**United States House Energy and Commerce Committee**

**Subcommittee on Health**

**Hearing on "Securing Our Nation's Prescription Drug Supply Chain"**

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

**April 25, 2013**

Chairman Pitts, Ranking Member Pallone and Members of the Committee:

Thank you for conducting this hearing and for providing me the opportunity to share my views and perspective as an independent pharmacist and small business owner on the issue of securing the pharmaceutical supply chain. My name is Tim Davis of Beaver, Pennsylvania. I am the owner of Beaver Health Mart Pharmacy and have been a practicing pharmacist for 12 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 United States pharmaceutical supply chain is largely safe and secure. Most practicing pharmacists today have a heightened awareness of the possibility of counterfeit or diverted drugs and therefore recognize the critical importance of purchasing medications only from trusted trading partners or wholesalers.

In addition, pharmacists, as an integral part of their training and day to day practice, are taught to carefully examine and make note of both the drug packaging and the appearance of the drug itself to be sure there are no suspicious anomalies.

It has been my observation that certain types of prescription medications tend to be the target of counterfeiters or "bad actors" in the supply chain. Relatively expensive drugs that can be easily produced and readily sold enable counterfeiters to create an attractive profit margin. Some drugs that I have seen that are particularly susceptible are lifestyle drugs, such as Viagra, as well as very costly injectable medications such as Procrit or more recently Avastin, that are not always carried in community pharmacies, but rather are dispensed through consolidated specialty pharmacies, health systems, or directly by physicians. In my career, I have seen one example of counterfeiting at a local level. We received manufacturer information that a particular drug, Procrit, had entered the drug supply chain in counterfeit form and we were instructed how to recognize the genuine product against the fake. Upon receipt of a daily shipment from our local wholesale distributor, we checked and found that an item that we received was indeed one of the counterfeit products. We immediately contacted and discussed the situation with our wholesaler. Our particular solution was actually to stop doing business with that wholesaler due to the lack of a believable and reliable response.

In response to concerns about the safety of prescription medications in the United States, over half of the states have passed "drug pedigree laws" that require drug products that move outside of "normal distribution" to be accompanied by a "pedigree" or record of prior transactions. However, this approach and the differences in each state's laws has created a "patchwork" of varying pedigree laws across the United States. Federal policy makers and supply chain participants alike have been discussing what a possible federal system to provide further assurances of supply chain security would look like for a number of years but due to the widely varying business models, financial resources and technological capabilities of those involved in the pharmaceutical supply chain, the process has not yielded a coherent, comprehensive national proposal yet on the federal level.

In the past, there have been numerous discussions about the practicality of a system that would track prescription drugs at the individual unit level. Pharmacists have had significant concerns about any system that would require each individual unit of medication to be electronically "scanned" upon arrival in a pharmacy due to the capital outlays that would be required and the time and labor costs associated with such a system. At the present time, the technologies that would be required to implement such a system are not fully developed and have not been designed or scaled to be feasible or affordable for use in individual community pharmacies.

Of great concern is the California “e-pedigree” law that will begin to be implemented for manufacturers in 2015 that will require the electronic tracking and tracing of all drug product packages, in real-time, in the drug distribution supply chain at the individual unit level through “electronic pedigrees” in an interoperable system. This well-intentioned system will require each individual participant in the supply chain to scan each individual item that will capture the transaction information. With each successive distribution, the e-pedigree must be updated with the new transaction data so that the e-pedigree continually grows as it makes its way to the pharmacy. In short, pharmacies will have the unenviable task of maintaining all drug pedigree data for all distributions above them and must be able to access it at any time. With the billions of drug product packages distributed, there will be billions of e-pedigrees and e-pedigree data that must be maintained and accessible—a massive amount of data. In addition, pharmacies must then pass back this information for each drug return.

The cost of compliance with this law will be extremely high especially for small community pharmacies—when factoring in both initial implementation and ongoing expenses necessary to maintain and access the data. Imposing these challenges particularly on small business supply chain participants like community pharmacies is not logical at a time when the nation is focused on trying to reduce the costs of healthcare.

All of these factors bring us to a place in which we need a uniform, federal framework to provide further assurances of supply chain security and that could be used to assist the FDA and other federal regulators in instances of recalls and other investigations. We need a reasonable, commonsense federal approach that will strike the appropriate balance between enhanced patient safety and minimizing unreasonable burdens on supply chain stakeholders, particularly small business pharmacies like myself.

NCPA is a member of the Pharmaceutical Distribution Security Alliance (PDSA), a working group comprised of representatives of all sectors of the pharmaceutical supply chain, which has been collaborating over the past year and a half to address supply chain security issues. The group has reached consensus around a number of different concepts. One of these concepts is that of establishing national requirements for wholesaler licensure standards. At the current time, there are some states in which the requirements necessary to obtain licensure as a drug wholesaler are less rigorous than others.

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. The second concept is that of attaching a unique identifier to prescription drugs at the unit and case levels. Products would be identified at the unit and case level with a two dimensional matrix bar code including the serial number (SNI), lot number and expiration date for the product in machine and human readable form.

Once a product is serialized, this would essentially pave the way for all supply chain partners to eventually be able to use this data in increased ways and to be able to collaborate with one another to more easily locate particular products that may have been compromised in some way. The PDSA coalition has built consensus around being able to use the unique identifier information to track products at the lot-level. NCPA is pleased to note the inclusion of all of these consensus points in both the recently released House Discussion Draft and the Senate Discussion Draft. NCPA believes that the proposed lot-level system is one that could be built upon at some point in the future if it was determined that this was advisable and if there were significant inroads made on the associated technologies so that it would not be prohibitively expensive or burdensome for small business pharmacies.

I 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 medications that we personally dispense to our patients and remain committed to working with our colleagues in the supply chain 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 trust the integrity of the medications that they depend on.

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

Thank you……