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FDA Reverses Course on Drug Pedigrees: Pedigrees No Longer Required Back to Manufacturer

On July 14, 2011, the Food and Drug Administration ("FDA" or "Agency") proposed to permit wholesale distributors to document the chain of custody (also known as a drug "pedigree") of prescription drug products only back to the last authorized distributor of record ("ADR"), instead of all the way back to the manufacturer.[1] As explained below, FDA's proposal (if implemented) will not impact the current operations of wholesale drug distributors, and it does absolutely nothing to address a more pressing problem facing the industry—an increasingly complex patchwork of diverse state pedigree requirements.

Background

PDMA

The Prescription Drug Marketing Act of 1987 ("PDMA") (Public Law 100-293) (21 U.S.C. § 353(e)(1)(A)) applies to wholesale distributors of prescription drugs and requires each person who is not the drug's manufacturer or the manufacturer's ADR to provide a pedigree to the person who receives the drug. The purpose of the PDMA and the pedigree requirement is to prevent diversion of prescription drugs and the introduction of counterfeit prescription drugs into the market. Every pedigree must include a statement "identifying each prior sale, purchase, or trade of such drug (including the date of the transaction and the names and addresses of all parties to the transaction)."[2] In 1999, FDA implemented a regulation, 21 C.F.R. § 203.50(a), that further requires each pedigree to: (1) list each transaction *back to the drug's manufacturer*, including names of all parties involved and dates of each transaction, and (2) contain information about drug dosage, container size, number of containers, and lot or control numbers.[3]

Compliance Issues

The pedigree regulation came under fire from secondary wholesalers who typically purchase drugs from ADRs (*i.e.*, wholesale distributors who are designated by manufacturers as authorized distributors). These secondary wholesalers complained that they could not comply with the pedigree requirements because (1) they purchase their products from ADRs, rather than from manufacturers, and therefore may never be able to obtain documentation of transactions back to the manufacturer; and (2) ADRs are not required by law to provide pedigrees, and most are unwilling to voluntarily provide them to secondary wholesalers. Consequently, in 2004, FDA delayed the effective date of the pedigree regulation until 2006, based on assurances by the wholesale drug distribution industry that it would voluntarily implement by 2007 electronic track-and-trace technology—a technology that would make pedigrees unnecessary to protect against diversion and counterfeit drugs. However, in June 2006, FDA announced that because it appeared that use of electronic pedigree would not be widely adopted by 2007, it did not intended to delay the effective date of the regulations beyond December 2006.

Injunction

In September 2006, a group of secondary wholesalers sued the Agency to block implementation of § 203.50(a), claiming that they could not comply with the regulation, in part because ADRs were not required to provide them a pedigree that they could pass on.[4] The group sought, among other things, a declaratory judgment that FDA had erroneously interpreted the statutory requirements for pedigrees (21 U.S.C. § 353(e)(1)(A)), and violated the U.S. Constitution's guarantees of equal protection and due process.

On December 8, 2006, the U.S. District Court for the Eastern District of New York sided with the industry and enjoined FDA from implementing the regulation (21 C.F.R. § 203.50(a)).

In response, FDA stated that it viewed the court order as affecting only what information is required in a pedigree, and how far back the pedigree must go. FDA conceded that pedigrees passed on by non-ADRs need only trace back to the manufacturer or the last ADR that handled the drug, but reiterated that the injunction did not affect the statutory PDMA requirement that pedigrees contain the dates of all listed transactions, and the names and address of all parties involved in those transactions.[5] FDA also stated that it considered all other definitions and provisions in 21 C.F.R. § 203 relating to the pedigree requirement in effect despite the injunction.

Proposed Rule

FDA has now proposed to remove 21 C.F.R. § 203.50(a) in its entirety. By doing so, the Agency has chosen to codify its current position (post-court order) on drug pedigrees. In addition, FDA has announced that it intends to exercise "enforcement discretion" with respect to § 203.50(a) while the rulemaking is pending. But because FDA has been enjoined for almost five years from enforcing this regulation, the Agency's decision to remove it and to exercise its enforcement discretion should have little to no impact on current industry operations.

FDA's proposal states that it will not initiate an enforcement action over § 203.50(a) or the related section of the PDMA, as long as each pedigree:

- Identifies the name(s) and address(es) of the last ADR that handled the drug
- Lists the associated dates of transactions involving that last ADR
- Identifies the names and addresses of all subsequent unauthorized distributors (i.e., non-ADRs) that handled the drug
- Lists the associated dates of transactions involving these unauthorized distributors

FDA also "encourages" wholesalers to include the drug, dosage, container size, number of containers, and the drug's lot or control number(s) in the pedigree.

In other words, to comply with federal law, unauthorized distributors should maintain pedigrees that include, at a minimum, information regarding transactions going back to either the manufacturer or the last ADR that handled the drugs, and the date of the transaction and the names and addresses of all parties to the transaction. Unauthorized distributors may also include, but are not required to include, the drug, dosage, container size, numbers of containers, and the drug's lot or control number(s) in each pedigree.

FDA is accepting electronic or written comments on the proposed rule until September 12, 2011 (identified by Docket No. FDA-2011-N-0446): electronic submission (www.regulations.gov); fax (301-827-6870); or mail/hand delivery/courier (Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Pedigree Issue Remains

While many appreciate FDA's decision to resolve the controversy over § 203.50(a), the Agency's action does nothing to simplify the pedigree process or help resolve one of the most pressing problems facing the drug distributor industry today: the increasingly complex, and often conflicting, state pedigree requirements, many of which are not fully established or have staggered implementation deadlines.

For instance, the pedigree requirements in California—which comprise one of most comprehensive and onerous pieces of drug pedigree legislation to date—have staggered implementation deadlines, requiring total compliance throughout the supply chain by July 1, 2017. California manufacturers must have a system in place for 50 percent of their products by 2015, and 100 percent by 2016; California wholesalers and repackagers must accept and pass pedigrees by July 2016; and California pharmacies and pharmacy warehouses must accept pedigrees by July 2017.[6]

To date, 25 states have passed or have proposed laws and regulations implementing pedigree requirements, each with varying degrees of complexity and need for advanced technology.[7] Unless Congress preempts these emerging laws, drug distributors will be forced to continue to allocate significant time and resources both internally and through outside vendors to maintain an effective state-based pedigree compliance system.

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[1] Docket No. FDA-2011-N-0446, CDER 201164. *Removal of Certain Requirements Related to the Prescription Drug Marketing Act; Opportunity for Public Comment* (July 14, 2011), available at www.regulations.gov.

[2] 21 U.S.C. § 353(e)(1)(A)..

[3] 21 C.F.R. § 203.50(a).

[4] *RxUSA Wholesale, Inc. v. Dep't of Health and Human Serv.*, 467 F. Supp. 2d 285 (E.D.N.Y. 2006), *aff'd* 2008 WL 269935 (2d Cir. 2008).

[5] *See Addendum to FDA's Guidance for Industry: PDMA Pedigree Requirements—Questions and Answers Related to the Preliminary Injunction ordered 12/5/06 in* RxUSA Wholesalers, Inc. v. HHS (Dec. 15, 2006); 21 U.S.C. § 353(e)(1)(A) (requiring pedigrees to identify "each prior sale, purchase, or trade of such drug (including the date of the transaction and the names and addresses of all parties to the transaction)").

[6] *See* Cal. Bus. & Prof. Code §§ 44034, 4163.

[7] Arizona, California, Colorado, Florida, Georgia, Idaho, Illinois, Indiana, Iowa, Kentucky, Louisiana, Maryland, Mississippi, Nebraska, Nevada, New Jersey, New Mexico, North Dakota, Oklahoma, Oregon, South Dakota, Texas, Virginia, Wisconsin, and Wyoming.

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