

Testimony by Karen L. Moody
President
National Coalition of Pharmaceutical Distributors
Before the United States Small Business Administration
Regulatory Fairness Hearing
March 12, 2008

I'd like to thank National Ombudsman, Nicholas Owens and the Small Business Administration for inviting the National Coalition of Pharmaceutical Distributors to testify again this year at the second Annual National Regulatory Fairness Hearing. It is truly an honor and a privilege.

My name is Karen Moody, President and Founding Member of the National Coalition of Pharmaceutical Distributors (the NCPD). I am here today to represent the 4500 small, independent pharmaceutical distributors that will be, and have been, impacted by the previous year's announcement by the FDA in the summer of 2006 to lift the 20-year stay on the pedigree rule of the Pharmaceutical Drug Marketing Act (the PDMA).

As you may recall, the PDMA was written in 1988 to regulate and secure the pharmaceutical supply chain. Since its inception, NCPD supports and works diligently to facilitate the intentions of Congress and applauds all of those actively participating in helping to make the pharmaceutical supply chain secure and safe for consumers across the country.

The pedigree rule of the PDMA, as originally written as well as with the various amendments and modifications made throughout the 20 years since its enactment, was never implemented and has repeatedly been considered unworkable. Even the FDA, as they interpreted it, acknowledged in 2001 that the pedigree rule created an unfair advantage to large wholesalers and threatened the very existence of the small or secondary supplier.

To review, the PDMA requires that a pedigree be passed by distributors or wholesalers documenting the lineage by creating a paper trail of a pharmaceutical from the manufacturer to the dispensing entity. The PDMA creates two distinct categories of

distributor: the authorized distributor of record (the ADR) and the non-authorized distributor (the non-ADR).

Historically, the only difference between the ADR and the non-ADR was simply that the ADR purchases directly from the manufacturer and a non-ADR purchases from the ADR. The two categories were created by the manufacturers to streamline their distribution partners, thereby decreasing expenses and at the same time, increasing various efficiencies internally. Typically, the manufacturers have chosen the larger distributors capable of meeting bulk-purchase minimums and product breadth and depth and encouraged small distributors to buy from their ADR's, often refusing to open accounts with small distributors or secondary suppliers or by setting contractual parameters that they could not meet.

The PDMA pedigree rule exempts the ADR, who distributes approximately 90% of all the country's pharmaceuticals, from having to pass a pedigree. Only the non-ADR, responsible for less than 10% of pharmaceuticals distributed, is regulated by the rule.

This exemption creates two major problems. First, and most importantly, the exemption leaves a hole in the distribution chain of pharmaceuticals the size of 90%, exposing the majority of pharmaceuticals consumed to counterfeiting and adulteration since no accountability or regulation would be required. Less than 10% of pharmaceuticals distributed would have the security of documentation of authenticity.

Secondly, with the exemption made to all ADR's, the supply of pharmaceuticals to the small distributor is cut off. Secondary distributors can obtain pharmaceuticals from their ADR's but cannot legally resell them without a pedigree. The pedigree must originate from the source that purchases from the manufacturer...the ADR. The creation and overall process of the pedigree is expensive and laborious. The ADR has no incentive to pass a pedigree to the secondary distributor. The expense of generating pedigrees for the non-ADR's exceeds that of their potential generated revenue.

During the summer of 2006, the FDA made the announcement that the stay on the pedigree rule of the PDMA was to be lifted in less than six months. This announcement came as a tremendous shock to the entire industry since there was no warning or indication that, after 20 years, this flawed law that has had no modifications since 2001, was going to be enforced.

Fortunately, in December of 2006, just days before the stay on the pedigree rule was to be lifted, through the swift actions of many small distributors and organizations, the stay was temporarily put back into position. Implemented through injunctive relief in Federal court in New York, this stay was reinstated with two specific criteria being met: 1.) the presiding judge cited the likelihood of irreparable harm coming to the secondary

distribution industry; 2.) the likelihood of the FDA rule being ruled unconstitutional and the underlying lawsuit prevailing against the FDA.

Early in 2007, the FDA filed an appeal to the court-imposed injunction on the proposed pedigree rule. This appeal is still pending before the court and a time for its consideration has not been established.

Prior to the FDA's attempt to lift the stay, all pharmaceutical distributors were represented by large wholesale organizations and manufacturers. The small distributor never had a voice of its own and therefore, there was little to no knowledge of our existence on Capitol Hill. Since 2006, NCPD has been that voice.

Over the past year NCPD, as well as many other interested parties and stakeholders, has made a concerted effort to help educate Congress of the integral role that the secondary supplier plays in the distribution of the United States' pharmaceuticals and how the PDMA pedigree rule, as it is interpreted by the FDA, would have no impact on the security of the pharmaceutical supply chain.

Secondary distributors, also known as specialty or independent distributors established themselves in the pharmaceutical distribution market by fulfilling a void created by the larger wholesalers. Small doctors' offices, urban clinics, home care facilities, small pharmacies and military installations incapable of meeting the financial minimum requirements set by the larger wholesalers or that have special client needs are supported by the specialty distributor. These niche-oriented distributors have built their business model based on the very specific needs of their customers and support them in a way for them to flourish.

Whether by design or coincidence, during the year following the injunction, approximately half of the states have independently adopted the PDMA or a version of the PDMA pedigree rule. Mimicking the rule, the secondary suppliers are, again, the only group of distributors that are required to pass a pedigree. For the secondary supplier, the PDMA pedigree rule is no longer conceptual; it is a reality that all national, small distributors deal with every day in 50% of the states. Businesses have suffered to dramatic realities. Many have succumbed to the inequities of the law and have been forced to shut their doors. Many are down to the bare bones of existence because of the exemption to the ADR to pass pedigree. Florida, the first state to adopt laws similar to the PDMA, reported approximately 2000 registered wholesalers prior to PDMA- like laws being implemented. Today, there are less than 200. My own company, Atlantic Biologicals, has downsized by 50% since the first of 2007, corresponding with our revenue for the year.

The entire secondary distributor industry has united. Working together and continuing to impress the significance of our role on Congress, both on a State and Federal level, that the interpretation by the FDA of the PDMA pedigree rule would, in essence, eliminate all regulation and security of the pharmaceutical supply chain as the only sector presently passing pedigree would be exterminated as a result of the rule. There would be no regulation and no accountability for 100% of pharmaceuticals distributed throughout the country.

Congress, in recognition of the misguided pedigree rule developed out of the misinterpretation of existing law by the FDA, is presently considering several existing and draft pieces of legislation in both the House and Senate. On a state level, many concerned states are also drafting alternate language as well as participating federally to rectify the issue and to pass a bill expressing the original intent of Congress; to secure the integrity of the pharmaceutical supply chain while enabling the small distributor to flourish.

The FDA, as a stakeholder, has also participated in discussions in both the House and Senate in the formation and language of these bills. However, the FDA is maintaining the PDMA pedigree rule as proposed although they support the House and Senate bills. If the FDA is not contesting these bills, that so differ from the PDMA pedigree rule, then why has the FDA continued to maintain the PDMA pedigree rule through Federal Court with appeals?

On behalf of NCPD and the entire secondary distributor industry, I respectfully request and implore the SBA to use whatever influence it has to urge the FDA to withdraw its appeal in Federal Court and continue to support their activities as in recent months on Capitol Hill and with Congress to pass a bill that secures the pharmaceutical supply chain and allows the small distributor to exist.