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Subcommittee on Health

"Assessing the Safety of Our Nation's Drug Supply"

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Chairman Pallone, Ranking Member Deal, and members of the Subcommittee, my name is John Theriault. I am the Chief Security Officer and Vice President of Global Security at Pfizer Inc, the world's largest pharmaceutical company. It is a pleasure to appear before you today to discuss an issue of critical importance: drug safety and efforts to protect the United States pharmaceutical supply from contamination with counterfeit products.

Prior to joining Pfizer, I spent more than 25 years as a Special Agent of the Federal Bureau of Investigation. During my FBI career I had substantial experience in international law enforcement and served for a number of years as the Legal Attaché in Ottawa, Canada and London, England.

Mr. Chairman, while my testimony today focuses on our experience with counterfeit Pfizer products, I wish to impress upon the Subcommittee that these problems are not limited to Pfizer. They threaten the entire pharmaceutical industry and most importantly, the U.S. patients who depend upon that industry.

As the Subcommittee is well aware, there is already importation of counterfeit and diverted medicines into the United States through the mail, courier services, and some unethical re-packagers and

wholesalers. Millions of Americans who assume that the prescription medicines they buy online are safe and effective are at risk. Regardless of the method of obtaining drugs from Canada or other countries, there is a real potential for fraud or harm. I would emphasize that every time a medicine changes hands represents an additional opportunity for counterfeit products to be introduced into distribution.

Counterfeit Pharmaceutical Products: What is the Scope of the Problem?

The problem of counterfeit medicines, once thought to be limited to developing countries with weak regulatory systems, is now recognized as a global problem from which no country is immune. The manufacture of counterfeits is not limited to China and India. They are produced in at least twenty-four countries, including Canada, the United Kingdom, and four other members of the European Union – Belgium, the Netherlands, Poland, and Portugal.

Since 1998, when the first counterfeit Viagra® tablets were discovered in the United Kingdom, Pfizer has developed a focused anti-counterfeiting program to protect the integrity of our products and supply chain. Staffing for that program has increased from one security professional based in New York, to seventeen security professionals based in the United States, Mexico, the United Kingdom, Germany, Turkey, China, Hong Kong, India, Thailand, and Malaysia. Our Product Integrity Steering Committee has set as Pfizer's goal ensuring that every patient who buys a Pfizer product receives an authentic Pfizer product.

We are waging a fierce battle against these counterfeiters. Pfizer products targeted by counterfeiters now include Aricept® (Alzheimer's disease), Lipitor® (cholesterol), Norvasc® (hypertension), Diflucan® (antifungal), Ponstan® (anti-inflammatory) and Viagra® (erectile dysfunction), Cabaser®

(Parkinson 's disease), Celebrex® (pain), Dilantin® (epilepsy), Vibramycin® (antibiotic), and Zoloft® (depression).

Although it is difficult to measure the true scope of the counterfeiting problem, the number of reported seizures by law enforcement of Pfizer products serves as a useful baseline. During 2006, authorities from 36 countries reported seizing more than 8.1 million counterfeit tablets, a 20.8% increase over 2005. That increase was most significant in Europe, the Middle East and Africa, where seizures increased by more than 332%

A Case in Point: Deadly Poison Masquerading as Medicine

Fake medicines are costing lives. In March 2007, we heard of a tragic story of a woman's death which, according to press reports, was caused by drugs she ordered online from a bogus Canadian pharmacy. Instead of treatment for her arthritis and allergies, Ms. Marcia Bergeron was slowly poisoned by products that contained dangerously high levels of strontium, uranium, and lead, heavy metals that had apparently been used as a cheap filler. Ms. Bergeron started losing her hair and had blurred vision and died a few days after Christmas in 2006.

We fear that there may be more terrible stories like this one. I'm sure you all have read the story from Sunday's New York Times about the hundreds of deaths in Panama from cough syrup from China that contained diethylene glycol.

It is virtually impossible to see differences between counterfeit and genuine medications. If you visited the manufacturing facilities, the differences would be shockingly obvious. Drug counterfeiters do not care about safety or sanitation. They only care about profits, and counterfeiting is highly lucrative. The

profitability of drug counterfeiting far exceeds that of the illicit drug trade. However, there is a lower chance that these counterfeiters will get caught, and if they do, the penalties are less punitive.

RxNorth: Profits before Patients

Another case involves the internet pharmacy RxNorth. A company whistleblower told a Canadian Television (CTV) news program that customers had received expired drugs, and that the expiry dates had been covered up on packages. In addition, the drugs were not Canadian. In fact, RxNorth was filling prescriptions for US citizens with counterfeit versions of Lipitor, Celebrex and other products. The CTV news program reported that many of the drugs RxNorth sold came from sources in the UK or Australia and were shipped to a dispensing facility in Freeport, the Bahamas, where Internet orders were filled and shipped to US customers.

Counterfeiters often use a convoluted shipping path to evade the authorities and trick customers. For example, on May 22, 2006, UK Customs intercepted a four-pallet shipment of pharmaceuticals, which had come to the UK from the United Arab Emirates (UAE). The shipment consisted of eight products manufactured by five major pharmaceutical companies: Pfizer, AstraZeneca, Novartis, Merck, and Proctor & Gamble. The shipper was the Oyster Corporation, of Sharjah, UAE. The intended recipient was Missouri-Bain Thomson, of the Personal Touch Pharmacy, in Freeport, the Bahamas. Investigation by the authorities determined that Personal Touch Pharmacy computers were connected to Rx North's servers. This is commonplace: according to a 2005 FDA study, fewer than two percent of the thousands of websites advertising cheap Canadian drugs are actually based in Canada.

Our infrared spectral analysis of the seized Lipitor® tablets showed that the Lipitor® was counterfeit, and contained about 82%-86% of the claimed concentration of active pharmaceutical ingredient

(API). The lot number printed on the packaging of the counterfeit Lipitor® was legitimate for a product produced for the Middle East market, and the counterfeit packaging was elegant. Pfizer analysts examined the packaging and determined that the 'i' in the word 'atorvastatin' on the blister foil was placed differently, indicating a difference in font size; and the breakage-line between the single cavities showed that the authentic blister has a tighter punching line than the sample. The counterfeit packaging also contained a patient information leaflet, although it was smaller than a genuine leaflet, and missing a page. The fact that the counterfeiters are using legitimate lot numbers is concerning, since it demonstrates a level of sophistication in their deception that makes the counterfeits that much harder to detect.

On June 1, 2006, Pfizer investigators notified the Bahamian authorities of the facts in this case, and on June 9th the Bahamian authorities raided the Personal Touch Pharmacy in Freeport. There they seized $3.7 million worth of products, spanning numerous different brands from 13 different manufacturers. The total amount of product seized amounted to 3.025 million dosage units of products. The Bahamian investigation determined that approximately $8 million worth of business was conducted at Personal Touch Pharmacy on a yearly basis. The investigation is ongoing.

We remain concerned that there are thousands of similar situations that remain undetected, and that consumers like Ms. Bergeron will be victims to this fraud and greed. As Congress develops drug safety legislation, it is essential that you carefully consider this very dangerous situation that has yet to be adequately addressed.

The facts are irrefutable. The importation of counterfeit, infringing, misbranded, and unapproved pharmaceutical products into the United States is increasing exponentially, and those products, by definition, pose a risk to public health and safety. The response by regulatory and law enforcement

agencies to this growing crisis must be reviewed, analyzed, and modified at all levels. The public health and safety depend upon the FDA's vigilance. The FDA and Customs must receive the additional resources necessary to fulfill their current mandate. Regulations currently in existence must be fully funded and fully enforced. The notion that somehow importation can be done safely by implementing so-called anti-counterfeit technology is to ignore everything we know about counterfeiting and counterfeiters. Similarly, the notion that importation on any scale will be as safe as the current system is to ignore all of the available evidence. Again, any time a medicine changes hands presents a new opportunity for the introduction of counterfeits into distribution. Instead of discussing ways to “de-regulate” the current safety system, we ought to be discussing ways in which the current system can be improved to mitigate these threats to patients.

Mr. Chairman, Ranking Member Deal, and distinguished members of the Subcommittee, thank you for this opportunity to express our concerns about this critical issue. I would be happy to answer your questions.