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DIAGNOSTIC LABORATORIES
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BLOOD SERVICES

July 3, 2000

J.S. Epstein, M.D.
Docket Management Branch (HFA-305)
Food & Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20857

Re: Docket Numbers 92N-0297 and 88N-0258

Dear Dr. Epstein:

On behalf of The Blood Center of Southeastern Wisconsin, Inc., in Milwaukee, Wisconsin, I am writing this letter to express my concern regarding the final rule implementing the Prescription Drug Marketing Act of 1987 (PDMA). In short, we believe it is in the greatest interest of our community (and all communities associated with blood centers) that blood centers be able to remain as both health care entities and as distributors of blood derivatives. The new rule to be effective October 1, 2001, would have a significant negative impact on The Blood Center and on the hospitals and patients that it services.

Our blood center is a community-shared organization providing all blood and blood products to hospitals in Southeastern Wisconsin and to several in Northern and Western Wisconsin. As well as providing blood and blood products, The Blood Center provides a number of patient care services including the following:

- 1) The Blood Center provides therapeutic hemapheresis services for all but two of the 33 hospitals in our Blood Services region, thereby decreasing the need for other institutions to maintain this capability and reducing the overall financial impact on hospitals to provide this service. By concentrating the service responsibility on one organization, it allows the development of a core of expertise in the area of hemapheresis which no single hospital would be interested in developing on its own.
- 2) The Blood Center provides infectious disease testing for all of its blood units and also provides the same type of infectious disease testing of organ donors and a number of patients involved in the transplant programs in this community. The Blood Center also provides this service to some patients cared for in hospitals and physician offices.
- 3) The Blood Center operates a diagnostic clinical laboratory providing unique services, some of which are found only at this blood center in the United States. This includes specialized coagulation reference laboratory testing, platelet immunology testing, red cell reference lab testing, and HLA testing for the transplant programs in its community. By providing these services, it prevents duplication of capacity at individual local hospitals and provides an unmatched core of expertise for the Southeastern Wisconsin area.

THE BLOOD CENTER OF SOUTHEASTERN WISCONSIN, INC. IS A NONSTOCK, NONPROFIT CORPORATION.

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- 4) As with many other blood centers, because it has pheresis capability, The Blood Center is uniquely prepared to collect and store peripheral blood stem cells for use in autologous peripheral blood stem cell transplants. The Blood Center of Southeastern Wisconsin currently provides autologous peripheral blood stem cell collection and processing service in cooperation with four of the hospitals in the community. By providing this service, The Blood Center provides a cGMP quality service that reduces the overall cost of this service to the community by not having each hospital develop its own stem cell capabilities.
- 5) The Blood Center provides red cell reference laboratory testing, which includes crossmatching of blood for patients with difficult serologic problems and provides the transfusion service activities for one hospital in this community.

Many of these health care entity services that The Blood Center provides give the community a tremendous benefit in terms of cost savings through service centralization and the development of a core of expertise that is not available anywhere else in the community. The community has been a strong supporter of The Blood Center providing these services, and relies upon the Center to maintain these services for the community that it serves.

In addition to these patient care and testing services, The Blood Center of Southeastern Wisconsin is a distributor of a number of blood derivatives which would be significantly adversely affected by the implementation of this new rule. The Blood Center has been nearly the sole provider of hemophilia blood product derivatives (Factor VIII, Factor IX, and products to treat patients with inhibitors) for over 20 years. In doing so, The Blood Center works closely with the Comprehensive Center for Bleeding Disorders which is now a part of The Blood Center. The Comprehensive Center for Bleeding Disorders is a nationally prominent treatment center which provides care for patients with hemophilia and a number of other bleeding disorders such as von Willebrand disease. It also has a close working relationship with the Great Lakes Hemophilia Foundation which holds the regional grant to support 17 treatment centers across the upper Midwest. Relative to the ability of patients to obtain coagulation factor products from other sources, the price that The Blood Center charges hospitals who treat these patients and the patients receiving these products at home has constantly been significantly less than what the hospitals and patients could obtain elsewhere. This has resulted in millions of dollars of cost savings to the hemophilia population, third party insurers, and our state government. This alone is a strong reason why the change in the rule would have an enormous negative impact on the patients requiring the hemophilia and related coagulation products in our community. For this alone, we strongly urge that this rule not be implemented.

The Blood Center has been a distributor of intravenous immune globulin, albumin, Rh immune globulin, varicella zoster immune globulin, hepatitis B immune globulin, as well as some other derivatives to a number of the hospitals that it serves. The reason for this is that The Blood Center acts as central inventory for many of these products for our hospitals. This significantly reduces the overall cost by not having each hospital maintain a large inventory of some of these products.

As a steward of the blood derivatives available for southeastern Wisconsin, there have been times when The Blood Center has used its position and expertise in transfusion to assist the medical community during times of blood product shortage. At times, The Blood Center was the only organization in our community that was able to obtain albumin. Our physicians have also

assisted in the procurement and conservative use of antithrombin III and anti-hemophilic factor in order to stretch the clinical impact and prevent inappropriate use of these sometimes limited products. The ability of The Blood Center to supply these products to some of its hospitals is an important component of a community service that benefits the hospitals we serve and the patients who reside in our region. The implementation of the final rule would adversely affect the care of patients, drive up the health care costs in our community, and limit the ability of our community to maintain a concentrated source of expertise in the use of blood derivatives.

In addition to these derivatives, The Blood Center is the sole entity carrying a number of rare blood products such as recombinant Factor VIIa, porcine factor VIII, and antithrombin III. As regional hospitals do not typically carry these expensive and rarely used products, if The Blood Center did not maintain an inventory, our hospitals may be unprepared for some medical emergencies.

Blood Center physicians carefully monitor the use of these products by having discussions with physicians in the community when there is an order for these products to ensure their appropriate use. This is an important educational process that is associated with all the use of the blood derivatives that The Blood Center supplies. This is perceived not as intervention by the physicians in the community but as a community resource of expertise in the use of these products.

In summary, the distribution of blood derivatives and the provision of health care services as described above are an integral part of our Blood Center and the support that we provide to our community, hospitals, physicians, and patients. We feel that our ability to provide each service is assisted by our ability to provide both together using the same set of physician and health care professional resources. The change in the new law would significantly alter the ability to provide these products in a cost effective and clinically appropriate manner. This would not only impact the larger hospitals in our community but also the smaller hospitals in our community that depend even more on the expertise that resides in the medical personnel within our Blood Center. We strongly encourage the FDA to allow blood centers to both be a health care entity and a distributor of blood products. We believe this is essential to the good health and economic well being of the hospitals and patients in our community.

Sincerely yours,



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