



# American Pharmacists Association

Improving medication use. Advancing patient care.

July 14, 2006

Division of Dockets Management  
HFA-305  
Food and Drug Administration  
5630 Fishers Lane  
Room 1061  
Rockville, MD 20857

Re: Draft Compliance Policy Guide 160.900

Dear Sir/Madam:

Thank you for the opportunity to comment on the Draft Compliance Policy Guide 160.900 on pedigree requirements under the Prescription Drug Marketing Act (PDMA). The American Pharmacists Association (APhA), founded in 1852 as the American Pharmaceutical Association, represents more than 57,000 practicing pharmacists, pharmaceutical scientists, student pharmacists, pharmacy technicians, and others interested in advancing the profession. APhA, dedicated to helping all pharmacists improve medication use and advance patient care, is the first-established and largest association of pharmacists in the United States.

Securing the safety of 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 Food and Drug Administration's (FDA) decision to implement the PDMA pedigree requirements will bring significant changes to the wholesale distribution process. Under the Agency's final pedigree rule and draft compliance policy guide (CPG), beginning December 1<sup>st</sup>, each individual or entity involved in the wholesale distribution of drugs, other than the manufacturer or authorized distributor, must provide a drug pedigree to the purchaser.

APhA supports the Agency's decision to implement the pedigree requirements provided that the necessary policies are in place. Pedigrees can provide pharmacists, pharmacies, and other members of the supply chain with documentation of a prescription drug's path within the distribution system. Having access to this information is useful as we work to protect our medication supply and prevent the introduction of counterfeit products into the system. Pharmacists serve as the last line of defense in protecting patients from counterfeit medications. However, APhA's concerns with a paper-based pedigree system and the difficulty "unauthorized distributors" may have generating or obtaining a pedigree – concerns that were communicated to the Agency in 2000 – still remain.

### **Ongoing Relationship**

The PDMA states that an authorized distributor is one that has an “ongoing relationship” with the manufacturer. The PDMA does not define “ongoing relationship”; however, the FDA has defined the term to include those distributors who have a written agreement with the manufacturer to distribute the manufacturer’s products. APhA is concerned that some wholesale distributors may not be able to obtain a written agreement with the manufacturer. Manufacturers may choose not to enter into a written agreement with small wholesalers who carry a limited number of products or purchase small quantities of a product, or may limit the number of wholesalers they contract with to provide select wholesalers with a competitive advantage in the marketplace. In this structure, manufacturers have the sole discretion to decide which wholesalers will be “authorized” and therefore not subject to the pedigree requirements.

It will be extremely difficult for wholesalers who are unable to obtain a written agreement with the manufacturer and are therefore considered an “unauthorized” distributor to provide a drug pedigree, because manufacturers and authorized distributors are not subject to the same requirement. It is 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 pedigree to unauthorized distributors, unauthorized distributors would effectively be prevented from reselling the product – or forced to construct a pedigree. If unable to obtain a drug pedigree and therefore unable to sell the drug products, an unauthorized distributor would be forced out of business. APhA is concerned that the closing of unauthorized distributors would undoubtedly create a disruption in the drug distribution system negatively affecting pharmacists’ ability to secure medications.

APhA encourages the FDA to monitor the implementation of the pedigree requirement. The Agency must address any situation in which the drug distribution market is manipulated by manufacturer refusal to establish written agreements with wholesalers. The Agency must also encourage manufacturers to execute written agreements with its distributors.

### **Electronic Pedigrees**

The draft CPG briefly addresses the movement toward electronic track and trace technology that would eliminate the need for paper pedigrees. According to the CPG, the Agency decided to implement the paper pedigree requirement because electronic pedigrees have not yet been widely implemented.

APhA strongly supports electronic pedigrees because a paper-based pedigree system presents a number of challenges. We are concerned that counterfeiters capable of reproducing product labels and the medications themselves are likely quite capable of counterfeiting the accompanying paper pedigree. A paper pedigree system could negatively impact the security of our drug distribution system by creating a false sense of security when the mere presence of a paper pedigree could be proof of little. A paper-based pedigree system may provide a track record of the product movement, or simply provide a counterfeit record of the product movement – a trail as fake as the product it accompanies. Additionally, pedigree requirements must be implemented in a manner that provides the highest degree of valid information with the least disruption to operations. Requiring members of the supply chain to produce and distribute massive amounts of paper that may or may not be legitimate is not a good use of resources.

While the industry works toward wide adoption of electronic pedigrees, we encourage the FDA to work with pharmaceutical manufacturers and wholesale distributors to develop a uniform paper pedigree. A uniform paper pedigree will not only simplify the pedigree construction process, it will also facilitate future efforts to move toward an electronic pedigree.

### **Factors to Consider for Enforcement Focus**

The CPG explains how the FDA intends to prioritize its pedigree-related enforcement activities in 2007. According to the CPG, the Agency will focus on drug products that are most vulnerable to counterfeiting, diversion, or other illegal activity. The CPG proposes that the most at risk drugs include those with a high market value or high cost, in high demand, or in short supply; those that have been previously counterfeited; and new drugs with a high probability of being counterfeited. APhA agrees that drug products meeting these factors are likely targets of counterfeiting, and that products meeting these factors are appropriate for increased enforcement by the Agency.

However, without the development of a list that identifies drug products that meet these factors, there will be no uniformity in the drug products prioritized for the creation of drug pedigrees and FDA enforcement. We do not expect every drug product will include a pedigree as of December 1<sup>st</sup>. It is possible the industry will phase-in pedigrees based on the risk factors included in the CPG. Each individual distributor will decide whether a product is high risk and whether or not the creation of pedigree is a priority. Under this system, confusion will abound: pharmacists will not know when they should expect a pedigree with a drug product as the implementation process is phased-in.

To help pharmacists gain a better understanding of this issue and other pedigree-related concerns, we request that the Agency work with APhA and other associations to develop educational materials that explain the pharmacist's role in the pedigree process. The educational materials could address questions such as:

- What pharmacists should do if they receive a drug product without a pedigree
- Pharmacists' responsibility to determine the authenticity of the pedigree
- Requirements to store the pedigree and for how long
- Whether pharmacists have to provide the pedigree when distributing the product to other pharmacies

Creating a basic educational resource will help pharmacists better understand the new pedigree requirements, therefore making the implementation of the new system and desired results – increased security – more likely.

### **Federal Requirement**

It is our understanding the federal pedigree requirement does not pre-empt stricter state requirements. To facilitate the implementation of these requirements, APhA supports applying these standards uniformly across all states. Allowing states to develop and enforce stricter pedigree requirements creates the potential for gaps in the system. Inconsistent requirements for products that can easily cross state lines inherently create loopholes that unscrupulous operators will exploit. APhA would support efforts to enact a federal pre-emption of the pedigree requirement, as well as efforts to develop a uniform paper pedigree, and we have communicated these interests to Congress. (See attachment).

Thank you for your consideration of the view of the nation's pharmacists. If you have any questions, please do not hesitate to contact Susan K. Bishop, Director of Federal Regulatory Affairs at 202-429-7538 or sbishop@aphanet.org, or Susan C. Winckler, Vice President of Policy and Communications at 202-429-7533 or swinckler@aphanet.org.

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.

John A. Gans, PharmD  
Executive Vice President

cc: Susan C. Winckler, RPh, Esq, Vice President, Policy and Communications & Staff Counsel  
Susan K. Bishop, MA, Director, Federal Regulatory Affairs