



**American  
Pharmaceutical  
Association**

2215 Constitution Avenue, NW  
Washington, DC 20037-2985  
(202) 628-4410 Fax (202) 783-2351  
<http://www.aphanet.org>

*The National Professional  
Society of Pharmacists*

June 30, 2000

Dockets Management Branch  
(HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Rm. 1061  
Rockville, MD 20857

RE: Docket Nos. 92N-0297 and 88N-0258

Dear Sir/Madam:

The American Pharmaceutical Association (APhA) is pleased to submit comments on the requirements of Sections 203.3(u) and 203.50 for wholesale distribution of prescription drugs by distributors that are not authorized distributors of record as published in the May 3, 2000 *Federal Register*. APhA, the national professional society of pharmacists, represents more than 53,000 practicing pharmacists, pharmaceutical scientists, and pharmacy students.

The wholesale distribution of drugs is obviously of vital interest to pharmacists, as they rely upon this distribution system to obtain prescription medications for their practice. The final rule implementing the Prescription Drug Marketing Act of 1987 (PDMA) as amended would bring significant changes to the wholesale distribution process. While APhA applauds the intent of PDMA, the Association fears that the changes proposed in the referenced sections may erect barriers adversely affecting pharmacists' ability to obtain prescription drugs. A disruption in prescription drug distribution would have a substantial negative impact on pharmacists, their pharmacies, and their patients. It is this disruption that most concerns the Association.

In 1999, pharmacists, physicians, patients and many other health care professionals faced a potential disruption of medication distribution from Year 2000 (Y2K)-related computer snafus. Concerns that Y2K problems would disrupt the nation's drug distribution channels and cause shortages of essential medicines were addressed, and January 2000 arrived with few problems. The foundation of the medication distribution system, and arguably the most important component to mitigating the effects of product shortages and carrying us through the Y2K challenge, is the complexity of the system. The pharmaceutical supply system is composed of a number of manufacturers, wholesale distributors, and pharmacies, and pharmacists have access to more than one source of a product. This complexity yields a safety net for the patient, a safety net of alternative distributors a pharmacist can access to ensure that the ultimate consumer receives necessary therapy.

Unfortunately, the final rule implementing PDMA, specifically §§ 203.3(u) and 203.50, threatens this safety net. The final rule will alter the manner in which drug manufacturers, wholesale distributors, and secondary wholesale distributors conduct business—and thus

88N-0258

C115

affect pharmacists and their patients. When implemented, the final rule would create a significant distinction between authorized and unauthorized distributors of prescription drugs. In order to be considered an authorized distributor of record, the distributor must have a written agreement with the manufacturer stating the drug products to be distributed and the duration of the authorized distribution. Manufacturers will be under no obligation to enter into a written agreement with a wholesale distributor. Distributors that are unable to obtain a written agreement with a manufacturer will be considered unauthorized distributors.

APhA understands that the Food and Drug Administration (FDA) believes that “Given the relative ease with which the agreement... can be created... it is highly unlikely that a manufacturer would refuse to enter into a written agreement with a distributor with whom it wishes to have a continuing business relationship.”<sup>1</sup> However, in comments filed by the Pharmaceutical Distributors Association (PDA) which represents wholesale distributors, PDA disputes this belief stating:

It is the experience of PDA member companies that manufacturers decline to make wholesalers “authorized” for a variety of reasons. One such reason is that the wholesaler is too small to carry a full line of the manufacturers’ products. Another is that it is too small to maintain a required line of credit. Another reason is that the manufacturer already has adequate coverage in the area in where the wholesaler is located.<sup>2</sup>

Wholesale manufacturers unable to obtain authorized distributor status would then be subject to new requirements under the final rule. The final rule requires unauthorized distributors to provide a drug origin statement, or pedigree, detailing each previous transaction of the drug upon each subsequent sale or trade of the drug. The drug origin statement must include: the name of the drug, its dosage, the container size, the number of containers, lot or control numbers, the name and address of each party involved in each previous transaction, and the date of each previous transaction.

Requiring a drug origin statement places an unfair burden on unauthorized wholesale distributors, primarily because manufacturers and authorized distributors are not subject to the same requirement. It is highly unlikely that a manufacturer or authorized distributor would *voluntarily* produce a pedigree for a drug product, especially after considering time, manpower, and cost restraints. If manufacturers and authorized distributors do not voluntarily provide a drug origin statement to unauthorized distributors, unauthorized distributors would effectively be prevented from reselling the drug product—or forced to construct a pedigree. It is logical to conclude that unauthorized distributors unable to obtain drug origin statements and therefore unable to sell the drug products would quickly be forced out of business.

---

<sup>1</sup> 64 Federal Register at 67,728.

<sup>2</sup> Petition for Stay of Action by the Pharmaceutical Distributors Association, March 29, 2000.

The potential ramifications of the final rule are extraordinary. If unauthorized distributors are unable to obtain a drug origin statement from current suppliers or find an alternative supply source, hundreds or thousands of smaller wholesale distributors may be forced out-of-business. Not only will this create lost jobs and the closing of numerous small businesses, a reduction in the number of distributors will likely lead to a decrease in competition and an increase in prescription drug prices.

Importantly, the closing of unauthorized distributors would undoubtedly create a disruption in drug distribution. As discussed earlier, the strength of the drug distribution system is its complexity—the multiple sources of supply available to pharmacists to secure medications. If wholesale distributors go out of business, pharmacists and patients are left with a safety net with many holes, and not much security. While the rule allows for exceptions to securing product in emergency situations, companies no longer in business cannot provide much assistance.

Every day a network of wholesale distributors delivers pharmaceutical products to the nation's community and chain pharmacies, hospitals, long-term care facilities, and countless other institutions. Each of these healthcare facilities relies on wholesale distributors to deliver the prescription drug products necessary for their business and for their patients. For example, many pharmacies maintain a small inventory of prescription drugs at any one time. The pharmacy relies on its daily delivery by a wholesale distributor to replenish its supply of a drug or fulfill a request for a drug that the pharmacy usually does not stock. If the unauthorized wholesale distributor serving that pharmacy goes out-of-business, prescription drug availability in that community will be severely affected. Even if larger wholesale distributors enter the market vacated by unauthorized distributors, the distributors may find it economical to switch to once a week deliveries or institute minimum order requirements – conditions under which many pharmacies could not operate.

APhA urges the FDA to return to the existing standard where an ongoing relationship (and thus characterization as an “authorized distributor”) could be established via two transactions in any 24 month period. The final rule places an unfair burden on unauthorized distributors of prescription drugs, an unfair burden that could limit patient access to medications. Statements from those representing the wholesale distributors and those representing small businesses illustrate the likelihood that hundreds of smaller distributors could be forced out-of-business.<sup>3</sup> Clearly this is not the intended effect of the rule.

At a minimum, the FDA should stay the implementation of the final rule to allow more careful study of the potential effects of the rule as it currently stands. APhA sees no immediate public health risk in delaying the implementation of the rule as the industry has operated safely under the guidance outlined in the FDA's *Compliance Policy Guide* issued in August of 1998.

---

<sup>3</sup> Petition for Stay of Action by the Pharmaceutical Distributors Association, March 29, 2000.

Thank you for your consideration of the views of the nation's pharmacists. Please contact Susan C. Winckler, APhA's Group Director of Policy and Advocacy, at 202-429-7533 or Susan K. Bishop, APhA's Manager of Regulatory Affairs and Political Action at 202-429-7538 with any questions.

Sincerely,

A handwritten signature in black ink, appearing to read "John A. Gans". The signature is fluid and cursive, with the first name "John" being the most prominent part.

John A. Gans, PharmD  
Executive Vice President

Cc: Lucinda L. Maine, PhD, Senior Vice President, Professional and Public Affairs  
Susan C. Winckler, RPh, Group Director, Policy and Advocacy  
Susan K. Bishop, Manager, Regulatory Affairs and Political Action