

July 14, 2006

Acting Commissioner Andrew von Eschenbach, M.D.
Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20857

RE: 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 Dr. von Eschenbach:

On behalf of McKesson Corporation, I am pleased to provide comments on the Draft Compliance Policy Guide (draft CPG) as it relates to the *Prescription Drug Marketing Act's Pedigree Requirements* described in the June 14, 2006 issue of the Federal Register.

McKesson has led the industry in the delivery of medicines and healthcare products to pharmacies, hospitals and other healthcare entities for over 173 years. Today, a Fortune 16 corporation, we deliver vital pharmaceuticals, medical supplies and health information technology solutions that touch the lives of more than 100 million patients in every healthcare setting. We purchase pharmaceutical products from more than 450 manufacturers and supply over 75,000 customer sites across America. Each week, we deliver over \$1 billion worth of pharmaceuticals, or one-third of all medicines used in North America, to healthcare providers in every state. Consequently, we understand the critical importance of medication safety and the need to protect the integrity of the pharmaceutical distribution network.

As the largest pharmaceutical distributor in North America, McKesson has an unwavering commitment to the safe, efficient and cost-effective distribution of pharmaceutical products. Based on our long history and experience in the distribution business, we support and appreciate the FDA's efforts to enhance the integrity of the pharmaceutical distribution network through the implementation of the Prescription Drug Marketing Act (PDMA) final rule.

Today, most medicines flow from the manufacturer to the Authorized Distributor of Record (ADR) to a pharmacy, a practice consistent with the PDMA final rule. Since the passage of the PDMA, however, changes have occurred in the distribution network and in state laws that were not envisioned when the law was originally written. We believe the FDA's interpretation of the PDMA final rule should reflect these changes in the marketplace. Therefore, we recommend that the FDA take the following actions:

- Broaden the definition of manufacturer and pharmacy;
- Address inconsistencies among state and federal pedigree requirements;
- Exempt "drop shipments" from pedigree requirements; and
- Recognize that RFID technology must begin at the point of manufacture.

Broaden the Definition of Manufacturer and Pharmacy

As a result of the growing number of complex medicines with special storage and handling characteristics, many manufacturers contract with “Exclusive Distributors” or “Third-Party Logistic Providers” (3PLs) to deliver medicines to another distributor or healthcare provider. These contracts do not allow the distributor to direct the sale of the medicine. For the purposes of interpreting the PDMA final rule and applying pedigree requirements, we recommend the FDA clarify that a transaction that utilizes an exclusive distributor or 3PL be considered the same as a transaction from a manufacturer to an ADR to a pharmacy.

Secondly, the narrow definition of pharmacy in the draft CPG does not reflect standard business transactions which are commonplace in today’s distribution channel. McKesson is contractually obligated to deliver pharmaceuticals directly to large pharmacy chain and independent pharmacy cooperative buying group warehouses. The chain pharmacies and cooperative buying groups distribute these medicines from their warehouses directly to their retail stores or affiliated independent pharmacies. This delivery method improves efficiencies and mitigates distribution costs, thereby reducing the cost of the medicines. Therefore, we recommend that the definition of a pharmacy should be broadened in the final CPG to include a pharmacy’s distribution warehouses.

Address the Inconsistencies among State and Federal Pedigree Requirements

While we support the FDA’s decision to lift the stay on the PDMA final rule, we are concerned that the federal pedigree requirement may not be in concert with some state pedigree laws. The definition of manufacturer and pharmacy varies among numerous states and the federal government. At least 12 states have adopted pedigree requirements that are different from those required under the PDMA final rule. These states have recognized the evolving nature of the distribution network and broadened their definition of a manufacturer and a pharmacy, with pedigree requirements for any transaction outside of that tightly controlled distribution channel.

Inconsistencies between state and federal laws and regulations governing distribution of pharmaceuticals, and the resulting potential to trigger a pedigree requirement, jeopardize our ability to rapidly and cost-effectively distribute pharmaceutical products across the country. By providing guidance in the final CPG to broaden the definitions of manufacturer and pharmacy, the FDA could resolve the disparities between state and federal pedigree requirements.

Exempt Drop Shipments from Pedigree Requirements

During product shortages or other emergencies, drop shipment transactions may occur in order to expedite the delivery of a pharmaceutical to a healthcare provider. Some manufacturers actually require *all* of their products to be distributed in this manner. Drop shipments typically represent the shipment of a product from a manufacturer directly to a pharmacy. Even though the distributor never has physical possession of the product, the transaction is treated as a sale by the distributor to the customer, and in most cases the distributor is deemed to have legal title to the pharmaceuticals from the time they are shipped by the manufacturer until their delivery to the pharmacy. Since the distributor never has physical possession of the product, guidance from the FDA is necessary to clarify that such distributors will be exempted from the pedigree requirements under these circumstances.

Recognize that RFID Technology Must Begin at the Point of Manufacture

McKesson appreciates the FDA's strong support for RFID as the most promising technology to track and trace pharmaceuticals through the distribution network. RFID technology, combined with product serialization, will facilitate the creation of an electronic pedigree (ePedigree) that can be used to verify a product's chain of custody, from the manufacturer to the distributor to the pharmacy. An RFID ePedigree system would make it significantly more difficult for illegitimate and rogue operators to develop entry points within the distribution network.

To authenticate the chain of custody for pharmaceutical products and therefore enhance the integrity of the supply chain, RFID technology and product serialization must be initiated by the manufacturer. The security of the supply chain cannot be assured if an ePedigree is created or RFID technology is applied by the distributor, rather than at the first step in the distribution process. As we have learned, criminal organizations and unethical wholesalers can easily exploit the pedigree requirement by creating a fake pedigree and introducing counterfeit or other compromised medicines into the nation's drug supply. Therefore, we urge the FDA to publicly endorse the use of RFID technology and product serialization at the point where the pharmaceutical product is manufactured.

Conclusion

McKesson appreciates the opportunity to provide comments and recommendations that are based on current business practices as well as over 170 years of experience in distributing pharmaceuticals. We applaud the FDA for lifting the stay on the PDMA final rule and acknowledge the efforts that were invested in drafting the CPG. Due to the changing marketplace as well as to varying pedigree laws enacted by states, we urge the FDA to take the following steps in order to provide clarity in the final CPG on these important issues:

- Broaden the definition of manufacturer and pharmacy;
- Address inconsistencies among state and federal pedigree requirements;
- Exempt "drop shipments" from pedigree requirements; and
- Recognize that RFID technology must begin at the point of manufacture.

McKesson remains committed to enhancing the integrity of the pharmaceutical distribution network, and we look forward to continuing our collaboration with the FDA. Should you have questions or require further information, please contact either Ron Bone, Senior Vice President of Distribution Support, at 415.983.7613 or ron.bone@mckesson.com, or me at 415.983.8494 or ann.berkey@mckesson.com.

Sincerely,



Ann Richardson Berkey

cc: Ilisa Bernstein, Pharm.D., J.D.