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Allan Coukell, director of drugs and medical devices
The Pew Charitable Trusts

Chairman Pitts, Ranking Member Pallone, and members of the Committee, thank you for the opportunity to provide testimony. My name is Allan Coukell. I direct drug and medical device work at The Pew Charitable Trusts.

Pew is an independent, nonpartisan research and public policy organization dedicated to serving the public.

Based on our analysis of the risks to the drug distribution system and the feasibility of addressing those risks, Pew supports the creation of a strong national system to protect American patients from the risks of counterfeit, stolen and diverted drugs.

The principles I will outline today are supported by other stakeholders, and I ask that a number of statements from consumer, patient, public health and industry groups be included in the record with my written testimony.[1]

There is general agreement on the need for a national system and how it would work. Manufacturers would put a unique serial number on each package of drug; the drugs would be tracked as they pass from hand to hand through the complex distribution system, and could be checked to ensure they are authentic.

This approach would bring us into line with standards in place in other countries and in individual U.S. states. Providing it creates a meaningful advance in safety, a single national system would be preferable to the current patchwork of 29 state drug pedigree laws.

Verification to prevent drug diversion

A recent example demonstrates how verifying a serial number on a drug package could have prevented a significant crime and risk to patients.

In July 2012, the U.S. Attorney for the Southern District of New York charged 48 individuals in a large-scale criminal diversion scheme to buy prescription drugs "on the street" from patients, re-package them and re-sell them back into distribution through licensed pharmaceutical wholesalers, who in turn sold the drugs to pharmacies.[2] The scheme included medicines for

HIV, schizophrenia, and asthma. In some cases, the criminals relabeled the drugs with new, fake labels.

This put patients at risk of counterfeit, outdated or mislabeled drugs. It also cost the Medicaid program in New York an estimated half-billion dollars. Similar schemes in other states are well documented, including one Tennessee in January of this year.[3]

This massive criminal recycling of government subsidized drugs could have been prevented by a serial number on a package. If the serial number was retired after the drugs reached the pharmacy, it would have been caught on its second trip around. Of course, that requires that the pharmacies and wholesalers purchasing the drug check that serial number. Without checking, the same serial number – real or fake – could be sold thousands of times over without detection.

Key elements of a national system

Pharmaceutical manufacturers are already making investments in drug serialization technology. To justify the expense – and the preemption of strong state laws – it is essential that any federal law achieve the following within a reasonable time frame:

- Participation of all members of the supply chain
- Traceability of drugs at the package level (not merely by lot, which includes thousands or tens of thousands of bottles), and
- Routine checking of drug serial numbers.

We have identified widespread support for measures to ensure that all members of the supply chain participate in a national system. In a soon-to-be-released study that Pew conducted with the consulting firm Booz Allen Hamilton, ten manufacturers, ten wholesalers, and eleven pharmacies were asked what features of a national unit-level serialization and traceability system were important to them.[4] 80% of respondents said that all sectors in the supply chain needed to participate, without exception.

As I've mentioned, serialization beginning with the manufacturer and going through to verification by the dispenser is already in place or being implemented in other countries. China, Brazil, Turkey, Italy and the E.U. require (or will soon require) pharmacy authentication of serialized medicines in order to protect their citizens and prevent fraud.[5,6,7,8]

Fortunately, a number of technological advancements, including cloud-based solutions, such as the one used in a 2012 track and trace pilot involving Abbott, McKesson, and the U.S. Department of Veterans Affairs, demonstrate how pharmacies may authenticate drugs and participate in a traceability system through use of a simple web portal.[9,10]

Unit level serialization and traceability

Another 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, to the patient.

A system that tracks drugs by the lot number instead of at the unit level may provide incremental benefit over the status quo, but would fail to catch unsafe drugs in many scenarios. A lot can contain numerous cases of many thousands of individual bottles. Each may be sold separately, and lot-level tracing does not allow industry or regulators to know who bought and sold a given drug during distribution.

Take the example of a product like growth hormone or some other performance enhancing drug, or of a drug in shortage, that investigators discover is being sold in the grey or black market. Without unit-level traceability, there is no way to know which pharmacy, hospital or clinic may have possessed the products or had the inventory "leak".

Today some companies are required to track a drug's transaction history through paper "pedigrees". An electronic system would be a welcome replacement to this paper-based paradigm; however, Congress should certainly not replace pedigrees, which are used by regulators and law enforcement, with a structure that does less to capture chain of custody than today's system.

Routine checking of drug serial numbers

Regular checking of drug serial numbers by supply chain partners is a powerful way to ensure illegitimate products do not enter the distribution system and reach patients. In addition to preventing drug diversion, routing checking could also help the supply chain catch stolen and counterfeit drugs that criminals attempt to sell as legitimate products.

One example is the 2009 theft of 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. Some of the stolen medicine 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. But only 2 percent of that stolen inventory was ever recovered.[11,12]

In another case, thieves stole $75 million worth of pharmaceuticals from an Eli Lilly warehouse in Connecticut.[13] Early last year those stolen drugs were discovered stored in South Florida.[14] Had they been sold back into distribution no automated system would have flagged them for a pharmacy or wholesaler as stolen.

Counterfeits are another risk. Three times in a little more than a year, the FDA has announced the recovery of counterfeit Avastin® – a critical drug used to treat several types of cancer. In one of these cases, the supply chain included a licensed wholesaler in Tennessee. While we don't

have full details about which members knew, or should have known, of the bogus product, the very existence of the fake drugs shows we can't be sanguine about the risks. Similarly, 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.[15,16,17] EMD Serono, 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.[18] Serono's program is an example of how drug distribution security can, and should, be improved.

Conclusion

I thank the Committee for holding this hearing and for its commitment to this issue. I also thank you for a discussion draft released this week. However this legislation, while it acknowledges the problem, does not offer a solution that will create meaningful protections for patients and does not address the comments that industry, patient, consumer, and public health groups made when Congress was contemplating this issue last year.

Congress first tried to address the kinds of risks I've been describing 25 years ago, through the Prescription Drug Marketing Act—a law that has never been fully implemented. Two years from now, California's comprehensive drug serialization law will begin to take effect. The opportunity today is great. We urge this committee to pursue a strong federal system that creates meaningful protections for patients.

Thank you again for the opportunity to testify, and I welcome your questions.

References

[1] These groups include the American Society of Radiation Oncology; the Cancer Support Community; Children's Cause for Cancer Advocacy; Fight Colorectal Cancer; International Myeloma Foundation; Kidney Cancer Association; the Leukemia and Lymphoma Society; National Coalition for Cancer Survivorship; National Lung Cancer Partnership; Ovarian Cancer National Alliance; Pancreatic Cancer Action Network; Prevent Cancer Foundation; Sarcoma Foundation of America; Susan G. Komen for the Cure Advocacy Alliance; Us TOO International Prostate Cancer Education and Support Network; the American Public Health Association; the Association of State and Territorial Health Officials; the National Association of County and City Health Officials; the Trust for America's Health ; Center for Medical Consumers ; Community Catalyst; Consumers Union; National Consumers League; National Research Center for Women & Families; National Women's Health Network; U.S. PIRG; WoodyMatters, along with , EMD Serono and Hewlett Packard.

[2] 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

[3] 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

[4] Ten pharmaceutical manufacturers include five branded small molecule, one generic small molecule, three biopharmaceutical, and one contract packager. Ten pharmaceutical wholesalers include a range of business sizes, including one major national wholesaler. Eleven pharmaceutical dispensers include eight hospital pharmacies, one chain retail pharmacy, one independent pharmacy, and one mail-order pharmacy

[5] 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.

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