Docket Nos. 92N-0927
88N-0258

UNITED STATES OF AMERICA

BEFORE

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

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COMMENTS OF THE

PHARMACEUTICAL DISTRIBUTORS ASSOCIATION

FINAL RULE CONCERNING POLICIES, REQUIREMENTS, AND ADMINISTRATIVE PROCEDURES; PRESCRIPTION DRUG MARKETING ACT OF 1987; PRESCRIPTION DRUG AMENDMENTS OF 1992

June 30, 2000

88N-0258

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The Pharmaceutical Distributors Association ("PDA"), a trade association of state-licensed wholesale distributors of prescription drugs, submits these comments on those parts of the final rule promulgated by the Food and Drug Administration ("FDA") 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)) 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)).

A. Background.

The Pharmaceutical Distributors Association. PDA is a trade association of companies that are wholesalers of prescription drugs. These companies buy drugs directly from manufacturers, from full line wholesalers who are "authorized" distributors for manufacturers, and from wholesalers who are not "authorized" distributors of all the drugs they sell. PDA members in turn resell the drugs they buy to other wholesale distributors, to retail pharmacies, to health care entities and to physicians.

PDA member companies are sometimes called "secondary" wholesalers because they do not carry a full line of pharmaceuticals as do major wholesalers like McKesson. By far the largest volume of secondary wholesale transactions involve the acquisition of pharmaceuticals from manufacturers before price increases. Like full line wholesalers, PDA members are licensed by each state in which they are authorized to do business and PDA member facilities are subject to inspection by FDA and state authorities. When these companies have two transactions in a two year period with a manufacturer, they are considered to have a continuing relationship with such

manufacturer and are "authorized" distributors of record in accordance with the August 1, 1988, information and guidance letter to the regulated industry regarding the then just enacted Prescription Drug Marketing Act of 1987 ("PDMA") ("1988 FDA Guidance"). If wholesalers cannot be considered to be "authorized" distributors of record, they provide a statement identifying prior sales (the prescription drug "pedigree") to their customer, as required by the PDMA amendments to the Federal Food, Drug, and Cosmetic Act.

At PDA's meeting with FDA staff on March 29, 2000, it appeared to PDA representatives that FDA staff present at the meeting did not have a full understanding of the details of how pharmaceuticals are distributed, especially at the level below the five major wholesalers. PDA is therefore describing, as a matter of background, how pharmaceuticals are distributed in this country.

Wholesale Prescription Drug Distribution. The wholesale pharmaceutical distribution business is dominated by five major distributors whose aggregate annual sales exceeded $69 billion in 1998. Among these five companies, at the secondary level, and among the four thousand distributors nationwide, the wholesale pharmaceutical distribution business is very competitive. These distributors compete on the basis of price, product availability, service and delivery speed with other wholesale distributors and with manufacturers who sell directly to retailers and other outlets. The development of alternative distribution channels, such as mail-order sales and internet-based electronic commerce could lead manufacturers to bypass distributors entirely and go directly to consumers, which will result in a drastic change in the way drugs are

distributed in this country.

The pharmaceutical industry in the United States is growing steadily; from approximately $59.9 billion sales in 1990 to approximately $108.9 billion sales in 1997 and from 8.6% to 10.0% of overall healthcare costs. Industry sales are expected to increase at a annual growth rate of 9.6% from $108.9 billion in 1997 to $206.9 billion in 2004, to represent 12.2% of overall healthcare costs by that year.[1]

1. Wholesale distributors represent the most important distribution channel for pharmaceutical manufacturers. Such manufacturers also sell directly to government entities and programs and to large retail outlets that have internal distribution systems. Manufacturers also actively seek relationships where they negotiate directly with organized customers (e.g., buying groups of retail pharmacies and health care entities) who receive the drugs they purchase through the distribution facilities of licensed wholesalers. In addition, the May 24, 1999 "Pink Sheet" reports some companies, such as Merck-Medco, are exploring direct sales to consumers through a computerized physician-prescribing service.

2. Wholesale distributors provide their customers with access to a wide range of pharmaceutical and healthcare products from various manufacturers. The five major wholesalers typically enter into preferred arrangements with manufacturers, retailers and healthcare institutions that include negotiated prices and require the

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[1] United States Healthcare Financing Administration, National Health Expenditures Projections: 1998-2008, Tables 1 and 14a.

wholesaler to provide all of the manufacturers' and customers' pharmaceutical product needs. Traditional wholesale distributors also typically provide their customers with inventory, delivery, and purchasing services. Thus, these wholesalers allocate their capital among a wide range of inventory and service responsibilities in order to meet the full service obligations they have undertaken with their suppliers and customers. The net profits and margins of these major wholesalers are small, and they have little capital to invest in pedigree or tracking systems that do not have a profit-increasing and capital recovery potential. To maximize profitability and returns on capital, many traditional wholesalers have trading divisions to take advantage of pricing opportunities available from manufacturers, other distributors or other participants in the marketplace.

Secondary wholesalers aggressively seek out and take advantage of price opportunities and sell to the major wholesalers described above, (those looking for low prices), as well as to the several thousand small wholesalers throughout the country. These small wholesalers form the approximately 4000 small businesses who distribute pharmaceuticals to clinics, nursing homes, dentists' and doctors' offices, veterinary practices and small pharmacies throughout the country. Many of these end users are too small or too rural to be economically served by large national distributors (who have never shown an interest in serving them).

Typically, small, regional wholesalers service a variety of outlets. In comments to these dockets, one small wholesaler (Mohawk Medical) reports its customer mix as follows:

- 208 physicians offices and clinics
- 21 state and county health departments
- 27 Federal establishments
- 30 Emergency and immediate care centers
- 6 other wholesalers
- 36 industrial health services
- 7 independent pharmacies

Another distributor, DH Wholesale Medical, reports that it services 2300 physicians and veterinarians. This is how prescription drugs are distributed "outside the Beltway," by small wholesalers, not "authorized," employing small numbers of people but servicing important parts of the healthcare system.

All distributors, large and small, are licensed under state laws. PDA surveyed state pharmacy boards and determined that there are approximately 33,305 wholesale distributor licenses issued in the fifty states and the District of Columbia. (Three states – Idaho, Maryland and Texas provided very rough estimates only). Attachment 1.

State licensing systems for wholesale distributors must meet FDA Guidelines for State Licensing of Wholesale Prescription Drug Distributors. 21 C.F.R. Part 205. These guidelines require that minimum requirements for prescription drug storage and handling be met (21 C.F.R. § 205.50(a) and (c)), that security be maintained (21 C.F.R. § 205.50(b)), that provision be made for returned, damaged and outdated goods (21 C.F.R. § 205.50(e)) and that records be kept regarding the receipt and distribution of prescription drugs and that these records be made available for inspection and copying by authorized Federal, state or local law enforcement officials for a period of three

years. 21 C.F.R. § 205.50(f). These statutes must also provide for background checks and appropriate qualifications for personnel. 21 C.F.R. §§ 205.5-205.7. Accordingly, wholesale distributors are licensed, pervasively regulated, and their records are subject to inspection. It is these PDMA-mandated licensing, warehousing and inspection systems, not PDMA's pedigree or "authorized" distributor provisions, that protect the public from adulterated drugs.

3. Retailers are facing significant pricing pressures under the ever changing reimbursement environment. In order to maintain profit margins in the face of price restraints, retail pharmacies have had to search for additional means of lowering their costs, including procuring product at advantageous prices from wholesalers who complement their primary suppliers.

4. Physicians, veterinarians, emergency and specialty practice clinics and medical practice groups are also retailer-dispensers of prescription drugs. These outlets buy from or through medical specialty and pharmaceutical distributors, but not usually from the big five "authorized" distributors. Thus, it is now not at all unusual for a physician to hand a patient a seven-day course of antibiotic therapy instead of a script for the same course.

B. <u>The Regulation and its Effect</u>.

On December 3, 1999, the FDA published final rules implementing the PDMA, as amended by the Prescription Drug Amendments of 1992 (collectively "PDMA"). The final rule was to be effective December 4, 2000, and requires, for the first time since PDMA was passed in 1988, that prescription drug pedigrees include prior sale

information back to the manufacturer even though 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).

On March 29, 2000, PDA filed a petition in these dockets requesting 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 stayed until October 1, 2001, to provide PDA and its members time to achieve a legislative resolution to the present controversy regarding these sections.[2] In addition, the Small Business Administration petitioned FDA to reconsider these sections of the regulations and to stay their effective date. By notice published in the Federal Register on May 3, 2000, FDA granted the PDA's petition for a stay and the SBA's petition for reconsideration. 65 Fed. Reg. 25639. The regulations described above are now stayed until October 1, 2001.

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[2] The initiation by PDA and its members of legislative oversight and discussions with respect to amendments to the PDMA should not in any way be construed as an admission by PDA or any of its members that FDA's final rule is lawful, that it properly interprets PDMA or that a legislative change is a necessary predicate to a return to the wholesale distribution provisions of the 1988 FDA Guidance.

Prescription Drug Pedigree. Since PDMA was enacted, the wholesale drug distribution industry has operated in the main on the basis of the 1988 FDA Guidance. That Guidance interpreted PDMA to require that the statement identifying prior sales, "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,
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> (b) The date of the sale, and
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> (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 FDA 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. [Emphasis added.]

According to the FDA's own economic impact analysis, about 4,000 small business distributors will be directly affected by the final regulation regarding the prescription drug pedigree. Very few of these distributors purchase directly from manufacturers the pharmaceuticals that they then wholesale to others. Because PDMA does not require those "authorized" distributors of record, full-line wholesalers from whom other distributors purchase, to provide prior sales history information, these smaller "unauthorized" wholesaler distributors cannot continue to do business. FDA recognized this fact in its notice staying the final regulation:

> 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 § 203.50. [65 Fed. Reg. at 25640, note 1]

Under the 1988 FDA Guidance, this Draconian situation was avoided by FDA's interpretation that the prior sales information go back to "the manufacturer or last

authorized distributor of record." The reason the 1988 FDA Guidance was drafted in this fashion is plainly apparent to PDA and its members – PDMA does not require "authorized" distributors to provide a pedigree (21 U.S.C. §353(e)(1)(A)) and allowing the option for the pedigree to go back to either the manufacturer or the last "authorized" distributor source preserved the drug distribution system. Thus, FDA in 1988 did not put itself in the position of promulgating guidance implementing newly enacted legislation that would have wrought havoc to the wholesale distribution industry that Congress plainly sought in 1988 to regulate, not to destroy.

So far as PDA is aware, neither the FDA nor the pharmaceutical industry believe that the 1988 FDA Guidance has created an environment that raises health or safety concerns regarding the quality of prescription pharmaceuticals distributed in this country and prescribed to consumers. Comments on that point are included herewith as Attachment 2. In comparison, the FDA's final rule will limit wholesalers who are not "authorized" to purchasing from manufacturers. Since many of these manufacturers will not do business with secondary wholesalers or with small wholesalers, the effect of the rule will be to drive some secondary and several thousand small wholesalers out of business, disrupting the supply of prescription drugs to consumers and affecting prices. The inexorable effect of this disruption will be to change completely the way prescription drugs are distributed in this country, a result that was never intended by PDMA.

"Authorized" Distributor. In the final rule, 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 is 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.]

Under the final PDMA rule, an "ongoing relationship" is defined by FDA to require a written contract for the distribution of the manufacturer's full line or for specific drugs for specific periods of time. The fact that a manufacturer sells to a distributor on a weekly basis is not enough for the distributor to be deemed to have an "ongoing relationship" with the manufacturer. This change by FDA is surprising because it wholly fails to recognize the realities of how prescription drugs are sold by manufacturers. And the change was made without any investigation of its impact on prescription drug distribution. FDA's final rule appears to have been crafted more out of pharmaceutical manufacturer concerns resulting from their inability or lack of resolve 1) to police their

own marketing departments, and 2) to police their own customers with respect to the restrictions these manufacturers impose on resale, than concerns about the integrity of the drug supply.

It is important for PDA members, and other wholesale distributors to be able easily to determine from prior transactions whether they have achieved a continuing relationship that allows them to be an "authorized" distributor of record. This is because written distribution contracts between manufacturers and wholesalers are the exception and not the rule in the pharmaceutical industry. Moreover, it is not by choice that PDA members are not contractually authorized by manufacturers to be their distributors. While manufacturers may do business with PDA members and other distributors, they may not choose to make these companies "authorized" distributors. Because FDA's regulation has no standards, a manufacturer can determine, for any reason whatsoever, not to enter into a written agreement with a licensed distributor and to thereby cause that licensed distributor to be burdened by the requirement of a statement identifying prior sales.

It is the experience of PDA member companies that manufacturers decline to make wholesalers "authorized" for a variety of reasons. One such reason is that the wholesaler is too small to carry a full line of the manufacturers products. Another is that it is too small to maintain a required line of credit. Another reason is that the manufacturer already has adequate coverage in the area where the wholesaler is located. Another is that it is not opening new accounts. Moreover, with rapidly developing mail order and internet capacities, another (unstated) reason for declining to

make wholesalers "authorized" may be that manufacturers would rather have less competition. Each of these reasons work against small businesses and, with the change in the requirement for a statement identifying prior sales as described above, will cause many of these small businesses to go out of business because they will no longer have a source of supply.

The experience of Mandaree Medical Company, a small Native American company located in Bismarck, North Dakota is typical. As set forth in that company's June 12 comments in these dockets, it sent out 80 letters to pharmaceutical manufacturers, seeking to become "authorized." Only three wrote back, all negative, and one called to say there was no need for new "authorized" distributors.

Supreme Distributors Company had a similar experience. See Attachment 3. Under the 1988 FDA Guidance, Supreme is "authorized" with 59 manufacturers. Following the promulgation of FDA's final rule, Supreme wrote to all 59 asking them to acknowledge that status in writing. Only eight of the 59 responded at all, seven gave the requested written acknowledgement while another declined. Written or verbal contact with 29 other manufacturers for whom Supreme is not "authorized" under the 1988 FDA Guidance elicited only seven responses, all negative. Thus, a total of 73 manufacturers simply ignored the inquiry.

Not being an "authorized" distributor of record puts distributors at a competitive disadvantage in the wholesale marketplace. This is because of PDMA's extraordinary requirement that distributors who are not "authorized" must disclose to their customer, in the statement accompanying the sale, prior sales of that drug, including the source of

the drugs they have sold. This requirement is a disability to full competition because it provides the wholesaler's customer the opportunity to identify and deal directly with the wholesaler's source of supply the next time they wish to buy that drug or drugs. Nonetheless, distributors who are not "authorized" have survived as businesses despite the handicap of disclosing their sources each time they engage in a prescription drug transaction.

FDA's final PDMA rule also imposes on manufacturers the requirement that they make available a list of their "authorized" distributors. This section will, PDA believes, become a burden to manufacturers because PDA does not believe that manufacturers will willingly provide such lists. To test this thesis, PDA wrote to 21 manufacturers with the request that it be provided a list of the manufacturers' "authorized" distributors of record. PDA received two responses, one was an invitation to journey to New Jersey to read the list. Attachment 4. Another manufacturer did provide its list of "authorized" distributors. The other 19 requests were simply ignored.

The best resolution of the list issue is to return to 1988 FDA Guidance under which two transactions with a manufacturer a two year period constitutes an "ongoing relationship" to make the distributor "authorized." Law enforcement inspectors can easily determine if this requirement is met because distributors are required under 21 C.F.R. § 250.50(f)(2)-(3), to keep records of their transactions in prescription drugs for three years and make them available for inspection and copying at the distributor's premises. This is no more difficult for inspectors than the final rule's requirement that contracts with manufacturers be made available. And if there are contracts with manufacturers, these can be made available as well. There is no need to involve the

manufacturer, and the lists required to be kept at manufacturers' corporate offices by PDMA can be kept there but would not necessarily be required to be disclosed. Indeed, this is what PDMA says, that "[e]ach manufacturer of a drug . . . shall maintain at its corporate offices a current list of the authorized distributors of record of such drug." 21 U.S.C. § 353(e)(1)(B).

Adverse Impact. Presently, when wholesale distributors are required to provide a statement identifying prior sales, they do so back to the last "authorized" distributor in the chain of distribution, as they are permitted to do under the FDA 1988 Guidance's contemporaneous interpretation of PDMA. This is as far back in the chain that they can go because "authorized" distributors of record are not required by PDMA to provide prior sales information to their customers and they do not do so. Under FDA's final rule, distributors who are not "authorized" are required to provide prior sales information back to the manufacturer even though FDA has acknowledged that "authorized" distributors are not required to provide that information to their customers. FDA's final rule has created an impossible situation for distributors who are not "authorized," one which was avoided by FDA in its 1988 contemporaneous interpretation of PDMA. PDA members and small distributors who buy from "authorized" distributors will not be able to comply with FDA's final rule and will now be shut out of doing business with those authorized distributors who do not voluntarily provide them with a "pedigree." If manufacturers refuse to sell to them as well, as many now do, they will be out of business entirely. As noted in their comments to these dockets, Mohawk Medical will be barred from 90% of their present business and DH Wholesale Medical from 50% of their present business under the final rule.

The change made by the final rule puts the issue of who may be an "authorized" distributor firmly in the control of manufacturers. Moreover, it appears to give real effect to one of the most pernicious parts of PDMA, the fact that it is a Federal law that delegates to private industry (pharmaceutical manufacturers) the ability to impose regulatory requirements on another segment of the same industry (their distributor customers). It is not only unseemly and bad public policy for Congress to delegate the ability to regulate their customers to manufacturers (in this case to impose extra paperwork and source-disclosure requirements on certain distributors), it is, as PDA will demonstrate in these comments, contrary to the Constitution under the interpretation and effect given to it by FDA.

FDA's final rule injects a pernicious effect into PDMA. The statute does not define "ongoing relationship." 21 U.S.C. § 353(e)(4)(A). FDA's 1988 Guidance was self-executing – if a manufacturer does two transactions in two years with a customer, the customer is "authorized." By defining this term in the final rule to empower manufacturers by contract to regulate their customers, FDA has given the statute an unconstitutional effect. Because of this, and the fact that pharmaceutical manufacturers should not need this additional power over their customers, PDA has asked the Pharmaceutical Research and Manufacturers of America to support PDA's efforts to have this part of the FDA's final rule withdrawn.

In the preamble accompanying the final rule, FDA stated that "[a]lthough the agency encourages authorized distributors to provide a drug origin statement to unauthorized distributors, they are not required to do so under PDMA or the final rule."

64 Fed. Reg. at 67747. The situation created by this comment belies another, equally pernicious aspect of the final rule – "authorized" distributors may now choose among which of their customers they will permit to serve as lower tier pharmaceutical distributors. By holding out the pedigree only to selected customers, "authorized" distributors can wield economic and regulatory power over these customers, just as manufacturers are able to do under the final rule with respect to which customers are "authorized" and which are not. Fortunately, the National Wholesale Druggists Association (NWDA), the trade association that includes many "authorized" distributors, supports PDA in its efforts to have this final rule vacated in favor of a rule that restates the 1988 FDA Guidance. Thus, "authorized" distributors have eschewed the market-regulatory power granted to them by FDA's final rule.

C. PDMA Does Not Mandate That The Pedigree Go Back to The Manufacturer

In response to inquiries from Members of Congress, FDA has explained the requirement that a pedigree report all prior transactions back to the manufacturer is grounded in the statute:

> We are aware that questions also have been raised about the requirements that unauthorized distributors must provide purchasers with information about all parties involved in previous transactions. The final rule is consistent with the statute which requires wholesale distributors who are not the manufacturer or an authorized distributor to provide "a statement . . . identifying each prior sale, purchase, or trade of such drug . . . ." As you may know, the legislative history of PDMA indicates that the pedigree must include all previous sales of the product. Thus, an unauthorized distributor would be required to provide a full drug origin statement in accordance with PDMA and the final rule regardless of whether it has purchased a prescription drug

> from an authorized distributor of record. Although we have encouraged authorized distributors to provide a pedigree to unauthorized distributors, they are not required under PDMA to do so.
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> Letter from Melinda X. Plaisier to the Honorable Barney Frank, March 30, 2000.

Contrary to the assertions in this letter, it is not at all apparent in the language of PDMA that FDA is required to cause the pedigree to set forth transactions back to the manufacturer. FDA stated its position on this issue in the preamble to the final regulation as follows:

> The agency declines to revise the proposal in the manner suggested by the comment. Section 503(e)(1)(A) of the act requires that, prior to completion of a wholesale distribution of a prescription drug by a person who is not the manufacturer or an authorized distributor of the drug, a statement must be provided to the recipient identifying each prior sale, purchase, or trade of the drug, including the date of the transaction and the names and addresses of all parties to the transaction. There is no indication in PDMA that Congress intended that the statement include only those sales, purchases, or trades since the drug was last handled by an authorized distributor. Thus, an unauthorized distributor is required to provide a full drug origin statement in accordance with PDMA and the final rule whether or not it has purchased a prescription drug from an authorized distributor of record. Although the agency encourages authorized distributors to provide a drug origin statement to unauthorized distributors, they are not required to do so under PDMA or the final rule.

64 Fed. Reg. at 67747.

When FDA states "there is no indication in PDMA that Congress intended that the statement include only those sales, purchases or trades since the drug was last

handled by an authorized distributor" (id.), FDA completely ignores the fact that the statute does not require "authorized" distributors to provide a pedigree. As we have explained in these comments, FDA's new interpretation follows after twelve years of successful PDMA implementation under its prior 1988 FDA Guidance. Because the FDA's new interpretation will destroy, numerically, most of the nation's licensed wholesale distributors, an effect never intended by Congress, FDA must agree that its present interpretation of the statute is simply wrong.

In the preamble to its 1994 proposal, FDA infers (but never states directly) that the requirement that a pedigree go back to the manufacturer somehow evolves out of the Prescription Drug Amendments of 1992 (Pub. L. 102-353, 106 Stat. 941):

> As Congress stated in the section-by-section analysis that accompanied PDA when it was introduced and passed, the stricter language in the PDA revision "makes it clear" that any wholesale distribution of a prescription drug by an unauthorized distributor, including any sale to another unauthorized distributor, an authorized distributor of record, or a retail pharmacy, must be preceded by a full and complete identifying statement. "The identifying statement," the analysis added, "must in all cases include the dates of each transaction involving the drug and the names and addresses of all parties to the transaction, and must contain any such other information as the Secretary may require." (Congressional Record, page S 12061, August 10, 1992; page H 6107, August 12, 1992.)
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> Passage of PDA thus gave added emphasis to Congress' intent, as stated in the legislative history of PDMA, to restore accountability to the wholesale sector of the pharmaceutical market and to regulate the wholesale distribution of prescription drug products. (H. Rept. 100-76, pp. 16-17; S. Rept. 100-202, p. 7.)
>
> Proposed § 203.50(a) would restate the statutory requirement that, before the completion of any wholesale

> distribution by an unauthorized wholesaler to another wholesale distributor or retail pharmacy, the seller is required to provide to the purchaser a statement identifying each prior sale, purchase, or trade of such drug. It would require that the drug pedigree include: (1) The proprietary and established name of the drug; (2) the dosage; (3) the container size; (4) the 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 involving the drug.

59 Fed. Reg. at 11857.

This analysis is flawed for several reasons. First, as it was originally drafted, PDMA's pedigree requirement was quite vague:

> (e)(1) Each person who is engaged in the wholesale distribution of drugs subject to subsection (b) and who is not an authorized distributor of record of such drugs shall provide to each wholesale distributor of such drugs a statement identifying each sale of the drug (including the date of the sale) before the sale to such wholesale distributor. Each manufacturer shall maintain at its corporate offices a current list of such authorized distributors.

Pub. L. 100-293, Sec. 6(e)(1). In particular, there was no specific requirement in PDMA's original provision for the parties to the transaction to be identified and there was no specific authority for FDA to promulgate implementing regulations. Moreover, after PDMA was enacted and FDA issued its 1988 FDA Guidance, certain "unauthorized" pharmaceutical distributors implemented a code system whereby prior transactions were disclosed by code number instead of by distributor name. This system is described in the preamble to the proposed (59 Fed. Reg. at 11857) and final rule (64 Fed. Reg. at 67747). The Prescription Drug Amendments of 1992 clearly

addressed this situation but, just as clearly, did not specify that the pedigree go back to the manufacturer:

> (A) Each person who is engaged in the wholesale distribution of a drug subject to subsection (b) and who is not the manufacturer or an authorized distributor of record of such drug shall, before each wholesale distribution of such drug (including each distribution to an authorized distributor of record or to a retail pharmacy), 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).
>
> (B) Each manufacturer of a drug subject to subsection (b) shall maintain at its corporate offices a current list of the authorized distributors of record of such drug.

21 U.S.C. § 353(e)(1). FDA cites legislative history regarding this provision to the effect that it "makes clear" that the pedigree contain detailed information:

> Section 4 also makes clear that any wholesale distribution of a prescription drug (any sale to anyone other than a consumer or patient, including any sale to an authorized distributor of record [or] to a retail pharmacy) by anyone other than the manufacturer or authorized distributor of record must be preceded by a statement identifying each prior sale of the drug. The identifying statement must in all cases include the dates of each transaction involving the drug and the names and addresses of all parties to the transaction, and must contain such other information as the Secretary of HHS may require.

138 Cong. Rec. H 8107 (Aug. 12, 1992). As with the statute itself, this language says <u>nothing</u> about the pedigree going back to the manufacturer. Congress in 1992 was specific about its concerns regarding the pedigree and those concerns are set forth in the statute and its legislative history – that the pedigree list transactions back to the

manufacturer was not one of those stated concerns.

In the preamble to the final rule discussion on this point, FDA stands PDMA and its legislative history on its head. Instead of relying on what the statute specifically requires (prior transaction details) and exempts ("authorized" distributors), and giving meaning to both of these provisions, FDA implies, wrongly in PDA's view, a negative – "there is no indication" Congress did not want the pedigree to go back to the manufacturer. This is word play and nothing more. The 1988 FDA Guidance was well-established in 1992. There was only one problem in PDMA's pedigree-requirement implementation -- the code system used by some wholesale distributors. Congress fixed that problem and left the 1988 FDA Guidance provision that the pedigree go back to the authorized distributor or the manufacturer untouched and intact. Thus, contrary to the preamble to the proposed and final rule, the Prescription Drug Amendments of 1992 are in truth and in fact an affirmation of that part of the 1988 FDA Guidance that declared the pedigree could go back to the authorized distributor.

D. The Final Rule Violates the Due Process Clause of the Fifth Amendment by Improperly Delegating Legislative Authority to Private Parties.

The final rule unlawfully delegates to prescription drug manufacturers unbridled authority to define exactly who is and who is not an "authorized" distributor, and, therefore, to whom the pedigree provision, with its "source-disclosing" paperwork requirements, applies. The final rule alters the 1988 FDA Guidance and the industry's now well-established practice by requiring a written agreement between a manufacturer and each authorized distributor. This power could be used competitively to

disadvantage certain wholesale distributors in their businesses.

As PDA has shown, this change makes it more difficult to become an authorized distributor and provides prescription drug manufacturers with unfettered discretionary powers to determine to whom the pedigree requirement applies. Manufacturers, who have historically been exclusionary in establishing relationships with distributors, would, under this final rule, be completely in control of whether or not a particular customer relationship that it has with a wholesale distributor constitutes an "ongoing relationship." Indeed, under the final rule, simply by refusing to enter into a contract or written agreement with a distributor who may be doing business with it on a weekly or monthly basis, a prescription drug manufacturer could prevent such distributor from being an "authorized" distributor.

The final rule plainly constitutes a delegation of governmental lawmaking power to private sector pharmaceutical manufacturers. The United States Constitution prohibits the unfettered delegation of legislative power to either of the two other branches of government, let alone to the private sector. This doctrine is derived from the separation of powers principle under which the core governmental powers should be exercised by separate branches of government. Marshall Field & Co. v. Clark, 143 U.S. 649, 692, 12 S.Ct. 495, 504 (1892).

In the seminal case of Carter v. Carter Coal Co., the Supreme Court invalidated a delegation of power to the producers and miners of coal to fix maximum hours of labor. This delegation to the private sector was criticized as follows:

> [t]he power conferred upon the majority is, in effect, the power to regulate the affairs of an unwilling minority. *This is*

> *legislative delegation in its most obnoxious form; for it is not even delegation to an official or an official body, presumptively disinterested, but to private persons whose interests may be and often are adverse to the interests of others in the same business.*

Carter v. Carter Coal Co., 298 U.S. 238, 311, 56 S.Ct. 855, 873 (1936) (emphasis added). See also Schechter Poultry Corp. v. United States, 295 U.S. 495, 55 S.Ct. 837 (1935).

Similarly, the power delegated here, i.e., the power to define who is or is not an authorized distributor of record who must comply with pedigree requirements, is delegated to prescription drug manufacturers. Furthermore, as in Carter Coal, and as described in these comments, the interests of these manufacturers are often adverse to those that FDA has given it the power to control, i.e., their customer-distributors. Delegation of such discretionary lawmaking power is indeed "legislative delegation in its most obnoxious form." Id.

Over the years, limited and circumscribed delegations to the private sector have been upheld by the Courts based upon facts which are clearly distinguishable from those here. Valid delegations generally involve situations where the government has retained significant governmental oversight, such as veto power over budgets, annual reports, or audits. See United States v. Frame, 885 F.2d 1119 (3d Cir. 1989); First Jersey Securities v. Bergen, 605 F.2d 690 (3d Cir. 1979), cert. denied, 444 U.S. 1074, 100 S.Ct. 1020 (1980) The situation presented by the final rule does not provide such oversight. Indeed, FDA proposes simply to allow pharmaceutical manufacturers to make the decision as to which wholesale distributors are "authorized" and which are not

– even where those manufacturers do business with the wholesaler on an "ongoing" and continuing basis.

This type of unfettered delegation of legislative power to the private sector was set aside in National Assoc. of Independent TV Producers & Distributors v. FCC, 516 F.2d 526 (2d Cir. 1975). The Court held that the FCC's adoption of a broad set of rules which admonished local stations not to utilize certain regulatory exemptions unless there was a "compelling public interest", without providing guidelines as to what constitutes a "compelling public interest," was an unconstitutional delegation to private parties. The Court was primarily concerned because the judgment of the licensees appeared to be "unfettered" -- i.e., there was no control over the local stations' determinations. FDA's final rule similarly places no controls on its delegatee manufacturers and removes the truly objective standard of the 1988 FDA Guidance – actual transactions between the manufacturer and the wholesaler.

A recent District Court decision set aside as unconstitutional a delegation of legislative authority to manufacturers who were allowed to exercise this power based on unreviewable and wholly discretionary decisions to contract (or not) with private parties within an industry. In Santa Fe Natural Tobacco Company, Inc. v. Judge, 963 F.Supp. 437 (M.D.Pa. 1997), the District Court ruled unconstitutional a provision of Pennsylvania's Cigarette Sales and Licensing Law that required that licensing applicants "received commitments from at least two cigarette manufacturers whose aggregate share is at least forty per centum of the Commonwealth's cigarette market." *Id.* at 439. The Court recognized that this statutory requirement "gives the major

cigarette manufacturers ... power to control who may or may not become a stamping agent." *Id.* at 441. The Court ruled:

> "[t]he Commonwealth most certainly may exercise control over the distribution and sale of cigarettes. In doing so, however, the legislature may not hand *de facto* control over the process to private parties, "uncontrolled by any standard or rule... not bound by any official duty, [and] free to withhold consent for selfish reasons or arbitrarily." *Id.* at 441 (quoting *Washington ex. rel. Seattle Title Trust Co. v. Roberge*, 278 U.S. 116, 122, 49 S.Ct. 50, 52 (1928)).

Just as the requirement that cigarette tax stamp license applicants receive commitments from at least two cigarette manufacturers is violative of the Due Process Clause, so too is the requirement that wholesale distributors must enter into a written agreement with manufacturers to be considered "authorized" distributors. These defects were avoided by the 1988 FDA Guidance. A manufacturer is free to do business with whomever it chooses. But, if it chooses to do business with a customer twice in two years, that customer is deemed "authorized." This is a reasonable, non-discretionary implementation of PDMA, and the one to which FDA should return.[3]

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[3] The experience of Drogueria Central, Inc. (DCI), the second largest distributor in Puerto Rico, is illustrative of how manufacturers have reacted to the written agreement requirement, and why the objective standard of the 1988 FDA Guidance should be reinstated. In June 21, 2000 comments to these dockets, DCI notes that the bulk of its pharmaceutical purchases are from manufacturers and that, in the past, manufacturers annually provided DCI with written supplier agreements, but that around 1994 these manufacturers stopped sending such agreements to DCI and other Puerto Rican wholesalers. Notwithstanding the discontinuation of such agreements, the manufacturers continue to sell to DCI in growing volumes. Obviously, these manufacturers cannot factually deny that they have an ongoing relationship with DCI. Under the final rule, however, they could deny such a relationship for PDMA purposes, a result which PDA respectfully suggests is preposterous.

E. The Final Rule Was Promulgated in Violation of The Regulatory Flexibility Act

The Regulatory Flexibility Act ("RFA") (5 U.S.C. § 601-612), requires an agency to consider the impact of its rulemaking on small businesses and to consider less burdensome alternatives. Under the RFA, agencies must prepare both an initial and final regulatory flexibility analysis for rules that may have a significant economic impact on a substantial number of small entities.[4] In practice, this requires agencies to prepare an analysis whenever a rule's impact on small entities cannot be described as *de minimis*. This regulatory flexibility analysis must be undertaken, unless an agency head provides a "certification," which is a finding of no significant impact on a substantial number of small entities.

FDA, in both its proposed and final rule implementing PDMA, "certified" that its rulemaking would *not* have a significant economic impact on a substantial number of small entities. 59 Fed. Reg. 11842, 11861 (Mar. 14, 1994); 64 Fed. Reg. 67720, 67750 (Dec. 3, 1999). FDA came to this determination simply by concluding that regulatory costs were almost all "paperwork requirements" and "most or many of the requirements ... [have or] had been [previously] implemented by regulated industry." *Id.* As we have shown above, this basic premise was simply erroneous insofar as it applies to requirements for the content of the prescription drug pedigree.

In the analysis accompanying the final rule, FDA concluded that all of the costs of

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[4] According to the Small Business Administration (SBA), distributors of drugs with 100 or fewer employees are considered small entities. In its final rule, FDA states that 94 percent of the

(footnote continued to next page)

the regulation's wholesale distribution requirements "were initiated by the enactment of PDMA and will not be significantly affected by the issuance of this rule." 64 Fed. Reg. at 67752. This is true only for those few companies that are able to remain in business after the final rule becomes effective. The "costs" of the regulation on those who cannot continue in their prescription drug distribution businesses after the final rule becomes effective are extraordinary and fatal.

Certification in Lieu of a Full Analysis. An agency must undertake a preliminary threshold analysis to determine the economic impact of a proposed rule on small entities before it can make a "certification," like the one made by FDA in this instance. 5 U.S.C. § 605(b). To "certify," an agency head provides certification that the rulemaking will not have a significant economic impact on a substantial number of small entities. *Id.* If the agency makes such a determination, it need not undertake an initial regulatory flexibility analysis, however, it must provide "a statement providing the factual basis for such certification" in the Federal Register at the time it proposes its rulemaking. *Id.* The RFA does not state what constitutes a significant economic impact on a substantial number of small entities, but cases decided under the law teach that rules have been set aside in circumstances similar to those in the FDA's PDMA rulemaking.

In North Carolina Fisheries Ass'n, Inc. v. Daley, 16 F. Supp.2d 647 (E.D. Va. 1997), *remanded* 27 F. Supp.2d 650 (E.D. Va. 1998), the court invalidated a certification

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drug distribution firms, or approximately 4,000 firms, are small. 64 Fed. Reg. 67720, 67753 (December 3, 1999).

made by the National Marine Fisheries Service (NMFS) regarding a 1997 flounder fishery quota. NMFS recommended a new quota "no different" from the previous year's quota without undertaking any analysis to determine if it had a significant economic impact on a substantial number of small entities. The NMFS's statement of "no difference" did not provide a factual basis demonstrating that there would be no impact. 16 F.Supp.2d at 652. Here, the statement by FDA that its proposed and final rule simply implemented prior practice, a statement that was not supported by any analysis and was flatly wrong, also does not provide the requisite factual basis.

The Initial Regulatory Flexibility Analysis. Where an agency cannot certify the lack of a significant economic impact, the RFA requires federal agencies to consider the impact of regulations on small entities at the proposal stage by conducting an initial regulatory flexibility analysis. 5 U.S.C. § 603(a). This analysis ensures that the agency has considered all reasonable regulatory alternatives that would minimize the rule's economic burdens or increase its benefits for the affected small entities, while achieving the objectives of the rule.

Under 5 U.S.C. § 603(b), an agency's initial regulatory flexibility analysis must contain:

(1) the reasons why action by the agency is being considered;
(2) the objectives and legal basis for the rule;
(3) an estimate of the number of small entities to which the proposed rule will apply;
(4) the reporting or recordkeeping the proposed rule would require;
(5) all Federal rules that may duplicate, overlap or conflict with the proposed rule.

The requirement of 5 U.S.C. § 603(c) that each initial regulatory flexibility analysis

contain a description of *any significant alternatives* to the proposal that accomplish the statutory objectives and *minimize* the significant economic impact of the proposal on small entities is detailed and specific. The analysis should discuss *significant alternatives* such as:

(1) differing compliance or reporting timetables;
(2) clarification, consolidation or simplification of compliance and reporting requirements;
(3) the use of performance rather than design standards; and
(4) an exemption from coverage of the rule, or any part thereof.

5 U.S.C. § 603(c).

In the FDA's proposal, there is no discussion whatsoever of the most significant and obviously available alternative of maintaining the status quo as set forth in the 1988 FDA Guidance. Moreover, the proposal never specifically discusses the change between the 1988 FDA Guidance and the proposal with respect to how the pedigree must in the future go back to the manufacturer as opposed to the manufacturer or the authorized distributor. Similarly, there is no discussion whatsoever of the impact of the proposal to require a written agreement with a manufacturer in order to have an "ongoing relationship" and be an "authorized" distributor under PDMA.

The Final Regulatory Flexibility Analysis. The RFA also requires an agency, when it issues a final rule, to prepare a final regulatory flexibility analysis or to certify the lack of a significant economic impact on small businesses. The final regulatory flexibility analysis must discuss the comments received, the significant alternatives considered and the rationale for the final rule. 5 U.S.C. § 604. The law requires that each final regulatory flexibility analysis contain:

(1) a statement of the need for and objectives of the rule;

(2) a summary of the issues raised by the public comments in response to the initial regulatory flexibility analysis, the agency's assessment of these comments, and a statement of any changes made;
(3) the number of small entities to which the rule will apply;
(4) the projected reporting, recordkeeping and other compliance requirements of the rule; and
(5) a description of the steps the agency has taken to minimize the significant economic impact on small entities consistent with the stated objectives of applicable statutes, including a statement of the factual, policy and legal reasons for selecting the alternative adopted in the final rule and why each one of the other significant alternatives to the rule was rejected.

5 U.S.C. § 604(a).

Importantly, as in the initial regulatory flexibility analysis, the agency must analyze the relative merits and demerits of the alternatives and explain the rationale for the final agency action. An agency may not simply rely on its preamble to the final rule to comply with the requirements for a final regulatory flexibility analysis. Agencies must provide specific discussion of small entity alternatives designed to reduce adverse impacts or enhance the beneficial impacts of a rulemaking. Small Business Administration, *Guide to the Regulatory Flexibility Act* (May 1996) at 12.

In the FDA's final rule, no such analysis was made and this failure of analysis occurred in the face of FDA's recognition in the preamble that the "ongoing relationship" definition changed existing practice under the 1988 FDA Guidance and that distributors believed this change would make it more difficult to become "authorized." 64 Fed. Reg. at 67727-728. The preamble to the final rule also recognized that "authorized" distributors would not be able to sell to "unauthorized" distributors unless those who were "authorized" voluntarily provided a prescription drug pedigree showing the origin of the drug back to the manufacturer. 64 Fed. Reg. at 67747. The FDA also recognized in the preamble that PDMA does not require "authorized" distributors to provide such

pedigrees and encouraged them to do so. However, the agency fails completely to discuss the economic impact this interpretation will have on the small businesses who buy from "authorized" distributors and the fact that the interpretation leaves these businesses at the mercy of whether their suppliers will respond favorably to FDA's encouragement.

Based on the foregoing, it is plainly apparent that the FDA has failed to perform the analysis required by the Regulatory Flexibility Act. It is PDA's position that such an analysis must be made before the stay entered by May 3, 2000 may be lifted and the final rule is allowed to go into effect. Without such an analysis, the rule would, PDA believes, be set aside. PDA has made its views on FDA's failure to analyze the impacts of the final rule known to House Committee on Small Business. A copy of PDA President Sal Ricciardi's June 8, 2000 testimony before that Committee's Subcommittee on Regulatory Reform and Paperwork Redaction appears as Attachment 5, hereto.

CONCLUSION

On the basis of the foregoing, PDA respectfully requests that FDA vacate 21 C.F.R. § 203.50(a) and 21 C.F.R. § 203.3(c) and replace them with the language of the 1988 FDA Guidance. PDA also respectfully requests that FDA resolve this matter promptly. As PDA has shown, the impact of these aspects of the final rule on PDA members and other "unauthorized" small distributors is likely to be fatal to their businesses. These businesses should not be made to continue operating with a cloud on their future. If FDA determines not to return to the 1988 FDA Guidance, it should say so promptly so that PDA and its members and others adversely affected can seek relief

in the Congress or from the Courts. Similarly, if FDA determines to return to the 1988 FDA Guidance, that decision should also be announced promptly so that we might all put this controversy behind and get on with the important business that we do.

Respectfully submitted,

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