

**Testimony before the
House Committee on Energy and Commerce, Subcommittee on Health
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Chairman Pitts, Ranking Member Pallone and members of the Health Subcommittee, thank you for the opportunity to present testimony. I thank you for holding this hearing and, in particular, applaud Representatives Bilbray and Matheson for introducing a bipartisan bill that would help protect Americans from counterfeit drugs.

Through research and critical analysis, the Pew Health Group seeks to improve the health and well-being of all Americans by reducing unnecessary risks to the safety of medical and other consumer products and supporting medical innovation.

The focus of my testimony today is the drug distribution system – the risks of counterfeit and stolen drugs, and the pragmatic steps Congress can take to reduce those risks.

In July of 2011, Pew released a report entitled “After Heparin: Protecting Consumers from the Risks of Substandard and Counterfeit Drugs.”¹ The report, which underwent extensive external review, was based upon information from regulatory and public documents, peer-reviewed journal articles and interviews with dozens of supply chain experts from numerous perspectives. It was informed by a two-day conference we hosted in March 2011 that included representatives of brand and generic pharmaceutical manufacturers, active drug ingredient makers, major and secondary pharmaceutical wholesalers, chain and independent pharmacies, consumer and health professional organizations, the U.S. Food and Drug Administration (FDA), state regulators and independent supply chain experts.

Risks to the drug distribution system

One of our key findings is that incidents of counterfeiting and drug diversion in this country – while thankfully far less common here than in other parts of the world – are a matter of serious concern. We currently have no national system to detect or prevent such incidents. The U.S. pharmaceutical distribution system is sometimes described as a “closed” system, meaning that it is not legal to import drugs that were not manufactured for the U.S. market. However, the system is not closed in the sense that we have over a thousand individual wholesalers licensed, providing multiple points of entry to the legitimate distribution system.

A few examples will help to illustrate the nature of the risks. First, the black market for resale of government-subsidized medicines. In 2010, three men were indicted for allegedly illegally purchasing prescription drugs—some directly from patients—and selling them to pharmacies through a licensed wholesaler in Texas.² Similar illicit purchases – some large scale – are well-documented in multiple states.

Another threat is drug theft. In 2009, thieves stole a tractor-trailer containing 129,000 vials of insulin. This drug, which needs to be refrigerated, disappeared for a number of months, before being sold back into distribution.³ While most of the stolen drug was never recovered, the FDA has said that some of it was found at retail chain pharmacies in Texas, Georgia and Kentucky, having passed through the hands of licensed wholesalers in at least two other states.⁴

In another case, thieves stole \$75 million worth of pharmaceuticals from an Eli Lilly warehouse in Connecticut. It was a sophisticated operation, the largest dollar-value loss from a warehouse in U.S. history.⁵ The fate of those stolen prescription drugs is unknown, but one investigator who spoke at the Pew conference and who is an expert in pharmaceutical distribution crime believes that a scheme of drug thieves is to steal the product then hold it, hidden, for a year or two, letting the alarm die down before selling it back in to the system.

Finally, we have incidents of outright counterfeits reaching unsuspecting American patients. It is the unfortunate truth that this hearing occurs just weeks after cancer patients in the U.S. were exposed to counterfeit Avastin® – a critical chemotherapy agent used to treat numerous types of

the disease. In 2001, counterfeit Serostim[®], a human growth hormone used to treat AIDS-related wasting, was found in at least seven states and passed through multiple wholesalers.^{6,7,8} The manufacturer of Serostim[®] has since put in place a secured distribution program, with a unique serial number assigned to each vial that must be verified by the dispensing pharmacy.⁹

A national serialization and traceability system to secure distribution

The United States lacks strong uniform national standards for licensure of pharmaceutical wholesalers, and we lack a standard system for companies to keep track of our pharmaceuticals during distribution. There is currently no way to check whether an individual vial or bottle is authentic or counterfeit.

Some state laws exist. California has put in statute a comprehensive system that would require manufacturers to put a serial number on each bottle or vial, and would require wholesalers and pharmacies to check the drugs they buy and sell to ensure they are authentic. California's law is scheduled to come into effect three years from now. Despite the strength of the law, a patchwork of state requirements is not ideal either for companies or for consumers.

Manufacturers, wholesalers and pharmacies, as well as the FDA, Congress, and other stakeholders have for years been discussing a federal system to better ensure distribution safety and security as well as facilitate compliance.

Congress is now considering a proposal from the Pharmaceutical Distribution Security Alliance – a consortium that includes many, but not all of the major industry stakeholders. We applaud their efforts to bridge widely divergent views on how best to create a single national standard. We believe that the perfect cannot be the enemy of the good. However, while we support a number of elements of the PDSA proposal (including the interim provisions to increase safety, as well as strengthening federal wholesaler licensure guidelines), we are concerned that in at least two crucial respects, the proposal, if implemented in its current form, would neither enable the identification of counterfeit medicines nor provide the building block for a more robust system in the future.

The proposed system does not support unit-level traceability

The key to improved security of drug distribution is knowing who handles the drugs as they move from manufacturer, through a succession of wholesalers, to the pharmacy or hospital and, ultimately, the patient.

The industry proposal calls for keeping track of drugs by the lot, but a lot can contain numerous cases of many thousands of individual bottles or packs of vials. Each case or vial may be sold separately, and tracking by lot does not allow industry or regulators to ever know who bought and sold a given drug through distribution.

Maintaining data about lots *may* provide an *incremental* benefit over the status quo, but it would fail to catch unsafe drugs in many scenarios.

For example, if regulators catch criminals selling diverted vials of expensive injectables, they will not be able to find out what legitimate players bought and sold those vials before they were diverted. They will only know the lot number – and this lot of drugs could have traveled through multiple distributors and reached multiple pharmacies.

Also, if part of a lot is stolen and illicitly reintroduced into commerce, a pharmacist or patient will have no way to tell if the product on their shelf is compromised. However if unit-level data is kept, specific stolen unit serials could be identified.

While the PDSA proposal would result in a unique serial number being affixed to each individual unit, keeping track of the drugs would be impossible unless the unit serial numbers can be associated with the case they are shipped in. The PDSA proposal explicitly excludes this so-called “aggregation” of serial numbers. If a system is constructed as proposed, it will be difficult or impossible to track drugs at a more granular level in the future.

The proposed system would not routinely check for, or identify, counterfeit drugs

A key reason to put serial numbers on prescription drugs is to ensure that pharmacies and others who handle the drugs use the numbers to verify the authenticity of the drugs. Under the PDSA

proposal, neither the pharmacy nor other parties in the system are required to verify the products they buy and sell. A criminal could sell a vial of counterfeit drug with a fake serial number, and no one would detect it because no one would be required to check it.

Pew supports required authentication of drug products by companies involved in distribution. Required checking would help ensure fake or otherwise flagged serials are caught, and not allowed to make it to patients. Such a requirement could have kept the unsafe insulin, sold back into distribution after it was stolen, away from the patients who instead experienced poor blood sugar control. Such a requirement would also support enforcement of responsible purchasing by wholesalers and pharmacies

Conclusion

The risk of stolen or counterfeit products reaching and harming patients through the drug distribution system is small, but real. Recently, both the U.S. Counterfeit Pharmaceutical Inter-agency Working Group and the office of the U.S. Intellectual Property Enforcement Coordinator have recommended implementation of a track-and-trace system to secure drug distribution against counterfeits in separate March 2011 reports.^{10,11} The impending implementation of California's law creates momentum for a single national standard. In 2008, major industry stakeholders committed to being ready for the California law by 2011. Similar promises were made when the law's implementation was delayed until 2015. We urge Congress to create a robust national system – one that protects patients today and provides the flexibility to ensure we can build upon it in the future.

References

- ¹ Pew Health Group. “After Heparin: Protecting Consumers from the Risks of Substandard and Counterfeit Drugs.” (2011) http://www.prescriptionproject.org/after_heparin_report
- ² United States Attorney's Office, Southern District of Florida. Three Indicted for Diversion of Prescription Drugs Press Release. March 18, 2010. <http://www.justice.gov/usao/fls/PressReleases/100318-01.html>, Accessed October 20, 2010.
- ³ U.S. Food and Drug Administration. Update to FDA Alert About Stolen Insulin. August 26, 2009. <http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm180320.htm>. Accessed November 12, 2010.
- ⁴ Ciolek, Michelle M., Special Agent, Office of Criminal Investigations, U.S. Food and Drug Administration. Affidavit in support of search warrant. July 21, 2009. USA v. Altec Medical Inc and RX healthcare Inc. Document number: 8:09-cr-00814-WMC
- ⁵ Forsaith, Chuck. Corporate Director, Supply Chain Security, Purdue Pharma L.P. “Cargo Theft.” Presentation, 2010 PDA/FDA Pharmaceutical Supply Chain Workshop. Bethesda, MD. April 26-28, 2010.
- ⁶ Serono, Inc. Serostim [somatropin (rDNA origin) for injection]. Press Release, January 2001. <http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm173895.htm>. Accessed February 17, 2011.
- ⁷ Otto, Alex. Counterfeit Serostim Found Nationwide. *Pharmacy Today*. American Pharmacists Association. March 1, 2001. <http://www.medscape.com/viewarticle/406804>. Accessed October 13, 2010.
- ⁸ *Dutchess Business Services Inc. v. Nevada State Board of Pharmacy*. No. 46345. September 11, 2008. <http://caselaw.findlaw.com/nv-supreme-court/1219556.html>. Accessed February 17, 2011.
- ⁹ Williamson, Joyce P. Statement of Serono before the task force on drug importation. <http://archive.hhs.gov/importtaskforce/session2/presentations/Serono.pdf>, Accessed February 17, 2011.
- ¹⁰ Counterfeit Pharmaceutical Inter-Agency Working Group Report to the Vice President of the United States and to Congress. March 2011. http://www.whitehouse.gov/sites/default/files/omb/IPEC/Pharma_Report_Final.pdf. Accessed April 22, 2011.
- ¹¹ Administration's White Paper on Intellectual Property Enforcement Legislative Recommendations. March 2011. http://www.whitehouse.gov/sites/default/files/ip_white_paper.pdf. Accessed April 22, 2011.