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**Sent:** Friday, November 17, 2000 6:40 PM  
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**Subject:** Docket No. 92N-0297

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Please accept for filing the enclosed comments of the Pharmaceutical Distributors Association in the above-captioned docket.

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92N-0297

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**BEFORE**  
**THE UNITED STATES OF AMERICA**  
**DEPARTMENT OF HEALTH AND HUMAN SERVICES**  
**FOOD AND DRUG ADMINISTRATION**

**OPPORTUNITY FOR FURTHER COMMENT ON REGULATIONS IMPLEMENTING**  
**THE PRESCRIPTION DRUG MARKETING ACT, AS AMENDED**

**DOCKET NO. 92N-0297**

**COMMENTS OF THE PHARMACEUTICAL DISTRIBUTORS ASSOCIATION**

The Pharmaceutical Distributors Association ("PDA") is an association of licensed prescription drug wholesalers that are not "authorized distributors of record" for all of the pharmaceuticals that they distribute. Nonetheless, association members have an ongoing relationship with the manufacturers from which they purchase drugs on a regular basis. This association was formed to assure that the Prescription Drug Marketing Act, as amended ("PDMA"), is interpreted fairly and equitably and in a fashion that will not destroy the businesses of its members.

These comments follow upon the hearing held October 27, 2000 at which questions were raised regarding the operations of prescription drug wholesalers under the present regulatory framework. PDA offered to provide information on this subject

but indicated at the time that it has been difficult to involve small distributors in the process. Against that background, PDA wishes to make a number of points.

**1. State Licensure.**

One of PDMA's requirements is that prescription drug wholesalers be licensed in the state where they reside. Many states also require licensure of those doing business within the state. Many thousands of licenses have been issued. Almost every state contacted by PDA inspects a wholesale distributor prior to issuing a license. And a handful of states do follow-up inspections on a an annual or semi-annual basis. Most do follow-up inspecions randomly. On a comparative basis, the initial inspections may be more frequent than the Administration's own inspections of OTC or "not new drug" manufacturing facilities.

The Administration has promulgated Guidelines for State Licensing of Prescription Drug Distributors, 21 C.F.R. Part 205. Importantly, these regulations require records of all transactions to be maintained. And these records form the principal basis for tracing the distribution of the drugs. These regulations are comprehensive but, as discussed below, they could be strengthened in those areas where the Administration has determined there is a public health basis and purpose.

**2. Present PDMA "Pedigree" Compliance.**

As stated during the hearing, it is PDA's view that there is little compliance with PDMA's requirement that a prescription drug pedigree accompany transactions by "unauthorized" distributors at the lower levels in the chain of distribution. Secondary wholesalers, those engaged in arbitrage, are well aware of this PDMA requirement and

they abide by it. Smaller wholesalers, those who distribute to clinics, physicians' offices, veterinarians and to small pharmacies, do not provide pedigrees and are not generally aware of PDMA requirements other than state licensure. The reason for this is simple. There has been little state or Administration enforcement of this requirement and the industry is not organized in a fashion that allows the Administration to use speeches or trade newsletters as a vehicle to get the word out. Accordingly, even if the final PDMA regulations regarding prescription drug pedigrees are changed as requested by PDA and others, the impact on small business will be substantial because they are not currently in compliance.

### **3. Facilitation of Drug Recalls.**

It is PDA's view that the prescription drug pedigree has no role whatsoever in facilitating drug recalls. PDA members receive information regarding drug recalls from manufacturers with whom they are direct customers and from other wholesalers who do business with them. A pedigree works in the opposite direction, it tells the recipient the names of distributors who have received and sold the drug since the last authorized distributor. In a drug recall, the important information is the lot number and the name of the drug. No one uses a pedigree to track that information.

### **4. Tracing of Possibly Counterfeit or Adulterated Drugs.**

Concern was expressed at the hearing with the possibility of counterfeit prescription drugs entering the wholesale distribution system. As hearing participants explained, the pedigree has only minimal value in tracing the source of drugs in the wholesale distribution scheme. First, anyone engaging in the extraordinary level of

felonious intent required to traffic in counterfeit drugs would likely falsify any document required to accompany the drugs in commerce. Because of this, the pedigree is not a signal of a possible counterfeit. Second, the experience of PDA's members is that counterfeits are difficult to detect. If counterfeit is a serious health and safety concern for the Administration, PDA would work with the Administration to strengthen the wholesale drug distributor licensure guidelines to address that concern. The pedigree is not part of that solution. The solution lies, in our view, in requiring more careful inspection by wholesale distributors as they receive drugs for further distribution.

**Conclusion.**

PDA continues to be concerned that pharmaceutical manufacturers do not seem to understand the impact of the PDMA final rule on the distribution of their products. That lack of understanding was made clear by the testimony of the representative of the manufacturers' trade association at the hearing. Accordingly, it is PDA's view that manufacturers intend to use the final rule, if it is allowed to go into effect, to further strengthen their economic power over prescription drug pricing and distribution. This is not a result that was intended to flow from PDMA.

On the basis of the foregoing, and the other comments submitted by PDA and its members, PDA respectfully requests that the relief it has requested from the final PDMA regulations be granted.

Respectfully submitted,

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