

**America's Blood
Centers**

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OUR MEMBERS SERVE COMMUNITIES NATIONWIDE

February 25, 2000

Jay S. Epstein, MD
Director
Office of Blood Research and Review (HFM-300)
Center for Biologics Evaluation and Research
1401 Rockville Pike
Room 400N
Rockville, MD 20852-1448

Dear Dr. Epstein:

On behalf of America's Blood Centers ("ABC"), I am writing to explain why many not-for-profit regional and community blood centers consider it vital to the public health needs of the communities that they serve to remain both distributors of blood derivatives (also known as "blood products") as well as health care entities. This dual status has been part of the role of many blood centers for decades and is important to their continuing role as hospital-shared service organizations in our local communities. ABC is the national association of not-for-profit regional and community blood programs ("blood centers") responsible for providing about half 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.

As presently structured, a blood center's ability to carry out both its role as a wholesale distributor of blood derivatives and a health care entity will end pursuant to the final rule implementing the Prescription Drug Marketing Act ("PDMA") which takes effect on December 4, 2000. As discussed fully below, this is clearly contrary to the public health of the local communities served by blood centers.

Even more troubling is the fact that the requirement of the final rule, which provides that a licensed wholesale drug distributor cannot also be a health care entity for purposes of PDMA (21 C.F.R. § 203.3(q)), is not an explicit requirement of the statute itself. Rather, it is an administrative expansion of FDA's authority presumably intended to further Congressional intent.¹ Yet the principal Congressional author of that legislation, Representative John Dingell (D-MI), wrote to FDA on May 27, 1994 urging FDA to address the issue since FDA's proposed rule "... could create obvious difficulties for the community blood centers in this position" (see attached letter). Representative Dingell concluded his letter to FDA as follows:

For a complete legal analysis, see ABC's comments submitted to the docket in this rulemaking. (These comments were filed on May 31, 1994 under ABC's previous name, the Council of Community Blood Centers ("CCBC").

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"The Subcommittee understands that the FDA intends to address this issue in order to avoid disrupting the supply of biologics sold as prescription drugs to individuals such as hemophiliacs and individuals with compromised autoimmune systems. The Subcommittee will work with you to resolve this issue so that important services are not disrupted."

The final rule unfortunately left the ban on being both a state-licensed wholesale drug distributor and a health care entity in the final rule in place.

Blood centers are hospital shared-services organizations. That means that blood centers, by design, centralize multi-faceted blood related and health services for the hospitals in a community so that such services do not have to be duplicated at each hospital, resulting in a higher quality of blood service provided to all hospitals. In this context, blood centers collect, process, store and ship blood and blood components to their hospitals. Blood and blood components are exempt from the state wholesale drug distribution requirement of PDMA. However, blood centers also purchase blood derivatives from manufacturers and distribute them to their hospitals along with blood and blood components. Many of these derivatives are manufactured from plasma that are provided by blood centers, as historically safer and more specific derivatives have replaced many of the plasma transfusions that formerly were used to treat patients in need of plasma factors. (Indeed, to help assure a community's supply for derivatives, some blood centers link the amount of derivatives from a pharmaceutical manufacturer to the amount of plasma that they supply.) Blood derivatives, such as anti-hemophilic factors and other blood coagulation factors, albumin, intravenous immune globulin and alpha-1 anti-trypsin, are not exempt from PDMA. This means for purposes of PDMA that blood centers that ship blood derivatives in interstate commerce must be state-licensed wholesale drug distributors.

Additionally, many blood centers provide health care services to patients, which includes blood centers under the definition of a health care entity. Simultaneous provision of these two services--distribution of blood derivatives and certain health care services, are not allowed by a not-for-profit blood center under the final rule.

The prohibition on being a health care entity and a wholesale drug distributor under the PDMA regulations impacts relatively small but growing and vitally important services provided by blood centers. Many hospitals rely on blood centers to carry out several critical health care functions, including:

- 1) Therapeutic hemapheresis (such as plasma exchange, photopheresis and immunoadsorption to treat various neurologic, hematologic and autoimmune diseases, and red cell exchanges in sickle cell anemia);
- 2) Therapeutic phlebotomies (for patients with hemachromatosis and other polycythemias);
- 3) Collection, processing and use of stem cells (for treatment of a variety of malignancies); and
- 4) Transfusion services (such as crossmatching services and home and outpatient transfusions, often a far lower costs and higher quality than prevailing facilities).

These health care functions are carried out by blood centers under supervision of medical experts in conjunction with the hospital and/or the patient's own physician. Since a blood center can carry out these activities for an entire or large section of its community, it provides an opportunity to share a higher level of medical expertise than may be possible for an individual hospital, especially in smaller communities. Indeed, because blood centers have such expertise, hospitals do not have to duplicate the medical expertise necessary for these types of blood-related activities, nor do patients have to seek such expertise outside their own communities. Importantly,

since all blood centers must comply with FDA's Good Manufacturing Practices ("GMPs") for the majority of its functions, these health care functions are carried out in a GMP-compliant environment.

An example of how a blood center's role as derivatives distributor and healthcare facility may be intertwined is that some centers operate the hemophilia treatment centers in their communities in conjunction with the local hemophilia society. Some of these hemophilia treatment centers have operated for many decades as the treatment for hemophilia advanced from whole plasma transfusions to cryoprecipitated antihemophilic factor to clotting factor derivatives. In this capacity, blood centers provide the clotting factors (both human and recombinant) at the lowest possible costs to patients, while also providing expert health care, education on use of the products, disposal of resulting biohazardous waste (as many of these patients are infected with HIV and/or hepatitis), and administering the products as required.

The distribution of blood derivatives is also a small but extremely valuable part of a blood center's services to the community. The distribution of these products to hospitals is done at the same time that blood and blood components are distributed. Having all blood-related products distributed by a blood center allows the hospital to manage its own inventories more carefully and to reduce storage needs.

Also of critical value to hospitals is that the blood center, as a neutral entity, is able to distribute products in short supply equitably throughout the community it serves, preventing hoarding of products by hospitals and providing for the smooth transfer of products as necessary between hospitals. This function has been especially valuable over the recent past given the critical shortages of intravenous immune globulin ("IVIG") and alpha-1 anti-trypsin. Further, the blood center's specialized medical expertise provides valuable consultative services with regard to the proper use of blood derivatives. Two examples of recent actions by a blood center dramatically highlight this point.

- 1) In providing a hemophilia factor product to a particular hospital for a specific patient, it became clear to a blood center that inordinate amounts were being distributed. The medical director at the blood center followed up with the hospital and the patient's physician. It was discovered that the patient was keeping excessive amounts of the product at home thereby increasing the risk of improper storage and, therefore, inappropriate use.
- 2) The medical director of a blood center gave a lecture to the medical staff of a major community hospital about appropriate use of a particular blood derivative. The lecture resulted in a 50% decrease in use of this product, a multi-faceted public health benefit.

These kinds of examples occur throughout blood centers. They highlight the critical role of the blood center's medical expertise and consultative role in the proper use of these products in local communities.

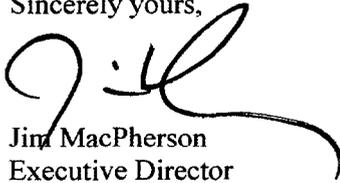
While neither the distribution of blood derivatives nor the provision of health care services as described above is the principal role of a blood center, each of these activities provides a vital public health service to local communities. The value of the specialized medical expertise that exists in blood centers is critical to community health care, and the ability of the blood center to provide this medical expertise is subsidized by the small margins they earn on the sale of plasma products. Such specialized medical expertise, by and large, does not exist in the majority of local hospitals. Especially for smaller hospitals, this specialized expertise is often not available. It is therefore imperative that a rule that weakens a blood center's ability to carry out this public health function, FDA in its role as part of the Public Health Service and the Department of Health and Human Services should be promulgating rules that encourage safer, more medically appropriate uses of blood, blood components and blood derivatives. As recognized by Representative Dingell in his letter to FDA, such FDA rules should not

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inhibit blood centers from carrying out their vital community-wide distribution role generally. This is even more critical in times of shortages.

As not-for-profit hospital shared-services entities, blood centers can objectively carry out these functions with a single goal in mind: the best interests of the public health of their local communities. ABC requests that FDA revise its regulations to encourage not discourage that goal. To serve their communities, blood centers must remain able to distribute blood derivatives under appropriate wholesale pharmaceutical licenses as required by the PDMA.

Sincerely yours,



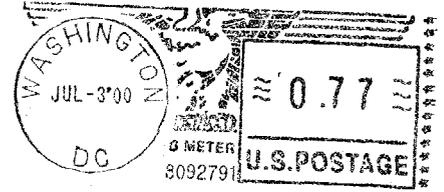
Jim MacPherson
Executive Director

Attachment



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