United States Senate

Committee on Commerce, Science, and Transportation

Hearing on

“Short-supply Prescription Drugs: Shining a Light on the Gray Market

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Statement for the Record Prepared by:

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Good afternoon, first I would like to thank Chairman Rockefeller, Ranking Member Hutchison and distinguished Members of the Committee for the Committee's strong leadership in addressing the critical problem of short-supply prescription drugs in the supply chain. The record shortage of drugs we are currently experiencing has had an adverse effect on the health and safety of communities across the country, and is a contributing factor to rising healthcare costs.

I am here today to represent the views that the National Coalition of Pharmaceutical Distributors (NCPD) and its members, which are predominantly small and independent pharmaceutical distributors, have regarding the distribution of short-supply prescription drugs and the role that the coalition's members play in distributing the drugs in the U.S. supply chain. The three key issues presented in this discussion are ones that NCPD believes the committee has brought to light for this hearing.

I can offer this insight because I am an expert in the pharmaceutical distribution supply chain, having spent more than twenty-six years in the industry, working with large and small distributors as a senior executive on supply chain management as it relates to hospitals and group purchasing contracts, as well as running distribution centers. My background has resulted in me being called as an expert witness in federal court cases

INTRODUCTION

In recent months, there has been a great deal of controversy and speculation swirling around the entire distribution chain offered by people who do not understand or have first-hand knowledge of how the health care supply chain fits together. The issues raised fit into three basic categories:

1. So-called "price gouging" or mark-ups
2. Several companies being involved in the handling of a product
3. Fake pharmacies

I will address each of these objections in turn, but I wanted to start by helping everyone here understand the various companies involved in supply chain management.

Drug sales and distribution is a complex market with many key players, including "primary" traditional wholesalers, who are members of HDMA, group purchasing organizations – otherwise known as (GPOs), and "secondary" distributors, members of NCPD. All play a vital role in ensuring that quality medicines reach a patient in the safest, fastest and most cost-effective way possible. Small distributors fill a gap in the market, offering versatility and flexibility that primary distributors can't provider while also serving less profitable rural regions of the country.

ROLE OF SMALL DISTRIBUTORS – FILLING A GAP

I cannot emphasize enough the value that small – or secondary – pharmaceutical distributors bring to the health care system. These organizations are there when no one else is – in the middle of the night, on the weekends and in remote parts of the country where no one else wants to deliver because it's not considered profitable. As a result, small distributors help save lives every single day. They save lives by making it their business to ensure that quality medicines reach a patient in the safest, fastest and most cost-effective way possible – no matter the time or location.

Few others can say the same thing.

Their value is so profound that we have email after email from customers – including the NIH – thanking them for the help they have provided to find medicine or deliver it at the last minute to save a life (and at a reasonable price) – a function primary distributors are simply just not geared to perform.

Our members do this work as part of long standing relationships they have with health care providers in which they fill in the gaps when the primary has a drug shortage. The secondary distribution industry primarily serves smaller medical facilities, doctor's offices and pharmacies, many of which are found in rural

or other underserved locations around the country. As a practical matter, large distributors are organized to take advantage of volume sales; therefore, they set prohibitively high minimum monthly purchasing requirements for a health care provider to have an account with them and they organize their supply network around major population centers, where they are more likely to find facilities that meet their minimum requirements. They are not well suited to cost-effectively distribute medication to more remote locations.

This is where secondary distributors come in. Hospitals, health care centers and pharmacies in rural locations and those too small to meet the minimums of large distributors rely on secondary distributors to fill critical needs for life-saving medicine. What's more, every sector of the health care industry depends critically upon secondary distributors because they act as the safety-net in times of national shortages to secure and distribute scarce drugs in short supply.

While they are crucial in getting life-saving drugs to critically ill patients, small distributors are on an individual basis, one of the smallest customers of “traditional” wholesalers. These same wholesalers do billions of dollars of sales to large hospitals, but will not supply smaller clinics and facilities. In addition, small distributors are required to pay the highest acquisition cost offered in the U.S. supply chain, putting them at a competitive disadvantage.

Despite their value, small, secondary distributors have come under fire recently because few people really understand them or have taken the time to see where they fit in the supply chain. The arguments have ranged from accusations of price gouging to shifting product between multiple companies as a means to increase profits to working with fake pharmacies.

These allegations are little more than character assassinations and are not grounded in reality. What's more, these characterizations fail to reflect one basic fact of this market: There are thousands of small distributors that work with hospitals across the nation. To remain competitive, they must comply with all laws, follow pedigree and handling requirements to the letter and still offer an economical price point that allows for only a modest profit margin. If they do anything else, they run the risk of permanently losing a customer.

That's because hospitals comparison shop. If they don't like a price offered by one company, they will call another.

This is a reality that every small distributor out there is well aware of. And they know that if they were to engage in the types of activities you accuse them of, they would not be in business very long.

As you learn more about this industry you will see that the activities you are trying to paint as nefarious actually have legitimate and reasonable explanations:

1. SO-CALLED "PRICE GOUGING" OR MARK-UPS:

Drug prices are established on an intricate system that is far more complex than most free markets. Manufacturers set a number of price points for a product, including the Wholesale Acquisition Cost – or WAC – which is the lowest price at which a wholesaler or distributor can buy the product. As with many markets, hospitals and physicians can negotiate the price they are willing to pay for a drug. The more product a hospital or doctor expects to use, the more power they have in securing to negotiate a lower price. Neither large nor small distributors have the ability to influence drug price negotiations. To secure the best prices for patients, most hospitals belong to one of the major GPO’s, which leverage the strength of the collective buying power of their members when negotiating contracts with manufacturers. GPOs require hospitals to adhere to specific rules, such as select a primary wholesaler – generally one of the Big3: McKesson, Cardinal or AmerisourceBergen -- and if their primary does not have a drug, they are prohibited from using another primary. Instead, they must contact their second-line – or “secondary – distributor to supply their needs. Secondary distributors are able to work with all of the primary wholesalers, plus their network of small distributors to locate and secure drugs, even those that are in

short-supply. Because small distributors are not restricted by GPO contracts, they are able to use avenues that hospitals cannot, such as large distributors that compete with the hospital's primary wholesalers.

Small distributors have been inaccurately portrayed when it comes to the price of products. As I noted before, secondary distributors pay the highest prices for drugs in the entire U.S. supply chain – sometimes as much as 91 percent more than one of the Big 3 would ultimately pay for the same product. What's more, many people will look at a pedigree and compare the cost a distributor paid for a drug to the price he sold it for and assume the entire amount was pocketed as profit. That's the furthest thing from the truth. The reality is that the pedigree does not show how much was spent on things like shipping, which can be much more expensive than the drug itself if the hospital needs it delivered overnight.

As I said before, every small distributor knows that the hospitals they work with are going to comparison shop. If a hospital doesn't like the price that one secondary distributor quotes to them, they will call another. Or, if they need it right away and can't risk losing it, they will buy it, but will find another secondary distributor to work with moving forward. When it comes to working with secondaries, health care providers do not face the restrictions they do with the Big 3. They are free to move their account elsewhere, so secondary distributors have to remain competitive and will often sacrifice their own profit margins to make sure they keep a customer.

2. NUMBER OF COMPANIES INVOLVED IN DISTRIBUTION OF A SINGLE PRODUCT

We are all aware, Mr. Chairman, that you are in possession of a handful of pedigrees that show multiple distributors handled a product before it made its way to a patient. While I cannot defend these pedigrees specifically because I do not know the circumstances that led to this situation, what I can say is that these incidents are anomalies. Our members work tirelessly to make sure that the route from distributor to customer is as straight as possible. No detours, no additional mark-ups, no changing of hands multiple times. Why? Because our members are concerned about making sure the products get to those who need it as fast as possible, and because they know that they face stiff competition. Even when a drug is in a shortage situation, more than one distributor will still be able to get it, and hospitals comparison shop – looking for new ways to get the product at a lower price.

So, for every one pedigree you can find that shows multiple touch points, we have literally thousands of pedigrees that show a straight line in which only one or two distributors were involved with only a nominal profit realized. In fact, one distributor that I work with handles 1.2 million pedigrees every year – enough to stretch more than 680 miles if laid end-to-end. And that's just one distributor. The handful that you have shown would not even equal one-tenth of 1 percent of what the number of products he handles every single year.

His focus – and the focus of all of our members – is to provide much-needed products at the most competitive price they can while still making a modest profit. If they did anything else, they would be out of business very quickly.

3. FAKE PHARMACIES

Under law, pharmacies are allowed to sell a small portion – 5 percent or less – of their inventory to distributors, as long as they comply with state regulatory requirements. In most cases, pharmacies take advantage of this law to sell drugs that will expire within 90 days that they do not believe they can dispense in that timeframe. Instead of letting them go to waste, many pharmacies will sell the products to an authorized distributor – both small, independent companies, as well as large wholesalers – at a discounted rate. The authorized distributor, in turn, will sell it to a hospital, medical clinic or physician office that can use it immediately.

Ultimately, this practice is a win-win – drugs don't go to waste, pharmacies don't lose large quantities of money on products that are expiring and providers are able to get pharmaceuticals at a discounted rate. This is a legitimate and necessary practice, and is not a fake pharmacy.

Unfortunately, there is a small group of people out there who have discovered this and have set up a few "fake pharmacies" across the nation. Fake pharmacies are those that buy and sell pharmaceutical products, but do not actually dispense drugs to patients. Let's be clear here – dispensing pharmacies that exercise their right to sell a small portion of their inventories are legitimate. Only those that do not dispense drugs are fake pharmacies.

It is the position of the NCPD that fake pharmacies are detrimental to the integrity of the entire health care supply chain. The coalition and its member companies constantly looking for companies operating in the black market and report any company they believe is operating a fake pharmacy.

Further, it is the position of NCPD that legitimate pharmacies that sell a small portion of inventory into the supply chain are working to ensure that every drug in the supply chain is available to people in need and these operations should not be under scrutiny.

ROLE THAT NCPD MEMBERS PLAYED IN DISTRIBUTING SHORT-SUPPLY DRUGS

Much activity has driven these secondary relationships that have been the realities for the pharmaceutical supply chain during this period of increasing short-supply of critical drugs. One of the practical circumstances that have fed the expansion of these relationships in the secondary distribution industry is the fact that this industry of small suppliers primarily serves as a safety-net or back-up supplier to all hospitals, both large and small in the U.S. Add to that, the fact that this industry is the primary supplier of all drugs to smaller medical facilities, doctor's offices and pharmacies. Despite their crucial role in getting life-saving drugs to critically ill patients, they are also on an individual basis, one of the smallest customers of the "traditional" wholesalers that do billions of dollars of sales to these large hospitals and are required to pay the highest acquisition cost offered in the U.S. supply chain. As a practical matter, every sector of the healthcare industry depends critically upon secondary distributors due to the fact that they act as the safety-net in times of national shortages to secure and distribute scarce drugs in short supply.

During the protracted recent drug shortages, customers of the Big 3 wholesalers were placed on product rationing based upon historical purchase volumes. For the secondary distributors, who may by necessity have much smaller average monthly purchase volumes, this often meant receiving only a handful of items each month under rationing process – certainly not enough to satisfy the demands of the smaller facilities who depend upon the secondary distribution industry. Importantly, it also meant that secondary distributors were unable to meet the monthly purchasing minimums required to maintain a Big 3 account (not to mention those direct manufacturer accounts with similar minimums). The Big 3, other large ADR distributors and many manufacturers used the inability of secondary distributors to meet these minimums as the justification for broadly terminating or closing secondary distributor's accounts during 2010, 2011 and 2012. The real impetus underlying these terminations, however, appeared to be a desire of these larger entities to distance themselves from the widespread negative publicity about secondary distributors that had been engendered by the media and other's false and misleading report alleging "price gouging."

Despite losing their primary Big 3 accounts, the primary customer base and their loyal, secondary customer base continued to need critical medications to treat their patients. As a result secondary distributors found themselves clamoring to develop new supplier relationships that could replace the loss of their Big 3 accounts and ensure that these medications continued to be available for the health and welfare of underlying patients. These practical realities, as much as anything, drove increasing use by the secondary distribution industry of accepting short-supply drugs from multiple distributor links reflected on a small number of pedigrees that have surfaced during this committee's investigations. However, given that these secondary suppliers do thousands for transactions per month leading to hundreds of thousands on annual basis, only a handful of these transactions seem to have been outside their normal distribution channels that in reality are pedigreed from the manufacturer…to an ADR wholesaler…to a distributor…to another distributor…and ultimately to the end dispenser.

DOING THE RIGHT THINGS

Many of the assertions made in recent reports include activities that are illegal and would cause a small distributor to lose its license, but more importantly would cause them to lose their loyal customers that support the business model of their entire segment.

The NCPD members have stayed in business for the last 20 to 30 years (and even longer for some) because they bring a valuable service to their loyal customers. They know if they are perceived as "price gougers" and "profiteers", they will not get repeat business and their goals depend on that customer coming back to them month-in and month-out, not just in times of drug shortages. Again as a practical analysis of this segment would show, primary wholesalers guarantee to supply 98% of the non-backordered products 98% of the time, not 100%. Therefore, the business model for secondary distributors depends on them doing the right things, at the right times and keeping their customers coming back every month.

If the implications that these companies routinely charge prices that are in excess of their usual and customary cost of the drugs plus a mark up that covers their higher cost of ordering, receiving, handling, packaging, shipping and special delivery that equates to their business model based on price gouging and profiteering, they would not have repeat customers – nor would NCPD be standing here today defending that practice.

What we are saying is that drug sales and distribution is a complex market with many key players and at times on the surface, an analysis will find the anomalies, the special circumstances where higher mark-ups were passed from one distributor to another or a cost averaging model is used to achieve an average net profit on all items in certain categories. These selected examples are just samplings that reflect an example of what happens in a situation where a reaction to supply and demand rarely has anything to do with suppliers taking advantage of customers, but more to do with reacting to market conditions that included rationing, loss of access to products from normal supply chain and finding a solution to getting a critically needed product to fill a high demand request of a hospital that had a patient in life-threatening situations.

NCPD represents the interests of small and independent reputable distributors. All member distributors go through a thorough background check and must meet all licensing standards. The NCPD and its members condemn all drug distribution activities conducted by "gray market' distributors including stealing and selling drugs, setting up "fake" pharmacies, buying back drugs and reselling them, stockpiling drugs that are needed, and gross "profiteering." The NCPD is actively and aggressively lobbying in support of the most comprehensive and stringent federal pedigree standard for the industry. As part of this, the NCPD has pushed for enhanced licensure standards and penalties for all distributors who fail to comply with laws and standards.

The NCPD recommends that hospitals work with their trusted secondary distributor to fill needs that primary distributors may not be able to provide and to report offers from a distributor they do not know or medicine that is offered at priced well below or well above that offered by other distributors to regulatory agencies.

Thank you Mr. Chairman, Ms. Ranking Member and members of this committee.