



OUR MEMBERS SERVE COMMUNITIES NATIONWIDE

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April 19, 2004

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20857

Re: Docket No. 1992N-0297

Dear Ladies and Gentlemen:

Introduction

America's Blood Centers ("ABC"), www.americasblood.org, the nation's federation of independent, community-based non-profit blood centers, submits the following comments on the Notice of February 23, 2004 (RIN 0905-AC81) ("the Notice").

The Notice has postponed—until December 1, 2004—the applicability of 21 CFR § 203.3(q) of the FDA's final PDMA regulations to wholesale distribution of blood derivatives by health care entities. As stated in the Notice, "[T]he further delay of the applicability of § 203.3(q) to wholesale distribution of blood derivatives by health care entities is necessary to give the agency additional time to consider whether regulatory changes are appropriate and, if so, to initiate such changes."

ABC agrees that a permanent change in the final rule is appropriate. However, ABC is now concerned that the contemplated exemption for blood centers from § 203.3(q) may be too narrow. The exemption should extend to *any* distribution of blood-related products by blood centers, not just to "blood derivatives." That is what Congress intended and it makes sense in the context of allowing blood centers to fulfill their mission to patients. Accordingly, ABC submits the following comments.

Background

As FDA is aware, the 75 blood centers across the nation (comprising half the nation's blood supply) that belong to ABC draw blood from volunteer donors, test and process the donations, and then supply various blood products primarily to hospitals in return for service fees that are intended to (but do not always) cover their costs. Blood centers also perform varying degrees of direct patient care. Although this direct patient care is typically a small part of what blood centers do, it generally qualifies them as health care entities for purposes of PDMA.

92N-0297

For some time, ABC has been concerned about an unintended problem for our members in the PDMA regulations as originally promulgated by FDA. Specifically, some blood centers, as part of their core blood-related mission, also supply their hospital customers with certain blood-related products. *These include, but are not limited to, derivatives from human blood.* In doing so, the centers act in effect as distributors of these products.

As we read the PDMA, this activity was not intended to be prohibited, so long as the members have state licenses to be wholesale distributors (21 U.S.C. § 353(e)), which in all cases they do. Indeed, in a May 27, 1994 letter (copy attached), Congressman Dingell confirmed to then-FDA Commissioner Kessler that the Subcommittee had not intended in the legislation to prevent community blood centers from operating as both health care entities and wholesalers.

Nonetheless, the final PDMA regulations (21 CFR § 203.3(q)) provided generally that “A person cannot simultaneously be a ‘health care entity’ and a retail pharmacy or wholesale distributor.” Fortunately, FDA has repeatedly postponed the effect of § 203.3(q) to the extent it prohibits blood centers from acting as wholesale distributors of “blood derivatives.” See 65 FR 25639; 67 FR 4912; 68 FR 4912. The Notice is FDA’s latest postponement.

Blood Centers Should Not Be Prohibited from Distributing Blood-Related Products So Long As They Have State Licenses to Be Wholesale Distributors

While ABC appreciates and supports FDA’s decision to postpone the effective date of § 203.3(q) as to distribution of “blood derivatives,” there is no reason to limit the exemption to blood-related products that are actually derived from human blood. This is too narrow and is not supported by the underlying legislation or congressional intent. FDA-licensed blood centers should be able to continue to act as both health-care entities (for the purposes of performing therapies such as therapeutic phlebotomies, plasma exchanges, stem cell collections, outpatient transfusions, etc.) and distributors of all blood-related products.

For example, ABC members that support hemophilia treatment centers distribute synthetic as well as human-derived coagulation factors. Several ABC members also are regional distributors of recombinant erythropoietin and other cytokines. As blood centers are also regional centers of transfusion medicine (and tissue and stem cell, etc.), it makes sense for them to continue to distribute any blood-related drug regardless of source. For example, hemoglobin based oxygen carriers derived from both human and bovine blood are in development and may be licensed in the near future. Blood centers are the source of human red cells for the former and would logically be involved in the supply chain of such pharmaceuticals.

The current system whereby blood centers offer community hospitals the full range of blood-related products (as well as trained personnel and expertise in handling those products) is cost-effective and makes economic sense. If individual community hospitals are to maintain their own inventories of these specialized products, duplication of costs and inefficiencies will result. Also, because these are relatively low-use products for hospitals, blood centers and buying groups like ABC’s can negotiate better prices. Blood centers can also offer utilization reviews to hospitals. The current system has emerged in the marketplace because it is sensible, and it should be preserved for the same reason.

We at ABC must share some of the blame for the present wording of the Notice. As we re-read our letter to you of July 3, 2000 (copy attached), we were probably not as clear as we should have been that the PDMA regulations ought to permit any distribution of a blood-related product by a blood center, even if the product is not directly derived from human blood. Nonetheless, we

by a blood center, even if the product is not directly derived from human blood. Nonetheless, we did use the term "blood-related" at several points in the letter, and we think that logic and the law support an exemption of this scope.

Legally, as we read the language of PDMA, blood centers that are licensed wholesale distributors should be permitted to distribute any drug. But clearly the history and mission of blood centers would support, at minimum, allowing the distribution of any drug related to blood and cell therapies.

Conclusion

As Congressman Dingell's letter indicates, the impetus behind § 203.3(q) was "not to prevent community blood centers from operating as both a health care entity as well as a wholesaler, but rather to address practices by certain physicians who were abusing the existing system." ABC respectfully asks that blood centers be permitted to continue to offer their efficiencies and expertise in the field of all blood-related products. This is a limited field, but to blood centers and the hospitals and patients they serve, an important one. Please consider postponing the effective date of § 203.3(q) for any distribution of blood-related products by blood centers.

Sincerely,



Louis Katz, M.D.
President

pc: Jay Epstein, M.D.

Encs: Letter to Docket, 7/3/00
Letter to Kessler, 3/27/94



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July 3, 2000

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

Re: Docket Nos. 92N-0297 and 88N-0258. Prescription Drug Marketing Act; Reopening of Administrative Record

Dear Sir/Madam:

On behalf of America's Blood Centers ("ABC") I am submitting the following comments in response to the Food and Drug Administration's ("FDA's") notice that it is delaying the effective date and reopening the administrative record regarding its final rule "Prescription Drug Marketing Act of 1987; Prescription Drug Amendments of 1992; Policies, Requirements, and Administrative Procedures." 64 Fed. Reg. 67720 (December 3, 1999) (hereinafter the "Final Rule").

ABC is the national association of not-for-profit regional and community blood programs ("blood centers") that are responsible for collecting almost half (47 percent) of the nation's volunteer donor blood supply. Founded in 1962, ABC, through its members, 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. ABC has been an active participant in FDA's Prescription Drug Marketing Act of 1987 ("PDMA") rulemaking process and welcomes this opportunity to again address the status of blood centers under the Final Rule.

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Currently, FDA's Final Rule prohibits blood centers from simultaneously functioning as "health care entities" and "wholesale drug distributors." As described in detail below, many blood centers have maintained these dual roles for decades and it is vital that they be permitted to continue doing so in order to fully meet the public health needs of the communities they serve. If FDA persists in its decision to prohibit any blood center from simultaneously acting as a health care entity and state licensed wholesale drug distributor, potentially serious consequences will arise from the inability of blood centers to continue operating as part of hospital-shared service organizations. See Comments submitted by individual members of ABC to the Docket. FDA has specifically invited comment on the economic and public health impact of such prohibition and ABC urges the agency to reconsider the impact the of the prohibition on blood centers and their communities and revise the Final Rule accordingly.

Brief Legal Analysis

There is no question that under the Final Rule, any full service blood center that falls within the definition of a "health care entity" will be prohibited from engaging in the wholesale distribution of blood derived products as of the delayed effective date of the Final Rule (October 1, 2001). The analysis describing that result has been fully explored by ABC in its prior submission to the PDMA

Rulemaking Docket.¹ At the heart of ABC's objection to the Final Rule is FDA's definition of a health care entity:

Health care entity means any person that provides diagnostic, medical, surgical, or dental treatment, or chronic rehabilitative 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.*

21 C.F.R. § 203.3(q)(emphasis supplied). ABC members fall within this definition to the extent that they provide diagnostic and therapeutic services to patients, including for example, disease marker testing, therapeutic hemapheresis, stem cell collection and processing, transfusion services and intraoperative blood salvage.

However, blood centers also act as wholesale distributors subject to FDA's final regulations "Guidelines for State Licensing of Wholesale Prescription Drug Distributors." 21 C.F.R. Part 205; 55 Fed. Reg. 38012 (September 14, 1990). Those regulations implement the provisions of PDMA requiring minimum standards, terms, and conditions for the licensing by State authorities of persons who engage in wholesale distribution in interstate commerce of prescription drugs. 21 C.F.R. § 205.2. Although FDA's State licensing guidelines specifically exempt blood and blood components intended for transfusion from the licensing requirements, FDA does not exempt all licensed blood products. For example, blood derivatives, such as anti-hemophilic factors and other blood coagulation factors,

¹ See Comments to FDA Docket No. 92N-0297 (May 31, 1994), filed under ABC's previous name, the Council of Community Blood Centers (CCBC)(copy attached).

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albumin, intravenous immune globulin and alpha-1 anti-trypsin, are not exempt from PDMA. Blood centers that purchase these types of blood products from manufacturers and distribute them to the hospitals they serve have, since the early 1990's, complied with the State licensing requirements of PDMA by obtaining State wholesale distributor licenses.

The Final Rule's prohibition on health care entities maintaining wholesale distributor status will end the ability of blood centers, as they are currently organized, to distribute licensed blood products, other than those intended for transfusion, to local health care communities. ABC continues to maintain that FDA's application of that prohibition to blood centers inappropriately expands the statutory intent of PDMA. Indeed, the principal Congressional author of PDMA, Representative John Dingell (D. Mich.), recognized that FDA's prohibition could disrupt the ability of community blood centers to supply biologics sold as prescription drugs to hemophiliacs and other individuals with compromised autoimmune systems, and believed that FDA would address the issue in order to avoid such result. See Dingell Letter of May 27, 1994 (copy attached). Unfortunately, however, FDA's Final Rule continues the ban against acting both as a state-licensed wholesale drug distributor and a health care entity.

Adverse Impact on Public Health

Without relief from the Final Rule's current prohibition on simultaneously operating as a health care entity and wholesale distributor, the public health of the communities served by blood centers will be negatively

impacted. For example, a 20+ year arrangement between the New York Blood Center and a hemophilia treatment center for the provision of products will be prohibited as of the effective date of the Final Rule. As detailed in a recent letter to Dr. Epstein, Director of FDA's Office of Blood Research and Review, both the ability to distribute blood derivatives and to provide health care services, even if only a small part of a blood center's operations, are vital to the public health care of the communities that blood centers serve. See Letter from ABC to Jay S. Epstein, MD (February 25, 2000)(copy attached). No PDMA purpose is served by changing the decades old ability of blood centers to distribute critical care products to patients under well established methods that have a long history of success.

Regarding their health care entity role, most blood centers provide a limited amount of blood related and health care services that fall particularly within their medical expertise to patients that are served by the hospitals in their community. Despite the limited nature of such services, they are critical to public health in that they provide patients access to a higher level of expertise than would be possible to obtain or practical to maintain at individual community hospitals. Thus, by providing for such services through a centralized blood center, the medical expertise of the blood center can be leveraged in a manner that ensures community wide access to the highest quality blood services available.

Adverse Economic Impact

Aside from the public health ramifications, ABC is concerned that forcing blood centers to chose between acting as a health care entity or a wholesale

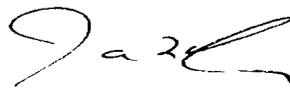
distributor will have a negative economic impact on the provision of blood services and products. While the scope of health care services currently provided by blood centers is fairly limited, they are critical to efforts to contain health costs in that they eliminate the need to duplicate such services at multiple locations. In order for hospitals to extend the same level of medical expertise with respect to blood related health care services as is currently provided by blood centers, significant additional expenditures would be required to attract and retain qualified medical personnel. The current system by which hospitals share the services provided by their community blood centers represents a much more cost efficient approach than will be dictated by FDA's Final Rule.

Economic costs associated with the distribution of blood related products will also be negatively impacted if blood centers are not able to act both as health care entities and wholesale distributors. Rather than being able to rely on the current centralized distribution system, hospitals will be required to maintain their own inventories and will bear additional storage costs. Moreover, during periods of shortage of blood related products, hoarding by individual hospitals will likely occur. Such practices result in artificially inflated prices and will likely leave some hospitals without necessary product. In contrast, the current distribution system, which relies on a centralized blood center serving more than a single community hospital, ensures that product distribution is achieved in a fair and efficient manner, and provides an objective mechanism for redistribution on an as needed basis during times of shortage.

Conclusion

As described above the multiple advantages currently associated with the current distribution and shared service arrangements between hospitals and their community blood centers will be lost if blood centers are denied the ability to act as both health care entities and wholesale distributors. Rather than forcing blood centers to eliminate one or the other of such functions, or fundamentally change their business structure, ABC requests that FDA revise the Final Rule so as not to prohibit blood centers from simultaneously acting as health care entities and wholesale drug distributors. Forcing blood centers to make a Hobson's choice between these two important roles may disrupt a valuable source of products and/or services, without any corresponding public health, economic or other benefit. In lieu of such an outcome, ABC urges FDA to revise the Final Rule to accommodate the dual functions of community blood centers and the important public health needs of the communities they serve.

Sincerely,



Jim MacPherson
Executive Director, ABC

Attachments