

February 24, 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: Anti-Counterfeit Drug Initiative Workshop and Vendor Display; 71 Fed. Reg. 1759;
January 11, 2006 [Docket No. 2005N-0510]***

Dear Dr. von Eschenbach:

On behalf of McKesson Corporation, I am pleased to submit comments to the Food and Drug Administration (FDA) regarding the Prescription Drug Marketing Act (PDMA) Final Rule. We appreciate the opportunity to elaborate on the expert testimony we provided at the FDA Anti-Counterfeit Drug Initiative Workshop earlier this month.

For over 170 years, McKesson has led the industry in the delivery of medicines and healthcare products to pharmacies, hospitals and other healthcare entities. Today, a Fortune 15 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 more than 75,000 healthcare customer sites across America. Therefore, we understand the critical importance of medication safety and the need to protect the integrity of the pharmaceutical supply chain.

As the largest pharmaceutical distributor in North America, McKesson is committed to the safe, efficient and cost-effective distribution of pharmaceutical products. Based on our long history and expertise in the distribution business, we welcome the opportunity to share our insights regarding the PDMA Final Rule and a comprehensive “Anti-Counterfeiting” strategy which will help to ensure that our nation’s drug supply remains safe.

PDMA 1999 Final Rule

McKesson supports the PDMA Final Rule that permits pharmaceutical products to flow from the manufacturer through an Authorized Distributor of Record (ADR), and potentially to a second ADR, to the pharmacy without the need for a pedigree.

Over the past seven years, significant changes have occurred in the way pharmaceutical products are shipped from the manufacturer through the distribution channel to a pharmacy or patient.

The main factors contributing to the changing marketplace include:

- advances in the design of complex biological pharmaceutical products with special storage and handling characteristics, and
- the steps that supply chain partners have taken to reduce distribution costs to meet the economic demands of our customers.

In light of these changes in the distribution network, we strongly encourage the FDA to broaden the definition of manufacturer and pharmacy to account for standard business transactions that occur in today's normal distribution channel. Attached to this document is a description of the product flow through the distribution network from the manufacturer to the wholesaler to the pharmacy and to the patient. These transactions constitute today's normal distribution channel in the marketplace and therefore should not require pedigrees.

Comprehensive Anti-Counterfeiting Strategy

The FDA's leadership is essential to create a framework that permits nationwide distribution of pharmaceutical products and ensures uniformity in the regulations that are implemented. We urge the FDA to collaborate with the pharmaceutical industry and state government entities to determine and set the parameters for supply chain security across the country. The following components are essential to attaining this objective:

1. Federal Wholesaler Licensure Standards

McKesson commends the states for their well-intended efforts to impede the introduction of counterfeit pharmaceuticals into the distribution network; however, we have significant concerns that the states are creating an inconsistent patchwork of pedigree regulations and requirements. These incongruous laws will not comprehensively enhance the security of the distribution network, but they will slow and perhaps halt our ability to provide critical medicines to our customers and their patients in a timely and cost-effective manner.

Medical emergency shipments highlight some of the negative and harmful consequences that differing state pedigree laws would have on our ability to meet the needs of our hospital customers and their patients. Emergencies can be of the scale of Hurricane Katrina or an avian flu pandemic. Our recent experience with Katrina is a good example of the need for a national standard. Since we had advance warning of the potential impact of Katrina, we moved critically needed pharmaceutical products from our Louisiana warehouse to our warehouses in adjacent states. The day after the storm hit, we were able to deliver needed medications from these out-of-state warehouses to our hospital and pharmacy customers in Louisiana as well as in other impacted states. A patchwork of state pedigree regulations will compromise our ability to rapidly move vital medicines across state lines.

Emergencies also include our hospital and pharmacy customers who have patients needing lifesaving drugs. Often these drugs must be urgently delivered to patients on weekends or holidays. In an emergency, a state could become isolated from our nationwide pharmaceutical distribution network due to inconsistent and varying pedigree laws. This will delay and may prevent us from providing this critically needed service when state boundaries need to be crossed.

In time-critical situations, medicines are shipped directly from manufacturers to hospitals to respond to overnight emergencies. These “drop shipment arrangements” will also be subject to delays as they await the required pedigree documentation. Since they are shipped directly from the manufacturer, these products should be exempt from pedigree requirements.

We support national uniform licensing standards. In addition, we strongly advocate physical inspection of facilities and thorough screening procedures prior to the issuance of licenses to wholesale drug distributors. Implementation and enforcement of stringent licensing standards will limit the opportunities for rogue distributors to introduce counterfeit pharmaceutical products into the distribution network.

2. Criminal Penalties

The FDA should collaborate with the appropriate legislative and law enforcement officials at the federal and state level to institute stronger criminal penalties for those who counterfeit pharmaceuticals or knowingly distribute those compromised products. The penalties should be stiffer than those imposed upon traffickers in illegal drugs. We believe tougher criminal penalties coupled with more stringent licensure requirements will remove many of the incentives and opportunities for counterfeit drugs to be introduced into the system.

3. Electronic Pedigrees via Radio Frequency Identification (RFID) Technology

McKesson supports the use of electronic track and trace technology via RFID and product serialization to authenticate the chain of custody for pharmaceutical products. RFID technology 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 wholesaler to the pharmacy. An RFID ePedigree would make it significantly more difficult for illegitimate and rogue operators to develop entry points within the distribution network.

In order for this technology to be implemented, manufacturers must embrace RFID and assume the responsibility for placing electronic tags on their products, while wholesalers and pharmacies must install the necessary infrastructure. RFID ePedigrees will significantly enhance efforts to protect the integrity of the distribution network, and more importantly, negate the need for paper pedigrees and two-dimensional barcode systems which will add additional costs to the distribution network without enhancing the safety of the pharmaceutical products.

We are deeply concerned that some states have or will attempt to mandate pedigree solutions based on tracking lot numbers and transaction dates. These pedigree systems do not uniquely track and trace products through the supply chain and require significant investments in a less efficient, interim technology; thereby diverting attention and needed resources from time-critical investments in RFID. We believe it is vital that the industry stay focused on one compatible RFID ePedigree system to be developed for use throughout the supply chain, across state lines, and by all trading partners.

We heard from representatives of states who commented at the Anti-Counterfeit Drug Initiative Workshop that they would welcome uniform standards for pedigree systems from the federal government.

Industry Steps to Secure the Pharmaceutical Supply Chain

RFID Standards and Pilot Project

Through our leadership and proactive involvement with EPCglobal and Jumpstart, McKesson is on the leading edge of a cross-industry effort to develop standards and implement electronic track and trace technology to create ePedigrees. EPCglobal is developing the standard for the use of a serialized RFID in support of an ePedigree for pharmaceutical products.

In an industry-supported pilot project, a major pharmaceutical manufacturer is currently shipping RFID-tagged pharmaceuticals into the domestic supply chain to test the utilization of this technology to track products.

Sound Pharmaceutical Buying Practices

McKesson strongly believes that sound buying practices are a critical component to any effort to eliminate counterfeit pharmaceuticals in the supply chain. McKesson purchases 100 percent of all pharmaceutical products directly from the manufacturer or the manufacturer's designated distributor, and we sell them directly to our pharmacy customers.

Conclusion

McKesson appreciates the opportunity to provide its comments and recommendations based on our experience and current business practices. We applaud the FDA's commitment to providing a safe channel for pharmaceuticals, and strongly urge the Task Force to take the lead in the following areas:

- develop uniform federal standards for licensure and tougher criminal penalties for counterfeiters;
- assure our ability to swiftly and effectively respond to emergencies; and
- establish parameters for serialization and electronic pedigrees that can be used across the country.

We look forward to continuing collaboration to ensure the integrity of the pharmaceutical distribution system. Should you have questions or require further information, please contact Ron Bone, Senior Vice President, Distribution Support, at 415.983.7613 or ron.bone@mckesson.com.

Sincerely,

Ann Richardson Berkey
Vice President, Public Affairs
McKesson Corporation

Attachment

McKesson's Recommended Amendment to the PDMA Final Rule to Account for Normal Distribution Channel Transactions

The following language broadens the definition of normal distribution channel to reflect current standard business transactions which do not require a pedigree:

“Normal distribution channel” means the route that the legend drug travels:

- (a) From a manufacturer to a wholesale drug distributor, to a pharmacy, and to a patient;
- (b) From a manufacturer to a wholesale drug distributor, to a chain drug warehouse, to a pharmacy affiliated with the chain drug warehouse, and to a patient;
- (c) From a manufacturer to a wholesale drug distributor, to a pharmacy buying cooperative warehouse, to a pharmacy that is a member owner of the buying cooperative operating the warehouse, and to a patient;
- (d) From a manufacturer to a third party logistics provider or the manufacturer’s exclusive distributor to a wholesale drug distributor, to a pharmacy, and to a patient;
- (e) From a manufacturer to a third party logistics provider or the manufacturer’s exclusive distributor, to a wholesale drug distributor, to a chain drug warehouse, to a pharmacy affiliated with the chain drug warehouse, and to a patient;
- (f) From a manufacturer to a third party logistics provider or the manufacturer’s exclusive distributor, to a wholesale drug distributor, to a pharmacy buying cooperative warehouse, to a pharmacy that is a member owner of the buying cooperative operating the warehouse, and to a patient;
- (g) From a manufacturer to a third party logistics provider or manufacturer’s authorized distributor of record to a wholesale drug distributor to one of the following wherein the legend drug is delivered directly by way of a drop shipment arrangement:
 - (i) a pharmacy or other persons authorized under law to dispense or administer prescription drugs to a patient;
 - (ii) a chain drug warehouse to its intracompany pharmacy to a patient; or
 - (iii) a pharmacy buying cooperative warehouse to its member to a patient.
- (h) In limited situations where a documented product shortage, back order or emergency exists, from a manufacturer or that manufacturer’s third party logistics provider or sole authorized distributor of record to an authorized distributor of record to one other authorized distributor of record to:
 - (i) a pharmacy or other persons authorized under law to dispense or administer prescription drugs to a patient;
 - (ii) a chain drug warehouse to its intracompany pharmacy to a patient; or
 - (iii) a pharmacy buying cooperative warehouse to its member to a patient.

The terms used in describing these transactions are defined as follows:

- "Third party logistics provider" means an entity that provides or coordinates warehousing, distribution, or other services on behalf of a manufacturer, but does not take title to the legend drug or have general responsibility to direct the legend drug's sale or disposition.
- "Chain drug warehouse" means a permanent physical location for drugs and/or devices that acts as a central warehouse and performs intracompany sales, and sales and transfers of drugs or devices to chain pharmacies, which are members of the same affiliated group under common ownership and control. Chain drug warehouses must be licensed as wholesale distributors.
- "Pharmacy buying cooperative warehouse" means a permanent physical location that acts as a central warehouse for drugs and from which sales of drugs are made to a group of pharmacies that are member owners of the buying cooperative operating the warehouse. Pharmacy buying cooperative warehouse must be licensed as wholesale distributors.
- "Authorized distributor of record" means a distributor with whom a manufacturer has established an ongoing relationship to distribute the manufacturer's products.
- "Ongoing relationship" means an association that exists when a wholesale drug distributor, including any affiliated group, as defined in Section 1504 of the Internal Revenue Code, of which the wholesale drug distributor is a member (i) is listed on the manufacturer's list and the list is updated monthly; or (ii) has a written agreement currently in effect with the manufacturer.
- "Drop shipment arrangement" means the physical shipment of a legend drug from a manufacturer, that manufacturer's third party logistics provider or that manufacturer's authorized distributor of record directly to a chain pharmacy warehouse, pharmacy buying cooperative warehouse, pharmacy or other persons authorized under law to dispense or administer prescription drugs but wherein the sale and title for the legend drug passes between a wholesale drug distributor and that party that directly receives that legend drug.
- "Manufacturer's exclusive distributor" means an entity that contracts with a manufacturer to provide or coordinate warehousing, distribution, or other services for a manufacturer and takes title to that manufacturer's drug or controlled substance.