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June 20, 2000

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

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

Dear Sir or Madam:

On behalf of the Sacramento Medical Foundation Blood Centers, I am writing to explain why it is vital that not-for-profit, regional and community blood centers be allowed to distribute plasma derivatives.

It is important for the FDA to understand that plasma derivatives are NOT routinely carried by retail pharmacies. They are also NOT kept in inventory at most small to medium sized hospitals. This is due to the fact that these scarce and costly products would be likely to expire prior to use, because most facilities would only need them infrequently. A blood center that services a large geographic area can stock these products and distribute them on an as needed basis. Thus, decreasing the risk that they would expire and be wasted prior to use.

I would like to emphasize that prohibiting blood centers from providing this service would not affect large urban hospitals that are capable of providing their own inventory of plasma products. But it would have devastating effects on smaller, rural hospitals, physicians' offices in rural areas and our State Prison Medical Facilities. We provide this service not as a money making venture, but as a public health service to the people of our community. In fact, we have historically lost money in the provision of this service. However, we feel that a regional blood center is uniquely equipped to provide plasma products to those in need.

The Sacramento Medical Foundation Blood Centers provides the following products for our customers:

SACRAMENTO BLOOD CENTER  
1625 Stockton Boulevard  
Sacramento, CA 95816-7089  
TEL 916/456-1500  
FAX 916/452-9232

NORTH STATE BLOOD CENTER  
1880 Park Marina Drive  
Redding, CA 96001  
TEL 530/243-0160  
FAX 530/243-0580

NORTH VALLEY BLOOD CENTER  
285 Cohasset Road  
Chico, CA 95926  
TEL 530/893-5433  
FAX 530/893-2537

CENTER FOR BLOOD RESEARCH  
1631 Stockton Boulevard  
Sacramento, CA 95816-7089  
TEL 916/456-1500  
FAX 916/456-2414



88N-0258

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- Factor VIII and Factor IX – These plasma derivatives are administered to control bleeding in hemophiliacs who have been injured or are undergoing surgery.
- Rh Immune Globulin – This product is administered to pregnant women who are Rh-negative, to prevent formation of antibodies to the Rh Factor. If this product is not received in a timely fashion, there is significant risk that the current, or a future, fetus will develop hemolytic disease of the newborn, a potentially fatal disorder.
- Varicella Zoster Immune Globulin – This product is administered to immunocompromised individuals after they have been exposed to Varicella Zoster (the virus that causes chicken pox and shingles). Infection with Varicella Zoster can be fatal in this patient group.

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We also provide, free of charge, 24 hour per day access to a physician with specialized knowledge in the appropriate administration of these plasma products.

If the Sacramento Medical Foundation Blood Centers are prohibited from distributing these products, I do not know how our customers will possibly be able to obtain them. The current system works well because our physicians have the medical expertise to advise the administering physician in the use of the product. We also have a built in delivery system since we already provide blood components to these facilities.

I would like to suggest that a simple solution to the problem would be to regulate plasma derivatives in the same way blood components are regulated, since they are both considered “drugs”. This would allow blood centers to distribute plasma derivatives to their customers while providing a valuable public health service.

Thank you for your consideration of this matter.

Sincerely,

A handwritten signature in cursive script that reads 'Patricia M. Kopko, MD'.

Patricia M. Kopko, MD  
Associate Medical Director  
Sacramento Medical Foundation Blood Centers