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before the
House Committee on the Judiciary
Subcommittee on Crime, Terrorism and Homeland Security

Hearing on
H.R. 4223, the "Safe Doses Act"; H.R. 3668, the "Counterfeit Drug Penalty Enhancement Act of 2011"; and, H.R. 4216, the "Foreign Counterfeit Prevention Act."

March 28, 2012

Chairman Sensenbrenner, Ranking Member Scott, and members of the subcommittee, it is an honor to be asked to testify today about two important criminal law problems that have serious implications for consumer safety: large-scale pharmaceutical product theft and counterfeiting.

My name is Tom Kubic, and I'm President and CEO of the Pharmaceutical Security Institute ("PSI"), a non-profit association dedicated to protecting the public health by ensuring the distribution of pharmaceuticals that are safe and effective. PSI is composed of the security directors from 26 pharmaceutical manufacturers with business operations in more than 160 countries, and we share information on the counterfeiting of pharmaceuticals and initiate enforcement actions through the appropriate authorities. We have developed the PSI Anti-Counterfeiting Strategy and a unique, internationally recognized counterfeit medicines reporting system known as the Counterfeit Incident System.

I've worked closely with INTERPOL in the development of international operations against counterfeiters lead by the Medical Product Counterfeiting and Pharmaceutical Crime Unit, as well as the World Health Organization's IMPACT Enforcement Working Group. I am a member of the scientific committee of the Paris-based International Institute against Counterfeit Medicines. For the past six years, I have been an advisor to the Permanent Forum on International Pharmaceutical Crime. Prior to joining PSI, I had a 30-year career in the U.S. Federal Bureau of Investigation (FBI), including serving as a Deputy Assistant Director.

I'm here today on behalf of The Coalition for Patient Safety and Medicine Integrity, which is a group of pharmaceutical, medical device and medical products companies focused on patient safety. The Coalition's purpose is to protect patients from the risks posed by stolen and inappropriately handled medical products re-entering the legitimate supply chain, and its members include Abbott, Eli Lilly, GlaxoSmithKline, Johnson & Johnson, Novartis, Novo Nordisk, Sanofi, and PhRMA. The coalition's efforts are supported by PSI, the National Insurance Crime Bureau (NICB), the Healthcare Distribution Management Association (HDMA), the Biotechnology Industry Organization (BIO), and the National Community Pharmacists Association (NCPA).

I want to begin by commending Chairman Sensenbrenner and the other sponsors of the SAFE DOSES Act and Congressman Meehan, the sponsor of the Counterfeit Drug Penalty Enhancement Act, for your leadership in protecting patients. Both H.R. 4223 and H.R. 3668 are important measures for addressing the illegal activity that puts unsafe medical products into the legitimate supply chain, and ultimately into the bodies of unsuspecting patients.

Background on Medical Product Theft

Large-scale medical product theft is a significant problem. By "large scale," I mean entire tractor-trailer loads and warehouses full of medical products. Thefts of this magnitude are conducted by sophisticated criminal organizations that are hijacking tractor-trailers at rest stops, breaking into warehouses and evading alarm systems, forging shipping documents, producing high-quality counterfeit labels with altered expiration dates and lot numbers, and otherwise thwarting the intense security measures used by the industry. Some criminal organizations employ sophisticated surveillance equipment and techniques in order to learn exactly when and where they can steal the particular shipments they want. Then they sell the stolen medical products back into legitimate channels. While the criminal organizations face little risk of being caught, the patients face a significant risk of injury from unsafe product.

The risk to patient safety is illustrated by an incident that occurred in 2009. Early in that year, 129,000 vials of insulin were stolen in North Carolina. A few months later (in June), the FDA received a report that some of the vials had been reintroduced into the supply chain when a diabetic patient reported to a medical center in Houston with an adverse reaction after using insulin from the stolen lot. The FDA issued a warning that the insulin had likely not been stored correctly and could still be in the market – at that time only 2% of the stolen product had been recovered. The compromised product was ultimately found in pharmacies in 17 states, with additional patients experiencing adverse reactions. An investigation linked the theft to an organized crime ring. Some arrests have been made in this case, but over 125,000 units are still unaccounted for.

You might expect this problem to involve narcotics and other substances that could be sold on the street, but all kinds of pharmaceuticals, medical devices and specialty nutrition products are being stolen. High-value pharmaceuticals, including treatments for serious diseases, are frequent targets. Unfortunately, these high-value items are the very type of sensitive products that need the most careful handling and temperature control. Many medical products can become ineffective if stored at the wrong temperature, even for a brief time.

H.R. 4223 -- The SAFE DOSES Act

The SAFE DOSES Act is bipartisan legislation that would modernize the federal criminal code. Passage of this statute will allow law enforcement to utilize well-established investigative tools against an increasingly sophisticated criminal element that traffic in stolen medical products without regard for public safety. I would note that the companion bill in the Senate has 34 bipartisan cosponsors and was recently unanimously approved by the Senate Judiciary Committee.

Background on Pharmaceutical Counterfeiting

In contrast to stolen medical products, counterfeit medicines are deliberately and fraudulently produced and/or mislabeled in order to appear to be a genuine product. This counterfeiting occurs to both branded and generic products, and it presents a wide range of dangers. For example, counterfeit medicines have been found to contain less than or more than the required amount of active pharmaceutical ingredients (API) used in the authentic version or even contain the correct amount of API but have been manufactured in unsanitary, unsafe conditions.

Genuine medicines can also be counterfeited. For example, cases have been discovered where genuine medicines have been placed in counterfeited packaging to extend the expiry date or to commit a fraud against various government programs.

As with medical product theft, counterfeiting occurs on a broad scale. Globally, in 2010, there were 2,054 incidents we've documented which involved 593 different pharmaceutical products. The number of products found in a single incident ranged from one drug to thirty-two different drugs. Pharmaceuticals in every therapeutic category are targeted by criminal organizations. Medicines in the genito-urinary, anti-infectives and central nervous system therapeutic categories contained the largest number of incidents. The metabolism therapeutic category led with the largest percentage increase at one hundred eighty-two percent (182%). Categories with the percentage increases also included oncologics (+20%) and cardiovascular (+5%). Just as with thefts, counterfeiting is occurring in large volumes. In 2010, for example, nearly half of the seizures made by law enforcement were confirmed as being of "commercial" size.

H.R 3668 -- The Counterfeit Drug Penalty Enhancement Act

It is already illegal, of course, to introduce counterfeit drugs into interstate commerce, but the penalties provided by current statutes do not reflect the serious danger the crime poses to ordinary consumers. Federal counterfeiting laws do not distinguish between trafficking counterfeit medicines and counterfeit wallets. While the manufacture and sale of counterfeit products are serious crimes in any context, counterfeit medicines pose a grave danger to public health that warrants a harsher punishment. Current penalties are simply not suited to deter this problem. The Counterfeit Drug Penalty Enhancement Act would increase penalties for the trafficking of counterfeit drugs to a level commensurate with similar offenses, such as those assessed for trafficking narcotics under the Controlled Substances Act. This commonsense legislation, sponsored by Senate Judiciary Committee Chairman Leahy in the Senate, was passed by the full Senate on March 6, 2012.

What the industry is doing

It is important for policymakers to know that the industry is taking aggressive measures to address these problems everywhere they can. Let me assure you that pharmaceutical, medical device and medical products companies are continually updating their already sophisticated security systems and practices. Many have instituted strict protocols for their truck drivers, including instructions on where they can stop for breaks. Some companies even provide escorts for their most sensitive shipments. Although

these efforts are making it more difficult for the criminals to get what they want, only the genuine threat of significant criminal penalties can provide effective deterrence.

Meanwhile, PSI has developed several innovative initiatives to combat counterfeiting worldwide, including:

- The Counterfeit Incident System – a global system allowing law enforcement in different countries to link illegal manufacturing operation to suppliers to retail outlets.
- A law enforcement awareness program reaching over 2,000 police officers, customs and drug regulators.
- The SAFEDRUG Checklist: an 8-step guide to boost your knowledge of your medicine safety and tips on what to do if you suspect your medicine may be compromised.
- The SafeMeds Blog: a timely discussion forum with experts on safe medicines.

Summary

Thank you again for the opportunity to testify here today, and for your attention to these very serious problems. The legislation pending before this Committee, if passed, will go a long way towards avoiding serious dangers to the public. I would be happy to answer any questions.