

Prescription Drug Marketing Act (PDMA) and its Pedigree Requirements

Background:

PDMA, acronym for the Prescription Drug Marketing Act, became law on April 22, 1988¹. The primary objective of this law was to assure safe and effective distribution of prescription drugs and to minimize risks to consumers from taking counterfeit, adulterated, sub-potent or expired drugs².

PDMA, among other things, established a “pedigree” requirement for wholesalers and distributors who are not manufacturers or so called authorized distributors.³ A drug pedigree is nothing more than “a statement of origin that identifies each prior sale, purchase, or trade of a drug, including the date of each of those transactions and the names and addresses of all parties to those transactions.”⁴ However, Congress^[MSOffice] excluded the so called authorized wholesalers and distributors from the “pedigree” requirement of PDMA.⁵

Therefore, one of the by products of PDMA was the emergence of two distinct categories of drug wholesalers and distributors: 1) Authorized, where the wholesaler is the “official” distributor of a pharmaceutical manufacturer and 2) Unauthorized, where the wholesaler or distributor purchases from authorized wholesalers.

Since the enactment of the PDMA in 1988, the metamorphosis of drug distribution business has been significant. Back in the eighties, the drug distribution business was fairly linear: Manufacturer → Wholesaler/Distributor → Consumer. Today a drug may go through several transaction cycles before arriving in the hands of a consumer.⁶

Today, secondary wholesalers, the so called unauthorized wholesalers and distributors, account for 5%-10% of the \$200 billion wholesale pharmaceutical market.⁷ And the transactions often move between authorized and unauthorized wholesalers. The Healthcare Distribution Management Association (HDMA) told the FDA that top drug wholesalers purchase 2%-4% of their products from non-manufacturers.⁸ One of the leading drug wholesalers reported that of \$16 billion total inventory, approximately \$350 million was purchased from non-manufacturers.⁹

¹ The Prescription Drug Marketing Act Report to Congress June 2001, U.S. Food and Drug Administration.

² Ibid

³ Pharmaceutical Pedigree Requirements, Implementing Electronic “Track and Trace”, Gary C. Messplay, J.D. and Colleen Heisey, J.D., *Contract Pharma*, July/August 2006.

⁴ Ibid

⁵ The Prescription Drug Marketing Act Report to Congress June 2001, U.S. Food and Drug Administration.

⁶ Ibid

⁷ Ibid

⁸ Ibid

⁹ Ibid

Section 503(e)(1)(A) of Federal Food, Drug, and Cosmetic Act requires that the pedigree must identify “each prior sales, purchase or trade.” The Agency’s 1988 guidance letter indicated that the pedigree could start with either the manufacturer or the authorized distributor¹⁰. This assumption probably was based on the premise of linear distribution channel. Since the issuance of the Agency’s 1988 guidance, the unauthorized distributors have construed the Agency’s guidance to mean that the pedigree need only go back to the most recent authorized distributor handling the drug¹¹. This interpretation is also known as the *status quo*.

However, the language of the current regulation expands the definition of “pedigree” to include “each prior sale, purchase, or trade of such drug” (Section 203.50(a)) and include ‘all parties to each transaction...starting with the manufacturer” (Section 203.50(a)(6)).¹²

This interpretation of the statute is incompatible with the *status quo* currently adopted by the non-authorized drug wholesalers and distributors.

Since authorized wholesalers are exempt from the pedigree requirements and, in most cases, are reluctant to provide pedigree documents to whomever they sell pharmaceuticals to, the implementation of the pedigree provision in December 2006 will effectively shutdown the secondary drug wholesaler and distributor market¹³.

The only way to circumvent this hurdle is for secondary wholesalers to buy directly from manufacturers. Unfortunately, “big” pharmaceutical companies repudiate this notion.

The Federal Food and Drug Administration had delayed the implementation of the provision of PDMA that requires complete documentation of the custody chain of drugs in the distribution channel five times.¹⁴ Originally the pedigree requirement was scheduled to take effect in December 2000.¹⁵ However, after the publication of the final guidance in 1999, the Agency received numerous public comments. This prompted the agency to delay the implementation date. In February 2004 the Agency again delayed the enforcement of the pedigree provision because the Agency wanted to give the pharmaceutical industry more time to adopt electronic technology (RFID) for tracking drugs through out the distribution channel. The decision was partly based on the premise that the Agency believed that electronic technology for tracking drugs would be wide spread by 2007.¹⁶ The Agency contended that the wide spread adoption of RFID would create the equivalent of an “electronic pedigree”, tracking the movements of drugs all throughout the drug distribution channel.¹⁷

¹⁰ Ibid

¹¹ Ibid

¹² Ibid

¹³ Ibid

¹⁴ American Society of Health-System Pharmacists; ASHP News: FDA to Enforce Drug Pedigree Rules; www.ashp.org/news

¹⁵ Ibid

¹⁶ Ibid

¹⁷ Ibid

In February 2006, the Agency capitulated to the fact that the 2007 timeline is unattainable.¹⁸ The Agency's Counterfeit Drug Task Force refuses to forecast a new timetable for the possible implementation of electronic track-and-trace technology.¹⁹ The Counterfeit Drug Task Force determined that an electronic pedigree through a track-and-trace method, i.e. an "e-pedigree", would secure the integrity of the drugs in the distribution channel.²⁰ Paradoxically although the Task Force is unsure of a possible implementation date of the RFID, it nevertheless recommended that the pedigree provision of the PDMA should be implemented effective December 2006.²¹ And the Agency decided to adopt the Task Force's recommendation.²²

The Agency's decision may also have been influenced by states' initiatives to enact distinct pedigree requirements in absence of a federal regulation, potentially burdening the drug distribution channel which could affect consumer access to drugs.²³

The Task Force also recommended that the Agency issue a draft Compliance Policy Guide to focus the Agency's pedigree enforcement efforts on drugs most vulnerable to counterfeiting and diversion.²⁴ The Agency has already published a Compliance Policy Guide relating to the enforcement of the pedigree provision of the PDMA. The guideline seems to indicate that the agency is likely to take a risk-based approach to utilize its enforcement authority.²⁵

Radio Frequency Identification (RFID) Device:

A Radio Frequency Identification device is a small electronic identification chip attached to drugs products.²⁶ The chip contains data in the form of electronic product code (EPC). This product information is transmitted via wireless to "readers".²⁷ The information is then gathered, analyzed, and stored in a database, providing an electronic blueprint of a drug's movement from point-of-origin to destination.²⁸

The Agency is a strong proponent of the widespread use of Radio Frequency Identification devices: "FDA continues to believe that RFID is the "most promising" technology for tracking and tracing drugs in the supply chain, said Randall Lutter, FDA's associate commissioner for policy and planning."²⁹ However, the Agency's earlier

¹⁸ Ibid

¹⁹ Ibid

²⁰ Pharmaceutical Pedigree Requirements, Implementing Electronic "Track and Trace", Gary C. Messplay, J.D. and Colleen Heisey, J.D., *Contract Pharma*, July/August 2006.

²¹ Ibid

²² Ibid

²³ eSource: Regulatory

²⁴ Pharmaceutical Pedigree Requirements, Implementing Electronic "Track and Trace", Gary C. Messplay, J.D. and Colleen Heisey, J.D., *Contract Pharma*, July/August 2006.

²⁵ Ibid

²⁶ eSource: Regulatory

²⁷ Ibid

²⁸ Ibid

²⁹ American Society of Health-System Pharmacists; ASHP News: FDA to Enforce Drug Pedigree Rules; www.ashp.org/news

prediction of widespread use of Radio Frequency Identification devices by year 2007 seems unrealistic. Several issues are blamed for the slow acceptance of Radio Frequency Identification devices by the pharmaceutical industry³⁰:

1. The limitations of RFID
2. The uniform adoption of RFID
3. The cost
4. The unknown effect of RFID on biologics
5. Privacy issues

In spite of the above outlined concerns, the Agency's exuberance on Radio Frequency Identification devices continue to remain high: "We're hoping that the industry will continue to move forward with some speed to get the e-pedigree in place as quickly as possible," commented Steve Niedelman, assistant commissioner for regulatory affairs at FDA.³¹

The Impact of the Implementation of Pedigree Provision of PDMA:

1. Uneven Playing Field among Drug Wholesalers and Distributors:

- a. Congress exempted authorized distributors from the pedigree requirements of PDMA.³² Due to this, most authorized distributors do not maintain or pass on pedigree, creating enormous problems for unauthorized distributors wishing to purchase from authorized distributors for resale. Once PDMA is implemented in December 2006, it will be illegal to resale prescription drugs without a pedigree.³³ This would have an adverse effect on consumers' access to pharmaceuticals and the price they pay for them.
- b. When PDMA was enacted, the drug distribution channel was linear (explained above). Today the drug distribution channel for the delivery of pharmaceuticals in the hands of consumer is much more involved than before. Therefore, authorized distributors should also be required to provide and maintain pedigree.
- c. The Agency has expressed its concerns relating to the pedigree exemption provision of authorized distributors under PDMA.³⁴
- d. The only way the secondary wholesalers and distributors can legally operate after December 2006 is to purchase pharmaceuticals directly from

³⁰ eSource: Regulatory

³¹ American Society of Health-System Pharmacists; ASHP News: FDA to Enforce Drug Pedigree Rules; www.ashp.org/news

³² The Prescription Drug Marketing Act Report to Congress June 2001, U.S. Food and Drug Administration.

³³ Ibid

³⁴ Ibid

manufacturers. Unfortunately, most “big” pharmaceutical companies refuse to open new distributors.

- e. Bill Hubbard, former FDA associate commissioner for policy and planning said in an interview with *Pink Sheet* that the ADR provision creates an “unlevel playing field” in the industry and Congress should eliminate the provision.³⁵

2. Potential for Oligopoly Condition in the Drug Distribution Channel:

- a. The big-three wholesalers already control 95% of the drug wholesaler market. The implementation of the pedigree provision is likely to force many secondary wholesalers and distributors out of business. This would mean that the big-three wholesalers will gain even more control of the drug wholesaling market than today. As one would expect, reduced competition would increase the price paid by consumers for pharmaceuticals.
- b. Independent drug stores are most susceptible to this potential emerging market condition. The inability of the secondary wholesalers to provide pedigree could force the independent drug stores to buy branded drugs from the big-three wholesalers perhaps at a higher price than previously possible from secondary wholesalers.
- c. Since independent drug stores most likely will pass on the increased cost to consumers, this will ultimately add to the already spiraling prescription drug cost.
- d. The pharmacies unable to pass on the increased cost to remain price competitive will experience shrinking gross margin. This could push many pharmacies to the brink of closing.
- e. If the big-three wholesalers enhance their market dominance, the cost of generic pharmaceuticals to independent drug stores will increase. Generic pharmaceuticals are already a major profit opportunity for big-three wholesalers, yielding between 15%-30% gross margin. To maximize their profit opportunity, it is not uncommon to find that the big-three wholesalers often impose a purchase target for generic pharmaceuticals. Failing to meet this pre-determined target could translate into higher acquisition cost of brands, and in some cases, could mean termination of purchasing relationship.
- f. Selling of generic pharmaceuticals by secondary wholesalers at a margin lower than the big-three wholesalers is keeping the price of generic pharmaceuticals for independent drug stores in check. If the secondary

³⁵ The *Pink Sheet*, July 10, 2006

wholesaler market is eclipsed, independent drugstores and consumers are likely to pay higher price for generic pharmaceuticals.

- g. The Healthcare Distribution Management Association (HDMA), which had a great deal of influence with the Agency and Congress in crafting the pedigree provision of PDMA, is essentially the voice of authorized distributors. The association perhaps to limit the voice of unauthorized distributors and wholesalers has recently created a different classification for this group: non-authorized distributors, or “associate membership”, as opposed to ‘full membership’^[MSO file2].
- h. We believe the FDA’s June 9th comment, released when the task force decided to lift the stay of the PDMA, that “they have not heard the concerns raised in the past regarding the impact on small wholesalers” is a function of HDMA taking the voice away from the secondaries/ “associate members”, thus making the ‘full members’ voice, the only one heard.

3. The Loop-holes for the Entry of Counterfeit Drugs into the Distribution Channel Continues

- a. The exemption of authorized distributors from the pedigree requirement compromises the very goal of PDMA: To avoid the unacceptable risk of counterfeit and adulterated drugs from being taken by consumers.³⁶ This exemption perhaps allows an unscrupulous wholesaler or distributor (or individuals within that company) to sell a counterfeit drug without giving any pedigree, just because they are an ‘A/D’, authorized distributor, and are not required to maintain or pass on a pedigree when the drugs are resold. Therefore, the PDMA, if implemented in its current form, will not provide the American consumer 100% protection against counterfeit, adulterated, or diverted drugs.

4. The Pedigree Exemption is Tantamount to “Wiping the Slate Clean” Each Time Drugs Pass through Authorized Distributors

- a. The PDMA pedigree exemption is not only bad for unauthorized distributors, but also has the effect of “wiping the slate clean” each time drugs touch the authorized distributors’ dock. This keeps the door open for counterfeit, sub-potent, and misbranded drug back into the distribution channel, compromising health of consumers.³⁷

³⁶ Ibid

³⁷ Ibid

5. *Universal Pedigree Requirement is an Additional Deterrent against Marketing Counterfeit Drugs*

- a. While there is no bullet-proof protection against the entry of counterfeit drugs into the distribution channel, universal pedigree requirement would make it difficult for someone planning to introduce counterfeit or diverted drug into the distribution channel.

In summary, the enforcement of the PDMA in its current form will not guarantee that drugs purchased by consumers are safe and effective, however it will cause the secondary wholesale and distributor class of trade to become defunct. The law, as it remains, will significantly burden the drug distribution channel, and negatively impact both access and price, of prescription drugs, especially generics. The Authorized Distributor exemption should be removed from the FDA regulations.