



David A. Smith  
President and CEO

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VIA ELECTRONIC SUBMISSION  
(<http://www.fda.gov/dockets/ecomments>)  
(Original Sent Via Regular Mail)

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

Re: Comments--Prescription Drug Marketing Act Pedigree Requirements; Effective Date and Compliance Policy Guide; Docket Nos. 1992N-0297, 1988N-0258, and 2006D-0226 [71 Fed. Reg. 34249, June 14, 2006]

Dear Ms. Bernstein:

PSS World Medical, Inc. (PSSI) appreciates the opportunity to comment on a recent proposal by the Food and Drug Administration (FDA) to permit the written drug pedigree requirement of the Prescription Drug Marketing Act (PDMA) to go into effect on December 1, 2006. We have also reviewed your draft Compliance Policy Guide (CPG) related to the Agency's enforcement priorities in this regard. Comments on both these matters are included below for your review and consideration. Please forgive the delay in forwarding this information to the Agency.

A. Introduction

PSSI's Physician Sales & Service division is the leading distributor and marketer of medical supplies, equipment and pharmaceuticals to office-based physicians in all 50 states, where we are licensed and in full regulatory compliance. Office-based physicians, unlike hospitals and pharmacies, order approximately \$1.5 billion in pharmaceuticals from distributors in very small quantities, because of storage constraints and utilization patterns. We focus on providing and offering products and services tailored to each practice's unique needs in urban and rural settings. We deliver timely, efficient, affordable and personalized service through a combination of sales representatives, customer service representatives and delivery personnel, with each possessing a thorough knowledge of their customers.

While we do not purchase and distribute nearly the same volume of prescription pharmaceuticals as the so-called Big 3 (McKesson, Cardinal and AmeriSource Bergen), PSSI sells more than \$300 million of prescription drugs per year. Unlike the Big 3, our primary focus is distribution of specialty pharmaceuticals. PSSI frequently purchases from the manufacturer directly and distributes all therapeutic classes of Rx drugs to more than 100,000 medical clinics and physician offices. However, pharmaceutical companies

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frequently seek to maintain exclusive distribution relationships. They also often impose huge minimum purchase requirements for direct purchasers. Because of the type of customer we serve, it is a common and efficient practice within the distribution community for companies like PSSI to arrange smaller purchases/shipments from the Big-3 or other ADRs to serve immediate customer needs, than the enormous minimum quantities often required by particular product manufacturers.

## B. Background

The PDMA, as modified by the Prescription Drug Amendments of 1992 (PDA), amended the Food Drug and Cosmetic Act (FDCA) to, among other things, establish requirements related to the wholesale distribution of Rx drugs in interstate commerce. As was stated by Randall W. Lutter, Ph.D., FDA's Associate Commissioner for Policy and Planning, in a July 11, 2006 hearing before the House Government Reform Subcommittee on Criminal Justice, Drug Policy, and Human Resources, on Pharmaceutical Supply Chain Security, the law requires "... each person who is engaged in the wholesale distribution of a drug ... who is not the manufacturer or authorized distributor of record of such drug ... to provide to the person who receives the drug a statement ... identifying each prior sale, purchase, or trade of such drug [all the way back to the manufacturer] (including the date of the transaction and the names and addresses of all parties to the transaction.)" §503(e)(1)(A) FDCA.

In December 1999, FDA published final regulations (Title 21 CFR Part 203) intended to take effect in December 2000. Those provisions, many of which were objected to by various stakeholders, defined ADRs (for which a written pedigree for each transaction was not required to be prepared) as "a distributor for whom a manufacturer has established an ongoing relationship to distribute such manufacturer's products." 21 CFR §2.3.3(b). An "ongoing relationship" generally means a written agreement between the parties designating which drugs are authorized to be distributed, *Id.* at §203.3(u), a stricter test than FDA has previously employed.

FDA delayed the effective dates of the written pedigree provisions (§§203.3(b), (u) and 203.50) at least five times because of arguments advanced by the stakeholders and advocates for consumers and small business: e.g., (1) pedigrees could not be compiled since manufacturers and the exempt ADRs would be unwilling to provide the necessary information back to the manufacturer; (2) ADR market dominance would increase, driving out smaller distributors; (3) written paper pedigrees would not provide sufficient protection to justify the enormous administrative burden of compiling them for millions of individual transactions since they could themselves be counterfeited and FDA lacks the resources for adequate audit; and (4) electronic track and trace technology would render paper pedigrees obsolete to prevent diversion or counterfeiting. For example, the Small Business Administration's Office of Advocacy submitted comments in February 2000, reconfirmed in November 2002, that the rules as written would have a "severe economic impact." A critical deficiency is that the scheme requires pedigree information to be provided on sales through licensed wholesalers and distributors that do not have ADR status with a particular manufacturer, but provides no means to ensure that pedigree

information can reach them, while the exemptions for ADR sales create an opportunity and perhaps even incentives for these smaller wholesalers and distributors to be cut off. The conditions for ADR status are also unnecessarily restrictive. Proposals have been advanced for the FDA to mitigate the harmful effect of the rules by returning to its own prior guidance language defining ADR status more flexibly and, where purchases are made by a wholesaler from an ADR, permitting the pedigree documentation to commence at that point.

Rather than address any of these complaints, which FDA has viewed as valid in justifying its prior enforcement delays (*see* for example transcript of October 27, 2000 Part 15 Hearing and Preambles of *Federal Register* Notices announcing implementation delays), by modifying the language of its regulations, on June 8, 2006, FDA announced that those regulations would be enforced commencing on December 1, 2006. Its rationale was based on a 2006 update of its Counterfeit Drug Task Force Report. That report found that manufacturer initiated electronic tracing technologies were proceeding too slowly and that States were moving forward on their own inconsistent pedigree requirements. In a draft CPG released with the Report, FDA stated that it would prioritize its enforcement resources to focus on pedigrees for drug products most vulnerable to counterfeiting and diversion (e.g., (1) high market value or high sales volume; (2) prior cases of counterfeiting and diversion; (3) new drugs with an insufficient marketing history; (4) distributors of counterfeit drugs). The FDA announcement also inexplicably reported that the FDA "has not heard that the concerns raised in the past regarding the impact on small wholesalers remains." *FDA News*, June 9, 2006.

### C. Discussion

PSSI, which is headquartered in Jacksonville, FL, has been intimately involved in state legislative endeavors, including Florida. We recognize the benefit of implementing a uniform Federal pedigree standard. My colleagues and I stand ready to assist all industry and consumer advocates of a uniform preemptive Federal standard in the interest of efficient and cost effective interstate commerce. We hope that FDA, the Department of Health and Human Services and the Bush Administration will make preemptive uniformity a priority since it has elected to implement the written national pedigree requirements of the PDMA. While we will work with outside constituencies and with FDA's offered technical assistance, it is incumbent on the political leadership at FDA and HHS to request of the Office of Management and Budget that this preemptive authority be included in relevant FDA-related legislation, such as the reauthorization of the Prescription Drug User Fee Act.

Based on 23 years working with manufacturers and wholesale distributors of prescription pharmaceuticals and medical devices, we recommend that the clarifications of the implementing PDMA pedigree regulations (§§203.3(b) and (u) and 203.50) outlined below be included in the CPG. These clarifications are essential to: (1) maintain a "level playing field" between ADRs and other distributors; (2) prevent the regulation from having the unintended anticompetitive and anti-consumer impact of facilitating monopolistic conduct and market power of the Big 3; (3) maintain affordable and efficient drug availability; and (4) maintain a workable system in which accurate

pedigrees are transmitted with drug shipments. These actions will not eliminate the need for changes in the regulation, but should help mitigate its harmful effects, while preserving the pedigree requirement's intended benefits.

1. Require manufacturers to list their ADRs publicly on their company websites. In many cases, despite the obligation of manufacturers to provide ADRs with written letters of authorization, the identity of those ADRs remain in question to FDA, to the distributors themselves and to those seeking to do business with the ADRs.
2. Require product manufacturers and ADRs to provide basic information to wholesalers to which they sell/transfer Rx drugs. Even though an ADR buying directly from the manufacturer is not itself required to pass a written pedigree, others to which those drugs are passed may be required to prepare a pedigree document. Without confirmation concerning the manufacturer, date of production and delivery, lot nos., etc., an accurate written pedigree cannot be prepared, and the drug may not be legally provided to the physician.
3. Clarify that if FDA becomes aware that ADRs are intentionally withholding sales to other wholesale-distributors based on an unwillingness to provide basic product and sales information to the downstream purchaser, or failure of manufacturers to provided needed information, it will work with the Federal Trade Commission to institute an investigation of the impact on consumers and competition of those practices and determine if either appropriate law enforcement initiatives or changes in FDA requirements are needed.
4. Compile and release periodically in Level 1 agency guidance a list of drugs that are considered priority candidates for written pedigrees by FDA because they fit within the four factors contained in the CPG. Allow public input before the list becomes final. Otherwise, the CPG merely permits FDA to prioritize the use of its limited enforcement resources, but requires wholesalers to maintain a full pedigree system immediately for every drug sold. Wholesalers will not be able to accurately gauge FDA's interpretation of these four factors (e.g., previously diverted or counterfeited drugs may not be publicly revealed; high priced or high demand drugs is a subjective standard administered at the sole discretion of FDA; insufficient marketing history would apply to all recently released or new drugs; etc.). The drug list used in Florida to implement its initial pedigree program (which was applicable only to particular listed drugs) could serve as a template for this agency listing.
5. Allow for the use of electronic tracking and inventory management systems to satisfy wholesaler obligations under the rule utilizing the principles of FDA's own Rule 11 (21 CFR Part 11) (e.g., available audit trail, recordable records, etc.).

D. Conclusion

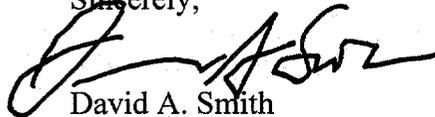
FDA has determined that the pedigree law should now be implemented at the Federal level. Now that this important decision has been taken, the Agency has an obligation to work with allies in industry to insure that the Federal system does not become merely a 51<sup>st</sup> approach to recording drug sales, but a system that expressly preempts inconsistent state regimes. Without one uniform national standard, smaller wholesalers may face the unmanageable additional burden of compiling separate written pedigrees which follow disparate substantive and procedural requirements in each state. Surely, this offends or violates the interstate commerce clause of the U.S. Constitution, which is intended to effectuate the interstate sale of important health care products.

It is also important that this system not become a "tail that wags the dog" by altering efficient existing marketing and sales practices. Major wholesalers could quickly hide behind these requirements to deny sales to smaller competitors. Manufacturers could use their power to anoint ADRs to elicit further concessions that could lead to higher prices and reduced availability. Harmful unintended consequences exist for physicians and patients, as well as supply chain inefficiencies driven by unfair competition. Real dangers exist from the regulations as written, unless mitigating measures are taken to assure flow of pedigree information and to avoid distribution bottlenecks. Finally, wholesalers should receive clear and unambiguous notice concerning the drugs for which FDA considers a written pedigree most important without opening themselves to unanticipated compliance action when following these FDA enforcement priorities.

We request the opportunity to meet with you and other decision-makers within the Agency to share our experience and assist with the implementation of this important policy initiative. In the meantime, please contact me or my colleagues if we may be of further assistance.

Best regards.

Sincerely,



David A. Smith  
President and CEO

cc: Ilisa Bernstein, Esq. ([ilisa.bernstein@fda.hhs.gov](mailto:ilisa.bernstein@fda.hhs.gov))  
Thomas A. Scully, Esq.  
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