

Docket Nos. 92N-0927

88N-0258

BEFORE

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

PETITION FOR CONTINUATION OF STAY OF ACTION

BY THE

PHARMACEUTICAL DISTRIBUTORS ASSOCIATION

FINAL RULE CONCERNING POLICIES, REQUIREMENTS, AND

ADMINISTRATIVE PROCEDURES;

PRESCRIPTION DRUG MARKETING ACT

OF 1987; PRESCRIPTION DRUG AMENDMENTS OF 1992

January 26, 2006

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January 25, 2006

The Pharmaceutical Distributors Association ("PDA"), a trade association of state-licensed wholesale distributors of prescription drugs, submits this petition pursuant to 21 C.F.R. § 10.35 to request the Commissioner of Food and Drugs to continue the stay and to suspend the effective date of those parts of the final rule in Docket Nos. 92N-0297 and 88N-0258 which require a prescription drug pedigree to list all prior sales back to the manufacturer (21 C.F.R. § 203.50(a)(6)) and which require a written agreement to evidence an ongoing relationship between a wholesale distributor and a manufacturer (21 C.F.R. § 203.3(u)). Those parts of the final rule are presently scheduled to go into effect on December 1, 2006. 69 Fed. Reg. 8105, Feb. 23, 2004

A. Decision Involved.

The Prescription Drug Marketing Act ("PDMA") was enacted on April 22, 1988 (Pub. L. 100-293) and amended on August 26, 1992 (Pub. L. 102-353). Promptly after PDMA was enacted, the Food and Drug Administration ("FDA"), on August 1, 1988, issued a letter to industry to provide guidance on compliance with the new law ("1988 guidance"). Also in 1988, FDA proposed regulations setting forth minimum requirements for state licensure of wholesale drug distributors. These regulations were made final in September of 1990 and appear at 21 C.F.R. Part 205. It was not until March of 1994, however, that FDA proposed rules regarding the paperwork requirements of PDMA. And, five years later, on December 3, 1999, the FDA made these into a "final rule." 64 Fed. Reg. 67720.

The final rule requires, for the first time since PDMA was passed in 1988, that the paperwork accompanying wholesale distributions of prescription drugs ("prescription drug pedigree") include prior sale information back to the manufacturer

even though some wholesale distributors, known as authorized distributors, are not required to provide pedigrees when they sell drugs to other distributors. 21 C.F.R. §203.50(a)(6). In addition, these regulations, also for the first time, require a written agreement between a wholesaler and manufacturer to be in place as evidence of the ongoing relationship necessary to achieve authorized distributor status. 21 C.F.R. §203.3(u).

B. Action Requested.

The final rule was published December 3, 1999, and had an effective date of December 4, 2000. By Notice published May 3, 2000 the FDA stayed the December 4, 2000 effective date to October 1, 2001. 65 Fed. Reg. 25639. A further stay of the effective date to April 1, 2002 was promulgated on March 1, 2001. 66 Fed. Reg. 12850. Another stay of the effective date to April 1, 2003 was promulgated on February 13, 2002 (67 Fed. Reg. 6645). At 68 Fed. Reg. 4912, January 31, 2003, the effective date was further stayed until Apr. 1, 2004, and at 69 Fed. Reg. 8105, February 23, 2004, the effective date was stayed until December 1, 2006.

This petition requests that those portions of the regulation regarding the need for a written agreement as evidence of an ongoing relationship between a manufacturer and a distributor (21 C.F.R. § 203.3(u)) and those that require that the "identifying statement for sales by unauthorized distributors" identify "all parties to each prior transaction involving the drug, starting with the manufacturer" (21 C.F.R. §203.50(a)(6)), be further stayed until one year after the Administration has had the opportunity to evaluate the efforts of the pharmaceutical manufacturing and distribution industries to put in place track and trace technology that would overcome

some of the difficulties presented by the final rule, or December 31, 2009, whichever is earlier. In granting such a stay, it is requested that FDA issue an interpretation to state that only drugs first shipped by a manufacturer into interstate commerce after any new effective date will be required to be in compliance with the reconsidered final regulation and that the new final regulation be made to be effective one year after its publication, the same time that was provided for affected parties to come into compliance that was granted with respect to the December 3, 1999 final rule. This is not an unusual or controversial request and it is common and usual for the FDA to make its regulations effective in this fashion. E.g., Uniform Compliance Date for Food Labeling Regulations, 63 Fed. Reg. 71015, Dec. 23, 1998 ("All food products subject to the January 1, 2002, compliance date must comply with the appropriate regulations when initially introduced into interstate commerce on or after January 1, 2002). Indeed, Congress took a similar approach with respect to the requirements of the Food Allergen Labeling and Protection Act, making its provisions effective only to "food that is labeled on or after January 1, 2006." Section 203(d), Public Law 108-282. It allows predictability and stability in commerce and business and assures that inventories of valuable, safe and effective pharmaceuticals are not lost to the technicalities of a recordkeeping regulatory initiative. FDA's failure to grant this request in the past has had no reasoned basis whatsoever.

C. Statement of Grounds.

After the final rule was promulgated in December of 1999, PDA and a delegation of other adversely affected trade associations met with FDA on March 29, 2000 to express their concerns regarding the final rule. On that same date, PDA filed a petition for stay of those parts of the final rule that are the subject of this petition. A

similar petition was submitted to the FDA by the Small Business Administration. In a Notice discussing the meeting, the petitions and other communications received from various associations and from Members of Congress, FDA stayed those parts of the final rule sought to be stayed herein until October 1, 2001. 65 Fed. Reg. 25639 (May 3, 2000).

On May 16, 2000, in its report accompanying the FDA Appropriations bill for 2001 (Rept. 106-619), the House Appropriations Committee stated that the FDA should thoroughly review the potential impact of its PDMA regulations on the secondary wholesale pharmaceutical industry. The Committee directed the FDA to provide a report by January 15, 2001, to summarize the comments and issues raised by the public and to propose FDA plans to address those concerns.

In order to gather information about the impact of the PDMA and the final rule, the FDA held a public hearing on October 27, 2000 to receive comment and to dialog with wholesale distributors, representatives of manufacturers and public interest groups. Written comments were received through November 20, 2000. The FDA's Congressional Report on Prescription Drug Marketing Act, House Report 106-619, ("PDMA Report to Congress") was signed and sent to the Congress on June 5, 2001.

Since the PDMA Report to Congress was delivered, FDA has promulgated successive stays to the Final Rule. The historical basis for the stay is set forth below:

1. Authorized Distributor. In its original petition, PDA challenged the final rule where FDA has defined 'ongoing relationship" for purposes of determining whether one is an authorized distributor of record, in 21 C.F.R. § 203.3(u) as follows:

"Ongoing relationship means an association that exists when a manufacturer and a distributor enter into a written agreement under which the distributor is authorized to distribute the manufacturer's

products for a period of time or for a number of shipments. If the distributor is not authorized to distribute a manufacturer's entire product line, the agreement must identify the specific drug products that the distributor is authorized to distribute."

This final rule was a complete departure from FDA's 1988 guidance which stated:

"Ongoing relationship," as used in the definition of "authorized distributors of record," may be interpreted to mean a continuing business relationship in which it is intended that the wholesale distributor engage in wholesale distribution of a manufacturer's prescription drug product or products. Evidence of such intent would include, but not be limited to, the existence of a written franchise, license, or other distribution agreement between the manufacturer and wholesale distributor; and the existence of ongoing sales by the manufacturer to the distributor, either directly or through a jointly agreed upon intermediary. The Agency would consider two transactions in any 24-month period to be evidence of a continuing relationship. [Emphasis added.]

In its PDMA Report to Congress, the FDA agreed that the ongoing relationship definition of the final rule "is restrictive and places control of who can be an authorized distributor in the hands of manufacturers," and that "it could prohibit many secondary distributors, including those who make regular purchases from manufacturers, from qualifying as authorized distributors of record." PDMA Report to Congress at 19. The FDA also concluded that "this could have anticompetitive consequences without the corresponding benefit of protecting the public health." *Id.* Moreover, the FDA determined it "could broaden the definition of *authorized distributor* – although this change could result in even fewer wholesalers than before maintaining and passing on pedigrees for prescription drugs."

PDA has provided FDA with extensive comments on the anticompetitive impact of §203.3(u) as it is presently drafted. Those comments conclude that two

transactions in the previous twenty-four month period should be sufficient evidence of the on-going relationship required by PDMA and in the PDMA Report to Congress, FDA stated that it “believes that an on-going relationship could be demonstrated by evidence of two sales within the previous 24-month period.” PDMA Report to Congress at 20. Because there is agreement on the anticompetitive impact of 203.3(u) in its present form, this provision should be stayed and its effective date suspended until a new regulation can be promulgated in its place.

2. Pedigree. Since PDMA was enacted, the wholesale drug distribution industry has operated in the main on the basis of the guidance provided to industry in FDA's guidance letter of August 1, 1988. That letter interpreted PDMA to require that the statement identifying prior sales (the “pedigree”) contain the following:

5. Statement identifying prior sales. FDA requests that the statement identifying prior sales of prescription drugs by unauthorized distributors be in writing, that it bear the title “Statement Identifying Prior Sales of Prescription Drugs by Unauthorized Distributors Required by the Prescription Drug Marketing Act,” and that it include all necessary identifying information regarding all sales in the chain of distribution of the product, starting with the manufacturer or authorized distributor of record. FDA also requests that the identifying statement accompany all products purchased from an unauthorized distributor, even when they are resold. Identifying statements are not required to include information about sales completed before July 22, 1988. FDA requests that the identifying statement include the following information:

- (a) The business name and address of the source from which the drug was purchased,
- (b) The date of the sale, and
- (c) The identity, strength, container size, number of containers, and lot number(s) of the drug. [Emphasis added.]

The final regulation published December 3, 1999 changes the 1988 guidance to a regulation requiring the following:

§ 203.50(a) Identifying statement for sales by unauthorized distributors. Before the completion of any wholesale distribution by a wholesale distributor of a prescription drug for which the seller is not an authorized distributor of record to another wholesale distributor or retail pharmacy, the seller shall provide to the purchaser a statement identifying each prior sale, purchase, or trade of such drug. This identifying statement shall include:

- (1) The proprietary and established name of the drug;
- (2) Dosage;
- (3) Container size;
- (4) Number of containers;
- (5) The drug's lot or control number(s);
- (6) The business name and address of all parties to each prior transaction involving the drug, starting with the manufacturer; and
- (7) The date of each previous transaction.

According to the economic impact analysis performed by the FDA with respect to the final rule, about 4,000 small business distributors will be directly affected by the regulation regarding statements identifying prior sales. In its June 5, 2001 PDMA Report to Congress, the FDA noted that that 83 percent of the estimated 6500 prescription drug wholesalers in this country have fewer than twenty employees. The vast majority of these are "secondary wholesalers" who do not purchase directly from manufacturers the drugs that they then wholesale to others and do not otherwise meet the definition of "authorized distributor."

The PDMA's pedigree requirement applies only to wholesale distributors who are "not the manufacturer or an authorized distributor" of the drug being distributed. 21 U.S.C. §353(e)(1)(A). Thus, large full line wholesalers are not required to provide a pedigree when they wholesale drugs to others. Because PDMA does not require the full line wholesalers from whom other wholesalers purchase to provide a pedigree containing prior sales history information, the many secondary wholesaler distributors cannot continue to do business because to do so would violate the requirement of the final rule that the pedigree they provide their customers contain a complete sales history back to the manufacturer. As the FDA stated in footnote one to its May 3, 2000 Federal Register notice (65 Fed. Reg. at 25640):

"An unauthorized wholesale distributor that purchases a product from a manufacturer or authorized distributor of record without an identifying statement showing the prior sales of the drug could not provide an identifying statement to its purchasers and, therefore, could not conduct further wholesale transactions of the drug in compliance with Sec. 203.50."

Under the 1988 guidance, this situation was avoided by FDA's interpretation that the prior sales information go back to "the manufacturer or last authorized distributor of record." This was a reasonable interpretation of PDMA and one which gave effect to both its requirement that a prior sales history be provided by those wholesalers who are not authorized and its provision that those who are authorized need not provide such information.

The FDA has also recognized that: "In the years since issuance of the 1988 guidance letter, unauthorized distributors have interpreted the Agency's guidance

letter to mean that the pedigree need only go back to the ***most recent*** authorized distributor who handled the drug. This interpretation is what pharmaceutical distributors consider the *status quo*. As a result, under the *status quo*, whenever a prescription drug is sold to an authorized distributor of record, the transaction history prior to that sale is no longer maintained.” PDMA Report to Congress at 5.

In its PDMA Report to Congress, the FDA has concluded that 21 C.F.R. §203.50, one of the final rules for which this petition seeks a continued stay and suspended effective date, “reflects the language of the statute,” and that that it therefore cannot “revise the regulation to make it consistent with the *status quo*.” PDMA Report to Congress at 23. According to the FDA, “Such a requirement would necessitate a statutory change.” *Id.* And “The Agency believes, . . . , that concerns related to continuing to exempt authorized distributors from the pedigree requirement and to the exact meaning of the phrase *each prior sale*, can be addressed only through statutory remedies.” PDMA Report to Congress at XII.

PDA respectfully disagrees with this conclusion. FDA has the power to interpret this statute in such a way that it does not put thousands of licensed wholesale distributors out of their businesses. Plainly, PDMA was not enacted to put small wholesalers out of their businesses and to concentrate wholesale pharmaceutical distribution into the few wholesalers who buy directly from manufacturers.

3. The Agency's most recent decision to delay the effective date was based on the reaction of wholesalers and manufacturers to FDA's Counterfeit Drug Task Force's Interim Report (FDA Docket 03N-0361).

As part of its Counterfeit Drug Initiative, the Agency sought comment on the feasibility of using an electronic pedigree in lieu of a paper pedigree. That pedigree would start with the manufacturer. The majority of those commenting supported the eventual use of an electronic pedigree for all drug products in the supply chain and indicated that an electronic pedigree should be considered as a long-term solution to fulfilling the PDMA requirements codified at Sec. 203.50, the provision sought to be stayed herein. At the time that the most recent stay was granted, FDA stated that:

"it appears that industry will migrate toward and implement electronic track and trace capability by 2007. If this capability is widely adopted, a de facto electronic pedigree will follow the product from the place of manufacture through the U.S. drug supply chain to the final dispenser. If properly implemented, this electronic pedigree could meet the statutory requirement in 21 U.S.C. 353(e)(1)(A) that ``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*** provide to the person who receives the drug a statement (in such form and containing such information as the Secretary may require) 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.)" The permanent electronic pedigree would address the concerns that have been expressed by wholesalers, particularly secondary wholesalers, regarding access to pedigrees because the required information would travel with the product at all times, regardless of whether a party to the transaction is an authorized distributor of record." 69 Fed. Reg. at 810X, February 23, 2004.

On November 1, 2005, , Randall W. Lutter, Ph.D., FDA Acting Associate Commissioner for Policy and Planning testified before the Subcommittee on Criminal

Justice, Drug Policy, and Human Resources, House Committee on Government

Reform, as follows:

“It is important to gain a better understanding of the effects of RFID on drug products, particularly biological products because they may be more susceptible to change in their environment. We developed a protocol for companies to follow for studies examining the impact of radio-frequency on drug and biological products. Also, a laboratory within FDA’s Center for Devices and Radiological Health is conducting analyses of the heating and the radio-frequency field strengths induced in certain liquid pharmaceuticals by some RFID systems. To date, we have not received much data looking at the effects on drug and biological products and are looking at several options for how to obtain this information.

FDA continues to play an active role in supporting public and private sector efforts toward developing an “electronic safety net” for our drug supply, including the adoption and widespread use of reliable track and trace technology by 2007. We continue to facilitate and monitor standard-setting activities, including efforts by epcGlobal (an entity that has taken a lead role in developing standards) to establish standards for numbering systems, chip frequency, electronic pedigree, and data-sharing and security. In addition, we continue to encourage and foster research on the use and potential impact of RFID on drug and biological products.”

Plainly, while progress is being made, it does not appear likely that track and trace technology will be widely available by 2007.

4. Inventory. Unless a continued stay and suspension of the effective date is granted as requested herein, PDA members will soon begin to suffer irreparable injury. In its October 27, 2000 hearing testimony and in a letter submitted on November 3, 2000 to the FDA docket in this proceeding, PDA noted that if the final rule were to apply to drugs already in distribution as of the effective date of the final rule, a significant number of these drugs would have to be taken out of distribution because of the absence of a proper pedigree as defined by the final rule. What PDA

stated in November of 2000 -- that if the final rule as published were to go into effect October 1, 2001, distributors would need to stop buying drugs that do not have the required pedigree under the final rule and would have to begin to exhaust existing inventories of drugs that do not have acceptable pedigrees by the beginning of the year 2001 to avoid economic harm -- is equally true now with respect to the December 1, 2006 effective date. As its is doing now, PDA then sought a decision by FDA that the final rule not apply to prescription drugs already in distribution as of any new effective date so those drugs could be continue to be distributed.

5. Small Business. There is a substantial public policy in favor of small businesses, small businesses that will be most adversely impacted by the final rule unless the stay requested herein is granted. Moreover, there is a substantial public policy against concentration in the wholesale prescription drug industry. FDA's PDMA Report to Congress describes five major wholesalers but mergers have reduced that number to three. The public policy against market concentration will be advanced if the relief requested herein is granted.

6. The Public Interest. The stay requested herein and the resulting delay in the implementation of the portions of the final rule that are being discussed in the legislative arena is not outweighed by public health or other public interests. FDA and the prescription drug wholesale industry have operated under the 1988 guidance for eighteen years. And FDA has already stayed the effective date of the final rule from December 4, 2000 to December 1, 2006, continuing to operate under the 1988 guidance as requested herein, until RFID is in place.

Even the Pharmaceutical Research and Manufacturers of America has noted that the PDMA final rule is unworkable because of the authorized distributor of record exemption. PhRMA recognized in its November 6, 2003 comments on the Agency's Anti-Counterfeit Drug Initiative that there are "concerns that the PDMA does not require authorized distributors of record (ADRs) to pass pedigree information to their customers... ." PhRMA suggested that if

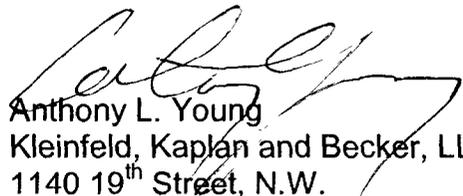
"FDA is concerned that secondary wholesalers will not be able to obtain information tracing the drug back to the manufacturer because of the refusal of ADRs to pass on this information, FDA can exercise its enforcement discretion in this area. In other words, FDA can commit that it will not take enforcement action against a wholesaler if the wholesaler fails to provide pedigree information back to the manufacturer as long as the wholesaler provides pedigree information back to the first ADR who received the drug from the manufacturer. PhRMA believes that this would be an appropriate exercise of FDA's enforcement discretion to facilitate a functional and effective pedigree system while FDA works with Congress to address the weakness in the current law."

Thus, PhRMA understands that the PDMA final rule would disable small wholesalers in their businesses. PDA disagrees with PhRMA's proposed solution because it would implement a flawed statute and implementing regulation and cause businesses to operate on the basis of enforcement discretion. PDMA's paper pedigree requirement is an antiquated system in this age of technology. PDA believes that its own proposal for a continuing stay and for recommended guidelines for pharmaceutical distribution integrity provides a much more substantial advance in assuring the integrity of the drug distribution system while FDA explores state of the art technological mechanisms to protect the integrity of the drug supply.

D. **Conclusion.** There is no public health or other public interest consideration that would justify the disruption in the wholesale pharmaceutical distribution system that will occur if the provisions discussed above are stayed pending legislative discussions. The industry has operated since 1988 under the FDA guidance that has been changed in the final rule without any public health impact. The wholesale distributors that may be put out of their businesses by these provisions ought to be allowed to seek relief in Congress before the final rule goes into effect.

Accordingly, PDA requests the regulations noted above be stayed and suspended until one year after the FDA issues the reconsidered final regulations implementing the PDMA or December 31, 2009, whichever is earlier.

Respectfully submitted,



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