

United States Senate Commerce, Science, and Transportation Committee

Testimony for:

“Short Supply Prescription Drugs: Shining a Light on the Gray Market”

July 25, 2012

Chairman Rockefeller, Senator Boozman, and Members of the Senate Commerce Committee. I am John Coster, Ph.D., R.Ph., Senior Vice President of Government Affairs for the National Community Pharmacists Association. I am a licensed pharmacist in the states of New York, Maryland, and Virginia. Thank you for conducting this hearing and for allowing us to submit our views on this very important and timely issue. NCPA represents the owners and operators of more than 23,000 independent community pharmacies in the United States. Our members provide about 40% of all outpatient prescription drugs in the United States. We are also major providers of pharmacy services to long term care and assisted living facilities. Our members are also prevalent in urban and rural areas.

We appreciate your focusing this hearing on the issues surrounding the shortages of prescription drugs. While most of the drug shortages to date have been experienced by hospitals and other institutional settings for injectable and infusion drugs, many community pharmacies also experience daily shortages of vital prescription medications. In particular, recently there have been critical shortages of medications to treat ADD and ADHD. The newly enacted FDA law will take important steps to help address these types of shortages, as well as require better coordination between FDA and the Drug Enforcement Administration (DEA) on determining and updating the quotas for the production of these medications. We appreciate the bipartisan steps that Congress took to address this shortage situation.

Pharmacies Rely on Combination of Wholesalers

How do community pharmacies manage an inventory of the thousands of drug products on their shelves and handle drug shortages? Pharmacy inventory is a function of many factors, including local prescribing patterns and the patient population served. Pharmacies do their best to efficiently and effectively manage their inventories because drug products are very expensive.

A typical independent community pharmacy has a great deal of capital invested in inventory items, likely hundreds of thousands of dollars. Over 90% of the average independent pharmacy's dollar inventory is tied up in prescription products. However, the last message a pharmacist wants to deliver to a patient standing at the counter is that their drug is not in stock, or worse, is temporarily unavailable.

The relationship between community pharmacists and their wholesale distributors is one of critical importance to manage inventory and prevent shortages. Community pharmacists rely heavily on their wholesalers to ensure that they have the necessary access to virtually all medications at all times in order to ensure that patient needs are met. Most community pharmacists rely on a primary wholesaler to meet the majority of their on-going prescription drug supply needs. However, community pharmacists typically need to have at least one or more "back-up" or secondary distributors that they can call upon in the event that their primary distributor for some reason cannot meet their needs at any particular time.

The term "primary wholesaler" generally describes entities that purchase the vast majority of their product directly from drug manufacturers. This market is highly concentrated, as the "big three" wholesalers generate approximately 85% of all revenues from pharmaceutical wholesaling in the United States. Most manufacturers typically limit the number of entities that they will sell to directly and most do not sell directly to smaller companies that are not interested in purchasing extremely large, bulk amounts

The term "secondary" wholesaler generally describes distributors that do not purchase the majority of their products directly from a pharmaceutical manufacturer. They often play an important role for patients and pharmacies by serving as a "back-up" source of supply to pharmacies who may use a primary wholesaler for their usual and expected day-to-day needs. They also provide necessary competition for the primary wholesalers which helps keep costs down.

Illicit Activities by "Shell" Pharmacies and Gray Market Distributors Unethical

Recently, there have been troubling reports of "shell pharmacies" or "paper pharmacies" that seem to have been established for the sole purpose of buying medications in short supply from primary wholesalers in order to sell them to seemingly unethical secondary wholesalers. NCPA condemns these activities and applauds the Committee for its investigative work in this area. No pharmacy should be in the business of acting as a conduit to facilitate the activities of an illegitimate gray market.

It is our understanding that the Committee's investigation focuses mainly on injectable and infusion drugs that are not typically sold to or dispensed by most community pharmacies. The aberrant purchases by these pharmacies should have been a strong warning signal to wholesalers selling these drugs to these pharmacies that something could be wrong.

How was it that these shell pharmacies could even open and operate in the first place? Typically, state boards of pharmacy conduct an on-site inspection of any new pharmacy; however, sometimes boards may issue a temporary license with the permanent license withheld pending the results of an actual inspection.

Efforts to Curb Unacceptable Practices Should Not Harm Patient Care

Beyond the actions already taken by Congress to address drug shortages in the recently-enacted FDA bill, Congress continues to examine ways to further secure the pharmaceutical supply chain. We support these discussions and want to continue to serve as a resource to Congress on the best ways to achieve these objectives in a seamless, efficient, patient-oriented manner. What current practices allow pharmacies to address shortages of medications to meet patient needs, while managing their inventory?

First, it is in the normal course of business that community pharmacies return outdated or short dated products to wholesalers or distributors, or products that were sent to the pharmacy in error. Pharmacies need a way to return products because of the significant amount of pharmacy capital tied up in these returns. We appreciate that our business partners work with us on taking back these returns, and we urge Congress to continue to allow us to return these products.

Second, at times, where permitted by law, community pharmacies do sell pharmaceutical products to other pharmacies. For example, some state pharmacy practice laws allow retail pharmacies to sell a small amount of their inventory in certain situations. Pharmacies will do this on occasion to alleviate temporary shortages, to assure that patients are able to receive needed drugs, or to assure that “short dated” drugs will not be wasted before they expire. We believe that this is an appropriate practice. This helps to facilitate the functioning of the market and helps to assure timely and appropriate cost effective patient care. This is particularly important in rural areas where daily wholesaler deliveries may be more sporadic.

Finally, some states permit pharmacy sales to wholesalers. These sales are permitted to alleviate a temporary shortage of drugs. In surveying our members, however, we have found very few that hold both types of licenses. Having said that, we think that this situation contrasts with the unethical practices found by the Committee where a pharmacy was knowingly buying short supply inventory it knew it would not use and did not need, with the intended purpose of selling it into the illegitimate gray market.

However, one of the options discussed to address the issues identified by the Committee is a potential prohibition of pharmacies selling drug products to wholesalers. While this would appear to be a logical solution to the problem, we ask the Committee to carefully consider whether this option would have unintended consequences for patients.

Supply Chain Partners Need to Know Their Customers

We would want to work with the Committee to assure that community pharmacies can continue to manage their pharmaceutical inventories, while being able to meet the prescription drug needs of individual patients, including in shortage situations.

For example, NCPA supports the implementation of federal standards for wholesale distributors, as well as a proposed lot-level tracking system for prescription drugs that will make it much easier to keep track of the purchase and sale of pharmaceuticals. Uniformly raising the bar for all entities that wish to engage in this line of business should provide a greater assurance for all participants in the supply chain that they are doing business with a legitimate entity.

In addition, there should be greater emphasis on the importance for all participants in the supply chain to also perform their “due diligence” with respect to their business partners. NCPA currently publishes a manual that provides assistance to pharmacists who are seeking to open their own pharmacy and a portion of this document deals with the selection of a wholesaler or wholesaler(s). The manual includes a list of questions that each pharmacy should ask before retaining the services of any wholesaler. Notably, NCPA also stresses the fact that every pharmacy needs to have more than one wholesaler “because no wholesaler can offer every product that you may need to stock.”

In conclusion, it is necessary for pharmacies to have options to address temporary shortages in the marketplace. We urge Congress to not take actions that might limit the ability of pharmacies to take care of their patients. The primary and secondary wholesaler markets both play an important role in ensuring that all patients have seamless access to virtually any product that they may require.

Having said that, it is unethical for pharmacists to act as a conduit for the illegitimate gray market, which is contrary to the goal of providing the best patient care at the lowest cost. Problems or questionable practices should certainly be investigated and addressed, but any solution needs to be carefully tailored so that the pharmaceutical supply chain is not unduly disrupted and patients do not suffer due to shortages that may occur. We appreciate the opportunity to provide our views to the Committee and I look forward to answering any questions.