

United States of America

Before the

**Subcommittee on Regulatory Reform and Paperwork
Reduction**

of the

Committee on Small Business

United States of House of Representatives

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June 8, 2000

I am Sal Ricciardi, President of Purity Wholesale Grocers, Inc. of Boca Raton, Florida. I am speaking today for Supreme Distributors, a Purity division that is a wholesale distributor of prescription drugs, and on behalf of the Pharmaceutical Distributors Association, a trade association of ten such distributors. But most importantly, I am informally representing the approximately 4,000 state licensed prescription drug distributors across the United States who are, by any definition, small businesses, many of whom are our customers, and who are threatened with economic ruin by a final Rule of the U.S. Food and Drug Administration (64 Fed. Reg. 67720, Dec. 3, 1999) that has now been stayed for ten months (65 Fed. Reg. 25639, May 3, 2000). Most distributors operate in more than one state and we have recently conducted a telephone survey of state licensing authorities which found that over 32,000 wholesale distribution licenses have been issued. These small businesses compete, by pricing and service, to distribute pharmaceuticals to many thousands of other small state licensed businesses, such as doctors, medical groups, clinics, nursing homes, and veterinarians, all of whom would be forced to find alternative sources of affordable service and supply.

The Prescription Drug Marketing Act

The final FDA regulations that I am going to describe implement the Prescription Drug Marketing Act ("PDMA"), which was enacted in 1988 to ensure the safety and efficacy of prescription drugs that are distributed in the U.S. The law has been quite

successful, including the provisions relating to state licensure of all prescription drug wholesalers and wholesale distribution of prescription drugs. Distribution has been governed by paperwork requirements set forth in an "interim" FDA policy Guidance in place for about the last 12 years. Despite the positive experience under this Guidance, FDA in December 1999 finalized regulations, proposed over six years earlier, which changed the agency's interpretation of the law relative to wholesale drug distribution and created a "Catch-22" type situation in the paperwork requirement which will make it impossible for most licensed drug distributors to buy and distribute prescription drugs.

PDMA is unusual because it puts paperwork burdens on small businesses – and specifically exempts large businesses from those burdens. PDMA requires all prescription drug wholesalers who are not "authorized distributors," *i.e.*, those that are not major wholesalers who have an ongoing relationship with and purchase products directly from drug manufacturers, to provide their customers with a detailed sales history of the drug product before it can be resold. After the law was enacted in 1988, the FDA provided interim Guidance requiring wholesalers who do not purchase product directly from a manufacturer on an ongoing basis to trace the sales history of that product back to the "authorized distributor" and to provide that history to their customer.

FDA's 1988 Guidance appeared to recognize some of the business realities of wholesale distribution and the potential impact PDMA's requirement would have on smaller wholesalers. First, FDA made the sales history requirement only go back to the last "authorized distributor," *i.e.*, the last distributor not required by law to provide a sales history. Second, an authorized distributor was defined as any company that had an "ongoing relationship" consisting of two transactions in two years with a

manufacturer. This meant that many smaller distributors were deemed to be authorized under the FDA Guidance because they were occasionally able to buy directly from manufacturers. Drug manufacturers have been reducing the number of authorized distributors for the last several years, and the FDA's Rule would accelerate this trend by requiring written contracts, thus letting manufacturers determine who is "authorized," regardless of the actual volume or number of sales to a wholesaler.

Prescription drug distribution in the U.S. is dominated by five major full line prescription drug wholesalers, the largest of which is McKesson. Next in size are another seventy or so regional wholesalers. Almost all drug sales by manufacturers go first to the big five or the regional distributors. There are also secondary wholesalers like my company that actively seek out prices lower than average wholesale – through "deals," sales before price increases and overstock. Finally, there are the 4,000 small wholesaler businesses that buy from other wholesalers (the big five, the seventy and the secondaries) and distribute to small pharmacies, physicians, dentists, veterinarians, nursing homes, and small clinics. These small businesses exist because service is still meaningful to their customers and because the large wholesalers do not, have not, and will not seek to penetrate down to that level.

FDA Creates a "Catch 22" Requirement

Although this system has worked well for the last twelve years, the FDA in its Rule changed its interpretation of the law to require that wholesalers trace the sales history of the product all the way back to the manufacturer and deleted the option of

going back to the "authorized distributor." This seemingly small change has huge consequences because, as I said earlier, when Congress enacted this law, "authorized distributors" – the big distributors – were exempted from the requirement to provide a sales history. For the last twelve years, small distributors have been able to provide sales history information back to the authorized distributor. Now they must do so back to the manufacturer. But they cannot reasonably obtain sales information back to the first sale by the manufacturer because the big authorized distributors are not required by PDMA to provide this sales history information to subsequent sellers.

FDA's response to this "Catch-22" is that the Agency urges "authorized distributors" voluntarily to provide sales history information. See 64 Fed. Reg. at 67747. Don't hold your breath. The cost of segregating and tracking the huge volumes of products in the manner now required of small companies by PDMA would be prohibitive for the large national distributors even if they desired to provide this information to their customers voluntarily. It requires tracking every lot by purchase date and with their volume of purchases and sales, it would necessitate a monumental change in their business practices. But without this very detailed sales history, secondary wholesalers and those 4,000 smaller wholesalers cannot legally buy and resell these prescription drugs purchased through the big distributors.

FDA's Impact Analysis on Small Business Is Seriously Deficient

We are here before this Subcommittee because the FDA's analysis of the impact of the Rule on small business was seriously deficient. Indeed, small business distributors were simply overlooked by FDA.

The FDA's Small Business Analysis of the Rule published in the Federal Register on December 3, 1999 (see 64 Fed. Reg. at 67753) concluded that "the majority" of the estimated 4,000 distributors "will not be affected by the rule." The reason for this is that FDA never looked to see what its 1988 Guidance required and how the Guidance worked and compared that practice to its Rule. Had FDA done so, it would have found a devastating impact on small business. The one comment made in 1994 against the rule was brushed aside by FDA. In fact, if FDA had bothered to look, it would have found that virtually all small distributors could be forced out of business if the FDA Rule goes into effect, destroying thousands of small, family run businesses and displacing countless employees. The FDA analysis also failed to make any assessment of the potential health and safety risk to patients, whose access to life saving drugs may well be seriously disrupted if an important segment of the national distribution system for prescription drugs is literally wiped out.

The end result of the FDA Rule, if it were to go back into effect, is that an estimated 4,000 distributors who are small businesses will be economically crippled or driven out of business entirely. Their employees will lose their jobs and their owners will lose their investments along with years of hard work and service that has created the customer goodwill that makes their businesses valuable. The 4,000 small distributors

occupy a niche in the market which large distributors either cannot or chose for economic reasons not to fill. They are particularly important in rural areas and to other customer categories with relatively low volumes. It is not at all clear that alternative sources of supply for these providers would be available on a timely basis or at a reasonable cost.

Secondary source wholesalers also play an important role in restraining drug prices. By purchasing in advance of price increases, buying products from large full line distributors who are temporarily overstocked in a particular product and need to free up warehouse space, or taking advantage of regional product promotions, secondary wholesales seek to obtain product at prices lower than the average price at which a manufacturer sells to a large national distributor. These lower priced goods are sold to retailers and to other wholesalers, providing an important source of competition and a restraining influence on drug prices. Eliminating this segment of the market would tend to increase prices, costing consumers and taxpayers more money. The FDA did not provide any estimate of the increased costs which might well occur if competition in the wholesale pharmaceutical marketplace was significantly reduced.

A Legislative Solution is Needed

By failing to perform a proper impact analysis of the Rule, the FDA has painted itself into a corner. While the agency has, however reluctantly, responded to our Association's petition (copy attached) and to heavy Congressional pressure – including, thankfully, from Chairman Talent of the full committee – and agreed to stay and reopen

the final Rule and consider additional comments, the prospects for a fundamental revision in the Rule that would mitigate the disastrous impact on small businesses appear small. The FDA has clearly indicated in letters to Members of Congress and elsewhere that it believes that its flexibility to interpret the law and revise the Rule is very limited – despite twelve years of success under its prior interpretation. The only solution is to enact corrective legislation in this Congress. While the final Rule has been stayed until October 1, 2001, the FDA has not provided for the grandfathering of product inventory, and distributors will have to sell existing stocks and cease to order replacement product well before that date. Thus, the impact on the national drug distribution system will be felt many months before October 1, 2001.

I strongly commend to the attention of the Chair and the Members of the Subcommittee H.R. 4301, a bipartisan bill that would fix the problems in the FDA's Rule relative to drug distribution. I would hope that Members of the Small Business Committee would become familiar with the substance of this bill and take the lead in cosponsoring and enacting this technical corrective legislation that will substantially reduce paperwork burdens on state licensed pharmaceutical distributors.