

**United States House of Representatives Energy and Commerce Committee  
Subcommittee on Health**

**Hearing on FDA User Fees 2012: Issues Related to Accelerated Approval, Medical Gas,  
Antibiotic Development and Downstream Pharmaceutical Supply Chain**

**Testimony of Timothy Davis, Independent Pharmacist and Member of the National  
Community Pharmacists Association**

**March 8, 2012**

Chairman Pitts, Ranking Member Pallone, and Members of the Subcommittee: Thank you for conducting this hearing and for providing me the opportunity to share my views and perspective as an independent pharmacist on the issue of securing the pharmaceutical supply chain.

My name is Tim Davis of Beaver, Pennsylvania. I am the owner of the Beaver Health Mart Pharmacy and have been a practicing pharmacist for twelve years. I am here today representing the National Community Pharmacists Association (NCPA), which represents the pharmacist owners, managers and employees of more than 23,000 independent community pharmacies across the United States. These pharmacies provide about 40 percent of all community-based prescriptions.

It is my belief that the current pharmaceutical supply chain in the United States is safe and secure. I believe that today most practicing pharmacists have a heightened awareness of the possibility of counterfeit or diverted drugs in the supply chain, and therefore recognize the critical importance of purchasing medications only from trusted wholesalers or trading partners. In addition, most pharmacists today make a concerted effort to carefully examine and make note of drug packaging and the appearance of the drug itself to be sure that there are no suspicious anomalies.

In the past, it has been my observation that certain types of prescription medications were likely candidates to be the target of counterfeiters or “bad actors” in the supply chain. High dollar medications that can be easily produced and readily sold generally enable counterfeiters to create an attractive profit margin. Low-cost generics are typically not a target for this type of activity, and now almost 80 percent of all prescriptions are dispensed with generics. Some drugs that I have seen that are particularly susceptible are lifestyle drugs, such as Viagra or Cialis, as well as a number of very expensive injectable medications such as Procrit or Lovenox.

That being said, NCPA does believe that there are a number of different approaches or tactics that could be employed to assure pharmaceutical integrity. These strategies could include national, uniform federal license standards for wholesale distributors and logistics providers, increased oversight or security measures to deter pharmaceutical cargo theft and potentially some form of tracking for prescription drugs.

### **National, Uniform Federal License Standards for Wholesale Distributors and Logistics Providers**

As a result of greater oversight by states of their drug wholesale distributors, many of the bad actor wholesalers have already been eliminated from the marketplace. However, as part of a comprehensive approach to supply chain security, or perhaps as a stand-alone proposal, NCPA recommends that national, uniform, federal license standards for wholesale distributors and logistics providers (3PLs) also be developed. At the present time, wholesale distributors are licensed at the individual state level, which has resulted in a patchwork of conflicting requirements of varying rigor.

By setting a high bar for wholesale distributors nationwide, we could further safeguard the supply chain by making sure that only appropriately credentialed and legitimate entities are able to participate in the drug distribution aspect of the pharmaceutical supply chain. These new federal standards would preempt existing state requirements, although the individual states would still certify compliance with the federal standards and register wholesalers for an appropriate fee.

As I mentioned earlier in my testimony, the relationship between the community pharmacist and his or her wholesaler is one of critical importance. Most independents only purchase from a single primary wholesaler, but they also have other reputable sources of supply if the primary wholesaler doesn't stock or runs out of the product. Raising the standards for wholesaler licensure in a uniform fashion would provide the community pharmacist at any location in the United States with an additional layer of confidence in the integrity of the medications purchased from such companies.

### **Other Measures to Secure the Supply Chain**

There are a number of other related measures that are currently being proposed, both in stand-alone proposals as well as in a number of comprehensive approaches that could also further secure the pharmaceutical supply chain. For example, S. 1002, *The Safe Doses Act*, would expand the penalties for pharmaceutical cargo theft.

In addition, H.R. 4095, the *Online Pharmacy Safety Act* would create a publicly available “white list” of legitimate internet pharmacies to be managed by the FDA or its contracting organization. This list would help educate consumers and crack down on the “rogue” internet pharmacies that currently exist and are used by consumers looking for “bargain” prescription medications.

### **Pharmaceutical Distribution Security Alliance and Use of RxTec Act**

NCPA is currently a member of the Pharmaceutical Distribution Security Alliance (PDSA), a working group comprised of representatives of all sectors of the pharmaceutical supply chain that has been collaborating on a comprehensive proposal to address supply chain security issues. This proposal, the RxTec Act, is currently in draft form; however it includes language that would create a “registry” of legitimate on-line pharmacy websites, increased penalties for counterfeiters as well as the tracking of prescription medications at the lot level.

The tracking of prescription drugs through the supply chain is a topic that has been discussed for a number of years. Independent community pharmacists have had significant reservations in the past due to concerns about the cost of the hardware and software that would be required to set up such a system as well as the significant time and labor costs associated with it. This is a complex issue because of the integrated technologies necessary to implement it. In addition, each of the sectors involved in the supply chain operate under completely different business models and vary greatly in terms of financial resources and technological capabilities and sophistication.

Independent community pharmacies are largely small business owners, many of whom are single store owner or operators. Unlike our chain counterparts, we do not have a “corporate” office to rely upon with regard to operational upgrades or have a surplus of staff. Any system that would require pharmacists to individually “scan” each item would create a burdensome and time consuming exercise that would further limit the amount of time a community pharmacist has to provide actual patient counseling and other activities necessary to keep the pharmacy up and running. For these reasons, NCPA has in the past, and continues to be, opposed to electronic tracking systems that would require the pharmacist to individually “scan” each prescription drug unit that arrives from the wholesaler into a pharmacy’s stock.

It is important to note that the implementation of a tracking system would not necessarily alleviate or “fill in” all of the potential gaps in the pharmaceutical supply chain; however, such a system could serve as a useful tool to strengthen the chain and assist in FDA investigations and recalls.

As mentioned earlier, NCPA has been participating in the PDSA coalition and one element of that coalition's proposal provides for the tracking of prescription medications at the lot level. The proposal specifies that the encoded information on each finished prescription drug unit must be in both machine readable and human readable form. The proposal would also enable independent community pharmacists to rely upon the records of their trusted wholesaler if needed and agreed to by both parties, to confirm or double check the lot numbers in question.

## **Conclusion**

On the front lines of patient care, community pharmacists take seriously their responsibility to remain vigilant against counterfeit or diverted drugs. One way that we currently do this is to buy products only from trusted trading partners, remain alert to packaging and medication appearance anomalies, and follow all manufacturer alerts and recalls. Diverted or counterfeit drugs often enter the supply chain as a result of pharmaceutical cargo thefts and illegitimate on-line drug sellers. In addition, under the current laws in effect, counterfeiters stand to reap enormous profits from their illicit activities while the legal penalties associated with the activity are not rigorous enough to serve as any type of deterrent. Any strategy or plan to tighten up the supply chain must be a multi-pronged approach, with the understanding that any one measure by itself is not sufficient to realize a discernible improvement.

As a practicing community pharmacist today, I personally have a greater degree of confidence in the United States drug supply than I did just a few years ago—largely due to the heightened awareness of those in the supply chain to the possibility of counterfeit or diverted medications. That being said, community pharmacists take seriously our role in ensuring the safety of the medications that we personally dispense to our patients and we remain committed to working with our colleagues in the supply chain—other pharmacy organizations, wholesalers and manufacturers—as well as with state and federal authorities to make any needed improvements. Moving forward, it is essential that all stakeholders make a concerted effort to keep the lines of communication open so that consumers can continue to implicitly trust the integrity of the medications that they depend upon.

I appreciate the opportunity to address the Subcommittee today and would be happy to address any questions that you may have. Thank you.