Testimony of John Theriault
Vice President, Corporate Security, Pfizer Inc.

Chairman Breaux, Ranking Member Craig, distinguished Members of the Committee, it is indeed a pleasure to appear before you today to discuss the critically important issue of counterfeit medicine.

My name is John Theriault and I am Vice President of Corporate Security at Pfizer Inc. In this position, I am responsible for implementing policies and procedures to protect Pfizer's personnel, products, facilities, and intellectual property. This responsibility is global in scope.

Prior to joining Pfizer, I was a Special Agent of the FBI for 25 years and served in a variety of investigative, management, and executive positions. I spent 7 years outside of the United States serving as Legal Attaché in Ottawa, Canada, and in London, England. During the London assignment I was also diplomatically accredited to our Embassies in Ireland and all of the Scandinavian countries. I have substantial experience in international law enforcement. When I retired from the FBI in 1995 I was a member of the Bureau's Senior Executive Service.

Pfizer is a diversified, global health care company and the world's largest pharmaceutical company with annual sales of over 30 billion dollars and approximately 90,000 employees around the world. 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.

Mr. Chairman, while my testimony today focuses on my own experience, and that of my company, Pfizer, I want also to convey to you the very significant message that the problems of counterfeiting, copying, adulterating, and misbranding prescription drugs are faced by many companies and are not the exclusive purview of Pfizer.

You will hear FDA mention today, as they have in the past, their experiences with numerous product problems, that range from out-and-out counterfeiting to dangerous re-packaging and re-labeling of outdated, subpotent, or otherwise ineffective and unsafe drug products made by many U.S. pharmaceutical companies.

Therefore, I hope as you listen to Pfizer's experiences with one of our very significant products -- and thus one that has been a popular target for criminals -- that you will extrapolate those experiences to many products manufactured by many companies other than Pfizer. This is indeed a problem that faces the entire research-based pharmaceutical industry.

I have attached to my testimony a number of commentaries on products other than the one I will discuss here today. I hope this information will be as helpful to you as will my testimony regarding my direct experiences with the Pfizer product, Viagra.

A significant aspect of my job is to protect the health and safety of consumers by identifying counterfeit, diverted, adulterated, or unsafe Pfizer products in the marketplace and ensuring that

prompt and decisive action is taken to eliminate them. Pfizer takes this responsibility seriously, and has taken some of the most innovative and aggressive steps in the industry to deal with an emerging global counterfeiting problem that could have disastrous consequences for consumers. I would like to share with you some of the actions we have taken, using well-documented cases involving Viagra to illustrate what I think is a much larger problem facing the entire pharmaceutical industry.

Soon after we launched Viagra, we began receiving reports that it was available in markets where it had not yet been approved. We made purchases of the product in those markets and tested for authenticity. In most cases we found authentic product that had been diverted from approved markets. But in one instance, a man in New Delhi complained that the product was not effective. We tested it and found our first counterfeit. You can see that the packaging is similar to ours, as is the tablet.

Later that year (1999) we became aware of an organized crime investigation being conducted by the National Crime Squad in the United Kingdom. One of the targets, Ken Bloom, was charged with conspiring to import counterfeit Viagra from Caplin Point Pharmaceuticals in India. The managing Director of Caplin Point, P. C. Parthabaan, was also charged in that case. I think this case has serious implications for a number of reasons, most importantly because it shows the interest of organized crime in the counterfeit drug business and the willingness of an officer of a publicly traded Indian company to become involved in providing counterfeit product.

China

As Pfizer's efforts expanded we became increasingly aware that China was evolving into a major manufacturing source for counterfeit medicine. In response to this Pfizer established an anti-counterfeiting program that focused on three key elements: identifying the extent of the counterfeiting problem in a given country through various methods including limited market surveys; encouraging law enforcement and administrative action against those identified; and raising the issue to a political level in cases where public policy review is warranted.

In 2001 we conducted a limited market survey in seven major population centers in China. We purchased Viagra (and other products), tested for authenticity, and established a chemical fingerprint library to identify common sources of manufacture where possible. As a result of our survey, we enlisted the help of Chinese officials who conducted 122 raids, arrested 58 individuals, and seized 146,336 counterfeit Viagra tablets.

Between January and April 2002, at our urging, Chinese officials have seized almost 1 million counterfeit Viagra tablets and 86 kilograms of sildenafil citrate (the active pharmaceutical ingredient in Viagra). They have made several arrests and shut down some manufacturing operations. Much more needs to be done in tracking down the major manufacturers and shutting down the factories.

Elsewhere in Asia
Taiwan

Historically, police in Taiwan have been more aggressive in addressing product counterfeiting issues than other countries in the region. Between November 1999 and May 2001 Taiwan law enforcement officials conducted 9 raids, arrested 18 individuals, and seized 533,000 counterfeit Viagra tablets and 147,000 counterfeit Norvasc tablets. Norvasc is the world's best-selling medicine for high blood pressure. They also seized counterfeit packaging, including holograms.

Thailand

Working on the internet, we identified a Turkish national living in Thailand who was offering Viagra for sale. We made several covert purchases and then made arrangements to meet with him personally to close a major deal. Working with the Royal Thai Police Crime Suppression Division, we met with the individual, later identified as Gokhan Ozek, in March 2002. He delivered 150 bottles of counterfeit Viagra and stated that for the last 18 months he had been selling approximately 1,500 30-count bottles per week, primarily to the US and the Middle East. The Thai police, who also raided two operating factories and a warehouse, arrested Ozek. They seized 2,038,000 counterfeit Valium tablets and 80,150 counterfeit Viagra tablets, all believed to be under the control of Ozek. The following photographs reveal the conditions at one of the manufacturing sites.

We have experienced problems with counterfeit Viagra in other countries in the region and through chemical fingerprint analysis have identified most of the counterfeit product as Chinese in origin.

The facts I have cited give a view of just the tip of the counterfeit iceberg – one product in a few countries. The problem is much bigger than that, and I would like to cite cases that illustrate the potential risk to the US drug supply.

United States (Ohio)

In September 2001, Hassib R. Selbak, a self-employed carpet cleaner doing business as "Mr. Spotless" and "Dr. Shwab," was arrested for selling counterfeit Viagra on the basis of information that we developed and local authorities in Ohio corroborated. During the investigation, authorities intercepted 36,000 counterfeit Viagra tablets consigned to "Mr. Spotless" from a fictitious toy company in China. The Viagra, along with pill bottles, foil bottle seals, and labels were concealed in stuffed animals.

Information indicated that Mr. Selbak had a fairly extensive distribution network and he Food and Drug Administration's Office of Criminal Investigations is conducting follow-up investigation to determine the extent of that network.

United States (New York)

On May 17, 2002, seven individuals and five companies were indicted by a New York grand Jury and charged with manufacturing and selling counterfeit Viagra over the internet. The investigation, which we initiated, covered a 17-month period during which investigators purchased 28,000 bogus Viagra tablets from India and China.

One of those indicted and arrested, Girish Vishwanath of Benzo Chemical Industries in India, actually sold undercover operators a tablet-punching machine and offered a constant supply of tablet blend so that his customer could manufacture his own Viagra.

Another individual indicted and arrested, Winhway Lee of Tienjin, China, claimed to be the supplier of Jane Ye and Raymond Chan. The following slide shows the linkage between Ye and Chan and the other people charged in this matter.

During the investigation, those indicted bragged that they could deliver 2.5 million Viagra tablets to New York each month. It is important to note that 100% of the counterfeit Viagra seized in the US has been of Chinese origin. Illegal prescription product sales via the Internet are of great concern for a number of reasons, not the least of which is the consumers' complete lack of knowledge about the source of the products. Today, many products are imports from countries where controls are far less scrupulous than in the U.S. But if the drug product importation border between the U.S. and Canada were lifted, for example, Canada will almost certainly become the counterfeiters' warehouse of choice.

One might think that these cases involving Viagra are interesting, but should not be taken too seriously on the grounds that Viagra is "just a life style medicine." It would be foolish and dangerous to dismiss these cases for a number of reasons. The main points I hope the Special Committee would take away from my presentation today are the following:

Our experience with Viagra has been illuminating. It has lifted the curtain and allowed us to see into a world of clandestine drug manufacturing that we might not have discovered otherwise. It is a world that could not care less about regulatory and legal standards of medical quality, good manufacturing practices, consumer health and safety, or the affordability of prescription drugs. It is a world of sophisticated (and some not so sophisticated) organized criminal enterprises accountable to no one. Other drugs are being counterfeited extensively, as some of my testimony indicated. What we have learned from Viagra should be taken as a warning about what can happen and is happening with other products.

Indeed, news reports and press releases in recent weeks confirm that Pfizer's experience with Viagra is far from unique. The stories below demonstrate that counterfeiting of medicines is a growing problem in the U.S. and that dangerous counterfeit drugs can find their way onto pharmacy shelves and into medicine cabinets even under current law.

On May 4, Eli Lilly notified pharmacy professionals of several incidents of product tampering involving Zyprexa (olanzapine). The drug is indicated for the treatment of schizophrenia and acute bipolar mania. Pharmacists found that genuine 60-count Zyprexa bottles (for the 10 mg and 15 mg dosages) had been emptied and filled with white tablets marked "aspirin." The counterfeits were found in Minnesota and Wisconsin. See attached May 4 "Dear Pharmacy Professional" letter.

On May 8, Amgen notified healthcare professionals about the existence in the U.S. of a counterfeit drug product labeled as Epogen (epoetin alfa). Epogen is primarily used for the treatment of anemia associated with chronic renal failure for in patients on dialysis. The counterfeit vials were filled with a clear liquid that contained the active ingredient of Epogen,

but at a diluted level. See attached May 8 "Dear Health Care Professional" letter, found at www.fda.gov/medwatch/SAFWTY/2002/epogen.html.

On May 10, GlaxoSmithKline issued a letter to pharmacy professionals announcing that it had received reports of bottles of Ziagen (abacavir sulfate) that were incorrectly labeled as Combivir (lamivudine plus zidovudine), due to third party tampering. Both drugs are approved for treatment of HIV infection. The counterfeit products were found in California, Connecticut, Florida, and Maryland. The company reported it believes two patients took improper medication. According to an FDA press release, the risk to patients is primarily due to the fact that approximately 5 percent of individuals who receive abacavir sulfate develop a potentially life-threatening hypersensitivity reaction. See attached FDA press release, at www.fda.gov/medwatch/SAFETY/2002/ combivir.htm, and Wall Street Journal article dated 5/14/02.

On May 16, 2002, Serono issued a press release announcing that it had become aware of a counterfeit lot of Serostim (somatropin (rDNA origin) for injection. Serostim is indicated for treatment of wasting due to AIDS. Preliminary information indicated that the counterfeits had been distributed via the Internet. See attached FDA press release, www.fda.gov/oc/po/firmrecalls/serono05_02.html.

On June 6, Johnson & Johnson issued a letter to healthcare professionals about counterfeit drugs labeled as Procrit (epoetin alfa). The counterfeit vials, which were found in Texas, contained only one-twentieth of the drug's active ingredient. The drug is used to treat anemia associated with chemotherapy, chronic renal failure (pre-dialysis), zidovudine treatment in HIV patients, and patients undergoing elective, noncardiac, nonvascular surgery. See attached letter from FDA website, available in PDF form at www.fda.gov/medwatch/SAFETY/2002/safety02.htm.

These are only the counterfeiting incidents during the last nine weeks. Many other equally dangerous incidents have occurred over the past few years, and they are increasing in frequency. The problem is widespread and poses a serious risk to public health in the U.S. Every pharmaceutical company has a corporate security officer and security personnel focused on the detection, investigation, and prosecution of counterfeiting.

These stories demonstrate that notwithstanding current, stringent border controls and importation requirements, counterfeit medicines are a constant threat. There is no doubt in my mind, that as we sit here today and discuss this issue, criminals are attempting to figure out ways to get counterfeit medicine into the United States. This is organized crime and organized crime will always seek out the weakest entry point. Any public policy measure that eases the current border controls simply makes it easier for the criminals to target American patients.

Mr. Chairman, thank you for the opportunity to testify before this important committee. I look forward to answering questions from you and your distinguished colleagues.