

**Testimony of John P Clark
Chief Security Officer, Pfizer Inc and Vice President, Global Security
Before the House Judiciary Committee**

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Chairman Smith, Ranking Member Conyers, distinguished Members of the Committee. It is indeed 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. In those positions 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 Immigration and Customs Enforcement (ICE) Deputy Assistant Secretary, 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, US Customs, I held a variety of investigative, management and executive positions.

Pfizer is a diversified, global health care company and the world's largest biopharmaceutical company. Our core business is the discovery, development, and marketing of innovative pharmaceuticals for human and animal health, and we are committed to ensuring the integrity of those products when they reach the market.

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, longer lives. For that reason, I commend the Chairman and Ranking Member and the many members who are co-sponsors of the Stop Online Piracy Act for their legislative effort. It is a positive step forward in our fight against counterfeit medicines.

Counterfeit medicines pose a 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 is immune. And, while my comments today focus on Pfizer's experience in combating counterfeit medicines and the positive impact the Stop Online Piracy Act can make in that effort, it is a threat to the entire pharmaceutical industry.

Pfizer's Program to Mitigate that Threat

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. Through our efforts we have, since 2004, prevented more than 138 million doses of counterfeit Pfizer medicines – more than 68 million finished doses and enough active pharmaceutical ingredient to manufacture another 70 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. As part of those partnerships, we not only refer the results of our investigations, but also provide support as required in investigations and test – free of charge – 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 September 30, 2011, we have provided training to authorities in 117 countries, often in conjunction with programs sponsored by the US Patent and Trade Office (USPTO) 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.

These training efforts have produced tangible results in increased enforcement activity in Egypt, Jordan, Lebanon, the UAE and Poland, and the passage of strong anti-counterfeiting legislation in Jordan and Kenya.

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

One example of our collaboration with CBP is the use of our “mobile labs”, which we have used in pilot programs with CBP at International Mail Facilities in San Francisco, Los Angeles, New York, Miami and Chicago.

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. Based on that data, we have confirmed counterfeit Pfizer medicines in at least 101 countries, and having breached the legitimate supply chains of 53.



While Viagra is our most counterfeited medicine, counterfeiters have targeted more than 50 of our products, including Aricept (*Alzheimer's*), Celebrex (*anti-inflammatory*), Genotropin (*human growth hormone*), Lipitor (*high cholesterol*), Metakelfin (*anti-malarial*), Norvasc (*high blood pressure*), Prevnar (*vaccine to prevent infection caused by pneumococcal bacteria*), Sutent (*for*

treatment of treatment of rare cancer of the stomach, bowel or esophagus (GIST), advanced kidney cancer (RCC, and a type of pancreatic cancer (pNET), Viagra (erectile dysfunction), Xanax (anxiety disorders), Zithromax (anti-infective) and Zoloft (depression).

And counterfeit versions of 23 of those medicines, including Celebrex, Genotropin, Lipitor, Metakelfin, Norvasc, Plevnar, Sutent, Viagra, Xanax and Zithromax, have breached supply chains around the world.

The Online Threat

The major threat to patients in the U.S., however, is the Internet and the many professional looking websites that promise safe, FDA-approved, branded medicines from countries such as Canada or the UK. And, for that reason, we appreciate the Chairman and Ranking Member's focus on that threat in Title I of the bill. Giving the Attorney General new tools and incentivizing private stakeholders to act against rogue websites if immunity is in place for every stakeholder's actions would be an important step forward.

Patients are 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). To be accredited, a pharmacy must comply with the licensing and inspection requirements of their state and each state to which they dispense pharmaceuticals. If they meet these criteria they are designated VIPPS sites – Verified Internet Pharmacy Practice Sites. Pharmacies displaying the VIPPS seal have demonstrated to NABP compliance with VIPPS criteria including patient rights to privacy, authentication and security of prescription orders, adherence to a recognized quality assurance policy, and provision of meaningful consultation between patients and pharmacists. VIPPS pharmacies represent only a small percentage of online pharmacies. In a recent survey of more than 8000 websites selling medicines, the NABP found that 96% were not operating in accordance with pharmacy laws and standards.

Case Study: RxNorth

The case of RxNorth is an excellent example of how easily patients can be deceived, and the risks to which they expose themselves when ordering online from a rogue website, which the Stop Online Piracy Act aims to shutdown.

Patients, who visited the RxNorth website, thought they were ordering from a Canadian Pharmacy and would receive authentic FDA-approved medicines.



In reality, however, the medicines dispensed from RxNorth were traced from China, where they were manufactured, through Hong Kong, Dubai, to the UK where they were intercepted. Among the medicines seized by UK Customs were Lipitor – found to contain only 82 to 86% of the claimed dosage of active pharmaceutical ingredient – as well as counterfeit versions of medicines from four other companies, including one found to contain traces of metal.

Subsequent investigation revealed that had they not been intercepted, those medicines would have been sent to a fulfillment center in the Bahamas, where they would have been split from their pallets and placed in individual packages corresponding to customer order. To gain “credibility”, the packages would then have been shipped to the UK, from where they would have been sent to the U.S. patients who had placed their orders with RxNorth, believing it to be a “safe” pharmacy in Canada.



As a result of this investigation, the FDA warned consumers not to place orders with RxNorth and not to take the medicines they had received. But, more needs to be done to combat these rogue websites.

Case Study: Operation Cross Ocean

Operation Cross Ocean also demonstrates the threat to unsuspecting U.S. patients who order their medicines online. Chinese and U.S. authorities worked together to dismantle an operation that manufactured counterfeit versions of Viagra and other medicines in China, then dispensed them via the Internet through a network of brokers, largely in the US and Europe.

When they raided the manufacturing site (pictured below), authorities seized 10 lines of manufacturing equipment and counterfeit medicines, including 570,000 finished pills and enough active pharmaceutical ingredient to manufacture 1.82 million more.



Case Study: Kevin Xu

The case of Kevin Xu, convicted of misbranding drugs and trafficking in counterfeit goods, demonstrates how attractive a target the U.S. supply is for those who counterfeit our medicines and how weak our current penalties for counterfeiting medicines are.

An investigation initiated in our Asia-Pacific region identified Xu and his company, Orient Pacific International, as a major manufacturer and distributor of counterfeit medicines, including several Pfizer products. During meetings with our “undercover” consultant, Xu boasted of the global scope of his criminal enterprise, including his responsibility to oversee the quality of counterfeits produced in China, and provided a list of branded medicines that he could provide, which included Pfizer’s Alzheimer’s drug, Aricept, ulcer drug, Cytotec, cholesterol lowering drug, Lipitor, kidney cancer drug, Sutent and erectile dysfunction drug, Viagra.

The evidence we gathered was shared with ICE, which had already begun an investigation of Xu. An order placed by an ICE undercover was filled with counterfeit Aricept, Pfizer’s Alzheimer’s drug, packaged for the French market. When the tablets were tested, they were found to contain only insignificant levels of the active pharmaceutical ingredient found in authentic Aricept.

Xu was arrested in July 2007 and charged with manufacturing counterfeit versions of medicines intended to treat prostate cancer (Casodex, Astra Zeneca), blood clots (Plavix, Bristol Myers Squibb), schizophrenia (Zyprexa, Lilly), and Alzheimers (Aricept, Pfizer), mislabeling them as chemicals, and smuggling them into the U.S. where they were to be introduced into our supply chain.

The likelihood of Xu’s success was high. European authorities have identified Xu as the source of counterfeit versions of non-Pfizer products – Zyprexa (Lilly, anti-psychotic), Plavix (Bristol Myers Squibb, blood thinner), and Casodex (Astra Zeneca, prostate cancer) –recalled from the legitimate supply chain in the UK, a supply chain as tightly regulated as ours, in May 2007.

As reported in a press release by the US Attorney’s Office for the Southern District of Texas, Xu was “sentenced to 78 months in federal prison without parole, the maximum sentence under the applicable U.S. Sentencing Commission guideline range for conspiring with others in the Peoples Republic of China to traffic in counterfeit pharmaceutical drugs and causing the introduction of counterfeit and misbranded drugs into interstate commerce.”
<http://www.cybercrime.gov/XuSent.pdf>, accessed on November 10, 2011

This is a good example of the punishment not rising to the level of the seriousness of the crime and why we need stronger penalties. The Stop Online Piracy Act takes a positive step forward and we would welcome the opportunity to work with you to perfect the penalty section.

Case Study: Arab China Network

Based upon information provided by Global Security, more than 300 Chinese law enforcement officers, from both the Public Service Bureau (PSB) and State Food and Drug Administration (SFDA), initiated enforcement actions that dismantled one of the most prolific counterfeiting organizations ever uncovered in China. The network, comprised of males of Middle East descent living in the southern provinces of China, was responsible for distributing large quantities of counterfeit medicines, manufactured in China, throughout the Gulf States and US.

In two separate but related enforcement operations, authorities raided two manufacturing sites and 26 storage facilities, making 26 arrests. They seized vast amounts of finished products – a mix of counterfeits and generics – including counterfeit Pfizer’s ulcer drug, Cytotec, Viagra and Pfizer’s anti-anxiety drug, Xanax. Initial estimates by authorities placed the pill count as high as

200 million, including counterfeits of Pfizer medicines as well as those of four other pharma companies. Also seized were large quantities of active pharmaceutical ingredient, including barrels of sildenafil, the active pharmaceutical ingredient in Viagra, which may be beyond the capability of the authorities to accurately weigh. The seizures included equipment – 54 machines and 1230 moulds, tools and dies, at least 200 of which are for Pfizer medicines – with which to manufacture the counterfeits.

In a subsequent release to Chinese Media, authorities stated that they had seized approximately 7 million counterfeit Viagra in those raids.

Case Study: Operation Eagle Eye

Based on information provided by Pfizer, China's Ministry of Public Security (MPS) raided sites in Eagle Eye Action in Henan, Zhejiang, Guangdong provinces, making 36 arrests. They seized more than 5.6 million counterfeit tablets including medicines from Pfizer (Aricept, Lincocin, Lipitor, Viagra, Xanax) and two other major pharmaceutical companies, as well as 45 machines.

The head of the operation was sentenced to life imprisonment. Other members of the criminal network received sentences ranging from 2 to 15 years in jail.

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 low risk, high profit criminal activity that 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 are confident that even if they get caught, they will get a mere slap on the wrist. Even here in the U.S., the maximum sentence imposed under the Food Drug and Cosmetics Act is 3 years. Recognizing the inherent risk that any counterfeit medicine poses to patients, we must enhance the penalties for pharmaceutical counterfeiting to provide a greater deterrent. Expedited procedures must be put in place to shutdown "rogue" websites dispensing counterfeit medicines to U.S. patients.

The Stop Online Piracy Act is a significant step forward in those efforts and I thank the Chairman and Ranking Member for introducing this important piece of legislation. I would like to work with you so that our laws recognize the grave health and safety risks posed by counterfeit medicines and serve as a deterrent.

I work with foreign government representatives in the global fight against counterfeiting. It is hypocritical for us to speak with foreign government representatives, as I do, about their lack of effective legislation when U.S. law is still lacking. This bill, if enacted with strong penalties and mechanisms to shut down rogue websites, will be highly effective in our global argument for all governments to fully appreciate the serious health and safety aspects of this problem and encourage similar efforts.

Conclusion

Thank you again for this opportunity to express my views. For Pfizer, pharmaceutical counterfeiting is first and foremost an issue of patient health and safety. We look forward to working with you on the global fight against counterfeit medicines.