

**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**

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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.

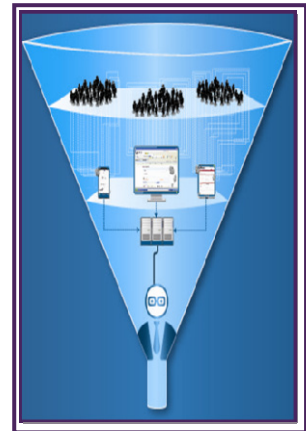
Unsuspecting patients are easily lured by the ease with which they can order their medicines online, often without the need to consult a doctor or provide a valid prescription. They do not realize that many of those sites have failed to disclose the true source of the products they dispense or even where 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.

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.



The program disrupts networks at their choke points.

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 Yakuza 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 Waseem'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.