

Statement at the House Committee on Energy and Commerce  
Hearing on the Food and Drug Import Safety Act (H.R. 3610)

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Alan Goldhammer, PhD  
Deputy Vice President, Regulatory Affairs  
Pharmaceutical Research and Manufacturers of America

Thank you Mr. Chairman and members of the Energy and Commerce Committee. My name is Alan Goldhammer, Ph.D., and I am the Deputy Vice President for Regulatory Affairs at the Pharmaceutical Research and Manufacturers of America (PhRMA), a trade association representing the leading research-based pharmaceutical and biotechnology companies. We are pleased to have been invited as part of this discussion, and look forward to continued work with the Committee to ensure patient safety.

PhRMA members alone invested an estimated \$43 billion in 2006 in discovering and developing new medicines, and patients and their health care providers quite reasonably expect these medicines to safely and effectively treat the diagnosed medical condition. America's patients trust that the drugs dispensed for their conditions are not counterfeit. Pharmaceutical companies obviously don't want patients getting counterfeited medicines, because such medicines could result in ineffectual or even dangerous medical outcomes.

The Prescription Drug Marketing Act of 1987 (PDMA), was a critical piece of consumer legislation passed as a result of Congressional concerns regarding the integrity of the drug distribution system that existed at the time. The passage of this legislation established the closed distribution system that we have today. The PDMA coupled with the exacting regulatory requirements of the Food and Drug Administration (FDA) helps minimize the possibility of a consumer receiving a counterfeit drug.

Pharmaceutical companies manufacture products following exacting standards that have been reviewed and approved by the FDA. They employ extensive quality systems to assure that innovative medicines provide consistent positive health outcomes. However, even the most effective medicines cannot help patients if those medicines are compromised by loopholes or breakdowns in the pharmaceutical distribution system, which could provide opportunities for diversion and counterfeiting. The remainder of this testimony will focus on the FDA regulatory system that assures quality, the steps manufacturers take to implement quality systems, and finally some thoughts about what policy makers might consider to further secure the pharmaceutical supply chain.

Throughout the drug development process, pharmaceutical companies focus on

the quality of the product and put in place manufacturing controls that result in a medicine that is consistent from lot to lot with respect to its purity and potency. Information is collected on the product's stability so that the patient can be assured that the expiration date is based on sound science and that the medicine if used within this period of time will provide the therapeutic dose the doctor has prescribed. All of this information is submitted to the FDA for review in the New Drug Application (NDA) (or Biologics License Application (BLA) for biologics and biotechnology products). FDA not only reviews all of this data but also conducts a pre-approval inspection of the manufacturing facility to insure that it is in compliance with Good Manufacturing Practice (GMPs) requirements as outlined in 21 C.F.R. Parts 210 and 211.

The GMPs cover the quality control unit; buildings and facilities; equipment; control of components and drug product containers and closures; production and process controls; packaging and labeling control; holding and distribution; laboratory controls; records and reports; and finally returned and salvaged drug products. When companies use outside vendors or contract manufacturers for any components of the finished medicine, extensive qualification and standards testing regimes are put into place to assure that the materials received meet the standards established by the pharmaceutical company. Companies regularly audit their suppliers to make sure source materials are produced in a manner consistent with the specifications outlined in the manufacturing agreement(s).

Quality assurance is an ongoing part of the business; it does not stop when the NDA is approved and production commences. Companies have a regulatory responsibility to continuously monitor so that each lot released to the commercial distribution system meets the FDA approved specifications.

While PhRMA believes that the United States drug distribution system is the safest in the world, there are some steps that we have advocated that we believe will further secure the pharmaceutical supply chain.

**1. *Increase Requirements for Repackagers.*** PhRMA believes that FDA should re-assess its policies and procedures regarding repackaging operations. Repackaging has been identified as a weak spot in the drug distribution system that can be used as an entry point and distribution center for diverted and counterfeit drug products. Repackagers remove drug products from their original packaging and labeling, thereby destroying any counterfeit resistant technologies employed by the original manufacturer. Consequently, additional oversight is necessary to ensure that repackaged drug products are authentic and are not compromised by repackaging operations. PhRMA believes that FDA could better regulate the authenticity and quality of repackaged drug products if it had authority to require prior approval of repackaging operations. At a minimum, FDA should increase its inspections of repackagers and, where appropriate, initiate enforcement action. In addition, repackagers should be subject to the same requirements regarding overt and covert counterfeit resistant technologies

as original manufacturers.

**2. Strengthen Federal Requirements for Wholesalers/Distributors.** PhRMA supports efforts to strengthen the licensure requirements for wholesalers and distributors. Recent investigations, particularly by the Florida Grand Jury and the Washington Post, have identified systemic weaknesses in the oversight of the wholesale drug industry in many states. These weaknesses permit individuals, even those with prior felony convictions, to obtain wholesaler licenses for operations that deal in diverted and counterfeit drug products. PhRMA supports efforts by Florida and Nevada to strengthen requirements for the licensure of wholesalers by, for example, requiring the posting of a substantial performance bond (e.g., \$100,000) and conducting detailed pre-licensure background checks and facility inspections. PhRMA believes, however, that licensure requirements should be strengthened consistently across all states to prevent diverters and counterfeiters from re-locating to states without strong licensure requirements. This can best be accomplished through revisions to 21 U.S.C. § 503(e)(2) specifying higher minimum standards for state licensing of drug wholesalers and distributors similar to those currently in place in Florida and Nevada. FDA also should review state requirements for the licensure of wholesalers to ensure that they meet any enhanced minimum federal regulatory requirements.

**3. Increase Criminal Penalties for Counterfeiting Activities.** PhRMA believes that the criminal penalties for counterfeiting prescription drug products must be significantly increased. The current penalty under the Federal Food, Drug, and Cosmetic Act (FFDCA) – a maximum of three years imprisonment – does not reflect the serious public health risks associated with counterfeit drugs or serve as an adequate deterrent to prospective counterfeiters. PhRMA thus supports increasing the maximum criminal penalty for counterfeiting drug products from three to twenty years imprisonment. PhRMA also believes that criminal penalties should be imposed against entities that create a market for diverted and counterfeit drug products by purchasing drug products without adequate due diligence into the source and authenticity of such drugs. PhRMA thus supports making it a prohibited act under the FFDCA to purchase prescription drugs from a wholesale distributor without first obtaining and verifying the information provided on a drug pedigree.