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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20857

Re: FDA Final Rule on New Policies, Requirements and Procedures Pertaining to the Prescription Drug Marketing Act of 1987 and Prescription Drug Amendments of 1992. 64 Fed. Reg. 67720 (December 3, 1999). [Dockets Nos. 92N-0297 and 88N-0258]

Dear Sir/Madam:

The International Academy of Compounding Pharmacists ("IACP") respectfully submits these comments in response to the Food and Drug Administration's ("FDA's") final rule, published December 3, 1999, which implements the Prescription Drug Marketing Act of 1987 (Pub. L. No. 100-293, 102 Stat. 95 (1988)) (the "PDMA"), as modified by the Prescription Drug Amendments of 1992 (the "PDA"). 64 Fed. Reg. 67720 (Dec. 3, 1999) (the "final rule")[1]. IACP submits these comments on behalf of certain of its members who

[1] These comments are filed pursuant to a recent Federal Register notice which delayed the effective date of the December 3, 1999 final rule and reopened the administrative record for submission of comments addressing the impact of the final rule on the wholesale distribution system. 65 Fed. Reg. 25639, 25641 (May 3, 2000).

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supply bulk pharmaceutical substances to compounding pharmacies and pharmacists. IACP is specifically concerned with: (1) FDA's application of the PDMA's pedigree requirements to the wholesale distribution of bulk pharmaceutical substances despite clear Congressional intent to limit the application of the statute to finished dosage form drugs; and (2) FDA's requirement of a written agreement to demonstrate an "on-going relationship" between distributors. These two elements of the final rule constitute a significant and unwarranted departure from 12 years of FDA and industry practice. In addition, the rule will result both in a significant competitive disadvantage to small wholesale distributors and their customers, and harm public health by disrupting the availability of bulk drugs to pharmacists.

Background

The PDMA was enacted to prevent the diversion of prescription drugs outside of the normal channels of distribution. It was intended to protect American consumers from "mislabeled, subpotent, adulterated, expired and counterfeit pharmaceuticals," and to "restore the competitive balance in the marketplace" by preventing the anticompetitive effects of such diversion against wholesale distributors and retail pharmacies. See, S. Rep. No. 100-303, at 57; H. R. Rep. 100-76, at 6 (1987). The PDMA establishes a number of restrictions and requirements regarding the marketing and distribution of human prescription drugs to increase accountability in the chain of distribution of these drugs.

On March 14, 1994, the FDA issued a proposed rule to implement the PDMA, as modified under the PDA. 59 Fed. Reg. 11842 (1994). These regulations were not finalized until December 3, 1999.

FDA's final rule, if implemented as it now stands, will apply the PDMA's accountability requirements to distributors of bulk pharmaceutical substances despite Congressional intent that the PDMA was enacted to address concerns about the chain of distribution of finished dosage form prescription drugs. The final rule constitutes a significant departure from FDA's own guidance notices, and from the language, intent and spirit of the PDMA. In addition, although one of the PDMA's expressed purposes was to restore a competitive balance to the pharmaceutical marketplace, the FDA's final rule will create a competitive disadvantage for small wholesale distributors, specifically small firms that provide bulk pharmaceutical substances to compounding pharmacies and pharmacists.

COMMENTS

I. CONGRESS DID NOT INTEND THE PDMA TO APPLY TO BULK PHARMACEUTICAL SUBSTANCES.

The PDMA amended, among others, § 503 of the federal Food, Drug and Cosmetic Act (FDCA) to require that:

> Each person who is engaged in the wholesale distribution of a drug subject to [21 U.S.C. § 353(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 ... 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).
>
> 21 U.S.C. § 353(e).

This provision requires that wholesale distributors of prescription drugs, who are not deemed to be "authorized distributors" under FDA criteria, must provide a statement detailing the history - or pedigree - of the drug all the way back to the original manufacturer. The failure of an unauthorized distributor to provide the required pedigree could result in civil or criminal penalties against the distributor.

FDA first addressed the question of the applicability of the PDMA to distributors of "bulk drug substances" in the March 1994 proposed rule. FDA concluded that:

> The legislative history ('Report of the Committee on Energy and Commerce,') H. Rept. 100-76, April 30, 1987, and 'Report of the Committee on Finance,' S.Rept. 100-202, March 18, 1988) or the congressional hearing record do not suggest that bulk drug substances be treated any differently from other prescription drugs. Bulk drug substances are susceptible to the same problems of lack of accountability and diversion that this legislation was intended to remedy. It is clear that applying the provisions of the statute to bulk drug substances would help protect against the abuses that Congress intended to address and contribute to the protection of the public health. Accordingly, bulk drug substances are, as drugs within the meaning of [21 U.S.C. § 353], expressly brought within the scope of PDMA and these implementing regulations."
>
> 59 Fed. Reg. 11842, 11843 (1994).

This interpretation of the PDMA is inconsistent with both the language of the statute and the intent of Congress as demonstrated in the legislative history. The structure of § 503 shows that § 503(e) was not intended to apply to bulk drugs. There is no express reference to bulk pharmaceutical substances or unfinished drug materials in the PDMA. Nor is there anything in the statutory language of the PDMA which requires the FDA to include distributors of bulk pharmaceutical substances within the statute's purview. Thus, FDA does not have the authority to apply the PDMA to bulk pharmaceutical substances.

Furthermore, imposing the pedigree requirements on such drugs is unnecessary. Sufficient quality control and antidiversion safeguards and penalties exist to ensure that damaged, adulterated or counterfeit bulk drug components are not processed into finished form for distribution to consumers. Therefore, FDA's application of the PDMA to the distribution of unfinished drugs, prior to their manufacture into finished form prescription drugs, is a redundant layer of regulation. It does not advance Congress' objective of preventing the diversion or damage of drugs in the chain of distribution for finished form prescriptions drugs.

A. FDA's Interpretation Is Inconsistent with the Terms of the FDC Act

Contrary to what the final rule says, § 503(a) of the PDMA applies the pedigree requirement not to all drugs, but only to drugs that are subject to § 503(b). Bulk pharmaceutical ingredients are not subject to this provision. They are ingredients of drug

products that are subject to § 503(b), but they themselves do not fall under this section. Bulk drugs are not dispensed by pharmacists. § 503(b)(1)(c). Nor are they subject to the labeling requirements of § 503(b)(4). The labeling requirements applicable to prescription drugs, 21 C.F.R. § 201.109, do not apply to bulk drugs intended for use in compounding or further manufacturing. Id. §§ 201.120 and 201.200.

Indeed, the very title of the law — the Prescription Drug Marketing Act — shows that Congress was not seeking to regulate bulk drugs. Finished dosage form drugs are "prescription drugs." Bulk pharmaceuticals are used to make prescription drugs, but they are not referred to as prescription drugs themselves, and they are certainly not marketed as prescription drugs.

This interpretation is bolstered by consideration of the definition of the term "drug." Under § 201(g)(1)(D) of the FDCA (21 U.S.C. § 321(g)(1)(D)), a drug includes not only active ingredients, but excipients, containers, and other drug components. Using FDA's logic, anything that falls under the definition of a drug under § 201(g), including binders and other inactive ingredients, is regulated under the PDMA. These products, like bulk pharmaceuticals, fall within the broad sweep of the definition of a "drug." However, like bulk drugs, these products are not subject to the prescription drug provisions of § 503(b), and, therefore, do not need the pedigree information contained in § 503(e). See, Pharmanex, Inc. v. Shalala, 35 F.Supp. 2d 1341, 1347 (D.Utah 1999)(Rejecting FDA's

interpretation of 21 U.S.C. § 321(g) as applying to finished drug products and their components finding that "only a drug product has a composition, can have labeling, be in investigations, or be used under conditions set forth in the labeling – a component of a drug product cannot").

B. FDA's Interpretation Is Inconsistent with the Legislative History of PDMA

Thus, the PDMA does not, by its very terms, apply to bulk drugs. However, even if the PDMA was deemed silent on this point, the legislative history refutes FDA's interpretation. The sole focus of the legislative history of the PDMA is the distribution, handling and trade of finished form prescription drugs. The complete lack of evidence or discussion regarding bulk pharmaceutical substances in the legislative history of the PDMA demonstrates that Congress did not intend that the PDMA apply to the distribution of such bulk materials.

FDA has maintained, in response to comments filed after the 1994 proposal, that the PDMA applies to "bulk drug substances," to the extent that such substances include "those substances that become active ingredients when used in the manufacturing, processing or packaging of a drug." 64 Fed. Reg. at 67746. As a basis for its position, FDA contends that (1) "[a]lthough Congress did not specifically refer to [bulk drug substances] in the legislative history of the PDMA, it also did not specifically refer to the finished dosage forms;" and (2) "prescription [bulk drug substances] are used as components of prescription

drug products that are sold to consumers, and clearly any practices that adversely impact upon the quality of prescription [bulk drug substances] could ultimately harm consumers." Neither of FDA's contentions are supported by the legislative history of the PDMA.

FDA argues that the PDMA does not specifically refer to finished dosage form drugs. While the phrase "finished dosage form" is not used within the statute or the legislative history, FDA is wrong when it asserts that the legislative history does not "refer" to finished dosage forms. The legislative history is replete with references to instances of diversion of finished dosage form products – starting with the importation of the counterfeit birth control pills which spurred consideration of the PDMA, and including substantial testimony about law enforcement investigations into the diversion of finished dosage form products. In fact, the legislative record, including the House and Senate Reports, hearing testimony and exhibits, is comprised solely of information and evidence related to finished drug products.

Congress' consideration of the integrity of finished drug products only is illustrated in statements by members of the House Subcommittee on Oversight and Investigations of the Committee on Energy and Commerce.

> [E]ven legitimate pharmaceuticals marked 'American goods returned' pose significant health and safety problems to American consumers. The export and reimport processes contain inherent dangers, including lack of proper storage and handling controls. Drugs designed for foreign markets may be labelled (sic) differently than those designed for sale in our market. Thus, these prescription drugs

> may be expired, mislabelled (sic) or damaged from excessive heath, cold or moisture. There is simply no assurance that they are safe. . . [U]ntil the Subcommittee has had time to consider all the dimensions of this market and recommend appropriate changes in the law or its administration, the least we can do for the American consumer is to have the Government test the most suspicious drugs before they enter the market place.

Hearings Before the Subcommittee On Oversight and Investigations of the Committee on Energy and Commerce, House of Representatives, 1985 ("House Hearings"), at 37 (Statement of John P. Dingell, Chairman) (Referring to problems associated with the importation of pharmaceuticals under the guise "American goods returned," including the importation of one million counterfeit Ovulen 21 birth control pills from Panama).

> Through this illegal subterranean "diversion market" bargain price drugs which have been mislabeled, improperly stored, or are outright counterfeits, get into the retail chain and make their way to the public. These drugs are bad for business. They damage the reputations of manufacturers, retailers and wholesalers alike. ...There are several techniques used for diverting drugs, involving reportedly hundreds of millions of dollars in this illegal or quasi-legal market. There is the classic U-boat diversion, the sale of "surplus" pharmaceuticals by hospitals, the marketing of relabeled counterfeit or spoiled drugs and the diversion through non-profit institutions in unfair and illegal competition with private pharmacies.

House Hearings at 2 (Statement of Rep. Gerry Sikorski). Both of these statements, which are representative of the legislative history as a whole, address the diversion of finished form pharmaceuticals only, and not bulk pharmaceutical substances used in the manufacture of finished drugs.

The legislative history also cites numerous examples by law enforcement officials of drug diversion investigations in which "drugs were 'shucked' or removed from their original packaging and labeling" to hide the fact that they were expired, marked "Sample – Not to be Sold" or that they were manufactured in Mexico. Further, the word "sample" was scraped from the individual tablets, and the drugs then stored or resold in plastic baggies and other unauthorized containers. See, Hearings Before the Subcommittee On International Trade, Committee on Finance, U.S. Senate, on June 15, 1987 ("Senate Hearings"), at 14-15; House Hearings at 49-51, 61.

> The diversion market is supplied from a range of sources. They include nonprofit institutions that buy in excess of their needs and illegally resell the surplus; companies or individuals that obtain pharmaceuticals through false or fraudulent pretenses; samples that are intended for use in health care institutions or by doctors that are sold to wholesalers instead; pharmaceuticals that are produced in the United States, sold to foreign buyers, and then reexported back to the United States; foreign produced goods that are relabeled and/or repackaged prior to sale in the United States; stolen merchandise; and counterfeits, both foreign and domestic.

House Hearings, at 5 (Testimony of Stephen F. Sims, Special Assistant, Subcommittee on Oversight and Investigations).

Each and every comment and exhibit considered by Congress pertained solely to activities involving finished dosage form pharmaceuticals. The record demonstrates that Congress' intent in enacting the PDMA was to protect the integrity of the chain of distribution for finished form drugs, to protect the public from poor quality or counterfeit

finished form drugs, and to protect the market from unlawful competition from the distribution of unauthorized discount finished form drugs.

In striking contrast, there is no mention in the record, either expressed or implied, of any instances of diversion or potential diversion of bulk pharmaceutical substances. Nor was the diversion or adulteration of bulk pharmaceutical substances discussed by the drafters of the PDMA. FDA's post-enactment concern that bulk pharmaceutical substances were subject to quality assurance was never considered by Congress. Although the 1994 proposal speculated that bulk drugs were "susceptible" to the same problems as finished drugs, Congress itself never voiced this concern.

In proposing regulations of bulk drugs, FDA notes that Congress was silent on this issue. FDA therefore reasons that silence means bulk drugs ought not to be excluded. That inference is untenable. The reason why bulk drugs were not mentioned is simple: there was never any testimony or evidence regarding problems with bulk drugs. Thus, Congress' silence on the subject is a direct result of an utter lack of evidence of a problem. For FDA to use that silence as authorizing the regulation of bulk drugs perverts the legislative history.

In addition, FDA's rationale for applying the PDMA to bulk pharmaceutical substances is inconsistent with FDA's basis for determining that the PDMA does not apply

to blood products and blood component products.[2] In the 1992 final rule establishing state licensing requirements for wholesale distributors, FDA concluded that, while the "PDMA, by its literal terms, applies to all drugs that are subject to section 503 of the act; that is to all human drugs," the PDMA did not apply to the distribution of blood and blood components. FDA notes that "the legislative history lacks any discussion of PDMA's application to blood and blood components intended for transfusion." According to the agency, this "clearly shows that Congress intended that PDMA remedy problems associated with the distribution of those drugs that are popularly referred to as 'medicines' or 'pharmaceuticals.'" 55 Fed. Reg. at 38015. Bulk drugs are ingredients of "medicines" or "pharmaceuticals," and are not medicines themselves. Moreover, like blood products and unlike finished drugs, bulk drugs were not discussed by Congress.

Further, FDA explained that "blood and blood components are not promoted through samples and coupons ... [and therefore] the fact that such blood and blood components are not part of the system of distribution and marketing that Congress intended to regulate under the terms of PDMA further signals that Congress did not intend to include blood and blood components intended for transfusion within the scope of the PDMA." Id. The same statements apply equally well to the wholesale distribution of bulk pharmaceutical

[2] Although the FDA rejected a similar comparison by a commentor in the final rule, the FDA provides no rationale. 64 Fed. Reg. 67720.

substances. Thus, the same analysis that led FDA to exempt blood products applies to bulk drugs. FDA has provided no basis for its disparate treatment of these two classes of products that are both "drugs" under § 201(g)(1).

Further, FDA's argument that "any practices that adversely impact upon the quality of prescription [bulk drug substances] could ultimately harm consumers," such as adulteration and damage through improper storage or handling, proves too much. It would mean, for example, that excipients[3] and containers should be governed by § 503(e). Indeed, translating a general concern for product quality into a sweeping mandate to take all actions to regulate every part of the drug distribution process goes far beyond what Congress intended. That is clearly an absurd result. The plain language of the PDMA applies to prescription drug products, and not all "drugs." Using the standard of whether some hypothesized conduct "could harm consumers" would allow FDA to reach virtually any conduct, including conduct that Congress never contemplated regulating.

Moreover, federal and state regulatory safeguards already exist to protect the manufacture of bulk drugs, through FDA's good manufacturing practice ("GMP") regulations. These requirements mandate storage, security and testing, and production requirements to maintain the stability, integrity and effectiveness of the product when

[3] FDA's other rationale for regulating bulk drugs — that Congress did not specifically exclude bulk drugs — applies equally to excipients as well.

processed into a finished dosage form. The same regulations also apply to bulk drugs used for compounding.

These existing safeguards were highlighted in testimony provided on June 8, 2000, by Dennis E. Baker, FDA Commissioner of Regulatory Affairs, before the House Subcommittee on Commerce Subcommittee on Oversight and Investigations. Significantly, in addressing the issue of product quality, he never mentioned pedigree information. Rather, he referred to a far-ranging series of other agency initiatives. This testimony undercuts the stated rationale for pedigree information.

FDA provided an exception from the PDMA's state licensure requirements to wholesale distributors of drug samples based on the same circumstances — the existence of regulations to maintain the stability, integrity and effectiveness of the drugs. See, 55 Fed. Reg. at 38017. It follows that a similar exception from the pedigree provisions of the PDMA should be provided for wholesale distributors of bulk pharmaceutical substances.

FDA maintains that the expanded application of the PDMA pedigree requirements *to* wholesale distributors of bulk drug substances is grounded in protecting the public. Mr. Baker's testimony demonstrates that adequate safeguards already exist under current law. Moreover, FDA cannot use its perceived threat to the public interest as a tool to expand its legal authority beyond that contemplated by Congress. "[N]o matter how

'important, conspicuous, and controversial' the issue, and regardless of how likely the public is to hold the Executive Branch politically accountable, an administrative agency's power to regulate in the public interest must always be grounded in a valid grant of authority from Congress. And, '[i]n our anxiety to effectuate the congressional purpose of protecting the public, we must take care not to extend the scope of the statute beyond the point where Congress indicated it would stop.'" FDA v Brown & Williamson Tobacco Corporation, ___ U.S. ___; 120 S.Ct. 1291, 1315 (2000), *quoting* United States v. Article of Drug ... Bacto-Unidisk, 394 U.S. 784, 800 (1969).

The legislative history of the PDMA demonstrates clearly and unambiguously that Congress never contemplated the application of the PDMA to the distribution of bulk pharmaceutical substances. All of the testimonial and documentary evidence provided in the record as support for the PDMA involves the diversion of finished drug products. There is no mention of concern about the potential for diversion of bulk drug substances, and no examples cited of diversion at the level of wholesale distribution of bulk pharmaceutical substances. Therefore, the legislative history provides no basis for FDA's application of the PDMA beyond finished form drugs.

II. FDA's FINAL RULE FAILS TO CONSIDER THE SERIOUS ADVERSE IMPACT ON SMALL BUSINESSES.

FDA did not properly consider the impact of this regulation on small businesses. The Small Business Administration (SBA) has already demonstrated that FDA failed to

consider the impact of the rule on small wholesalers of prescription drugs. 65 Fed. Reg. at 25641; also, SBA Comments to FDA Final Rule filed February 29, 2000. By FDA's account, 94% of distribution companies (approximately 4,000 firms) are small businesses which will be affected by FDA's final rule. 64 Fed. Reg. at 67753. FDA however, maintains that the impact of the pedigree requirements of the final rule "would not be significant."

Significantly, in the final rule, FDA contends that the majority of the 4,000 small businesses will not be affected by the rule, because they "do not distribute samples." SBA Comments, p. 3. FDA's argument that small businesses will only be affected to the extent that they distribute drug samples supports IACP's argument that the PDMA was intended to apply only to finished drugs, which involve samples, and not to bulk drug substances.

Further, the SBA contends, and IACP agrees, that FDA's impact analysis with respect to small businesses is unacceptable. As demonstrated by the SBA,

> [A]ccording to industry experts, authorized wholesalers (even large ones) are not now able to and could not, at any reasonable cost, provide pedigrees to those whom they distribute drugs. Moreover, because they are authorized distributors of record they are not required to do so. Second, wholesalers buying from full line wholesalers that do not provide a pedigree will not be able to pass along to their customers a pedigree describing transactional information back to the manufacturer. And, third, full line wholesalers who now buy from the secondary market will not be able to do so because the secondary market will not be able to provide them with pedigrees back to the manufacturer. ... Not even the industry anticipated all of the adverse impacts that would be associated with implementation of this regulation. Drug products now in the inventory of wholesalers will have to be cleared out and

> new orders will have to cease or be severely limited in order to comply with the December 4, 2000 effective date.
>
> SBA Comments, p. 3.

The Pharmaceutical Distributors Association (the "Association") described the severe economic impact on the estimated 4,000 small wholesale distributors of prescription drugs.

> [These] small distributors occupy a niche market which large distributors either cannot or chose for economic reasons not to fill. They are particularly important in rural areas and to other customer categories with relatively low volume. It is not at all clear that alternative sources of supply for these providers would be available on a timely basis or at a reasonable cost.

Testimony of Sal Ricciardi, President, Purity Wholesale Grocers, Inc. and on behalf of the Pharmaceutical Distributors Association, June 8, 2000, before the House Committee on Small Business, Subcommittee on Regulatory Reform and Paperwork Reduction. Both the SBA and the Association, in their respective comments and petition regarding the final rule, demonstrate FDA's failure to consider the impact of the pedigree requirements of the final rule on wholesale distributors of pharmaceutical drugs, as well as their customers.

FDA similarly has failed to take into account the adverse impact that the pedigree requirements will have on small firms who supply bulk drug substances to compounding pharmacies and pharmacists. FDA has completely ignored the corollary impact on the

pharmacists who will no longer be able to compound. FDA cannot properly issue a final rule until it has considered these small business impacts.

IACP represents small firms that sell bulk drugs to pharmacists for use in compounding. In enacting the Food and Drug Administration Modernization Act, Congress specifically recognized the importance of compounding. Congress also was aware that compounding requires access to bulk drugs. 21 U.S.C. § 353a(b)(1)(A). See also, S. Rep. No. 105-43 (1997) at 67-69 ("The Committee has worked extensively with the [FDA] and other interested parties to read consensus on how to ensure continued availability of compound drug products as a component of individualized therapy"); H.R. Conf. Rep. 105-399 (1997) at 94-95.

FDA's rule could have devastating consequences on health care in the United States. Imposing pedigree requirements on wholesale distributors of bulk drugs would substantially reduce the ability of pharmacists to compound. In many cases, the wholesalers who supply pharmacists obtain the bulk drugs from other companies that purchase relatively small quantities of drugs from manufacturers. Because of these relatively small purchases, many wholesalers are unlikely to be listed as authorized distributors. This will trigger the need for pedigree information which, in some instances, will be difficult or impossible to obtain.

IACP does not know for certain how many bulk drugs will become unobtainable. However, the company expects that imposing pedigree requirements will mean the loss of at least _____. This, in turn, will affect approximately ___ pharmacies throughout the country. The net effect will be that some prescriptions will go unfilled for lack of pedigree information for the bulk drugs necessary for compounding. This impact will be felt both by pharmacists and by patients.

This fear is aptly demonstrated in the SBA's comments which cite to a manufacturer who already had begun to modify its procedures to ensure a timely compliance with FDA's final rule. This manufacturer has notified its customers that "[b]eginning on March 1, 2000, all invoices received without a complete pedigree will not be paid." SBA Comments, p. 4. Under this pattern, smaller distributors and, subsequently, their customers – such as compounding pharmacies – will be unable to obtain the bulk drug substances necessary to compound prescription drugs. It follows that patients would not be able to obtain medicines specifically compounded to meet their individual drug therapies as prescribed by their treating physicians. Thus, as a result of FDA regulating bulk drugs in a fashion never considered by Congress, patients will be deprived of the medication prescribed by their physician. Clearly, this will have a detrimental impact on the public health.

III. FDA'S FINAL RULE DEPARTS FROM 12 YEARS OF AGENCY AND INDUSTRY PRACTICE.

Since the enactment of the PDMA in 1988, the wholesale drug distribution industry has operated under an "interim" guidance letter issued by FDA on August 1, 1988 (the "guidance letter"). The guidance letter more accurately reflected the business realities of wholesale distributors of drugs by requiring that a distributor provide a sales history only back to the last "authorized distributor," not back to the original manufacturer.

In addition, the guidance letter provides a more reasonable criteria for conferring authorized distributor status. Under the PDMA, an authorized distributor means "those distributors with whom a manufacturer has established an ongoing relationship to distribute such manufacturer's products." 21 U.S.C. § 353(e)(3). The guidance letter provides that the requisite "ongoing relationship":

> [M]ay 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 ... the existence of ongoing sales by the manufacturer to the distributor, either directly or through a jointly agreed intermediary. The Agency would consider the two transactions in any 24 month period to be evidence of a continuing relationship.
>
> Guidance Letter, p. 2.

Under the guidance letter, smaller companies are considered to be authorized distributors based on occasional sales from manufacturers. The final rule, by requiring that a manufacturer enter into a written agreement with a distributor, makes it vastly more difficult for small wholesale distributors to be authorized distributors. The issue becomes

whether the manufacturer is willing to list a company, not whether it will sell to the company. Nothing in the PDMA or the legislative history supports FDA's requirement of a written agreement between manufacturer and distributor for the purpose of establishing the requisite ongoing relationship.

IACP believes that the final rule criteria for determining an "on-going relationship" for the purpose of establishing an authorized distributor are unduly restrictive. The agency states that it "continues to believe the term 'ongoing relationship' in the context of wholesale distribution infers a continuing business relationship between a distributor and a manufacturer where the intent exists to engage in wholesale distribution." 64 Fed. Reg. at 67728. Then FDA states that it is necessary to have a "formalized way" of establishing the ongoing relationship; hence, FDA proposes requiring a written agreement. However, this written agreement need not "rise to the level of a contract or create legally enforceable obligation for the parties." Id. Thus, ironically, FDA would be satisfied by a writing with no legal weight, but not by an actual sale, which itself entails a contract. A sale of a product in an exchange for money forms a contract. FDA is truly elevating form over substance.

Many large manufacturers may be unwilling to provide a written agreement to a small distributor. Those same manufacturers, however, are not averse to occasional transactions with smaller distributors, the type of transactions that would satisfy FDA's

current criteria for demonstrating an ongoing relationship. However, under FDA's final rule, the manufacturer could continue to sell to a distributor but decline to identify it in a formalized, publicly available document, making the distributor an unauthorized one that must supply pedigree information. Thus, FDA's final rule would make a distributor who has submitted purchase orders to a manufacturer and received products from it for the past twelve years into an unauthorized distributor, unless the manufacturer chooses to provide a written statement. FDA may believe that manufacturers will routinely provide these statements. They are not, though, obliged to do so. The decision to produce a statement, which must then be provided to anyone upon request, rests with the unfettered discretion of the manufacturer.

For over 12 years, the pharmaceutical industry has relied on the standard that two transactions within two years is sufficient to establish an ongoing relationship. The fact that FDA does not provide any valid reason for this departure from existing practice is telling. FDA does not cite to any examples of diversion of drugs that occurred due to the more reasonable application of the pedigree requirements under the guidance letter nor does FDA provide any reasons as to why it believes the guidance letter criteria no longer suffice.

FDA's change in its criteria for establishing an authorized distributor will primarily, and unfairly, affect small business. The inability of companies which buy only one or two drug products to obtain written agreements places such companies at a significant

competitive disadvantage by branding them as an unauthorized distributor. Facing extra paperwork and documentation requirements, unauthorized distributors will find it hard to compete.

Congress enacted the PDMA in part to restore and maintain competitive balance in the market place for prescription drugs. See e.g., S. Rep. No. 100-303, at 57; H. R. Rep. 100-76, at 6 (1987); House Hearings at 1 (1985)("Wholesale distributors and retail pharmacists suffer unfair and apparently illegal competition as a result of drug diversion."). The requirement for a written agreement has the opposite effect. It is imperative that FDA revise its final rule to remain consistent with the 1988 guidance letter and allow for an on-going relationship to be established by two purchases within twenty-four months.

Conclusion

PDMA was drafted to address a variety of issues. Preventing the diversion of bulk drugs was not one of them. There is no basis in the statute or the legislative history for FDA's application of the PDMA pedigree requirements to wholesale distributors of bulk pharmaceutical substances. Further, FDA's overbroad application of the PDMA advances no public health or safety interest.

In addition, FDA's change in the criteria for determining "authorized distributor" status is an unwarranted departure from 12 years of industry practice as established by FDA. Therefore, FDA's revised final rule should not apply the pedigree requirements to

bulk pharmaceuticals substances, and should allow a wholesaler to be considered an authorized distributor based on two sales in a twenty-four month period.

Respectfully submitted,

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