

# NACDS

## National Association of Chain Drug Stores

Craig L. Fuller  
President & CEO

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### **Docket No. 92N-0297; Prescription Drug Marketing Act of 1987; Prescription Drug Amendments of 1992; Policies, Requirements and Administration Procedures**

The National Association of Chain Drug Stores (NACDS) is submitting comments in response to the Food and Drug Administration's *Federal Register* notice (see 65 Fed. Reg. 56480) of September 19, 2000 regarding certain requirements regarding the final rule implementing the above-referenced acts, which were published in the *Federal Register* on December 3, 1999.

NACDS membership consists of nearly 170 retail chain community pharmacy companies. Collectively, chain community pharmacy comprises the largest component of pharmacy practice with over 94,000 pharmacists. The chain community pharmacy industry is comprised of more than 20,000 traditional chain drug stores, 7,800 supermarket pharmacies and 5,300 mass merchant pharmacies. The NACDS membership base operates over 33,000 retail community pharmacies with annual sales totaling over \$400 billion, including \$160 billion in sales for prescription drugs, over-the-counter (OTC) medications and health and beauty aids (HBA). Chain operated community retail pharmacies fill over 60% of 3 billion prescriptions dispensed annually in the United States. Some of NACDS members purchase pharmaceuticals from secondary wholesalers. These products provide an alternative source of supply for quality pharmaceuticals, and help to maintain competition among manufacturers and wholesalers in the pharmaceutical marketplace.

On Wednesday, May 3<sup>rd</sup>, FDA published a *Federal Register* notice delaying implementation of provisions of the final PDMA rule relating to requirements for secondary wholesale distribution of prescription drugs. NACDS supports the suspension of the implementation of these parts of the final rule. We believe that FDA should change the final rules to allow secondary wholesalers to continue to operate under current FDA guidelines, which have been in effect for over a decade, or allow sufficient time to change the law such that these wholesalers are able to continue operating in the marketplace.

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## Overview of Concerns with Final PDMA Rules

PDMA's goal is to assure that only quality pharmaceutical products are distributed in the United States. The final regulations were issued on December 3rd, 1999, and were scheduled to become effective December 4<sup>th</sup> 2000. On May 3, 2000, however, FDA suspended two specific parts of the final regulation regarding the conditions by which these distributors can operate. We support suspension of these particular provisions, and believe that changes need to be made to these sections, either through legislation or regulation, that will maintain the viability of the secondary wholesaler pharmaceutical marketplace.

That is because these requirements, if implemented, will cause significant disruption in this marketplace. Secondary wholesalers have traditionally served as a lower-cost wholesale source of quality pharmaceutical products for pharmacies, especially those in rural areas that may not be served by larger full-line wholesalers. The products obtained through these sources help to reduce pharmaceutical product costs for private and public payors, including Medicaid, and many consumers who pay out-of-pocket for medications, such as Medicare beneficiaries.

In particular, we believe that Sections 203.3(u) and 203.50(a) of the final PDMA regulations would place unreasonable and impractical paperwork and tracking requirements on these wholesalers before they could sell these products to retail pharmacies. We do not believe that it was the intent of Federal policymakers in enacting PDMA to create significant burdens for the distribution of quality pharmaceutical products by secondary wholesalers, or to eliminate them from the marketplace.

For example, new, unnecessary paperwork requirements (pedigree tracking) imposed under the PDMA rules make it virtually impossible for secondary wholesalers to sell prescriptions products, including to many of our member chains. Regulations that have been in effect since 1990, already require wholesalers to maintain records of transactions for two years. See 21 CFR 205.50(f)(2). This information is already available to FDA, state regulators, and law enforcement agencies. Given these existing requirements, we question the need for additional pedigree requirements, which would appear to simply add costs to the system. Moreover, it is simply impractical to expect secondary wholesalers to maintain extensive pedigrees of the sales of pharmaceutical products – all the way back to the manufacturer or authorized distributor - without requiring that such entities provide these pedigrees.

We also oppose the part of the regulation that empowers the manufacturer to determine solely those entities that are "authorized distributors" of pharmaceutical products. Current FDA guidance on PDMA implementation, in effect since 1988, designates a wholesaler or chain pharmacy as an "authorized distributor" if a manufacturer has two transactions with the entity within a 24 month period. We support this type of approach to the designation of "authorized distributor".

The final regulations, however, would only allow a manufacturer to make such a designation through a written agreement with the entity, regardless of the volume of sales or the number of transactions between the manufacturer and the entity.

This approach would create a competitive imbalance in favor of the manufacturer. Time, cost, and other constraints or considerations may preclude a manufacturer from entering into these written "authorized distributor" agreements with many of these secondary wholesalers. As a result, the secondary wholesalers would be unable to gain such a designation, and this would be subject to the extensive new pedigree requirements. As already discussed, they would likely be unable to obtain these pedigrees, and would be forced out of business. The ultimate effect of these requirements would be to reduce competition in this marketplace to the detriment of consumers, as well as public and private health care programs. In its September 19<sup>th</sup> notice, the agency asked several questions pertaining to the impact of the PDMA rule on distribution of prescription drugs.

**How does the final rule, as published, affect the ability of unauthorized distributors to engage in drug distribution. What specific requirements would be difficult or impossible for unauthorized distributors to meet? Why?**

The primary problem with the final rule is that it would require a sales history pedigree extending all the way back to the manufacturer, while not requiring the manufacturer or the authorized distributor to provide this information to the secondary wholesaler. Without this information, the unauthorized distributor could not legally resell products and would be forced out of business. There is no practical way for the unauthorized distributor to obtain the detailed information required (i.e. lot number, dosage form, date of sale) pertaining to the initial sale from the manufacturer to the authorized distributor. Moreover, there is no demonstrated health or safety reason why this additional burden should be required of any party in the sales chain. Existing FDA regulations already require secondary wholesalers to retain relevant information in their records and make it available to inspection by FDA, state authorities and law enforcement.

**If the final rule diminished the ability of unauthorized distributors to engage in drug distribution, what effect would this have on the distribution system? What, if any, adverse public health consequences would result? What would be the economic costs to manufacturers, distributors (authorized and unauthorized), and consumers of drugs?**

Secondary wholesalers play an important role in the efficient distribution of pharmaceuticals and in creating competition in the wholesaler and manufacturer prescription drug market. The elimination or reduction in this segment of the market would significantly reduce price competition and the efficient and economical distribution of drug products to remote or underserved areas.

The more than 4,000 secondary wholesalers nationwide also serve many small-end users, such as nursing homes, medical and veterinary practices, who are not and cannot be served by large, high volume distributors at an affordable price. Moreover, disruption of the secondary wholesaler system would threaten the health of patients served by these companies and their customers, whose existing supply channels would be reduced or eliminated. Finally, pharmaceutical manufacturers have been and are continuing to reduce the number of distributors to which they sell direct and which can become "authorized". Thus, the importance of secondary wholesalers in the national distribution system will continue to increase over time.

**If the act were amended by Congress to delete the requirement for provision of a drug pedigree by unauthorized distributors, would there be an increased risk of distribution of counterfeit, expired, adulterated, misbranded, or otherwise unsuitable drugs to consumers and patients?**

We believe that the current system that has been in place for well over a decade has worked well to assure the integrity of the pharmaceutical distribution system. We are unaware of any major cases of failure under the current distribution system that has created risk for patients. We do not believe that deleting these new PDMA pedigree requirements would increase risk. Under current law and regulation, the FDA and state authorities could verify the accuracy of all written certifications during periodic inspections, and this information would be available to law enforcement, if necessary.

**If actual sales by a manufacturer to a distributor were used by FDA as the only criterion to determine whether an ongoing relationship exists between them (and as a result, whether the distributor is an authorized distributor of record), would it result in more distributors being authorized than if a written authorization agreement is required? What other types of criteria might be used by FDA to make this determination?**

Using actual sales as the basis to determine that an ongoing relationship exists between a manufacturer and a distributor would clearly result in more distributors being authorized than if the FDA's proposed written agreement were required. The FDA's final rule, however, would give the manufacturer the absolute authority to designate which companies, if any, were authorized distributors quite apart from actual sales by that manufacturer to that distributor.

Since manufacturers have been reducing the number of distributors to whom they sell directly over the last decade or more, it is logical to expect that manufacturers would further reduce the number of authorized distributors under FDA's final rule. The other likely result of the FDA's final rule would be to give manufacturers pricing power that they do not now have in their negotiations with distributors.

There is value in being an authorized distributor, and the manufacturers would undoubtedly use the ability to designate companies as authorized distributors to extract a higher price in negotiations over yearly contracts with distributors. These higher prescription prices would be passed on to consumers and taxpayers.

The FDA's proposal to divorce the designation of a distributor as authorized from actual sales also runs directly counter to the plain language in the PDMA statute, which sets the criteria for becoming authorized as having "an ongoing business relationship" with a manufacturer. This language obviously contemplates sales by the manufacturer to the distributor as constituting the business relationship. FDA's initial guidance on this provision used exactly the same standard, which consisted of two purchases by a distributor in a 24-month period. There is no logic, or need, for the FDA to use anything other than actual sales of drugs by a manufacturer to a distributor to determine authorized distributor status.

We urge the agency to act quickly in making a decision on this issue. Secondary wholesalers and other distributors in this market will have to start selling off inventories, or refusing additional shipments, if these shipments have to meet pedigree requirements under the final rule, or if they are unable to sell the inventory because they are not authorized distributors. This could create supply problems for some of our member chains and other health care providers that rely on these suppliers.

We appreciate the opportunity to provide our perspectives on these very important questions. Comments or questions regarding this submission should be directed to John M. Coster, Ph.D., R.Ph., Vice President Federal and State Programs at 703-549-3001 X 126. Thank you for the opportunity to provide comments on these final rules.

Sincerely,



S. Lawrence Kocot  
Senior Vice President and General Counsel