CCBC
Council of Community Blood Centers

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May 31, 1994

Dockets Management Branch (HFA-305)
Food and Drug Administration
Room 1-23
12420 Parklawn Drive
Rockville, Maryland 20857

Re: Docket No. 92N-0297

Dear Sir or Madam:

The Council of Community Blood Centers (CCBC) submits these comments in response to the Food and Drug Administration's (FDA's) proposed rule implementing the Prescription Drug Marketing Act of 1987 (PDMA), as amended. 59 Fed. Reg. 11842 (March 14, 1994).

CCBC is the national association of not-for-profit regional and community blood programs ("blood centers") responsible for collecting over 35 percent of the nation's volunteer donor blood supply. CCBC is committed to ensuring the optimal supply of blood, blood components and blood derivatives, and to fostering the development of a comprehensive range of the highest quality blood services in communities nationwide.

CCBC is writing to request that FDA redefine "health care entity" as currently proposed so as not to preclude blood centers from simultaneously acting as "wholesale distributors" under the sales restriction provision of PDMA. CCBC fears that as proposed, FDA's regulations would unintentionally and unlawfully interfere with the unique and long-standing relationship between blood centers and the local health care communities they serve. The proposal would, at best, hamper, and quite possibly destroy blood centers' distribution of the full range of available licensed blood products, to the detriment of the Nation's blood system and the public health.

BACKGROUND

Blood centers and manufacturers are the primary providers of nearly all licensed blood components and products to local health care communities. In most instances,

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the relationships between the blood centers and their communities have developed and been maintained for 30 to 50 years. Originally, the close relationship between hospitals and blood centers arose because blood centers themselves, in addition to providing blood products for transfusion, handled all aspects of the processing and distribution of the plasma-based products derived from their blood donations. Consequently, hospitals came to rely on the expertise of their blood centers in fulfilling the majority of their blood product, laboratory service and expert medical consultative needs for all licensed blood products. As blood processing technology became more sophisticated, however, blood centers began selling the plasma from donations to drug manufacturers for further processing. Despite this shift in processing responsibility, hospitals and health care facilities have continued to receive the benefits of the blood centers' expertise because most blood centers have retained their role as the ultimate distributors of all licensed blood products, not just blood and blood products intended for transfusion. Such FDA-licensed products distributed by blood centers include Albumin, Immune Globulin (intravenous and intramuscular), and Antihemophilic Factor ("Factor VIII"). Blood centers also provide an increasing number of diagnostic and therapeutic services, including disease marker testing, therapeutic hemapheresis, stem cell collection and processing, transfusion services and intraoperative blood salvage, which establishes their status as "health care entities."

On March 14, 1994, FDA issued a proposed rule, "Prescription Drug Marketing Act of 1987; Prescription Drug Amendments of 1992; Policies, Requirements, and Administrative Procedures," implementing certain sections of the PDMA, as amended, that were not previously implemented under the Federal Guidelines for State Licensing of Wholesale Prescription Drug Distributors. 59 Fed. Reg. 11842.[1] In its proposed rule, FDA's definition of a "health care entity" provides that "a person cannot simultaneously be a 'health care entity' and a retail pharmacy or wholesale distributor." Proposed 203.3(n); 59 Fed. Reg. 11842, 11863. Read in conjunction with FDA's final regulations "Guidelines for State Licensing of Wholesale Prescription Drug Distributors," 55 Fed. Reg. 38012 (September 14, 1990), FDA's proposed definition of a "health care entity" potentially places blood centers in an untenable position.

Although FDA's State licensing guidelines specifically exempted blood and blood components intended for transfusion from the licensing requirements, FDA did not exempt all licensed blood products. Consequently, blood centers that engage in the wholesale distribution of licensed blood products in interstate commerce have complied with the State licensing requirements of PDMA. Any blood center that has obtained a license is therefore a wholesale prescription drug distributor ("wholesale distributor"). Consequently, FDA's proposed prohibition on health care entities maintaining wholesale distributor status may well end the ability of blood centers to

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[1]Under its proposed rule, FDA would fully exempt blood and blood components for transfusion from the remaining requirements and restrictions in PDMA. FDA previously exempted such products from the state licensing of wholesale prescription drug distribution provisions in its proposed rule entitled "Applicability to Blood and Blood Components Intended for Transfusion; Guidelines for State Licensing of Wholesale Prescription Drug Distributors." 55 Fed. Reg. 38027 (September 14, 1990). See 21 C.F.R. § 205.

distribute licensed blood products, other than those intended for transfusion, to local health care communities.

CCBC believes that as currently proposed, FDA's definition of a "health care entity" contradicts Congressional intent and disregards the clear language of the statute, resulting in inappropriate restrictions being placed upon the legitimate operations of blood centers. This clearly unintended consequence would result in significant changes in the relationship between blood centers and their local health care community customers, while serving no legislative or public health purpose whatsoever.

DISCUSSION

I. FDA's Proposed Definition of "Health Care Entity" Disregards the Clear Language of the Statute

The principal Congressional goal underlying the prohibition on resales of pharmaceuticals under section 503(c) of the PDMA was to prevent fraudulent diversion of discounted pharmaceuticals into the wholesale and retail distribution system. In its proposed regulations, FDA restates the statutory restriction regarding the resale of prescription drug products. Thus, proposed section 203.20 states:

> Sales restrictions.
>
> Except as provided in §§ 203.22, 203.23, and 203.24, no person may sell, purchase, or trade or offer to sell, purchase or trade any prescription drug that was:
>
> (a) Purchased by a public or private hospital or other health care entity; or
>
> (b) Donated or supplied at a reduced price to a charitable organization.

59 Fed. Reg. 11842, 11864. Since, however, "health care entity" is not defined in the PDMA, nor anywhere else by statute or regulation, FDA proposes to define that term in section 203.3(n) as follows:

> Health care entity means any person that provides diagnostic, medical, surgical, or dental treatment or chronic or rehabilitation care but does not include any retail pharmacy or any wholesale distributor. **A person cannot simultaneously be a "health care entity" and a retail pharmacy or wholesale distributor.**

Id. at 11863 (emphasis supplied). Unfortunately, as currently written, FDA's proposed definition of a health care entity improperly implements the sales restriction portion of the PDMA in that it fails to uphold congressional intent and specifically disregards, and therefore conflicts with, the language of the statutorily mandated exclusion contained in section 503(c)(3) of the PDMA which provides:

> **For purposes of this paragraph, the term "entity" does not include a wholesale distributor of drugs or a retail pharmacy licensed under state law. . . .**

Contrary to FDA's suggestion in the preamble to its proposed regulations (see 59 Fed. Reg. at 11845), the above-cited language of the statute as well as the legislative history leaves no doubt that Congress clearly envisioned scenarios where a health care entity could act as a legitimate wholesale distributor, and specifically designed the statute so as not to prohibit such activity. FDA offers no substantiation for its interpretation and the language of the statute, in fact, is antithetical to FDA's views.

Despite the clear language of the statute, FDA's proposed regulation maintains that a "health care entity" may not simultaneously be a "wholesale distributor." FDA based its decision to disregard the statute on information it has "learned" (but does not make part of the record) stating in a pertinent part that:

> . . . some hospitals and health care entities, including physicians, have obtained licenses as wholesale distributors in an effort to circumvent the statutory restrictions against the sale of prescription drugs by hospitals, health care entities and charitable institutions.

59 Fed Reg. 11842, 11845. Although CCBC respects FDA's motivations in attempting to prevent circumvention of the PDMA resale prohibitions, an absolute ban on entities acquiring wholesale distributor status not only goes much further than necessary to achieve that purpose, but completely ignores the explicit exemption carved out by the statute. In administering the PDMA, FDA must give effect to the unambiguously expressed intent of Congress. Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837 (1984); see also Estate of Cowart v. Nicklos Drilling Co., 112 S.Ct. 2589, 2594 (1992) (no deference will be granted to an agency position that is contrary to an intent of Congress expressed in unambiguous terms).

In addition to disregarding the clear language of the statute, FDA's proposed definition of a "health care entity" fails to comport with the agency's own interpretation of section 503(c)(3). As stated in the preamble to the proposed regulation:

> FDA interprets the first clause of the last sentence of section 503(c)(3) of the act to mean that the general prohibition against drug sales by hospitals, health care entities, and charitable institutions **was not intended to interfere with the operations of legitimate licensed prescription drug wholesalers and retail pharmacies.**

59 Fed. Reg. at 11845 (emphasis supplied). CCBC applauds FDA's recognition regarding the clear language of the statute and appreciates FDA's concern that section 503(c)(3) of the act:

> [N]ot open up a loophole for a hospital, health care entity, or charitable institution to avoid the statutory prohibition against drug sales simply by obtaining a wholesaler license.

Id. CCBC believes, however, that a clearly articulated enforcement policy would enable FDA to achieve its goal of preventing circumvention of the resale restrictions, without conflicting with the exemption provided under section 503(c)(3) of PDMA.

II. FDA's Proposed Definition of "Health Care Entity" Contradicts Congressional Intent.

A. Congressional Intent Behind the Sales Restriction Provisions

Among the purposes of PDMA was Congress' desire to eliminate the diversion submarket for prescription drugs that created an unfair form of competition for wholesale distributors and retailers who did not participate in diversionary tactics. Congress characterized the diversion submarket as the sale, barter or trade of drugs initially sold to hospitals and other health care entities at below wholesale prices. In support of its proposed definition of a "health care entity," FDA states in the preamble that:

> The legislative history, which addresses Congress' concern about donation to charitable institutions and institutional discounts for hospitals and health care entities, notes that some of these institutions had been sources of unfair competition and drug diversion, and explains that the statutory prohibition against the sale of drugs donated to or acquired at a reduced price by charitable institutions or purchased by hospitals or health care entities is directed at preventing unfair profits through resales of such drugs.

59 Fed. Reg. at 11845. Although FDA has interpreted Congressional intent correctly, to the extent FDA proposes an absolute prohibition on the ability to maintain "entity" and "wholesale distributor" status simultaneously, the agency ignores the clear wording of the statute and fails to adequately address the wrongdoing that requires remedy under PDMA. In doing so, FDA denies the statutorily mandated exception under section 503(c)(3) of the sales restriction provision of PDMA which expressly sanctions the simultaneous maintenance by an entity of wholesale distributor status. If given effect as currently proposed, FDA's definition of a health care entity would depart from and put aside the clear language of the statute. As a matter of law, FDA cannot do that. See Lynch v. Tilden Produce Co., 265 U.S. 315 (1924) (Internal Revenue regulation defining "adulterated butter" held invalid where definition conflicts with the act and the two could not be read in harmony). At most, FDA can prescribe some limits on the nature of that exception consistent with the statute and the legislative intent of the law.

The legislative history of the PDMA makes clear that the sales restrictions were intended to eliminate fraud committed against manufacturers and unfair competition,

not to prohibit legitimate wholesale distribution by health care entities.[2] As stated by Congress:

> Section 503(c)(3) would prohibit resales of pharmaceuticals by hospitals and other health care entities or charitable organizations with certain exceptions. This provision is intended to cover resales by both for profit and nonprofit health care entities. These institutions typically receive discount prices, substantially below the average wholesale price (AWP) for pharmaceuticals, based on their status as a health care entity or charity. When hospitals or other health care entities obtain pharmaceuticals at favorable prices and then resell those drugs at a profit, they are unfairly competing with wholesalers and retailers who cannot obtain such a favorable price. Such resales defraud manufacturers, who are led to believe that the drugs are for the use of the health care entity. In any case, these resales reward the unscrupulous and penalize the otherwise honest and efficient wholesaler or retailer while fueling the diversion market.

H. Rep. No. 76, 100th Cong., 1st Sess. 12-13 (1987). FDA's proposed definition of a health care entity penalizes not only the unscrupulous but also the "otherwise honest and efficient wholesaler." Thus, as proposed, the regulation is overly broad, at odds with statutory language and intent and therefore unlawful.

In notes accompanying the PDMA, Congress included the following finding:

> The bulk resale of below wholesale priced prescription drugs by health care entities, for ultimate sale at retail, helps fuel the diversion market and is an unfair form of competition to wholesalers and retailers that must pay otherwise prevailing market prices.

21 U.S.C. § 353 (note, sec. 2 (8)). That finding is consistent with repeated references in the legislative history accompanying PDMA, clarifying that Congress' primary concern regarding the resale of pharmaceuticals arose because of abuses in the system that permitted certain entities to acquire pharmaceuticals at discount (because of their special institutional status), and then resell those drugs at a profit in unfair competition with wholesale distributors and retailers not granted preferential pricing. Indeed, in speaking before the House of Representatives on the PDMA, Representative John Dingell (D-MI) stated:

> The resale of prescription drugs by certain health care entities . . . which are economical only because many manufacturers sell much more cheaply to certain institutions than to wholesale customers, provide an unfair competitive advantage to any wholesaler or retailer that can obtain

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[2]Although CCBC is obviously most concerned about the impact FDA's proposed regulation will have on blood centers, CCBC submits that the provision under PDMA section 503(c)(3) that an entity does not include a wholesale distributor or retail pharmacy, requires FDA to preserve the right of <u>any</u> entity to act as a wholesale distributor, consistent with the intent of PDMA.

> the preferentially priced goods. Moreover, the resales may well constitute fraud against the manufacturers, especially if the health care institution is allegedly purchasing the goods for its own use.

133 Cong. Rec. H3024 (May 4, 1987). By placing an absolute prohibition on the ability of a health care entity to concurrently maintain wholesale distributor status, FDA's proposed regulation fails to consider that blood centers (as well as other entities), may purchase pharmaceuticals (i.e. licensed blood products) that are not intended for their own use and that manufacturers understand the pharmaceuticals will be resold.[3] Under those circumstances, an entity may be a legitimate wholesale distributor acting in a manner that Congress in no way intended to penalize under the resale prohibitions of the PDMA and specifically exempted under section 503(c)(3). Thus, the plain meaning of section 503(c)(3) clearly shows that Congress recognized that a health care entity could be a legitimate wholesale distributor.

B. Congress Never Intended PDMA to Encompass Community Blood Centers or Licensed Blood Products

There has never been the slightest indication of any distribution abuse of the type banned under PDMA with respect to any licensed blood products, regardless of whether or not such products have been intended for transfusion. Thus, to the extent FDA's proposed definition of a health care entity prohibits blood centers from acting as wholesale distributors under all circumstances, it fails to effectuate any specified intent of Congress. Indeed, to the extent an absolute prohibition conflicts with the express exemption provided under section 503(c)(3), it directly conflicts with congressional intent.

Neither prior to consideration of PDMA, nor during the extensive Congressional investigations, was there any documented abuses that would suggest that Congress intended that blood centers be prohibited from simultaneously acting as health care entities and wholesale distributors. Moreover, Congress had no expectation that blood centers would be covered under PDMA at all. From the earliest implementation of PDMA, Representative Dingell, Chairman of the Committee and Subcommittee most directly responsible for the enactment of PDMA, sent FDA a clear message that blood products should be exempted from the requirements and restrictions of PDMA. In a September 29, 1988 letter submitted to FDA under Docket No. 88N-0258, Mr. Dingell stated:

> The inclusion of blood and blood components in the Sales Restriction Section of the Act derives not from explicit language in the statute or legislative history, but rather by virtue of the fact that FDA had previously defined such products as 503(b) drugs by regulation. [21 C.F.R. 606.3(a) and (c)]

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[3]To the extent some blood centers purchase blood products for their own use, for example where blood centers with hemophilia treatment facilities purchase Antihemophilic Factor for their own patients, manufacturers selling to the blood centers should be aware of the situation.

> Indeed, nowhere in the two-volume record of the drug diversion investigation by the Subcommittee on Oversight and Investigations, the House or Senate hearings and reports, or the Floor debate is the marketing of blood and blood products even mentioned.

That FDA's attempt to prevent circumvention of the sales restrictions under PDMA is totally inappropriate in the context of blood center operations is obvious in light of the manner in which such entities act as wholesale distributors. Currently, with respect to the resale of licensed blood products, community blood centers operate in much the same manner as traditional wholesale distributors. Manufacturers grant them volume discounts with the understanding that such savings will be passed on to the hospitals, hemophilia treatment centers, and other facilities the blood centers supply. To the extent blood centers compete with wholesalers in the distribution of licensed blood products, no unfair competition exists. Furthermore, the regulatory controls exercised over all licensed blood products and the limited supply of blood available ensures that no widespread drug wholesale distribution network exists that would give rise to the abuses PDMA intended to correct. Under the current distribution system for licensed blood products it is illogical (as well as illegal) for FDA to prohibit blood centers from simultaneously acting as entities and wholesale distributors.[4]

III. Suggested Revision of FDA's Proposed Regulations That Retains FDA's Ability to Enforce the Law

Despite the clear statutory language of section 503(c)(3), establishing that entities may simultaneously act as health care entities and wholesale distributors or retail pharmacies, CCBC also recognizes that Congress did not intend that this exemption from the resale restrictions would create a loophole for entities participating in any form of prescription drug diversion. CCBC submits, however, that section 503(c)(3) of PDMA mandates a regulatory scheme be devised whereby a health care entity can operate as a wholesale distributor or retail pharmacy within lawful parameters. In other words, a health care entity may not become a licensed wholesale distributor as a "sham" to avoid the re-sales restriction. In order for FDA to accomplish its regulatory goals consistent with the statute, the agency must amend section 203.3(n) of its proposed regulations, defining a health care entity by deleting the following portions of the proposed language:

> . . . but does not include any retail pharmacy or wholesale distributor. A person cannot simultaneously be a "health care entity" and a retail pharmacy or wholesale distributor.

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[4]CCBC continues to believe that no legitimate basis exists for distinguishing between transfusable blood products and all other licensed blood products for purposes of carving out an exemption from PDMA. As detailed in our November 13, 1990 comments submitted under Docket No. 88N-0258 (a copy of which is attached), CCBC would have FDA expand its proposed exemption from PDMA to all licensed blood products. CCBC reiterates that position and incorporates the arguments in its November 13, 1990 comments.

CCBC does not mean by this recommendation to suggest that FDA cannot enforce the sales restriction provisions of PDMA. Rather, CCBC encourages FDA to articulate, through the preamble to the final rule, the enforcement policy it intends to follow, consistent with the goals of the PDMA. Obviously, any health care entity found to be acting in a manner that violates the intent of the sales restriction provisions of PDMA (i.e. a "sham") remains subject to FDA's enforcement of the resale prohibitions, irrespective of whether the entity is also a state licensed wholesale distributor or retail pharmacy. Thus, FDA should clarify in the preamble to the final rule that any entity that defrauds a manufacturer by improperly obtaining below average wholesale prices on the basis that the prescription drugs purchased are for its own use, when such is not the case, and who then unfairly competes in the prescription drug resale market by selling those products received at below normal wholesale prices, will be subject to FDA enforcement of PDMA.

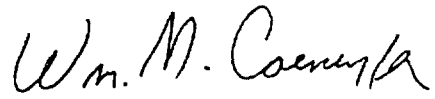
For purposes of refining its treatment of health care entities that are also licensed wholesaler distributors, CCBC points FDA to that part of the preamble to its proposed rule where the agency focuses on the improper transfer of prescription drugs, obtained at reduced prices by health care entities, to subsidiaries for resale. 59 Fed. Reg. 11842, 11846. In its description of that prohibited activity, FDA clearly recognizes the abuses PDMA's sale restrictions were intended to eliminate, i.e., resale of prescription drugs obtained at reduced price or through donations. In the same manner FDA intends to monitor those relationships, it can monitor the wholesale distribution activities of all health care entities. Nothing prohibits FDA from requiring health care entities licensed as wholesale distributors to maintain sufficient records detailing their purchase and sale of prescription drugs. This would be fully consistent with the way that PDMA and the FDA are regulating prescription drug samples. FDA could prohibit the resale of any prescription drugs purchased at below wholesale prices where such prices are obtained based solely on the status of the purchasing entity. Such regulatory controls would address Congress' concern regarding the deception of manufacturers, and would eliminate any unfair competition with traditional wholesalers, without arbitrarily proscribing the legitimate wholesale activities of honest and efficient health care entities.

Unfortunately, as currently presented, the preamble language might suggest that FDA should require a health care entity to convert its licensed drug wholesaler operations to a for-profit subsidiary. Not only would such an arbitrary rule fail to cure the conflict with the clear language of the statute detailed above, but it is not necessary for FDA to maintain full discretion to enforce the law. Blood centers should not have to restructure their corporate activities to meet an arbitrary requirement not contemplated by the statute. Rather, CCBC believes FDA should focus on whether a health care entity has obtained a State license to be a drug wholesale distributor as part of a sham for engaging in unfair competition. It is not the corporate status of the organization (profit vs. non-profit or health care entity vs. wholesale distributor) but rather the fraudulent and unfair competitive conduct of the organization that should determine compliance with the sales restrictions provisions of PDMA. Neither the statute nor the legislative history mandate such an arbitrary decision. Again, FDA must focus on conduct and intent rather than corporate status. To do otherwise is an unlawful extension of the law.

CONCLUSION

FDA's proposed definition of a "health care entity" is a matter of great significance to blood centers and the hospitals and other health care entities they serve. CCBC strongly supports FDA's ability to enforce all of the provisions of PDMA and believes that the recommendations set forth in these comments preserve that ability, while conforming to the language and intent of the statute. Ultimately, CCBC hopes that FDA realizes that no basis exists in the law for precluding a health care entity from acting as an honest and efficient wholesale distributor.

Sincerely,



William Coenen
President

Enc. Letter to Dockets, 11/13/90