

**Testimony before the  
House Committee on Energy and Commerce, Subcommittee on Health  
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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.

**Risks to the drug distribution system**

One of Pew's 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. 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. 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. Finally, we have incidents of outright counterfeits reaching unsuspecting American patients. Just weeks ago cancer patients in the U.S. were exposed to counterfeit Avastin® – a critical chemotherapy agent used to treat numerous types of the disease.

**A national serialization and traceability system to secure distribution**

The United States lacks a standard system for companies to keep track of our pharmaceuticals during distribution. Congress is now considering a proposal from the Pharmaceutical Distribution Security Alliance. While we support a number of elements of the PDSA proposal, 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 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 which may be sold separately. Tracking by lot 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.

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.

**In conclusion**, 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.