

**Testimony before the
Committee on Energy and Commerce, Subcommittee on Oversight and Investigations
United States House of Representatives**

February 27, 2014

**Elizabeth Jungman, Director, Drug Safety and Innovation
The Pew Charitable Trusts**

Chairman Murphy, Ranking Member DeGette, and members of the Oversight and Investigations Subcommittee, thank you for holding this hearing and for the opportunity to present testimony. My name is Elizabeth Jungman; I direct drug safety and innovation work at The Pew Charitable Trusts. Pew is an independent, nonpartisan research and policy organization dedicated to serving the public. We have a longstanding focus on the safety of the prescription drug supply chain.

Counterfeit drugs are far more than an intellectual property problem; they are a public health problem with real human costs. Counterfeit and other unsafe or illegitimate drugs have entered the U.S. drug supply numerous times over the past few decades. We have likely all heard of the recent example of patients exposed to counterfeit Avastin, and I have attached other examples to my testimony.

I am grateful to Congress for enacting two important recent laws to help secure the drug supply: Title VII of the FDA Safety and Innovation Act, which focused on “upstream” supply chain security, and Title II of the Drug Quality and Security Act (DQSA), which laid the groundwork for tightening the “downstream” drug distribution system.

My testimony today will focus on next steps, and particularly on the potential for policymakers and supply chain stakeholders to make full use of these tools and to go beyond statutory requirements to create even more robust protections.

We recognize the importance of better enforcement tools, including meaningful penalties, in deterring criminal behavior. Pew called for higher penalties in 2011, and we applaud the recent efforts of Congress and the Sentencing Commission to make drug counterfeiting and theft more

costly for those who undertake it. We acknowledge that there is likely still more to be done to ensure that prosecutors have the tools they need to protect our drug supply. However, the best way to prevent unsafe products from reaching patients is a tightly closed distribution system, and this is my focus today.

Use of drug serialization

In passing the Drug Quality and Security Act last year, Congress created a national serialization and traceability system for medicines sold in the United States. This will fundamentally change the distribution system for drugs in this country.

Beginning in late 2017, each package of prescription drugs will be given a unique serial number enabling it to be verified, and, eventually, allowing for its distribution history to be traced. The DQSA contains some requirements for companies in the supply chain to make use of these serial numbers, but in most cases only when there is an existing belief that a product is suspect.

An even more powerful use of serial numbers would be to use them as a proactive check to identify illegitimate product that otherwise might pass unnoticed into the drug supply chain. Pharmacists, physicians, payers, and border agents could use this important new tool to help stop fake products from reaching patients. Drug counterfeiters are capable of copying sophisticated packaging, and will be able to imitate the new serial numbers and barcodes required by the DQSA. Faking or copying a serial number is much harder, however, if that number is routinely verified against the manufacturer's database. For instance, a system could flag if the same serial number was checked repeatedly in different locations.

It is important to underscore that the risks go beyond counterfeit drugs. In 2009, for example, thieves stole a tractor-trailer containing at least 120,000 vials of insulin—an injectable drug that must be refrigerated. This stolen drug disappeared for months before being identified on the shelves of chain drugstores in Texas, Georgia, and Kentucky. No patient deserves to receive a prescription medicine that was handled by criminals, but only a tiny proportion of the stolen drugs was ever found.^{1,2} The lot number of the stolen drug was known: routine checking could have identified it immediately.

Verification should become routine in pharmacies. To achieve this, the system must be designed to ensure that verification is practical and efficient. Waivers of DQSA's requirements should be rare, lest we exempt businesses like the pharmacist in Chicago who was indicted last year for substituting Chinese counterfeits for legitimate products.³

Physicians can also make use of serial numbers. Doctors who purchased counterfeit cancer drugs last year may not have known they were fake. While the DQSA does not require it, routine verification should become the norm. This is a safety check patients deserve. Both physician societies and payers should consider the potential of this tool to protect patients.

Proactive verification of serial numbers is not without precedent—it is already in place or being implemented in several countries. For example, Italy and Turkey require pharmacy authentication of serialized medicines in order to protect their citizens and prevent fraud. Additional countries such as China and Brazil are advancing similar requirements.^{4,5} The United States is, unfortunately, behind the curve in this case: Our law requires only minimal verification for pharmacies, but it does give them the tools to make these checks if they choose to, or if Congress, regulators, or payers encourage them to.

Payers could also explore the use of serial numbers as a condition of reimbursement, both to ensure product legitimacy and to reduce fraud. The potential losses to payers from counterfeit, stolen and diverted products are significant.

Two years ago, the U.S. Attorney for the Southern District of New York charged 48 individuals in a large-scale diversion scheme in which criminals bought patients' prescription drugs, including medicines for HIV, schizophrenia, and asthma, and sold them back into distribution through licensed pharmaceutical wholesalers and pharmacies. Not only were patients at risk, but the Medicaid program was defrauded of \$500 million.⁶ Similar schemes in other states are well documented, including one in Tennessee in January of 2013.⁷

This massive criminal recycling of government-subsidized drugs could have been prevented by a serial number that was proactively verified. This, however, raises the importance of another system element not explicitly required in the DQSA: serial number “decommissioning.” If a serial number was retired after drugs reached the pharmacy the first time it would have been caught on its second trip around, after criminals bought it from a patient and resold it. Without proactive checking, and some form of serial number retirement, even a real serial number could be sold many times over without detection. As the FDA and stakeholders build the new verification system, and as Congress oversees that effort, they should consider allowing for features like decommissioning that, while not explicitly required by the law, would be useful in preventing patient harm and taxpayer fraud. Even if serial numbers are not initially decommissioned, the architecture of the system should be built to allow for this possibility at a later date.

Serial numbers could also be used at the border. An estimated 80% of drug ingredients and 40% of finished drugs used by Americans are manufactured overseas, so our border agents play a critical role in facilitating the import of legitimate medicines, and keeping counterfeits out. Once drugs sold in the United States are required to bear serial numbers beginning late 2017, agents could spot-check serial numbers when warranted to determine product legitimacy. This use of serials would complement the progress in regulating drug imports made in the 2012 FDA Safety and Innovation Act, including new controls at the border (such as the power to refuse an imported drug if the plant making it did not allow an FDA inspection, and the ability for FDA to require electronic submission of certain compliance information as a condition of granting entrance), an updated inspection framework, and new resources for this important work.

Use of new traceability tools

The DQSA requires that, in ten years’ time, manufacturers, repackagers, wholesalers, and pharmacies participate in an electronic, interoperable system that permits the tracing of each unique package of medicine in distribution. However, the law does not specify precisely how this system will function. Consequently, there is an opportunity to create a system that will be a stronger defense against the insertion of unsafe drugs into the legitimate distribution chain.

As FDA and stakeholders set up the new system, they should build it to enable automatic verification of each transaction between partners in the drug supply chain. If an unauthorized entity attempted to participate, or if the product sold did not have a verifiable transaction history, the system should quickly flag the inconsistency and allow legitimate actors to avoid purchasing an illegitimate product. Automatic verification is not required by the DQSA, but establishing the system architecture to include automated checks would protect every member of the supply chain from the business risks that come with counterfeit products, and it would protect patients.

Stakeholders do not have to wait until the fully interoperable system is in place, or even until product is serialized, to begin using DQSA tools to better secure the supply chain. In anticipation of the fully interoperable electronic system, doctors, pharmacists, and others can take advantage of other tools in the DQSA to ensure they are buying good products. For example, the DQSA will establish a public database of licensed wholesalers so that when a doctor is offered a too-good-to-be-true price on a product like Avastin, he or she could check out the wholesaler offering that deal. The DQSA also requires, for the first 10 years, that trading partners pass transaction histories; a pharmacy could check this documentation to provide assurance that the source is legitimate, particularly in situations, such as when buying a drug in short supply, where the incentives for fraud are high. We don't have to wait 10 years to start taking advantage of the DQSA – these are steps stakeholders can take next year to improve the integrity of our supply chain.

Conclusion

The DQSA and the FDA Safety & Innovation Act are important steps in securing our pharmaceutical supply chain, but, alone, they will not solve the problem. Congress, regulators, border agents and supply chain stakeholders can help create a safer drug supply by supporting robust implementation of these laws, and full use of the tools they provide.

REFERENCES

¹ 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

² U.S. Food and Drug Administration. "Update to FDA Alert about Stolen insulin". August 26, 2009.

<http://www.fda.gov/ForConsumers/Consumerupdates/ucm180320.htm>

³ U.S. Food and Drug Administration, Office of Criminal Investigations. "April 18, 2013: Suspended North Side Pharmacist Indicted for Allegedly Smuggling and Trafficking Counterfeit Viagra". U.S. Department of Justice Press Release, April 18, 2013. <http://www.fda.gov/ICECI/CriminalInvestigations/ucm349021.htm>. Accessed February 24, 2014.

⁴ Basta, Nicholas. "Serialization systems are going into operation around the world, but cross-industry collaboration awaits new legislation," Product Security Report, August 27, 2012 http://www.pharmaceuticalcommerce.com/index.php?pg=special_report&articleid=26610&keyword=2012%20product%20report-serialization-RxTEC.

⁵ Turkish Ministry of Health. "G.D. of Pharmaceuticals and Pharmacies Guidance on Implementation of Identification and Barcoding of Medicinal Products for Human Use, Version 1.2" Ankara, 2009. <http://www.clinicaltrial-storage.com/index.php/regulations-in-turkey-menu/89-turkish-drugs-barcode-guidance-v1-2>

⁶ United States Attorney's Office, Southern District of New York. Manhattan U.S. Attorney Announces Charges Against 48 Individuals in Massive Medicaid Fraud Scheme Involving the Diversion and Trafficking of Prescription Drugs. July 17, 2012. <http://www.justice.gov/usao/nys/pressreleases/july12/prescriptiondrugs.html> Accessed July 20, 2012

⁷ United States Attorney's Office for the Middle District of Tennessee. "Three Individuals Indicted For Prescription Drug Diversion Conspiracy". January 24, 2013. <http://www.justice.gov/usao/tnm/pressReleases/2013/1-24-13A.html>