious diseases for people in the US and abroad. Have Pfizer vaccines been counterfeited and if so where is it happening?

   In June 2010, based on evidence referred by Pfizer Global Security, authorities seized counterfeit doses of Pfizer's Prevnar from a pediatric clinic in El Salvador. The seizure of empty vials and stoppers indicated that doses of the counterfeit vaccine had been administered to patients at the clinic. Further investigation led to the identification and arrest of an individual who was distributing the counterfeits to several clinics in El Salvador.

   Lab tests on a sample of the counterfeit vaccine confirmed not only that it was counterfeit, but also that it was missing a critical ingredient, impacting its efficacy.

   Are counterfeit vaccines making their way to the US?

   To date, we have not confirmed the presence of counterfeit versions of Pfizer's Prevnar in the US. I cannot speak to the presence of counterfeit versions of vaccines produced by other pharmaceutical companies.

3. Mr. Clark, Pfizer is located in Sanford NC, which is in my district, and according to your testimony Pfizer launched a robust Internet Program in 2006 to identify and disrupt rogue online pharmacies (OLPs) that dispensed counterfeit Pfizer medicines to unsuspecting patients. Can you please update me on recent program activities and what you have been able to identify through this program since 2011?

   Patients in the US are most at risk for receiving counterfeit medicines when they order their medicines online, often without a valid prescription, from OLPs that have not been certified by the National Association of Boards of Pharmacies. To supplement monitoring activities of OLPs, begun in 2006, we have

   - *Collaborated with Microsoft in takedown of Rustock botnet, thought to be responsible for between 20 and 40% of all internet SPAM and sites dispensing counterfeit medicines (2011)*
   - *Replaced "cybersquatting" OLP, which used Pfizer name or product trademark in its URL, with Public Service Announcement advising patients (1) that the medicines sold were counterfeit and (2) how to buy safely online (2011)*
   - *Disrupted call center in Philippines that employed as many as 200 agents to call patients in the US, UK and Australia, encouraging them to refill orders for Viagra and other ED medicines (2012)*
   - *Extended monitoring efforts to ads appearing on Craigslist, made test purchases, referred sales of counterfeit Viagra to law enforcement, resulting in arrests across the US, including California, Florida, Maryland and Missouri, and Canada (2012 to present)*
   - *Launched OLP Disruption Program, in collaboration with Microsoft, to disrupt OLPs by disabling domains to disrupt web traffic and eliminating ability to process credit card*

transactions, resulting in takedown of two affiliate networks and disruption of more than 3200 OLPs (2013)

Sincerely,

John P Clark

cc: John Halliwell, Ken Cole

Summary

The adulteration and fraudulent manufacture of medicines[1] is an old problem, vastly aggravated by modern manufacturing and trade. In the last decade, impotent antimicrobial drugs have compromised the treatment of many deadly diseases in poor countries. More recently, negligent production at a Massachusetts compounding pharmacy sickened hundreds of Americans. While the national drugs regulatory authority (hereafter, the regulatory authority) is responsible for the safety of a country's drug supply, no single country can entirely guarantee this today. Illegitimate[2] drugs are an international problem, and there is wide consensus that action depends on international cooperation.

Productive international discourse has been stymied, however, by disagreement about how to frame the problem. The once common use of the term *counterfeit* to describe any drug that is not what it claims to be is at the heart of the argument. In a narrow, legal sense, a counterfeit drug is one that infringes on a registered trademark. The lay meaning is much broader, including any drug made with intentional deceit. Some generic drug companies and civil society groups object to calling bad medicines counterfeit, seeing it as the deliberate conflation of public health and intellectual property concerns. This report accepts the narrow meaning of counterfeit, and, because the nuances of trademark infringement must be

[1] The terms *medicine*, *drug*, and *pharmaceutical* are used interchangeably in this report in accordance with the definitions listed in the *American Heritage Stedman's Medical Dictionary*.

[2] *Illegitimate*, as explained later in the report, is a parent category for falsified and substandard medicines.

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dealt with by courts, case by case, the report does not discuss the problem of counterfeit medicines.

The trade in illegitimate drugs is, however, a problem of public health consequence and the topic of this report. In order to discuss this problem more precisely, the report distinguishes two main categories of poor-quality drugs. First, there are substandard drugs, those that do not meet the specifications given in the accepted pharmacopeia or in the manufacturer's dossier. The other main category of illegitimate products is falsified drugs, those that carry a false representation of identity or source or both. Many countries also have problems with unregistered medicines, those not granted market authorization in a country. Unregistered drugs may be of good quality, though some research indicates they often are not. Unregistered medicines usually circulate outside the controlled distribution chain and are therefore suspect.

The drug failures of public health concern can be divided into two main categories: falsified and substandard. Admittedly, the distinction between the two categories is not always clear. Falsified drugs are usually also substandard; national specifications referenced in the definition of a substandard drug can vary.[3] However, these terms cover the two main divisions of interest with sufficient precision. International endorsement of these two categories could advance public discourse on the topic.

Recommendation 1-1: The World Health Assembly should adopt definitions consistent with the following principles. Substandard drugs do not meet national specifications.[4] Falsified products have a false representation of identity or source or both. Products unregistered with the regulatory authority are also illegal.

The spirit of these definitions and the exclusion of the term counterfeit are central to this recommendation. The exact wording suggested is not.

THE HEALTH EFFECTS OF FALSIFIED AND SUBSTANDARD DRUGS

Falsified and substandard drugs may contain toxic ingredients; some of the most compelling stories of pharmaceutical crime are of frank poisoning. By far the more common problem, however, is medicine that simply does

[3] Some regulatory authorities may accept standards below those in international pharmacopeias. In such cases, a drug that would be generally regarded as substandard might be technically acceptable in a given country.

[4] An emphasis on quality system failures is not essential to the idea of a substandard drug and was removed from the recommendation after the report release. The supporting text describes the committee's understanding of a substandard drug.

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not work. Poor-quality medicines cause treatment failure, but doctors do not generally suspect medicines as a cause of disease progression. Lifesaving medicines can be of poor quality, which may be an uncounted root cause of high mortality in low- and middle-income countries.

No class of drug is immune to being compromised. Medications for chronic and infectious diseases alike have been found falsified and substandard. A considerable body of research indicates that inexpensive antimicrobial drugs in low- and middle-income countries are frequently of poor quality. Such drugs not only put patients at risk but also encourage drug resistance, thereby threatening population health for future generations.

Substandard antimicrobials often contain low and erratic drug doses, while falsified ones can be diluted. In either case, exposing pathogens to subtherapeutic doses of medicines selectively allows the growth of resistant organisms. Poor-quality drugs have contributed to the rise of drug-resistant tuberculosis. Drug-resistant staphylococcus infections are an emerging problem, especially in India, Latin America, and sub-Saharan Africa. Antimalarial resistance threatens to undo the good that artemisinin therapies have done, threatening global malarial control programs.

THE ECONOMIC AND SOCIAL EFFECTS OF SUBSTANDARD AND FALSIFIED MEDICINES

Falsified and substandard drugs increase costs to patients and health systems. Medicines are expensive; patients and governments waste money on ineffective ones. Lingering illnesses decrease productivity, causing workers to forgo pay and spend more on treatment. Through encouraging antimicrobial resistance, illegitimate medicines reduce the effective life of a drug. Society must bear the cost of drug development, an expense that increases as drugs become more complex.

Substandard and falsified medicines undermine confidence in the health system and in all public institutions. Fake[5] drugs are often the business of criminal cartels. Their sale finances other crimes, buys weapons and ammunition, and conveys power to corrupt officials. Victims of falsified and substandard drugs usually do not even know they are victims and are therefore deprived of their right to redress. In many ways, the trade in illegitimate pharmaceuticals further erodes the already weak political infrastructure that allows them to circulate, part of a vicious cycle of poverty and crime.

[5] As the report explains later, *fake* is a commonly used synonym for *falsified*.

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THE MAGNITUDE OF THE PROBLEM

It is difficult to measure the population burden of falsified and substandard drugs. Governments and industry monitor problems with drug quality, but this information is not usually public. The Pharmaceutical Security Institute, a network of the security divisions of 25 major pharmaceutical companies, has data that indicate that the illegal trade and manufacture of medicines is a global problem. It affected at least 124 countries in 2011, and the burden is disproportionately felt in the developing world.

Data from the U.S. Food and Drug Administration (FDA) Office of Criminal Investigations indicate that pills and tablets are the most commonly compromised products they investigate, mostly produced by individual criminals, not negligent businesses. Interpol, an international organization that facilitates police cooperation, has conducted 11 operations against illicit medicines since 2008. Police working in Interpol raids have confiscated tons of suspect products, leading to hundreds of investigations and arrests.

Much of the scientific literature about drug quality is in case studies: reports from clinicians who uncover substandard or falsified drugs in their routine work. This kind of report provides context on how and when different kinds of drugs are compromised; it can also trigger epidemiological investigation. Nonprobability or convenience samples are by far the most commonly used method to study drug quality. Such studies indicate serious problems with antibiotics in poor countries and antimalarial drugs in sub-Saharan Africa and Southeast Asia.

The best estimate of the burden of illegitimate drugs comes from systematic random samples, collected by patient actors from a representative cross section of drug sellers. Such studies are logistically complicated and few. More research in accordance with the recent guidelines on medicine quality assessment reporting would advance understanding and monitoring of the problem.

Lack of clarity regarding the magnitude of the falsified and substandard medicines market holds back coordinated international action. The World Health Organization (WHO) is developing a system for the global surveillance and monitoring of falsified and substandard drugs. Consistent use of this system, eventually linking it to national pharmacovigilance systems, would advance international action and give a more nuanced understanding of the type of falsified, substandard, and unregistered medicines in circulation and the extent of the trade.

Recommendation 3-1: Governments should establish or strengthen systems to detect substandard, falsified, and unregistered medicines. This surveillance should be integrated with established public health

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surveillance systems. Analysis and reporting should precisely describe the product's quality, packing, and registration.

CAUSES OF SUBSTANDARD DRUGS

The factors that encourage the proliferation of falsified and substandard drugs are different but overlapping. Failure to adhere to good manufacturing practices is the root cause of substandard drugs. Quality-control processes and verification add expense to manufacture, as does maintaining sterile water filtration and air handling systems. Proper quality control includes dealing only with quality-assured suppliers, but small- and medium-sized manufacturers often neglect supplier quality because of logistical obstacles and cost.

Multinational companies, both innovator and generic, operate on a scale that allows them to recoup the costs of running high-quality factories. Initial capital investments and infrastructure problems stand between quality medicines and many small- and medium-sized medicine manufacturers. Small- and medium-sized firms and companies in Africa have a difficult time securing business improvement loans. The only capital available to these companies is their profits, and reinvesting profits is not a quick or reliable path to building a modern manufacturing infrastructure. The companies need hard currency loans, which their national banks cannot supply.

The International Finance Corporation and the Overseas Private Investment Corporation can work to encourage better private sector pharmaceutical manufacturing in developing countries. With the initial investments made, governments can take on the more manageable role of encouraging partnerships with foreign manufacturers.

Recommendation 4-1: The International Finance Corporation and the Overseas Private Investment Corporation should create separate investment vehicles for pharmaceutical manufacturers who want to upgrade to international standards. Governments can complement this effort by encouraging partnerships between local and foreign manufacturers.

In practice, it is difficult to distinguish the quality failures that are to blame on a manufacturer's inability to meet international best practices from those that come from a decision to cut corners and produce inferior products for poorly regulated markets. When a producer capable of meeting international standards fails to do so consistently and only in product lines sold to the poor, one may conclude that noncompliance is part of a more insidious system.

Rich countries enforce high quality standards for medicines, and manufacturers recognize the need to use quality ingredients and good manufac-

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turing practices to sell in these markets. United Nations agencies and larger international aid organizations will also refuse to do business with companies that cannot meet stringent regulatory authority quality standards. Manufacturers are aware, however, that low- and middle-income countries are less likely to enforce these standards. When a manufacturer produces medicines of inferior quality for less exacting markets it is known as tiered or parallel production.

When regulatory checks on production are inconsistent, good procurement practices can ensure that quality medicines get the largest market share. The firms that offer the cheapest prices do so by buying impure ingredients and cutting corners in formulation. Good procurement dictates that the cheapest tenders are not accepted if they are of dubious quality, but it is difficult not to be swayed by price. Proper precaution in medicines procurement can prevent poor-quality products from infiltrating the market. Good procurement puts a strong emphasis on controlling corruption and promoting transparency. The WHO's Model Quality Assurance System for procurement agencies lays out the steps necessary for efficient and open procurement of the best-quality medicines possible.

Recommendation 4-2: Procurement agencies should develop a plan, within the next 3 to 5 years, to comply with the World Health Organization's Model Quality Assurance System for procurement agencies and work to remove any barriers to compliance.

CAUSES OF FALSIFIED DRUGS

In practice, one difference between falsified and substandard medicines is that the drugs regulator, having the authority to license manufacturers and register medicines, can act against unscrupulous or careless manufacturers. There is no such remedy when the manufacturer is falsely represented. The regulator can only confirm that the producer is unknown and turn the case over to law enforcement. The police and detectives who inherit these cases have a difficult job gathering sufficient evidence for a prosecution there is usually little if anything to tie the falsified drug in the market to the culprit.

Criminals run lucrative businesses making and trafficking fake medicines, and these crimes are mostly opportunistic, emerging where regulatory systems are weakest. When criminals target the products of multinational, innovator pharmaceutical companies, the companies' security staff build evidence for a conviction. Police are also investigating more pharmaceutical crimes, but most police action is limited to brief raids. It is difficult for police to keep up momentum for sustained action on pharmaceutical crime, especially given the immediate pressure to investigate murders and other violent crimes.

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CAUSES OF BOTH FALSIFIED AND SUBSTANDARD DRUGS

Much as poor-quality drugs are often both falsified and substandard, some potentiating factors encourage both kinds of problems. The high demand and erratic supply of drugs, weak regulatory systems, and uneven awareness contribute to the trade in both falsified and substandard drugs.

Medicines are what economists describe as an inelastic good; changes in the unit price of the medicine have proportionately little effect on the demand. Price inelasticity, combined with a high relative price, make medicines a major expense for patients around the world. The drug market is not stable; both price and supply fluctuate. Drug shortages drive up the price of medicines and push consumers to unregulated markets.

Reducing the costs and increasing the availability of medicines would help prevent drug scarcity. The WHO has recommended generic substitution as a way to keep medicine costs down, but this depends on a supply of quality generic medicines on the market. For generic manufacturers, companies that generally run on low margins, the costs of proving bioequivalence and preparing a manufacturer's dossier for regulatory review can be prohibitive to market entry. Different regulatory authorities have different, often widely divergent, requirements. To complicate the problem, many small regulatory authorities lack the technical depth to evaluate the bioequivalence data that generics manufacturers submit.

The high cost of market authorization impedes the development of a strong generics industry in poor countries. A more robust generic drug market could help prevent the drug shortages and price spikes that encourage the sale of poor-quality products. Regulatory authorities can work to better harmonize their procedures, thereby improving their own efficiency and reducing barriers to market entry for good-quality generics manufacturers. The use of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use Common Technical Document format for registration would ease the regulatory burden on generics companies. Regulators also reap a spillover benefit of more convergent regulatory systems without negotiating cumbersome mutual recognition agreements.

Recommendation 4-3: Regulatory authorities in low- and middle-income countries should use the International Conference on Harmonisation Common Technical Document format for product registration to better harmonize their procedures and reduce application costs for manufacturers. To the same end, they should also conduct joint inspections and use a common inspection report.

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An influx of generic medicines will only reduce the circulation in falsified and substandard drugs when there is a system to assure consumers of medicines' quality. A functioning medicines regulatory authority is a necessary condition for a robust generic medicines market. Strengthening the drugs regulatory system, building the inspectorate, enforcing quality standards, and licensing in accordance with international standards are essential to improving drug quality. Without a competent regulatory authority to inspect wholesalers, distributors, and manufacturers, opportunities to corrupt the drug supply abound.

A strategy for compliance with international standards can help reduce redundant work and fragmentation. Both industry and regulators should agree to work toward the priorities identified in the strategic plan, an openly shared document.

Recommendation 4-4: Governments in low- and middle-income countries should support their regulatory agencies to develop strategic plans for compliance with international manufacturing and quality-control standards. In the least developed countries, international organizations should support their efforts.

Large pharmaceutical manufacturing nations such as India and China suffer from fragmented regulatory systems and an unclear division of responsibilities between state and national governments. The United States has similar problems, evidenced by the recent fungal meningitis outbreak brought on by a contaminated injectable steroid drug, compounded under unhygienic conditions at the New England Compounding Center. Lack of clarity about the relative authority of the FDA and state pharmacy councils to regulate compounding pharmacies contributed to the outbreak. Neither the state of Massachusetts nor the FDA had clear control over the New England Compounding Center. Confusion about their responsibilities created a regulatory gap. Similar confusion causes regulatory gaps in other countries where national and local governments share responsibilities for drug regulation.

During times of crisis, such as the meningitis outbreak, public interest in drug quality peaks, but it can be difficult to maintain. Patients in developed countries have long taken a safe drug supply for granted. They may not realize the risks of circumventing the regulated distribution system. In poor countries, patients are often more aware of the problem, but there are knowledge gaps, especially among the poorest and least educated. Effective communication campaigns can raise awareness of the problem and give consumers empowering messages on how to protect themselves. Such campaigns have effectively promoted change in rich and poor countries alike.

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Recommendation 4-5: Governments and donor agencies should fund development of effective communication and training programs for consumers and health workers on understanding the quality and safety of medicines.

Targeted health worker education on falsified and substandard medicines would improve understanding of the problem around the world. This education should emphasize the correct reporting channels health workers can use to confirm suspected cases of bad drugs. Illegitimate drugs are a potential threat in all countries, though risk varies widely from country to country. An effective communication campaign should present accurate information in a way that empowers patients to protect their health.

THE DRUG DISTRIBUTION CHAIN

The modern pharmaceutical supply chain is complex. Medicines are made from ingredients sourced from different countries. Final formulations are then exported, and packaging, repackaging, and sale can happen in many other countries. Drugs change hands many times between the manufacturer and patient; every transaction is an opportunity for falsified and substandard products to infiltrate the market. Drug quality around the world could be improved with changes to the drug distribution system.

The systems differ markedly between developed and developing countries, however. Fewer, larger firms control manufacture and the wholesale drug markets in developed countries, where most patients get medicines from licensed pharmacies or dispensaries. In low- and middle-income countries, multiple parallel distribution systems of varying efficiency run in the same country. It is also difficult and expensive to transport medicines over poor roads to remote villages, as supply chain managers in poor countries must do.

The first step on the drug distribution chain is the wholesale market. There are two kinds of drug wholesalers: primary wholesalers who have written distribution contracts with manufacturers and buy directly from them, and secondary wholesalers who buy from other intermediaries. Both kinds of wholesalers buy and sell medicines to accommodate market demand. When they see that a medicine is scarce in one region, they can buy the same medicine from other wholesalers that may be flush with it. The markets are constantly fluctuating; products change hands many times. Wholesalers may repackage products repeatedly, and in the repackaging fake products can gain authentic labels.

In the United States, thousands of secondary wholesalers trade medicines, causing drug shortages and exploiting them for profit. Limiting the

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secondary wholesale market to vetted firms would improve the U.S. drug supply. The National Association of Boards of Pharmacy (NABP) wholesaler accreditation process requires criminal background checks on senior staff and proof of professional standards in record keeping and drug storage and handling. Some states require NABP accreditation of wholesalers, but unscrupulous businesses can seek out states with lower standards for their headquarters. And, because the wholesale trade is national, weaknesses in one state's system can become vulnerabilities in another.

Recommendation 5-1: State licensing boards should only license wholesalers and distributors that meet the National Association of Boards of Pharmacy accreditation standards. The U.S. Food and Drug Administration, in collaboration with state licensing boards, should establish a public database to share information on suspended and revoked wholesale licenses.

Similar weaknesses plague the wholesale system in developing countries, and action in the American market might give regulators around the world example and encouragement to tighten controls on the chaotic wholesale market.

More stringent licensing requirements can improve the wholesale system, but drugs will still need to move from factory to the vendor, passing through many hands before reaching the patient. With every transaction on the chain, there is a risk of the drug supply being compromised. Criminals take advantage of places where the distribution chain breaks down and medicines depart from the documented chain of custody. Drugs that leave the proper distribution system are called diverted drugs; the markets that trade diverted drugs or, more generally, markets that trade with little authorized oversight are called gray markets.

Drug diversion is the means through which medicines approved for sale in one country are sold in others, where they may not be registered. Small thefts and large heists compromise the integrity of the drug distribution chain and confidence in the quality of medicines. In rich and poor countries alike, drugs often circulate outside of the main distribution channels without a drug pedigree, a record of a drug's every sale and owner.

Drug pedigrees depend on attaching some form of unique identifying numbers to products. Products that lack identification numbers, or products with identification numbers that cannot be accounted for throughout the distribution chain, must be treated as falsified and removed from the market even if they come from licensed manufacturers. Radio frequency identification, traditional and two-dimensional barcodes, and mobile verification are methods for serialization that can facilitate drug tracking.

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Recommendation 5-2: Congress should authorize and fund the U.S. Food and Drug Administration (FDA) to establish a mandatory track-and-trace system. In the interim, the FDA should convene a working group of stakeholders, including the International Federation of Pharmaceutical Manufacturers and Associations and the Generic Pharmaceutical Association, to promote voluntary track-and-trace for all supply chain actors in accordance with existing guidance.

Tracking pharmaceuticals through the global distribution chain with unique serial numbers is a good defense against criminal infiltration. A method of tracking individual packages of medicines from the factory to the consumer could greatly reduce the chances of a dangerous product being sold at a reputable pharmacy. Problems will remain, however, with unlicensed drug shops. Medicines retail, the last leg of the drug distribution system, is often the most chaotic.

The drug distribution system becomes more disordered as the products leak out of regulated distribution chains. The risk increases as drugs move farther from manufacturer. Licensed pharmacies and dispensaries can control the quality of their stock, at least insomuch as they can trust their wholesalers. There are no such efforts at quality control in the unlicensed market. Unlicensed vendors may approach medicines dispensing as any other sales job and not want a customer to leave without making a purchase. In general, these vendors exploit the chaos inherent to street markets and dry goods shops in low- and middle-income countries and online drug stores in middle- and high-income ones.

A simple lack of alternatives pushes consumers in developing countries to buy medicine from unlicensed vendors, who may sell pills loose from large plastic bags or subdivide blister packs. Despite this and other gross violations of good practice, the shops often operate with the regulators' tacit approval, because they are the only source of medicines outside of major cities.

There are also too few trained pharmacy staff in developing countries, especially in sub-Saharan Africa and South and Southeast Asia. In many countries, the few trained pharmacists work in industry. Community pharmacy practice, especially in rural areas, suffers. Having a trained community pharmacist oversee every drug store is not an option in the parts of the world most hurt by falsified and substandard medicines. Governments should take action to increase the reach of legal drug shops staffed by sellers with appropriate minimum training.

Recommendation 5-3: Governments in low- and middle-income countries should provide an environment conducive to the private sector establishing high-quality medicines retail in underserved areas. Govern-

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ment incentives could encourage this. To the same end, governments, the World Health Organization, and the International Pharmaceutical Federation should support national pharmacy councils and education departments to train tiers of pharmaceutical personnel.

The private sector will invest in medicines retail if there is a good business reason to do so. Governments can take steps that would encourage private sector investment and create an environment where responsible private drug sellers will thrive. Governments can provide low-interest loans for improving drug shops and encourage private-sector accreditation or franchising programs. They can also work with their national pharmacy councils to set out tiers of training, including vocational training, for pharmaceutical personnel. Governments can also give incentives to keep trained staff in underserved areas.

Disorganized medicines retail is not confined to developing countries. Through the internet, unlicensed drug vendors sell around the world, mostly in middle- and high-income countries. Unlicensed internet pharmacies are similar to street drug bazaars, both in the quality of the products they stock, which is poor, and in the lack of official oversight of their operations.

In the United States the NABP runs the Verified Internet Pharmacy Practice Sites (VIPPS) accreditation program to recognize safe online drug stores. Accredited online pharmacies comply with state licensing requirements for both the state that the pharmacy is in and all the states in which it sells. Chief among these requirements are the authentication of prescriptions, observance of quality-assurance standards, and submission to regular state inspection. Accredited pharmacies display the VIPPS seal, and, because this seal could be copied, the project website lists both certified pharmacies and known fraudulent ones.

DETECTION TECHNOLOGY

The main categories of techniques for pharmaceutical analysis can be broken down as visual inspection of product and packaging; tests for physical properties such as reflectance and refractive index; chemical tests including colorimetry, disintegration, and dissolution; chromatography; spectroscopic techniques; and mass spectrometry. Within each of these categories, some technologies are appropriate for field use, while others require sophisticated lab equipment and a high level of technical expertise.

Understanding when, where, and why to use the various techniques can be difficult. The information a technique provides, as well as its reliability, cost, speed, and portability, make it more or less appropriate in any given situation. While any one test may suffice to label a drug substandard or falsified, no single analytical technique provides enough information

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to confirm that a drug is genuine. One challenge in both field and laboratory testing is determining how to combine tests for maximum efficiency. It is usually best to work through tests beginning with the easiest or least expensive ones. Only if samples pass these tests should the inspector move on to more difficult or expensive ones.

Making detection technology more accessible in low- and middle-income countries would be invaluable to controlling the trade in falsified and substandard drugs. Technologies can protect consumers and are useful to surveillance staff working to generate accurate estimates of the magnitude of the problem of poor-quality drugs. An understanding of the technological landscape, the range and gaps in available technologies, and the likely improvements in the near future is essential for using technologies in developing countries.

Recommendation 6-1: The National Institute of Standards and Technology should fund the development of a central repository for existing and newly innovative detection, sampling, and analytical technologies, ranging from field and rapid screening technology to sophisticated laboratory-based assessments, to identify substandard and falsified medicines.

CODE OF PRACTICE

Individual countries have the responsibility for protecting the national drug supply. This includes regulating good-quality manufacturers, preventing poor-quality drugs from entering the market, detecting them when they do, and punishing those who manufacture and trade them. Drug regulation, surveillance, and law enforcement are the necessary components of any national response to the problem.

A voluntary soft law such as an international code of practice could encourage international action against falsified and substandard drugs. The code of practice would contain guidelines on surveillance and international reporting of drug quality problems. The code would facilitate passage of national laws on how to punish and, when necessary, extradite those responsible for falsified drugs and criminally negligent manufacture. It would also promote harmonized regulatory standards for drug manufacture and licensing.

Recommendation 7-1: The World Health Assembly, in partnership with the United Nations Office on Drugs and Crime and the World Customs Organization, and in consultation with major stakeholders, should institute an inclusive, transparent process for developing a code of practice on the global problem of falsified and substandard medicines.

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The code should include guidelines on surveillance, regulation, and law enforcement, empowering states and the international community to prevent and respond to drug quality problems.

The manufacture and trade in falsified medicines is a growing, global problem. It is difficult to estimate the amount of falsified and substandard drugs in the market or to know the toll these products take on society, the number of deaths or excess illness they cause, or the amount of time and money wasted using them in treatment. There is evidence from some convenience surveys that antimicrobial drugs are often compromised in Southeast Asia and sub-Saharan Africa. In a larger sense, all drugs sold outside of legitimate chains are suspect. This includes medicines sold in unregulated markets and most drugs sold on the internet.

This report suggests a combination of actions that could reduce the global trade in falsified and substandard medicines. Some recommendations aim to improve medicine quality in the low- and middle-income countries that unquestionably bear a disproportionate burden of the problem. Other recommendations could improve weaknesses in the U.S. system, which would help the American consumer and build momentum for global action. Eliminating falsified and substandard drugs from the market requires international cooperation. A voluntary soft law could help advance harmonized systems for surveillance, regulation, and law enforcement.

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Summary

Food and medical product safety is crucial for public health. The food and medical products regulatory system (hereafter, the regulatory system) is a key piece of the public health system. In the United States, the Food and Drug Administration (FDA) protects consumers from unsafe food and drugs, an ever more complicated task as increasingly food and medical products travel through complex international supply chains. The past 10 years have seen contaminated heparin and pet food reach the American market from foreign factories. Thousands of Americans die every year from food poisoning and, although much of it is home-grown, foodborne epidemics are increasingly international. This is small compared to the product safety calamities in developing countries, where fake drugs and poisoned excipients kill tens of thousands against a constant background of aflatoxin poisoning and foodborne disease.

Product safety in the United States depends on systems in faraway places. The FDA estimates that more than 80 percent of active pharmaceutical ingredients and 40 percent of finished drugs come from abroad, as does 85 percent of seafood. Congress has reacted to these trends by requiring that the FDA inspect more producers. Meeting Congress's new inspection targets will be a great effort for the FDA. More importantly, Congress's most ambitious inspection plan still monitors only a small fraction of foreign manufacturers.

The FDA cannot do its job well without substantive improvements in the capacity of its counterpart agencies in emerging economies. With this in mind, the FDA commissioned this study to identify the core elements of food, drug, medical product, and biologics regulatory systems in develop-

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ing countries; to identify the main gaps in these systems; and to design a strategy the FDA and other stakeholders can use to strengthen food and medical products regulatory systems abroad.

In preparing this report, the committee heard from stakeholders from many low- and middle-income countries at conferences in Washington, DC, Beijing, São Paulo, Pretoria, and New Delhi. A brief summary of its findings and recommendations follows.

CORE ELEMENTS OF REGULATORY SYSTEMS

The committee identified the main characteristics of successful regulatory systems. First, a robust system is responsive; it can respond quickly in a crisis, and it can respond appropriately to new science and new ideas. Such a system also focuses on the outcomes and does not become overly concerned with prescribing methods that might get in the way of innovation. A robust regulatory system is a predictable system; rules are applied consistently and fairly and are designed to favor neither small nor large companies, neither imports nor domestic products. The system allocates controls proportionate to risk and regulates products with similar risks in similar ways. Finally, a robust regulatory system is independent; it is not unduly influenced by politics or money.

The main duties of a medical products regulatory authority are: product registration; the publication of clear licensure requirements; the provision of unbiased information; market entry notification; safety and effectiveness surveillance; quality control testing; inspection of manufacturers against good manufacturing practices; inspection of distributers against good distribution practices; and the evaluation of medical product performance through trials. In countries that produce vaccines, the regulatory authority is also responsible for the systematic lot release of the vaccine. The main duties of a food regulatory system are providing unbiased education and advice to all stakeholders; inspecting food production sites and processing plants against good agricultural practices and good manufacturing practices; evaluating hazard analysis and critical control points (HACCP) plans; conducting physical, chemical, and microbiological analysis of food; and doing epidemiological surveillance. These responsibilities make the regulatory system a main piece of the public health system.

Low- and middle-income country regulatory authorities are not able to execute all of these responsibilities. With this in mind, the committee identified minimal elements for a regulatory system. At a minimum, the country must have a rule-making process. This rule-making system should be open enough to allow all stakeholders to comment on new regulations. A minimally functional system also has a protocol for different agencies involved in product regulation to work together. It also has a way to identify when

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regulatory action is necessary. The minimal elements of a regulatory system emphasize the processes that let the system run well. Product safety is, of course, the goal of any food and medical products regulatory system. However, at a minimum there must be a process in place that allows the system to run. When this administrative framework is in place regulators have a way to execute their product safety responsibilities.

Cooperation with counterpart regulatory agencies is a core element of a modern regulatory system. Coordination among the different regulatory agencies within a country is also necessary for product safety, including coordination at different levels of government. The use of HACCP principles to control the food system and the regulation of active pharmaceutical ingredients are examples of areas where different regulators work together to their mutual benefit.

CRITICAL ISSUES IN DEVELOPING COUNTRY FOOD AND MEDICAL PRODUCT SAFETY SYSTEMS

The committee identified nine common problems that cut across developing country product safety systems. A brief summary of these nine critical issues follows.

1. Adherence to international standards is a clear problem; it requires good infrastructure and expensive equipment. The least developed countries often lack the scientific expertise to send active advocates to international standard setting meetings. Because their representatives do not participate in any meaningful way, the countries become standard-takers, not participants in standard setting.
2. There are many related problems in controlling supply chains. Food spoils quickly without refrigeration or proper storage, and it takes too long to get to market over poor roads. The vaccine supply chain and, to a lesser extent, the medicine supply chain are prey to breaks in the cold chain and to wastage. Inventory planning and demand management are difficult in places that have neither reliable transportation infrastructure nor sufficient managerial expertise in the health workforce.
3. Problems controlling supply chains are difficult to separate from infrastructure deficits. There are serious shortcomings in the market infrastructure in low- and middle-income countries, such as lack of pest control and refrigeration. Quality-control laboratories are woefully few, and the ones that do exist have outdated equipment and often have to depend on an unreliable power supply. Local manufacturing is complicated by more basic sanitation problems. Information technology could improve the jobs of regulators

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and industry in developing countries, but bandwidth is far too expensive and unreliable. All elements of the system require trained personnel, which is often scarce in developing countries.

4. A strong legal foundation is a prerequisite for food and medical product regulation. Some of the poorest countries have no laws governing product safety; others have a surfeit of confusing and contradictory ones. Enforcing product safety laws is a monumental task, one that is often neglected or executed unevenly. Product liability laws are often essentially non-existent.
5. Government regulators have too few staff, problems retaining their staff, and problems with morale. Corruption is both a cause and an effect of many of the workforce problems. Some staff are fired for political reasons; others grow frustrated and quit.
6. Regulatory responsibilities in low- and middle-income countries are often scattered among many different agencies. This is true in the United States and in many other developed countries as well, but it becomes a problem in places where the same responsibilities are assigned to different agencies or when there is no way for different agencies to communicate. Sometimes the agencies have limited authority to enforce laws; others have authority, but problems coordinating with other agencies.
7. Poor surveillance systems prevent regulators from evaluating emerging safety signals. They cannot monitor medical product safety, track epidemics, or do risk analysis without reliable surveillance data. Weaknesses in the vaccine safety surveillance system can aggravate vaccine scares. Pharmacovigilance systems are also weak; often doctors and pharmacists are not aware of their responsibilities to report adverse drug events.
8. Strong communication can do much to assuage the problems of fragmentation in a regulatory authority, but there are problems with communication among the different agencies responsible for regulation in developing countries. There are also problems communicating within agencies, especially from subordinate to senior staff. Often there is no appropriate forum for regulators to communicate with industry. Consumer groups, which communicate the public's needs to both government and industry, are often missing.
9. A push for product safety can come from the public, especially in large markets with good communications systems. When governments are accountable to their citizens, public opinion can drive political will. Politicians in emerging economies are often more concerned with economic growth. Some regulators are assigned a job that has both product promotion and regulatory responsibilities; they can do neither fully or well. Product safety is not a high

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priority in countries with skeletal health systems, poor sanitation, and high mortality. Ironically, the vast increase in foreign aid for health over the past 10 years has had an unintended consequence of decreasing national governments' allocations to health, to the detriment of food and medical product safety.

STRATEGY FOR BRIDGING THESE GAPS

After analyzing the nine main gaps in food and medical product regulatory systems in developing countries, the committee developed a strategy to bridge these gaps. This strategy emphasizes public health, market incentives, risk-based investments, and international coordination.

Unsafe food and medical products are at the root of many public health problems in poor countries. Foodborne disease often causes diarrhea, which in turn aggravates malnutrition. Malnutrition compounds the many infectious diseases common in developing countries, diseases that go untreated because of an unsafe or unreliable drug supply. No one would argue that improving public health is less than essential for international development, and the regulatory system is a key piece of the public health system. Yet, donors are disinclined to invest in regulatory systems, preferring to fund disease-specific programs or improve the primary health system.

There is much room for improvement in the way donor agencies, foundations, non-governmental organizations, and multilateral organizations invest in regulatory systems, not the least of which is an emphasis on risk. It is neither good management nor good sense to divide resources equally among all regulated products. Risk assessment is the foundation of modern regulatory science. An understanding of the same should guide investments in product safety.

The market can also drive improvements to regulatory systems, but not without deliberate incentives. The American food and medical products market is strictly controlled, as are all of the most lucrative markets. In emerging economies, small- and medium-sized businesses dominate much of the pharmaceutical supply chain and vastly more of the food supply chain. Economies of scale make it difficult for these industries to adhere to the standards that would allow them to export to hard currency markets. Proper monetary incentives can help developing country producers stay competitive in the global marketplace. Similarly, stricter product liability laws can work to the advantage of producers who make safety a priority.

Product safety cannot improve without international cooperation. Universities and multilateral organizations are often adept at collaborating across borders. Regional collaboration is an efficient form of collaboration that allows less technologically advanced countries to benefit from the systems in place in neighboring countries.

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INTERNATIONAL ACTION

Because of international trade, product safety failures in any one country can have ramifications around the world. The global foodborne disease outbreaks and contaminated drug scares have driven this point home over recent years. International trade is also a vehicle for economic development; jobs in high-value agriculture and manufacturing are ways out of poverty for many. Because everyone has a stake in product safety, everyone needs to take action to build regulatory systems. The committee's proposed international action will: increase investments in regulatory systems; encourage open dialogue among government, industry, and academia in emerging economies; work toward voluntary sharing of inspection results; and support surveillance.

Recommendation 5-1: In the next 3 to 5 years, international and intergovernmental organizations should invest more in strengthening the capacity of regulatory systems in developing countries. The United States should work with interested countries to add it to the G20 agenda. Investments in international food and medical product safety should be a significant and explicitly tracked priority at development banks, regional economic communities, and public health institutions. International organizations should provide assistance to achieve meaningful participation of developing country representatives at international harmonization and standardization meetings.

There is common ground where food and medical product safety, public health, trade, and economic development are mutually reinforcing. The development banks and regional economic communities work in this common ground; they should invest more in building regulatory systems in low- and middle-income countries. In particular, their investments should aim to improve the participation of scientists from these countries in international standard setting. The G20 is an excellent forum for industrialized and emerging economies to work together on development. In 2012, Mexico will host the G20 meeting. An emerging manufacturing nation with a vigorous export economy, Mexico would be an ideal leader for a global initiative on food and medical product safety. The United States and other G20 nations should support Mexico in this effort.

Recommendation 5-2: In emerging economies, national regulatory authorities, regulated industry, and industry associations should engage in open and regular dialogue to exchange expert scientific and technical information before policies are written and after they are implemented. Starting in the next 3 to 5 years, these regulatory authorities should

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identify third parties, such as science academies, to convene the three pillars of a regulatory system—government, industry, and academia—in ongoing discussion to advance regulatory science, policy, and training.

A robust regulatory system depends on input from industry and academia; government simply cannot shoulder the burden alone. In some counties this will require a cultural shift. Science academies are one neutral venue that can bring stakeholders together for open dialogue; public health institutes, although usually governmental, are another. Regardless of the venue that regulatory authorities use, they need to collaborate with industry and academia when designing their policies and when reviewing them.

Recommendation 5-3: Countries with stringent regulatory agencies[1] should, within the next 18 months, convene a technical working group on sharing inspection reports with the longer-term goal of establishing a system for mutual recognition of inspection reports.

Sharing inspection reports is an important first step in mutual recognition and international regulatory harmonization. In the next 18 months countries with stringent regulatory agencies should share their inspection reports of facilities in developing countries. This is a simple step that could reduce a great deal of waste. There is no need for American and European inspectors to duplicate each other's work, especially when a vast number of facilities go uninspected. Over the next decade, these agencies should participate in a working group on mutual recognition of inspection reports. In time, regulatory authorities in emerging economies would also be able to contribute.

Recommendation 5-4: Industry associations should, over the next 3 years, define an acceptable protocol for sharing of internal inspection results among their members. After agreeing on the methods, they should regularly share their results among their members.

Sharing inspection results is sensitive but crucial to an efficient product safety system. In the next 3 to 5 years, food and medical product industry associations can work with their members to decide what information to share and how to share it. They could also encourage members to make use of modern data management and to rely less on handwritten inspection reports.

[1] Countries with stringent regulatory agencies include the United States, European Union member states, and Japan. For the purposes of this report the committee includes ICH Observers and Associates, Australia, New Zealand, Norway, Iceland, Switzerland, and Canada in the category.

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Recommendation 5-5: Starting in the next 5 years, USAID, FDA, CDC, and USDA should provide (both directly and through WHO and FAO) technical support for strengthening surveillance systems in developing countries. This technical support could include development of surveillance tools, protocols for foodborne disease surveillance and post market surveillance of medical products, and training of national regulatory authority staff and national experts.

There is a wealth of surveillance expertise in the United Nations (UN) system; the U.S. government and universities have substantial technical depth in the same. These organizations need to strengthen surveillance systems in low- and middle-income countries. The CDC's PulseNet program, for example, is a surveillance program that has expanded to Latin America, Asia, the Middle East, and Europe. In the next 3 years, USAID, FDA, CDC, and USDA can work with their host country counterparts to develop manageable systems for pharmacovigilance. Within 5 years, an expansion of the CDC PulseNet program could elicit meaningful improvements in the foodborne disease surveillance systems in the poorest countries. Building a cadre of trained epidemiologists will take time, probably 10 years or longer, but is an important step of strengthening surveillance systems.

DOMESTIC ACTION

The Food Safety Modernization Act and the FDA's new *Pathway to Global Product Safety and Quality* make it clear that the agency is prepared to change its operations to keep pace with globalization. The committee recommended specific actions that the FDA and other government agencies should take to improve the capacity of regulatory authorities in low- and middle-income countries. The committee's proposed domestic action will: use risk as a guiding principle; use information technology; bridge training gaps; lead in adaptation of international standards; expand the one-up, one-back track and trace requirements; research inexpensive technology; give market incentives for supply chain management; and increase civil liability.

Recommendation 6-1: The FDA should use enterprise risk management to inform its inspection, training, regulatory cooperation, and surveillance efforts. Enterprise risk management should apply to the Agency's entire operation, and it should incorporate a number of set criteria such as country of manufacture or production, volume and type of product, facility inspection history, and trends or data shared from other regulatory authorities.

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A comprehensive use of risk management should guide the FDA, and it should employ risk management for its entire operation, not merely for inspections as is often advised. In the next 3 to 5 years, the FDA should use risk to run its international programs—to choose which offices to scale up, what trainings to run, and where to run them. In the next 10 years, the agency should use risk to determine how it allocates its resources to both domestic and international programs. To this end, it may need to ask Congress to revise the law governing it.

Recommendation 6-2: The FDA should develop an information and informatics strategy that will allow it to do risk-based analysis, monitor performance metrics, and move toward paperless systems. In the next 3 to 5 years, the FDA should propose, in all its international harmonization activities, a standardized vocabulary, a minimum data set to be collected, and the frequency of data collection.

The use of an enterprise-wide risk management system depends on efficient and reliable data management and on using a data format that lends itself to appropriate international sharing. In the next 3 to 5 years, the FDA can articulate a standard data collection format and vocabulary. The FDA should work with international forums such as the World Wide Web Consortium and the Institute of Electronics and Electrical Engineers to work out a minimum key data set that it and its counterparts can collect and share. These are steps to the goal of having a paperless system in the next decade.

Recommendation 6-3: The FDA should facilitate training for regulators in developing countries. The purpose is workforce training and professional development through an ongoing, standing regulatory science and policy curriculum. In the next 3 to 5 years, the FDA should broaden the scope of FDA University to educate FDA staffers on international compliance with its regulations. In the long term, the FDA should consider the options the committee puts forth in Chapter 6.

The FDA should use its diplomatic staff abroad and its gravity at international forums to facilitate the training of foreign regulators, though not necessarily to host it. There should be a predictable, standing regulatory science and policy curriculum that regulators from abroad could work through. Training-of-trainers will also be an invaluable way to educate in all languages and reach students in remote places. Over the next 3 to 5 years, the FDA can work through existing networks, such as the Asia Pacific Economic Cooperation's Partnership Training Institute Network, to train trainers. There is also value in an apprenticeship program akin to

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the CDC's Field Epidemiology Training Program. The committee understands that training regulators at an international regulatory college and developing an apprenticeship program will take about a decade. In the next 3 to 5 years, the FDA can broaden the scope of classes at its staff college to better educate American regulators on the international effects of and international compliance with U.S. regulations.

Recommendation 6-4: U.S. policy makers should integrate food and medical product safety objectives into their international economic development, trade, harmonization, and public health work. To this end, the FDA should lead in the development and adoption of international and harmonized standards for food and medical products.

The FDA is an accepted gold-standard regulatory agency; it should lead by example in the use of international standards. Harmonized standards facilitate trade and simplify compliance with product safety rules. The FDA should also work with other industrialized countries to streamline the criteria they use to evaluate conformance with standards. The FDA can also work with the U.S. Trade Representative to use international forums to promote harmonized standards for foods and medical products. In the next 3 to 5 years, the FDA can begin adopting harmonized international standards, but the full realization of integrating product safety into the larger U.S. international policy agenda will take a decade.

Recommendation 6-5: The FDA, which currently requires one-up, one-back track and trace requirements for food, should, in the next year, hold a multi-sector, international, public workshop on applying them to medicines, biologics, and (when appropriate) to devices.

Laws require food producers to identify the immediate prior and immediate subsequent recipient of all products in their supply chains. This is called one-up, one-back traceability. Expanding one-up, one-back requirements to drugs will be complicated, but all stakeholders need to think seriously about the costs and benefits of doing this. The FDA can demonstrate its commitment to strengthening global supply chains by hosting a public hearing on this topic in the next year.

Recommendation 6-6: Starting in the next 2 years, the FDA and the USDA should implement Cooperative Research and Development Agreements and other programs to encourage businesses and academia to research and develop innovations for low-cost, appropriate fraud prevention, intervention, tracking, and verification technologies along the supply chain.

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The U.S. government needs to encourage research into frugal technologies that would be useful in poor countries. The USDA and FDA should pursue Cooperative Research and Development Agreements with private companies to work together in research and development; the first of these could be issued in the next 2 years. They can also collaborate directly with researchers in developing countries. The technologies developed in these collaborations would also benefit small- and medium-sized producers in the United States into the future.

Recommendation 6-7: The FDA should ensure an adequate mix of incentives to importers of food and medical products that are confirmed to meet U.S. regulatory standards. One such promising initiative is the 2-year FDA Secure Supply Chain pilot program. The FDA should evaluate this program immediately after its pilot phase (scheduled to end in 2014). The program should be expanded, if successful, to include a greater number of importers and food.

The FDA does not have the authority to regulate all the upstream activities in complex international supply chains of food and medical products. The Secure Supply Chain pilot program rewards firms that trace their products thoroughly from manufacture to entry into the United States. The results from this pilot program should be evaluated when the pilot phase is over in 2014 with the goal of expanding the project to include more importers and more products in the next 3 to 5 years.

Recommendation 6-8: Over the next 10 years, U.S. government agencies should work to strengthen the ability of those harmed by unsafe food and medical products to hold foreign producers and importers liable in civil lawsuits.

Importers carry a great deal of product liability risk when they bring products into the American market. The U.S. government should give clear guidance to producers in low- and middle-income countries on the rights of consumers and the importance of product liability laws to trade and to health. In the next decade, U.S. government agencies including, but not limited to, the U.S. Trade Representative, the Department of Treasury, and the Department of Justice should work to increase liability for unsafe food and medical products.

CONCLUSION

Over the past 30 years, international trade, outsourcing, and improvements in telecommunication have created a more unified world economic

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system. This system benefits many, but it also presents new challenges. Individual countries can no longer depend on their national regulatory authorities to guarantee product safety in the domestic market. This report identifies the most pressing problems facing food and medical product regulators in developing countries. It outlines a strategy that can guide investments in regulatory capacity. It also recommends 13 specific actions the U.S. government and others could take to improve product safety and public health around the world.

The strategy for building regulatory systems and the 13 specific recommendations put forth in this report could do much to improve food and medical product safety in the United States and abroad. It was clear to the committee that product safety is a dynamic problem; it requires agile systems to respond to changing needs. The system should use enterprise risk management to inform its decisions. It is also clear that the FDA cannot act alone; it must develop ways to make the most of its extensive expertise and limited resources. Pooling data and planning inspections with other stringent regulatory agencies is an important first step. Other international organizations and regional communities are well-positioned to lead in training and education—key pieces of the solution. Finally, it has become clear that the FDA needs to refocus resources and attention on modern threats to the food and medical product supply. This will probably require rebalancing programs to give more attention to foreign producers and suppliers.

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EDITORIALS

What to do about unsafe medicines?

Because buyers cannot be aware of deceit in the sale of drugs, regulators need to balance the scales

Gillian J Buckley *program officer*[1], Jim E Riviere *university distinguished professor*[2], Lawrence O Gostin *university professor*[3]

[1]Board on Global Health, Institute of Medicine, Washington, DC 20001, USA; [2]College of Veterinary Medicine, Kansas State University, Manhattan, KS, USA; [3]O'Neill Institute for National and Global Health Law, Georgetown University Law Center, Washington, DC, USA

"Let the buyer beware," lawyers have cautioned since medieval times.[1] This is good advice when buying grain or livestock, but for as long as there have been markets people have recognized that some products' defects are not readily apparent to even the savviest shopper. This problem, now called information asymmetry, is perhaps most acute in the medicines market, where falsified and substandard drugs blend almost perfectly with good ones. Because buyers cannot be aware of the deceit in the sale of drugs, regulators need to step in and balance the scales. In much of the world, however, the regulation of drugs is neglected. In this vacuum, drug quality declines and patients suffer.

It is difficult to measure the human suffering caused by unregulated medicines, a recent Institute of Medicine report concluded.[2] Whereas the burden of specific diseases can be expressed in disability adjusted life years, quality adjusted life years, morbidity, or mortality, poor quality drugs go unnoticed by design. Some contain no active ingredient or reduced doses of the labeled drug. Others may mimic a therapeutic effect, disguising, for example, paracetamol in antimalarial packaging. Only through postmarketing surveillance do these problems come to light. Pharmacovigilance data give an understanding of what drugs are compromised and where they circulate. A better understanding of such trends could inform estimates of how much ineffective drugs cost society, translating the threat into concrete terms that compel governments and donors to act.

The irony of the problem is that the very data that could motivate investment in drug regulation depend on market surveillance. In a 2010 assessment, the World Health Organization found that only five of 26 drug regulatory authorities in sub-Saharan Africa had functional pharmacovigilance systems.[3] The situation in major drug producing nations is no better. In China and India, for example, short staffed regulatory agencies struggle to inspect and license thousands of manufacturers, with little staff time left for market surveillance. A 2012 Institute of Medicine report identified poor surveillance as one of the main barriers to developing drug safety systems in low and middle income countries.[4] The report recommended that the US government and international organizations invest in pharmacovigilance in these countries. In a larger sense, the report argued for more donor investment in medicines regulation in the developing world.

Donor countries stand to benefit from this investment as well. Modern drug manufacturing relies on ingredients sourced from around the world. Supervising multinational supply chains is an insurmountable job, even for well funded regulatory authorities. Drug importing nations would welcome investments in the technical skills of regulators in drug producing nations, because these regulators have the first responsibility for manufacturing oversight. Building health systems, especially drug regulatory systems, also protects donors' interests in global health. Development agencies have invested heavily in reducing maternal and child mortality and in treating major infectious diseases. These programs depend on effective medicines, something that cannot be ensured without a commensurate investment in drug regulation.

Regulators in developing countries should help initiate these investments. Their agencies have many competing needs: equipment, training, staffing, reference standards, and infrastructure. The scope of the needs can be overwhelming, leading to inaction. The Institute of Medicine report on falsified and substandard drugs recommended that regulators in low and middle income countries draft strategic plans for agency development.[2] This plan would identify the agency's priorities and guide decisions about where to invest first, a manageable first step even for a small agency. Regulators could then use the plan to advocate for better support from their ministers and to identify places where donors could contribute.

Investment in regulatory systems could bring about meaningful improvements in the health of the world's poorest people. These improvements are already well under way. The past 20 years have seen great advances in global health, but disease treatment programs may soon face the prospect of diminishing marginal returns. Their continued success depends on corresponding

gbuckley@nas.edu

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investments in health systems, of which the drug regulatory system is an important part. Until governments can ensure that the drugs in their countries are safe and reliable, patients face a hopeless disadvantage in navigating the drug market alone. Life saving drugs, although apparently plentiful, will remain out of reach for many.

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1 LeViness CT. Caveat emptor versus caveat venditor. *Md L Rev* 1943;7(177).
2 Institute of Medicine. Countering the problem of falsified and substandard drugs. National Academies Press, 2013. www.nap.edu/catalog.php?record_id=18272.
3 WHO. Assessment of medicines regulatory systems in sub-Saharan African countries: an overview of findings from 26 assessment reports. 2010. www.who.int/healthsystems/Assessment26African_countries.pdf.
4 Institute of Medicine. Ensuring safe foods and medical products through stronger regulatory systems abroad. National Academies Press. 2012. www.nap.edu/catalog.php?record_id=13296.

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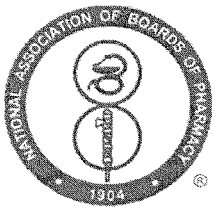

nabp
National Association of Boards of Pharmacy
1600 Feehanville Drive • Mount Prospect, IL 60056-6014
Tel: 847/391-4406 • Fax: 847/391-4502
Web Site: www.nabp.net

Internet Drug Outlet Identification Program

Progress Report for State and Federal Regulators: October 2013

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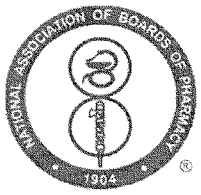


nabp
National Association of Boards of Pharmacy
1600 Feehanville Drive • Mount Prospect, IL 60056-6014
Tel: 847/391-4406 • Fax: 847/391-4502
Web Site: www.nabp.net

INTERNET DRUG OUTLET IDENTIFICATION PROGRAM
PROGRESS REPORT: October 2013

I. INTRODUCTION

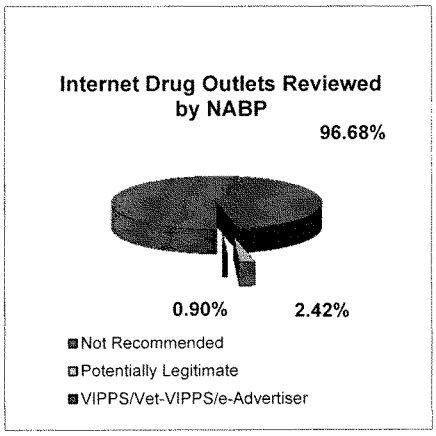
Whether referred to as fake, fraudulent, spurious, falsified, or counterfeit, unapproved drugs that defy established safeguards endanger patient health. There is little debate among national authorities that counterfeit or falsified medications pose a serious public health threat. Hindering resolution of this global scourge, however, is the continuing international debate over terminology and what constitutes a "counterfeit" drug. The lack of a consensus definition makes it difficult to gather definitive global statistics on the problem. Some national regulatory authorities and stakeholder groups emphasize trademark protections and intellectual property infringements as the crux of the counterfeiting problem and the path to a solution. They maintain that knockoff products fraudulently using trademarked brand names are almost always substandard, or worse. Because they do not meet established good manufacturing standards or criteria for drug safety and efficacy, these knockoff products come with a much higher risk to patients than those products manufactured and distributed in accordance with approved channels. Other national and international authorities reject the intellectual property (IP) issue as a matter of concern only to multinational drug companies and narrow their focus strictly to matters of safety. Some, particularly developing countries that do not recognize the intellectual property laws of other countries, argue that proponents of IP enforcement improperly lump generic drugs in with counterfeits. Either way, when discussing prescription medications not approved by national authorities, or circumventing approved distribution channels, the patient safety issue is inherent.

In its ongoing review of illegal online sales of prescription drugs to United States patients, National Association of Boards of Pharmacy® (NABP®) has found that most of the rogue online drug sellers reviewed in the last three months offer foreign or non-Food and Drug Administration (FDA)-approved medications, many fraudulently bearing trademarked brand names. Whether these are "counterfeit" is a matter of some debate. In nearly every case, however, their trademark violations are only one of many concerns; almost all of these sites also engage in other illegal

activities that further endanger patients. These findings, discussed further in the Results section of this report, illustrate the difficulty in completely separating IP-infringing medications from those that are falsified, fraudulent, or fake; one is often intrinsic to the other, and both pose significant risks to patient safety.

II. RESULTS

A. Findings of Site Reviews: As of September 30, 2013, NABP has conducted initial reviews and, via a subsequent review, verified its findings on 10,642 Internet drug outlets selling prescription medications. Of these, 10,288 (96.68%) were found to be operating out of compliance with state and federal laws and/or NABP patient safety and pharmacy practice standards. They are also listed as Not Recommended in the "Buying Medicine Online" section, under Consumers, on the NABP Web site, as well as on NABP's consumer protection Web site, *WWW.AWARERX.ORG*. The 10,288 Internet drug outlets currently listed as Not Recommended on the NABP Web site are characterized in the table below.[1]



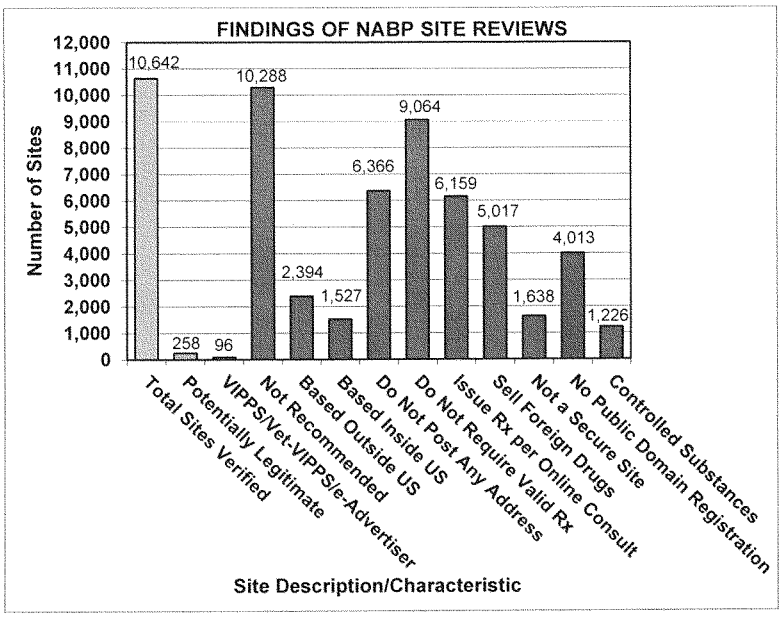
Of the total 10,642 sites reviewed, 258 (2.42%) appear to be potentially legitimate, ie, meet program criteria that could be verified solely by looking at the sites and their domain name registration information. Ninety-six (0.90%) of the 10,642 reviewed sites have been accredited through NABP's Verified Internet Pharmacy Practice Sites™ (VIPPS®) or Veterinary-Verified Internet Pharmacy Practice Sites™ (Vet-VIPPS®) programs, or approved through the NABP e-Advertiser Approval™ Program.

[1] It should be noted that the research findings NABP reports herein and on the Not Recommended list include the total number of Web sites selling prescription drugs to US patients that NABP staff has reviewed and found to be out of compliance with program standards, including those sites that were found to be noncompliant at the time of review but may since have been deactivated. Thanks to the successes of multistakeholder efforts to shut down rogue sites, many of these sites may now be defunct. It should also be noted that the numbers reported here do not represent the entire universe of Web sites selling prescription drugs illegally, but, rather, a representative sampling of the online environment over the last five years.

Physical Location:	2,394 (23.3%) outside US 1,527 (14.8%) inside US 6,366 (61.9%) no location posted on Web site
Prescription Requirements:	9,064 (88.1%) do not require valid prescription 6,159 (59.9%) issue prescriptions per online consultations or questionnaires only
Medications:	5,017 (48.8%) offer foreign or non-FDA approved medications 1,226 (11.9%) dispense controlled substances
Encryption:	1,638 (15.9%) do not have secure sites, exposing customers to financial fraud and identity theft
Server Location:	4,225 (41.1%) outside US 5,603 (54.5%) inside US 460 (4.5%) have unknown server locations
Domain Name Registration:	4,013 (39.0%) do not have a public domain name registration (WHOIS information is registered using a privacy or proxy service)
Affiliations:	9,450 (91.9%) appear to have affiliations with rogue networks of Internet drug outlets

The standards against which NABP evaluates Internet drug outlets are provided in Appendix A of this report.

In Appendix B is a new info-graphic developed as a public education tool through the AWAR$_X$E® consumer protection program, provided by NABP. AWAR$_X$E joins forces with patient safety advocates in reaching out to educate consumers on the dangers of rogue Internet drug outlets, substandard and counterfeit drug products, and the importance of proper medication storage and disposal. More information is available on the AWAR$_X$E Web site, *WWW.AWARERX.ORG*.



Findings of NABP Web site reviews, in total, as of September 30, 2013

B. Trends Among Internet Drug Outlets Selling Foreign or non-FDA-Approved Medications: From July through September 2013, NABP identified 109 additional Internet drug outlets that are operating out of compliance with pharmacy laws and practice standards and added them to the Not Recommended list. Of these 109 rogue Internet drug outlets, 84 (77.06%) offer foreign or non-FDA-approved medications. US federal law prohibits the importation of prescription drugs into the US from foreign countries by anyone other than the manufacturer. In the US, FDA approves a drug on the basis of scientific data proving it to be safe and effective. The manufacturing facilities and procedures for approved products are also carefully regulated by FDA to ensure product integrity. When foreign pharmacies ship prescription medications to the US, the medications are not subject to the safety requirements set by FDA to protect consumers and, therefore, US citizens cannot be certain the drugs meet the standards they expect, and the risk of receiving counterfeit medications is significantly greater.

Most frequently, Internet drug outlets offering non-FDA-approved medications offer "generic" versions of name brand erectile dysfunction medications. At this point in time, no FDA-approved generics exist for Pfizer's Viagra®, Eli Lilly and Company's Cialis®, or Bayer HealthCare Pharmaceuticals' Levitra®. However, the World Wide Web is plagued with Web sites offering to ship "Generic Viagra," "Cialis Soft Tabs," and "Levitra Jelly," to name a few, to US citizens. These products have not been subject to the safety and efficacy standards that their branded counterparts must successfully pass, and they are not sanctioned in any way by the companies whose names they use. Of the 84 sites selling foreign or non-FDA approved medications, 71 (84.52%) are selling drugs promoted fraudulently under approved brand names. Examples of these drugs include, but are not limited to, "Generic Cialis" (7), "Cialis Soft Tabs" (9), "Viagra Soft" (39), "Generic Viagra" (32), and "Generic Levitra" (1). Not only are these unapproved "generics" violating trademark laws, but they raise numerous patient safety concerns. Often, these illegal knockoffs will contain inaccurate amounts of the active ingredients, no active ingredients, or harmful fillers. The above is not an all-inclusive list of the non-FDA-approved medications offered on the 84 sample sites but reflects the most frequently promoted medications on these Web sites.

Also concerning is the fact that 82 (97.62%) of the 84 sites offering foreign or non-FDA-approved prescription medications are not requiring a valid prescription for the purchase of these drugs. This could lead to dangerous interactions with other medications patients may be taking, as well as other harmful side effects. Sixteen (19.05%) of the 84 sites are issuing prescription medications based solely on the results of an online questionnaire or consultation, which does not constitute a valid prescription. Twenty-two (26.19%) of the 84 sites posted physical locations outside of the US. Only four (4.76%) posted physical locations inside the US, while the remaining 58 (69.05%) did not post any physical address. Seventeen (20.24%) of the 84 sites do not use Secure-Socket Layer or equivalent technology for the transmission of protected health information (PHI). Therefore, patients' identifiable information, health records, as well as credit card information, are all susceptible to interception by unwanted third parties, subjecting customers to identity theft. Twenty-eight (33.33%) of the 84 sites are illegally selling controlled substances, allowing easy access to medications that should be carefully prescribed and monitored by an attending physician.

C. Sites Using Privacy or Proxy Domain Name Registration Services Raise Red Flags: As if neglecting to post an address on the Web site does not sufficiently obscure their identity, many illegal online drug sellers also register their Web site domain names anonymously. Recent studies have identified a correlation between Web sites utilizing privacy or proxy

domain name registration services (services that mask the identity of domain name registrants) and illegal activity on the Web. A September 2013 study conducted at the University of Cambridge shows that, in contrast to "legal pharmacies," which have a "low" rate of usage of privacy or proxy services (8.8%), "unlicensed pharmacies" have an "extremely high" rate of usage of privacy or proxy services (54.8%).

Of the 109 Internet drug outlets NABP discovered to be operating out of compliance with pharmacy laws and practice standards from July through September 2013, 45 (41.28%) of them utilize a privacy/proxy domain registration service, more than double that of domains in general. Of these sites, 42 (93.33%) do not require a valid prescription. Thirty-seven (82.22%) do not post a physical address, 33 (73.33%) offer foreign or non-FDA-approved medications, eight (17.78%) offer controlled substances without a valid prescription, and eight (17.78%) are not encrypted, exposing customers to financial fraud and identity theft. These findings further support the correlation between anonymous domain registration and illegal activity shown in the 2013 Cambridge study.

D. Recommended Internet Pharmacies: NABP, along with many patient safety advocates, continues to recommend that US patients use Internet pharmacies accredited through the VIPPS and Vet-VIPPS programs when buying medication online. These sites have undergone and successfully completed the thorough NABP accreditation process, which includes a review of all policies and procedures regarding the practice of pharmacy and dispensing of medicine over the Internet, as well as an on-site inspection of facilities used by the site to receive, review, and dispense medicine. Currently, 59 VIPPS and Vet-VIPPS pharmacy sites are listed as Recommended Internet Pharmacies. Several more applications are in progress.

E. Accreditation and Approval Programs: In addition to identifying rogue sites, the Internet Drug Outlet Identification program staff continues to assist in screening applicant Web sites for the VIPPS, Vet-VIPPS, and e-Advertiser Approval programs. Sites that have received e-Advertiser Approval status do not fill new prescription drug orders via the Internet, and thus, are ineligible for VIPPS, but accept refill requests from their existing customers, provide drug information or pharmacy information, or offer other prescription drug-related services. Sites that have received e-Advertiser Approval status have been found to be safe, reliable, and lawful. These sites are listed on the NABP Web site as Approved e-Advertisers. Currently, 37 entities are listed on

the NABP Web site as Approved e-Advertisers, and several more applications are in progress.

III. COUNTERFEIT MEDICINE: IP OR SAFETY ISSUE

While a precise, universal definition of a counterfeit medicine remains elusive, the fact that fake medicines pose a public health threat is recognized globally. The problem is cited as a concern by public health regulators in the US, United Kingdom, European Union, and regions of Asia and Africa, as well as by international groups including the World Health Organization (WHO), United Nations Office on Drugs and Crime (UNODC), International Pharmaceutical Federation (FIP), Group of 8, World Customs Organization, and Interpol. The problem is taken up as a charge by public and private organizations, regulatory agencies, and industry stakeholders, such as Partnership for Safe Medicines, Alliance for Safe Online Pharmacies, Center for Safe Internet Pharmacies, and European Alliance for Access to Safe Medicines. While it is, in many circles, also an economic concern, to such organizations as US Intellectual Property Enforcement Coordinator, Asia-Pacific Economic Cooperation, and World Intellectual Property Organization, overwhelmingly, even where economic interests are concerned, the problem of prescription drug counterfeiting is inherently, inextricably tied to public health.

A. The Name Game: WHO cites the lack of a universal definition of a counterfeit medicine as a barrier to fully understanding and combating the problem on a global scale. The debate has continued for more than two decades – since WHO convened the first international meeting on counterfeiting medicines in 1992, and participants agreed to a definition. WHO defined a counterfeit medicine as one that is "deliberately and fraudulently mislabelled [sic] with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredients or with fake packaging." Acceptance of this definition, however, was not universal. Countries including Brazil, India, and Thailand disagreed with this definition of the term "counterfeit." Critics suggested that its underlying intent was to target generics and protect IP rights of brand-name drug manufacturers, even in countries that do not recognize IP rights, and that it hindered patients' access to necessary drugs in the developing world.

WHO is currently engaged in negotiations with member states as to its future role in tackling the issue of what is currently referred to as spurious/falsely labelled/falsified/counterfeit" (SFFC) medical products. In a May 2012 fact sheet, WHO describes these products in terms very similar to its earlier definition of counterfeits – as medicines that are "deliberately and fraudulently

mislabeled with respect to identity and/or source," and can result in "treatment failure or even death," as well as "erosion of public confidence in health systems." They may include "products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient or too much active ingredient, or with fake packaging." SFFC medicines are found worldwide and "range from random mixtures of harmful toxic substances to inactive, ineffective preparations. Some contain a declared, active ingredient and look so similar to the genuine product that they deceive health professionals as well as patients. But in every case," WHO says, "the source of a SFFC medicine is unknown and its content unreliable. SFFC medicines are always illegal. ... Eliminating them is a considerable public health challenge."

In many developed countries, notably the US, counterfeits are intrinsically linked with IP rights, but still strongly linked to patient safety. US law defines a counterfeit drug as "a drug which, or the container or labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, or device, or any likeness thereof, of a manufacturer, processor, packer, or distributor other than the person or persons who in fact manufacture, processed, packed, or distributed such drug and which thereby falsely purports or is represented to be the product, or to have been packed or distributed by, such other drug manufacturer, processor, packer, or distributor."

By contrast, UNODC makes a point to separate IP violations from other forms of medication fraud. UNODC uses the term *counterfeit* in reference to "falsely-branded or unlicensed products, where the crime involved is intellectual property theft." It calls the act of deceiving buyers as to the content of what they are buying *fraud*. This includes misbranding but is broader, and – most importantly – encompasses products that do not contain what they purport to contain. Whether they also violate IP rights, which many do, is beside the point. For example, in an April 2013 report, *Transnational Organized Crime in East Asia and the Pacific: A Threat Assessment,* UNODC points out the "large share" of "bogus" anti-malarial and other essential medicines sold in Southeast Asia and Africa. "In some cases," the report states, "there is deliberate brand counterfeiting, but in many others, the drugs are generic. For the consumer, the results are the same."

European health care regulators prefer the term *falsified* and are careful to distinguish falsified medicines from counterfeit medicines. The Falsified Medicines Directive, new legislation that took effect in Europe in January 2013, addresses fraudulent products that endanger patient health. It aims to prevent the entry of falsified medicines into the legal supply chain at all phases of distribution, including the Internet. According to the European Commission, "Falsified medicines are not to be confused with counterfeit medicines. The latter term refers to medicines that do not

comply with EU law on intellectual and industrial property rights, such as registered trademarks or patent rights. The Directive on 'falsified medicines' does not deal with this aspect." Rather, the Directive defines falsified medicines as:

> *Any medicinal product with a false representation of:*
>
> *a) its identity, including its packaging, and labelling, its name or its composition as regards any of the ingredients including excipients and the strength of those ingredients;*
>
> *b) its source, including its manufacturer, its country of manufacturing, its country of origin or its marketing authorisation holder; or*
>
> *c) its history, including the records and documents relating to the distribution channels used.*

Most importantly, they are not approved by European public health regulators for sale in the EU. "Since they have not passed through the necessary evaluation of quality, safety and efficacy as required by the EU authorisation procedure," the Commission states, "they can be a major health threat." The European Commission notes on the trade policy page of its Web site, "Counterfeit products can also risk consumer safety and health."

The EU, along with several other countries, addresses IP violations through other designated channels. In 2012, the European Union, along with Mexico, signed on to the multinational Anti-Counterfeiting Trade Agreement (ACTA). Developed by the US and Japan in 2006, ACTA aims to establish international standards for IP rights enforcement pertaining to counterfeit goods, generic medicines, and copyright infringement on the Internet. As of February 2013, it had been signed by 31 states as well as the EU. Critics of ACTA have argued that, by focusing on IP violations, it treats all generic medications as counterfeits and deprives developing countries of cheaper versions of expensive drugs.

B. Supply Chain Controls Deemed Essential: Regardless of the terminology used to describe them, drug products that circumvent supply chain safeguards place patients at risk. On this point, it appears, nations more readily agree. Poor quality controls in developing countries, unregulated trade zones, and rogue wholesalers contribute to the problem. As reflected in the European legislation and as stated by FIP and other national and international groups, the key to reducing the availability of counterfeit and falsified medicines is maintaining the integrity of the quality controls at all stages in the manufacturing and distribution channel.

In its white paper, *Wholesale Drug Distribution: Protecting the Integrity of the Nation's Prescription Drug Supply*, released in October 2013, NABP points to the roles of unscrupulous wholesalers in distributing counterfeit drugs and unapproved foreign-sourced drugs that have endangered patients across the country. The paper highlights the need for wholesale distribution

regulation to address problems yet unsolved by the Prescription Drug Marketing Act of 1987 and the current patchwork of state regulations, in spite of which "questionable entities have managed to identify the gaps in the distribution and regulatory structure in order to swindle their way in to the drug distribution system." Due to emerging trends in the current drug market, drug products may pass through several steps in the distribution process before reaching their final destination, "leaving them vulnerable to counterfeiting or unregulated conditions." This multiple changing of hands is common in the online trafficking of prescription drugs, such that even well-intentioned sellers offering foreign unapproved drugs, themselves, may have little idea where the drugs originated, what exactly they contain, or, assuming they were safe and effective to begin with, whether they were stored appropriately during the journey to maintain their safety and efficacy. In light of these concerns, NABP continues to assess and strengthen its Verified Accredited Wholesale Distributor® (VAWD®) program, currently recognized in 21 states, to help to ensure supply chain integrity.

IV. DISCUSSION

Regardless of the nuances ascribed to the term, counterfeiting undermines the long established controls of medication quality, safety, and efficacy by defying the safeguards designed to protect public health, that are provided by established and licensed medication supply channels, from manufacturer, to wholesaler, to pharmacy, to patient. NABP encourages and continues to work with the state boards of pharmacy, federal regulators, and other public and private stakeholders to educate the public about counterfeit drugs and other potential dangers of buying medication from unknown and unapproved sources, including the Internet. The Association remains committed to upholding the integrity of the practice of pharmacy – in any practice setting – and ensuring that patients have access to safe and effective prescription drugs.

NABP prepares and releases these status reports quarterly to provide the boards of pharmacy, other state and federal regulators, and interested stakeholders with updates of Web site review findings and outreach efforts, as well as other events and trends related to Internet pharmacy practice. Through communication and cooperation, we hope to advance the efforts of regulators and other entities to curtail the online trade of illicit, falsified, and counterfeit medications. When aligned, the combined efforts of multiple parties are a powerful force in bringing about positive change and protecting the public health. For further information, please contact Melissa Madigan, policy and communications director, via e-mail at mmadigan@nabp.net.

V. APPENDICES

Appendix A

Internet Drug Outlet Identification Program Standards

1. **Pharmacy licensure.** The pharmacy must be licensed or registered in good standing to operate a pharmacy or engage in the practice of pharmacy in all required jurisdictions.

2. **DEA registration.** The pharmacy, if dispensing controlled substances, must be registered with the US Drug Enforcement Administration (DEA).

3. **Prior discipline.** The pharmacy and its pharmacist-in-charge must not have been subject to significant recent and/or repeated disciplinary sanctions.

4. **Pharmacy location.** The pharmacy must be domiciled in the United States.

5. **Validity of prescription.** The pharmacy shall dispense or offer to dispense prescription drugs only upon receipt of a valid prescription, as defined below, issued by a person authorized to prescribe under state law and, as applicable, federal law. The pharmacy must not distribute or offer to distribute prescriptions or prescription drugs solely on the basis of an online questionnaire or consultation without a preexisting patient-prescriber relationship that has included a face-to-face physical examination, except as explicitly permitted under state telemedicine laws or regulations.

   Definition. A valid prescription is one issued pursuant to a legitimate patient-prescriber relationship, which requires the following to have been established: a) The patient has a legitimate medical complaint; b) A face-to-face physical examination adequate to establish the legitimacy of the medical complaint has been performed by the prescribing practitioner, or through a telemedicine practice approved by the appropriate practitioner board; and c) A logical connection exists between the medical complaint, the medical history, and the physical examination and the drug prescribed.

6. **Legal compliance.** The pharmacy must comply with all provisions of federal and state law, including but not limited to the Federal Food, Drug, and Cosmetic Act and the Federal Controlled Substances Act (including the provisions of the Ryan Haight Online Pharmacy Consumer Protection Act, upon the effective date). The pharmacy must *not* dispense or offer to dispense medications that have not been approved by the US Food and Drug Administration.

7. **Privacy.** If the pharmacy Web site transmits information that would be considered Protected Health Information (PHI) under the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule (45 CRF 164), the information must be transmitted in accordance with HIPAA requirements, including the use of Secure-Socket Layer or equivalent technology for the transmission of PHI, and the pharmacy must display its privacy policy that accords with the requirements of the HIPAA Privacy Rule.

8. **Patient services.** The pharmacy must provide on the Web site an accurate US street address of the dispensing pharmacy or corporate headquarters. The pharmacy must provide on the Web site an accurate, readily accessible and responsive phone number or secure mechanism via the Web site, allowing patients to contact or consult with a pharmacist regarding complaints or concerns or in the event of a possible adverse event involving their medication.

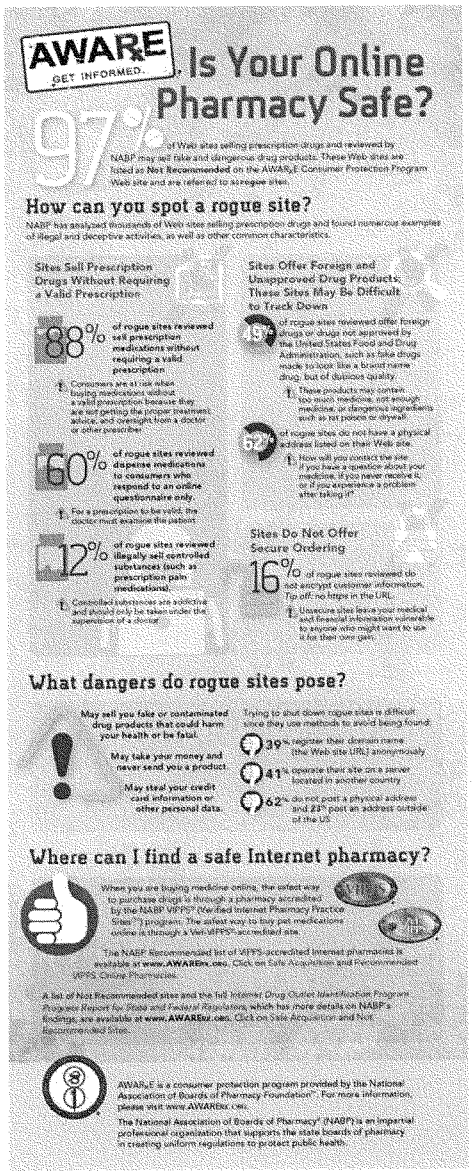
9. **Web site transparency.** The pharmacy must not engage in practices or extend offers on its Web site that may deceive or defraud patients as to any material detail regarding the pharmacy, pharmacy staff, prescription drugs, or financial transactions.

10. **Domain name registration.** The domain name registration information of the pharmacy must be accurate, and the domain name registrant must have a logical nexus to the dispensing pharmacy. Absent extenuating circumstances, pharmacy Web sites utilizing anonymous domain name registration services will not be eligible for approval.

11. **Affiliated Web sites.** The pharmacy, Web site, pharmacy staff, domain name registrants, and any person or entity that exercises control over, or participates in, the pharmacy business must not be affiliated with or control any other Web site that violates these standards.

APPENDIX B

AWAR$_X$E Consumer Protection Program Info-graphic



ASOP | ALLIANCE FOR SAFE ONLINE PHARMACIES

Key Data About Online Sales of Prescription Medicines

- There are believed to be between 35,000-50,000 active online drug sellers in operation. Often, these companies sell medicine without requiring a doctor's evaluation.[i]
- More than 96 percent of drug seller websites reviewed by the National Associations of Boards of Pharmacies do not meet pharmacy laws and practice standards.[ii]
- 50% of the prescription medicines sold online by websites that hide their physical address are counterfeit[iii]
- Large rogue Internet drug sellers can generate between $1 million and $2.5 million in sales each month.[iv]
- Online pharmacies have increased their market footprint, growing to an estimated $11 billion in sales in 2009.[v]
- Patients have been harmed and in some cases killed by unsafe medicines purchased from illegitimate sources on the Internet.
- A US study found that 85% of the 159 websites surveyed that offer controlled substances did not require a prescription.[vi]
- During the forth quarter of 2011, pharmacy spam constituted 31% of all spam.

Examples of Patients Harmed By Medications Purchased Online

These are just a few illustrations, in chronological order, of the serious and growing global problem of illegal online drug sellers.

1. On February 12, 2001, U.S. citizen Ryan Haight died from adverse reactions to painkillers that he purchased over the Internet. He was only required to fill out a questionnaire that was "examined" by a doctor who had never met him.[1]

2. On December 17, 2006, Craig Schmidt, a 30-year-old plastics salesman, purchased Xanax (an anxiety drug) and Ultram (a painkiller) from an online drug seller without seeing or speaking to the doctor that prescribed the medications. After taking the drugs, he nearly died and has been left permanently impaired with brain damage that inhibits him from driving or even walking without stumbling.[2]

3. Marcia Bergeron, a Canadian resident and US citizen, died in 2006 from heavy metal poisoning caused by the contaminated prescription medications she had purchased from an illicit online pharmacy. Otherwise healthy, the coroner determined that Bergeron died of cardiac arrhythmia caused by metal toxicity from counterfeit medication. According to the coroner, the website where Marcia bought her medicines looked reputable as did the box of pills, but the

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[1] "Don't underestimate the danger of drugs from abroad" San Diego Union-Tribune (February 25, 2011); available at *http://www.signonsandiego.com/news/2011/feb/25/dont-underestimate-the-danger-of-drugs-from-abroad/* This medicine was misused. The patient, without a prescription, purchased pain medications over the Internet. He had a serious reaction and died. The patient was only required to fill out a questionnaire that he was "examined" by a doctor who had never met him.

[2] "Online Extra: The Deadly Side Effects of Net Pharmacies" Bloomberg Businessweek (December 18, 2006); available at http://www.businessweek.com/stories/2006-12-17/online-extra-the-deadly-side-effects-of-net-pharmacies

drugs were actually shipped from overseas and had high levels of lead, titanium, and arsenic, which caused her death.[3]

4. On May 22, 2008, a man from Wichita, Kansas died from an accidental overdose of drugs he received from an online pharmacy. He obtained these drugs without ever visiting a doctor. The man's wife described her husband as "an addict --and that the Internet sites that sold him the drugs were his pushers."[4]

5. Steven Kovacs was a 22-year old aspiring psychologist in New York when he started buying medication online after first being prescribed Adderall, used to treat attention-deficit hyperactivity disorder, and Xanax, used to treat anxiety. Steven died of a prescription drug overdose on July 8, 2009 after mixing, Adderall, Xanax and OxyContin.[5]

6. Lorna Lambden, 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 an illicit foreign online pharmacy. The coroner report found four-times the therapeutic level of the drug, Amitrptyline in her blood.[6]

7. In January of 2010, 150 patients were admitted to hospitals in Singapore after taking counterfeit Tadalafil and herbal preparations that claimed to cure erectile dysfunction. Seven (7) of the patients were comatose and four (4) subsequently died from the online drugs which contained powerful ingredients used to treat diabetes.[7]

8. On June 3, 2011, an emergency room doctor, from Texas, suffered a stroke from ingesting counterfeit Alli from *www.2daydietshopping.com*. The counterfeit Alli was produced using the controlled substance sibutramine, rather than the approved ingredient orlistat, and then shipped to the US for redistribution. Two individuals operated the site. The first is a Chinese citizen who has been sentenced to 7 years in federal prison, $504,815.39 in restitution to victims, and deportation following his sentence. The second US citizen received 3 years probation.[8]

9. On April 4, 2012, a mother and son in Los Angeles were looking for cold medication. They purchased and fell victim to a counterfeit drug "vitamin injection." The victim's heart rate increased rapidly, experienced severe headaches, dramatic weight loss, pass-outs and numbness in lips. The victim was eventually hospitalized.[9]

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[3] "Counterfeit Pills Bought Online Leads to Death, Coroner Confirms," The Times Colonist (July 6, 2007); available at http://www.canada.com/victoriatimescolonist/news/story.html?id=05142ca2-9796-4868-bf42-76e939915fa5&k=29039 This medicine was contaminated with significantly high levels of metal.

[4] "Widow: My Husband Died from Online Drugs" CNN (May 22, 2008); available at http://www.cnn.com/2008/HEALTH/05/21/online.drugs/index.html?iref=allsearch This drug was misused and abused. The medicine was purchased online without a doctor's visit or a prescription.

[5] "Mom, Schumer urge Web Pharmacy Crackdown," Newsday, United States (July 10, 2011); available at http://www.newsday.com/long-island/mom-schumer-urge-web-pharmacy-crackdown-1.3016581 This medicine was obtained without a prescription and was abused because online prescription drugs were easily accessible.

[6] "Paramedic died after taking tablets she bought over the Internet to help her sleep," The Daily Mail, United Kingdom (May 20, 2011); available at http://www.dailymail.co.uk/news/article-1388795/Paramedic-Lorna-Lambden-died-overdosing-sleeping-tablets.html This medicine was purchased without a prescription and it was misused. The patient took anti-depressants as a sleeping aid.

[7] "Counterfeit Internet Drugs Pose Significant Risks and Discourage Vital Health Checks," Science Daily (January 20, 2010). This contaminated medicine, claimed to cure erectile dysfunction contained a powerful drug used to treat diabetes. http://www.sciencedaily.com/releases/2010/01/100120085348.htm

[8] "June 3, 2011: Chinese National Sentenced to Federal Prison for Trafficking Counterfeit Pharmaceutical Weight Loss Drug" U.S. Department of Justice (June 3, 2011); available at http://www.fda.gov/ICECI/CriminalInvestigations/ucm257912.htm
This medicine was contaminated with significantly high levels of metal. The patient suffered a stroke after ingesting the medication.

[9] "Cracking Down on Counterfeit Drugs" San Diego Union-Tribune (April 4, 2012); available at http://www.utsandiego.com/news/2012/apr/04/cracking-down-counterfeit-drugs/?page=1#article This medicine was contaminated.

10. On April 23, 2013, Sarah Houston, a 23-year old medical student in the United Kingdom, obsessed with her weight, purchased DNP, a deadly diet pill, through an online drug seller. The pill, sold as a weight loss aid through many illicit online pharmacies, is actually a pesticide with lethal consequences to humans.[10]

Recent Law Enforcement Actions Involving Illegal Online Drug Sellers

A few examples of recent U.S. and international law enforcement actions involving online drug sales, in chronological order:

1. In the summer of 2011, U.S. federal agents identified a 41-year-old, Shane Lance. The agents arrested Lance and indicted him on multiple counts, including conspiracy to traffic counterfeit drugs. Last spring, he pleaded guilty to one count of conspiracy to traffic and one count of trafficking, and in November he received his sentence: 10 months in prison and a $5,100 fine to be paid to Pfizer.[11]

2. In December of 2012, the State of Oregon fined Hayden Hamilton, founder of ProgressiveRx.com, $50,000 for operating without an Oregon pharmacy license. The 35-year-old Portland businessman has shipped medicine from India and other countries to customers in the United States and around the world.[12]

3. On April 24, 2012, two men pleaded guilty and were sentenced for smuggling counterfeit and misbranded pharmaceuticals into the U.S. Both men operated an Internet business in Israel that used multiple websites to illegally sell large amounts of prescription drugs to U.S. purchasers. In total, they sent approximately 9,000 separate drug shipments to U.S. purchasers, generating over $1.4 million in gross proceeds. Ultimately, one man received 10 months in federal prison, was fined $30,000 and forfeited $50,000. The other man received one year of probation, was fined $15,000 and forfeited $15,000.[13]

4. On August 5, 2012, Chinese government officials seized "more than $182 million of counterfeit pharmaceuticals last month in the latest attempt to clean up a food and drug market that has been flooded with fakes." Chinese police arrested more than 2,000 individuals and destroy 1,100 production facilities for producing counterfeit drugs.[14]

5. On August 9, 2012, a Puerto Rican man faced up to 10 years in prison after being found guilty by a jury on U.S. federal charges stemming from his role as a key operative for a drug ring that distributed large quantities of Chinese-made counterfeit pharmaceuticals throughout the United States and worldwide. Special agents with U.S. Immigration and Customs Enforcement's (ICE)

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[10] "Banned slimming drug kills medical student: Coroner attacks online dealers who target the vulnerable" The Daily Mail, United Kingdom (April 22, 2013); available at http://www.dailymail.co.uk/health/article-2312986/Sarah-Houston-Banned-slimming-drug-DNP-kills-medical-student-coroner-attacks-online-dealers-target-vulnerable.html This medicine was misused. The patient took both anti-depressants and a pill marketed as a weight loss aid containing lethal ingredients.

[11] "Inside Pfizer's Fight Against Counterfeit Drugs," Bloomberg Businessweek (January 17, 2013); available at http://www.businessweek.com/articles/2013-01-17/inside-pfizers-fight-against-counterfeit-drugs

[12] "State fines online pharmacy with Portland ties; Oregon shipments blocked" U.S. Department of Homeland Security (December 21, 2012); available at http://www.oregonlive.com/health/index.ssf/2012/12/state_fines_online_pharmacy_wi.html

[13] "2 Israeli men sentenced for smuggling counterfeit and misbranded pharmaceuticals into the United States" U.S. Department of Homeland Security (April 24, 2013); available at http://www.ice.gov/news/releases/1204/120424stlouis.htm

[14] "China Arrest 2,000 Individuals and Destroys 1,100 Production Facilities for Making Counterfeit Drugs" Rx-360 (August 5, 2012) available at http://hosted-p0.vresp.com/427409/59c2b9af06/ARCHIVE***#>

Homeland Security found more than 100,000 pills made to resemble a variety of popular prescription medications, including Viagra, Cialis, Valium, Xanax and Lipitor.[15]

6. On January 9, 2013, a pioneer of the Canadian Internet pharmacy business, Andrew Strempler, 38 years old, was sentenced in U.S. federal court in Miami to four years in prison for conspiracy to commit mail fraud in connection with the sale of foreign and counterfeit medicines to U.S. customers.[16]

7. On March 13, 2013, Edmond Paolucci, 54, of Coventry, Rhode Island and Patrick Cunningham, 44, of Cranston, Rhode Island, admitted to the court that they participated in a conspiracy to repackage illegal drugs and sell them under various names and labels to consumers who placed orders via the Internet. A significant portion of the proceeds realized from the sale of the illegal drugs was laundered back to individuals in Israel.[17]

8. On March 27, 2013, nine defendants were sentenced for their roles in illegally distributing controlled substances to customers who bought the drugs from illicit Internet pharmacies. The defendants were also collectively ordered to forfeit more than $94 million in illegal proceeds. Drug Enforcement Administration Acting Special Agent in Charge Bruce C. Balzano stated, "Prescription drug abuse has risen to alarming levels, often times leaving a trail of devastation behind and negatively impacting our communities. The individuals sentenced this week were involved in online pharmacy schemes that were illegally distributing controlled substances."[18]

9. On March 27, 2013, three men and one woman have been sentenced in relation to the illegal online supply of prescription only and counterfeit medicines. This follows an undercover operation by the Medicines and Healthcare products Regulatory Agency (MHRA). Searches of the homes of those involved uncovered stashes of counterfeit medication and generic prescription only medicine. This included Viagra, Cialis, diazepam and methadone. A study of a computer also showed email traffic between Andrew Luxton, Samantha Steed, Carl Willis and others indicating the previous supply of illegitimate medicine.[19]

10. On June 27, 2013 the U.S. FDA reported the successful execution of Operation Pangea VI, a law enforcement initiative resulting in the elimination of 1,677 websites selling illegal prescription drugs. In partnership with the Department of Justice, FDA's Office of Criminal Investigations, Interpol, and authorities from nearly 100 countries took action against 9,600 websites. Dangerous drugs valued at $41 million were seized.[20]

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[15] "Man convicted for role in international counterfeit drug distribution scheme
Search continues for organization's ringleader" U.S. Department of Homeland Security, ICE (August 9, 2012); available at http://www.ice.gov/news/releases/1208/120809losangeles.htm

[16] "Canadian Internet Pharmacy Founder Gets 4 Years In Counterfeit Drugs Case" Partnership for Safe Medicines (January 18, 2013) available at http://www.safemedicines.org/2013/01/fake-online-pharmacy-founder-andrew-strempler-guilty-of-mail-fraud-508.html

[17] "Two Plead Guilty to Participation in International Conspiracy to Import and Distribute Prescription Drugs and Anabolic Steroids" Department of Justice (March 13, 2013). http://www.justice.gov/usao/ri/news/2013/mar2013/steroids.html

[18] "Nine Sentenced For Illegally Distributing Controlled Substances Over The Internet" Department of Justice (March 27, 2013) available at http://www.justice.gov/usao/can/news/2013/2013_03_27_nine.sentenced.press.html

[19] "Three men and one woman sentenced in counterfeit medicines case" MHRA (March 27, 2013) available at http://www.mhra.gov.uk/NewsCentre/Pressreleases/CON254851

[20] "International operation targets online sale of illicit medicines" Interpol (June 27, 2013); available at http://www.interpol.int/News-and-media/News-media-releases/2013/PR077

[i] "Legitscript - Enforcement Page". Legitscript. Web. <http://www.legitscript.com/services/enforcement>. Last accessed June 20, 2012.

[ii] "Internet Drug Outlet Identification Program Progress Report for State and Federal Regulators: October 2011." The National Association of Boards of Pharmacy. Web. 2 Jan. 2012 <http://www.nabp.net/programs/assets/IDOI_Report_10-11.pdf>. Last accessed June 20, 2012; see also, LegitScript. Web. 2 January 2012 <www.legitscript.com>. Last accessed June 20, 2012.
[iii] World Health Organization

[iv] Krebbs, B. "Americans Use Spam for Cheaper Prescription Drugs." Technology Review. 11 July 2011. Web. <http://www.technologyreview.com/web/38023/page1/>. Last accessed June 20, 2012.
[v] "Online Risks in Pharmaceutical Market – Summer 2009." MarkMonitor: 1-14 pg. 6

[vi] Jackson et al. International Journal of Clinical Practice. 66.3, pp 241–250. (March 2012). <http://onlinelibrary.wiley.com/doi/10.1111/j.1742-1241.2011.02826.x/full>. Last accessed June 20, 2012.