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July 3, 2000

Jay S. Epstein, M.D.
Director, Office of Blood Research and Review (HFHM-300)

Docket Management Branch (HFA-305)
Food and Drug Administration
5630 Fischer's Lane, Room 1061
Rockville, MD 20857
Delivered by FAX to: (301) 827-6870

Dear Dr. Epstein:

Re: Docket Nos. 92N-0297 and 88N-0258

The purpose of this letter is to communicate one physician's concerns about the potential impact of proposed regulations concerning implementation of the Prescription Drug Marketing Act of 1987. Of particular concern to me is the statement that "under the final rule, blood centers functioning as health care entities could not engage in wholesale distribution of prescription drugs, except for blood and blood components intended for transfusion.... As discussed in the preamble to the final rule in response to comment (64 FR 67720 at 67725, 67726 and 67727), blood derivatives products are not blood or blood components intended for transfusion and therefore could not be distributed by health care entities, including full service blood centers that function as health care entities, after the final rule goes into effect."

Admittedly, as a practicing physician, I do not know the reasons that led to considering these issues when the law was initially passed in 1987, nor why FDA is reconsidering these issue today. However, it is clear to me that implementation of these rules as stated in the quote above would adversely impact both the finances of citizens of my state, the health of patients with bleeding disorders in southeastern Wisconsin, and the level of expertise in hemostasis evaluation and therapy available to the average physician caring for patients in my area.

To explain my position, I will review for you some of the history of the Blood Center of Southeastern Wisconsin, how coagulation expertise was developed in my region, and some of my own personal history:

The Blood Center of Southeastern Wisconsin has provided blood services in its region for over 50 years. During the bulk of this time, it has supported related research and related clinical activities. Dr. Richard Aster as President of the Blood Center of Southeastern Wisconsin, recruited Dr Robert Montgomery to this Blood Center for the purpose of expanding research and clinical expertise in the field of hemostasis. Dr Montgomery, a pediatric hematologist and prominent researcher in the field of von Willebrand disease and hemophilia saw that there was call for a quality reference hemostasis laboratory to support patient care in the regional hospitals, and for the application of scientific thought to the local care of patients with hemophilia and vonWillebrand disease. The ability of

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BY BLOOD CENTER OF SOUTHEASTERN WISCONSIN, INC. 2 A ROSELAND, KOSICE, WISCONSIN

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the Blood Center to provide coagulation factor support, followed in turn by research interests, sophisticated laboratory diagnosis and direct patient care together has provided a "critical mass" of material in the field of hemostasis. The synergistic interactions of physicians, lab personnel, blood center product distributors and patients have had impressive results. These include:

- Reliable supply of coagulation factors (even in times of USA shortages)
- The Reference Hemostasis Laboratory of the Blood Center
- The Comprehensive Center for Bleeding Disorders
- Transfusion Medicine physician consultation in Southeastern Wisconsin
- Research in the basic science aspects of hemostasis and thrombosis
- Research in infectious and other sequelae of transfusion

After completing my Hematology/Oncology fellowship in 1986, I wanted to find a place where I could further train in care for patients with coagulation disorders, including clinical care, laboratory evaluation and transfusion medicine support. The Blood Center of Southeastern Wisconsin was one of the prominent places in the USA where this all came together. After a Blood Center fellowship, I found a position at University of New Mexico. In New Mexico, the ability of United Blood Services (a not-for profit community blood center) to provide hemophilia treatment products at low prices allowed low acquisition costs for hospitals and individual patients. UBS also provided competition to home nursing services which held the costs of hemophilia treatment products low.

After eight years, I was recruited back to the Blood Center of Southeastern Wisconsin. The ability to provide individual patient care for persons with disorders of hemostasis through the Comprehensive Center for Bleeding Disorders (CCBD), to provide reference coagulation laboratory testing and physician consultation through direction of the Reference Hemostasis Laboratory, to provide physician consultation for use of both blood-derived coagulation factors and other non-blood derived pharmaceuticals through the distribution network of the Blood Center, and the availability of research endeavors, made return to Milwaukee very attractive to me.

I feel that the proposed "final rule" concerning PDMA 1987 threatens to degrade the care of patients in my community. It will also degrade the ability of the Blood Center of Southeastern Wisconsin to maintain a "critical mass" of expertise in hemostasis. Furthermore, it will drive up the cost of care born by patients and third party payers. The Blood Center activities in laboratory diagnosis and patient care via CCBD clearly make it a "health care entity." By withdrawing the ability of this blood center to act as the regional distributor of coagulation and other transfusion medicine pharmaceuticals (including antihemophilic factor, recombinant coagulation proteins, antithrombin, epsilon-aminocaproic acid, DDAVP, etc.) health care in my community is degraded. I will provide several examples of how why I feel this way.

1. The Comprehensive Center for Bleeding Disorders of the Blood Center is the MCHB/CDC recognized Hemophilia Treatment Center (HTC) in my area. Both during times of product shortage (whether it was Humate-P, Thrombate, Hyate-C, or something else), and as part of its routine operation, the Blood Center distribution staff asks physicians from the CCBD to telephone call community physicians requesting specialized coagulation products. The object is to promote appropriate

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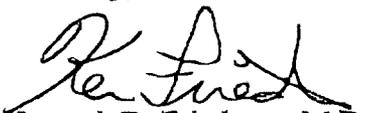
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- product use, to provide advice on potential alternatives for care and provide for the best use of scarce products during times of shortage.
2. The Blood Center makes "PHS-pricing" on hemophilia products available to individuals with hemophilia and other bleeding disorders in our region. This allows these patients access to the best pricing available, reducing treatment costs for individuals, third-party insurance providers and the State of Wisconsin. Both "PHS-pricing" and the fact that the Blood Center is a not-for-profit organization contribute to the low acquisition costs the patients see. The federal government through MCHB encourages participation in "340B pricing" to allow patients access to drugs at the lowest cost, and that provision should be respected in the current FDA ruling.
 3. The Blood Center acts as a central repository for rarely called-for products such as Hyate-C, Novo-seven and Thrombate. By providing this function centrally, local hospitals do not need to maintain inventory. This serves to both reduce costs for hospital care, and to insure that there is a place in the community where the products reside. Without such a centralized repository, I would be concerned that these rarely used product might either not be available in area hospitals (leaving them unable to provide care in an emergency) or some hospitals might maintain some inventory which could result in product out-dating, and increased costs passed onto the patient.
 4. The specialized knowledge of coagulation issues that is currently at the Blood Center is in part related to the many ways the Blood Center participates in coagulation and transfusion related issues in the community. This expertise is freely provided to community physicians. If the array of activities were restricted, the ability of the Blood Center to both amass the expertise and provide it would be limited.

Blood centers traditionally provide hemostatic transfusion products (FFP, platelet concentrate and cryoprecipitate) and therefore they have a logical involvement in the care of patients with bleeding disorders. From my perspective the current system of allowing community blood centers to serve as "health-care entities" and as a pharmaceutical distributors is a natural association. It allows blood centers to develop expertise in hemostasis and to then assist community physicians in the management of these complex disorders. The Blood Center of Southeastern Wisconsin grew in that environment, and the current system improves health-care provision in my community. I hope that FDA will not restrict blood center involvement in the areas of hemostasis, realize the logical role of blood centers in distribution of coagulation pharmaceutical products, and act in a way that promotes health care. The current version of the "final rule" would degrade health services in my region; it should be reconsidered.

Please feel free to contact me further if you require further clarification of my opinions, or if stating them in some other format would assist the FDA in reaching a conclusion on this matter.

Sincerely,



Kenneth D. Friedman, M.D.

Medical Director, Reference Hemostasis Laboratory
Associate Medical Director