

Testimony of John Theriault
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Chairman Surgeon General Carmona, distinguished Members of the Task Force. My name is John Theriault. I am Vice President of Global Security at Pfizer Inc. It is indeed a pleasure to appear before you today to discuss an issue of critical importance, protecting the United States pharmaceutical supply from contamination by counterfeit and unapproved generic products.

I have been Pfizer's Vice President of Global Security since 1996 and have, during that time, seen Global Security grow from less than 10 to more than 40 colleagues, with offices in New York, London and China. A significant portion of my time has been devoted to the development and implementation of an aggressive anti-counterfeiting program. The primary focus of that program is to detect and deter the counterfeiting of Pfizer products. Detection and deterrence of products that seek to mimic or infringe upon those products, as well as the diversion and repackaging of authentic products, are also key components of the program. The ultimate goal of our program is to identify and dismantle major manufacturers and distributors of counterfeit and unapproved generic products, as well as those that distribute authentic Pfizer products that have been diverted from their intended markets. The basis for this program lies not only in Pfizer's desire to maintain public confidence in the Pfizer name and the integrity of its products, but also to safeguard public health and safety.

Before I proceed further, I would like to tell you a little about my background. Prior to joining Pfizer, I had substantial experience in international law enforcement. I spent 25 years as a Special Agent for the FBI, retiring in 1995 as a member of the Bureau's Senior Executive Service. During my time in the Bureau, I held a variety of investigative, management and executive positions, including assignments as Legal Attaché in Ottawa, Canada and London, England. While assigned to London I was also diplomatically accredited to our Embassies in Ireland and the Scandinavian countries.

Pfizer is a diversified, global health care company and the world's largest pharmaceutical company. Our annual sales are more than 40 billion dollars and we have approximately 120,000 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 the impact of counterfeits on Pfizer, I wish to impress upon this task force that these problems are not limited to Pfizer, but threaten the entire research-based pharmaceutical industry.

Counterfeit Pharmaceutical Products: The Scope of the Problem

In July 2002, I appeared before the Senate Special Committee on Aging and detailed the steps taken by Pfizer Global Security to stem the flow of counterfeit Viagra into the United States. Our aggressive anti-counterfeiting program has continued, resulting in the identification and dismantling of manufacturers and distributors of counterfeit Pfizer products, primarily in Asia. Manufacturers of counterfeit Viagra were identified in China, Korea and Thailand. In

India, a source for both counterfeit Viagra and Feldene was identified. And in Taiwan, the manufacturer of counterfeit Norvasc was dismantled.

It is widely accepted that China is the major source of counterfeit pharmaceutical products marketed throughout the world. Before 1998, the United States and other developed countries were not particularly concerned about counterfeit pharmaceuticals. The security departments of the major pharmaceutical companies devoted few, if any, resources to the problem. It was indeed one of the well-accepted “truths” of counterfeiting that it was a problem only in China, India, and other less-developed countries.

Between 2001 and 2003, we began to see counterfeit Pfizer products throughout Europe, Asia, Africa, the Middle East and the Americas. With the exception of Italy and Luxembourg, counterfeit Pfizer products were found in each of the EU member countries, as well as in eight of the fifteen candidate countries (Bulgaria, Estonia, Hungary, Malta, Poland, Romania, Slovakia and Turkey). Australia, Israel, Japan, New Zealand, Norway, Switzerland and South Africa are also among the countries where counterfeit Pfizer products were detected. Seizures in the Asia-Pacific region included counterfeit packaging not for the local markets, but for those in the U.S. and Australia. A disturbing trend has emerged in Asia: while seizures of counterfeit Viagra tablets dropped from more than 1.8 million in 2002 to 760,000 in 2003, the number of counterfeit Norvasc tablets increased from less than 4,000 to more than 1.5 million in the same period.

Even with the realization that counterfeits were so widely available, there was still some comfort in the belief that those counterfeits were distributed only by “illicit” brokers or the unapproved pharmacies that proliferate the Internet. Thus, the “truth” that counterfeits were limited to less developed countries was replaced with the “truth” that the legitimate channels of

distribution in the well-developed countries, like the U.S., were immune from the dangers of counterfeits.

Counterfeit Lipitor: The Repackaging of Pharmaceutical Products

In May 2003, however, with the recall of more than 18,000,000 repackaged "Lipitor" tablets from the legitimate pharmaceutical drug supply in the U.S., that final truth came crashing down, exposing the vulnerabilities of our distribution system. Lipitor is the most prescribed pharmaceutical product for the reduction of cholesterol in the world. During 2003, for example, 68,958,000 prescriptions for Lipitor were written in the U.S. alone. To put that recall into perspective, more than 600,000 U.S. residents, after visiting their local pharmacy, or placing an order with their health plan by phone, mail or internet, may have received a thirty day supply of Lipitor that contained counterfeit tablets.

Last year, Global Security participated or assisted in the investigation of five U.S. firms involved in the repackaging and distribution of counterfeit Lipitor tablets. The most significant of those investigations concerned counterfeit Lipitor tablets repackaged by Med-Pro, of Nebraska, and distributed primarily by Albers Medical, of Missouri. Pfizer first became aware of the problem as a result of consumer complaints that the tablets dissolved quickly and tasted bitter. Tablets were obtained from the consumers, tested and found to be counterfeits containing Lipitor's active pharmaceutical ingredient, or API. The FDA was notified on April 29, 2003, and launched its investigation into both Albers and Med-Pro. Pfizer made further notifications to the FDA as additional complaints were received and more tablets were found to be counterfeit.

There were three separate recalls of the counterfeit Lipitor repackaged by Med-Pro. The first, a "voluntary" recall issued by Albers on May 22, was limited to bottles of Lipitor 10mg

bearing three lot numbers, despite indications that tablets from bottles bearing other lot numbers were also counterfeit. The second recall, which took place in early June, included bottles bearing three additional lot numbers, two of Lipitor 10mg and one of Lipitor 20mg. Less than one week later, Albers issued a recall of all Lipitor repackaged by Med-Pro. According to the FDA's then Commissioner, these recalls involved more than 18 million tablets. Chemical analysis of samples obtained during the investigation established that the tablets have the same formulation, suggesting that they were manufactured by the same source, one capable of producing large quantities of pharmaceutical products with a consistent chemical formulation.

While the Med-Pro-Albers recall was the largest, it was unfortunately not the only instance in which counterfeit Lipitor was repackaged and introduced into legitimate distribution channels. There were at least two other instances in which firms that had originally repackaged authentic Lipitor diverted from foreign markets began the far more lucrative practice of repackaging counterfeits.

In the first, Lipitor 10mg tablets repackaged by Alliance Pharmaceutical, of Illinois, were tested and found to be counterfeits matching the Med-Pro formulation. Alliance, which had been under FDA scrutiny since March 2003 for repackaging and selling Lipitor diverted from foreign markets, issued a voluntary recall of only one lot. Despite concerns that other lots of Lipitor contained counterfeit tablets, Alliance refused to expand the recall and the FDA was powerless to compel them to do so. Among Alliance's customers was Prescription Rx, a mail order pharmaceutical company that, in October 2003, sent recall letters to approximately 4,000 consumers after a consumer complaint filed with Pfizer confirmed yet another instance of counterfeit Lipitor matching the Med-Pro formulation.

In the second, Lipitor 40mg tablets repackaged by AQ Pharmaceutical, of California, and distributed by a pharmacy in New York, were also found to be counterfeits matching the Med-Pro formulation. Like Alliance, AQ had also come under scrutiny for repackaging and selling into the U.S. market pharmaceuticals intended for foreign markets. As the result of an investigation jointly conducted by the FDA and the Los Angeles County Sheriff's Office, it was determined that AQ and two related pharmaceutical companies were importing authentic Pfizer products intended for foreign markets, repackaging them, and then selling them in the U.S.. The principal Pfizer product being repackaged was Lipitor, obtained primarily from Canada. When search warrants were executed at those firms in February 2003, authorities seized large quantities of Pfizer products, including Lipitor. While some of those products were still in their original containers, others were in Ziploc bags, with handwritten notes identifying the product, lot number and expiry date.

One of the companies affiliated with AQ was licensed and registered to import pharmaceuticals for export as well as to repackage pharmaceutical products. When interviewed in February, the owner of that company admitted that although the repackaged products were intended for export only, she sold them domestically. Although she estimated her sales at approximately \$20,000 per week, subsequent analysis of financial records revealed that she had been depositing in excess of \$1,000,000 per week into a Canadian account. It was later discovered that the company, in order to create the appearance that the products it imported had been exported, filled the emptied pharmaceutical bottles with vitamins and then exported those misbranded bottles to a hospital in Vietnam.

Subsequent investigation revealed that the counterfeit Lipitor tablets distributed in the U.S. had been manufactured in Costa Rica, with API imported from Switzerland and excipients imported from the U.S., using tooling also imported from the U.S. On July 21, 2003, Julio Cesar

Cruz was arrested for his role in introducing counterfeit Lipitor into the U.S. supply. As reported in *The Star Ledger*, Cruz told authorities that bottles filled with the counterfeit tablets were imported into the U.S. for export to another country. Without detection by authorities, the bottles were emptied of the counterfeit Lipitor and refilled with another product. The counterfeit Lipitor remained in the U.S., where it was introduced into legitimate distribution channels; the refilled bottles were then exported. Equally revealing about the close ties between diverted and counterfeit pharmaceuticals was the FDA's finding, as disclosed in the affidavit filed in support of the criminal complaint against Cruz, that each bottle tested from a particular lot was found to contain a commingling of authentic and counterfeit tablets.

By October 2003, tests had confirmed that twenty consumers in fourteen states had received the counterfeit Lipitor tablets. The number of documented cases of counterfeits, based on the number of consumer complaints filed, was quite small in comparison to the number of tablets distributed because visually the counterfeits were virtually indistinguishable from the authentic tablets. Rite Aid, which had purchased some of the tablets repackaged by Med-Pro but was unable to determine which patients received those tablets, sent recall letters to all patients to whom Lipitor 10mg and 20mg tablets had been dispensed.

Cross Border Sales of Counterfeit Pharmaceuticals

Although some manufacturing operations have been identified here in the U.S., they are rather small in comparison to those detected elsewhere. The major threat to the U.S. pharmaceutical supply, however, is not from within the U.S., but from other countries, even our neighbors to the North and to the South.

Between October 2002 and April 2003, Pfizer received complaints from four consumers that the Lipitor they purchased in Algodones, Mexico was ineffective. Three of the complaints pertained to Lipitor 10mg; the fourth pertained to Lipitor 20mg. Packaging and tablets received from those consumers were tested and found to be counterfeit; the tablets contained none of Lipitor's active pharmaceutical ingredient ("API"). Although the purchases were made at three different pharmacies and bore four different lot numbers, the chemical composition of the tablets was found to be the same. The chemical formulation of those tablets also matched a sample provided by a consumer who had purchased Lipitor in 2001 while visiting Algodones. A limited market survey conducted earlier this year established that the same tablets were still available in Tijuana and Algodones. This suggests that, over a three-year period, counterfeit Lipitor has been manufactured by the same source, one capable of producing products with a consistent chemical formulation.

The proliferation of Internet sites through which U.S. residents may purchase pharmaceuticals from Canada has received much publicity, as has the recent appearance of storefronts designed exclusively to assist consumers in placing those orders. While we are not currently aware of any counterfeits received as a result of orders placed with those pharmacies, there is nonetheless cause for concern. Between January 30 and June 10 of 2003, Pfizer received complaints from six U.S. consumers that the Pfizer products they purchased in Canada, including Dilantin, Norvasc and Zoloft, were ineffective. One consumer, who obtained Dilantin from Canada, reported having a seizure after taking the Canadian product. Four consumers, each of whom had previously taken Zoloft obtained in the U.S., reported that the Zoloft obtained in Canada didn't work as well. One of those consumers complained of nausea, recurring depression and weakness; a second complained of palpitations and anxiety; a third complained of jitteriness, an inability to concentrate, and depression. Unfortunately, since

samples were not obtained from these consumers, we are unable to state with certainty that the products they obtained were indeed counterfeit.

We are, however, aware of one major counterfeiting operation in Canada that did target the U.S. as one of its markets. A joint investigation conducted by the Royal Canadian Mounted Police (RCMP) and the United States Drug Enforcement Agency (DEA), led to the identification of Naturtek, a site in Quebec, that had been manufacturing counterfeit Viagra since June 2002. In addition to two tablet presses and 32 counterfeit punches -- 16 to deboss "Pfizer" into the tablets, 8 to deboss "VGR 100" and 8 to deboss "VGR 50" -- a search warrant executed at that site in April 2003, yielded 2.95 kg of counterfeit Viagra tablets (approximately 4,770 100mg tablets) and 5 kg of sildenafil citrate (enough to make approximately 50,000 100mg or 100,000 50mg tablets). Investigators identified another Quebec firm, Pangeo-Pharma, formerly known as Formulex, as the source of the API used in the manufacture of those tablets. Although no instances of importation into the United States were found, it was clear from conversations intercepted during the investigation that it was the intent of those involved in the operation to sell their product into the lucrative U.S. market.

Lessons Learned

Counterfeiting is a global problem, and counterfeit operators around the world (whether they be manufacturers, packagers, distributors or middlemen) have a keen interest in penetrating the U.S. market. We already see the importation of counterfeit and diverted products into the U.S. through the mail and courier services and through unethical wholesalers and repackagers. Existing "strict regulations" are ineffective in preventing it.

The repackaging of pharmaceuticals can easily result in the introduction of counterfeit and unapproved products into the legitimate distribution channels. Repackagers must come under more careful scrutiny by the FDA. Regulations that apply to these firms must be strictly enforced and, where necessary, additional regulations enacted. Particular scrutiny of those engaged in import for export is required.

To ensure compliance with FDA regulations, the FDA must be given increased power. Unannounced inspections should be permitted. The giving of notice, which is now required, permits those engaged in criminal behavior, those placing the public health and safety at risk, to conceal the evidence of their conduct.

There must be more transparency in, and tighter control over, the flow of pharmaceuticals in the distribution process. The traditional distribution chain, where a manufacturer sells to a wholesaler who sells to retailers, is well understood. However, when products start flowing from wholesaler to wholesaler to wholesaler, or from pharmacy to pharmacy to pharmacy, existing oversight mechanisms lose force. Therefore we believe that the provisions in the Prescription Drug Marketing Act of 1988 requiring wholesalers to provide their customers with a pedigree documenting the sales history of the pharmaceutical products they sell should be implemented immediately. Due to lobbying efforts by wholesalers, the regulations to implement this requirement have not yet been finalized. Last year, the finalization of this requirement was adopted by the Pharmaceutical Research and Manufacturers of America (PhRMA) as part of its five-point program to preserve the integrity of the U.S. supply of pharmaceutical products. PhRMA has even offered to assist the FDA in its implementation of this program.

Recall procedures must be examined and revised. The FDA should have the authority to compel a recall as well as to approve and oversee even “voluntary” recalls. Recalls should issue more quickly when the presence of counterfeits has been documented, even when that documentation is provided by the manufacturer and not fully confirmed by the FDA. Where the manufacturer is cooperating in an investigation, FDA should be required to make that cooperation known to the public.

As shown by the release of unapproved sildenafil citrate products to more than 2,500 U.S. consumers in 2003, there must be clarification of the procedures pertaining to the disposition of counterfeit, infringing, misbranded or unapproved products that are seized by the FDA and Customs. Under existing regulations, the FDA is required to consult with the importer before it can either return the shipment to the exporter or destroy it. That notification requirement, while manageable when dealing with a large shipment, is unduly burdensome when dealing with large numbers of individual purchases and importations. Second, the procedure for declaring a product "contraband" should be simplified. It is suggested that any unapproved or misbranded product that is imported into the U.S. should be automatically classified as "contraband" and subject to destruction without prior notification to its intended recipient.

Finally, the penalties for counterfeiting pharmaceuticals must be enhanced. As long as the counterfeiting of pharmaceutical products remains a high profit, low risk criminal activity, it will continue to attract entrepreneurs, organized crime and terrorist organizations.

Conclusion

Thank you for this opportunity to express my concerns. The importation of counterfeit, infringing, misbranded and unapproved pharmaceutical products into the United States is on the rise. The response by regulatory and law enforcement agencies to the 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 mandate. Regulations currently in existence must be fully enforced. Where those regulations are found lacking, they must be enhanced. The safety of the U.S. supply of pharmaceuticals hangs in the balance.