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30 May 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, MC 20852-1448

Dear Dr. Epstein,

I am writing to explain why my not-for-profit blood center considers it vital to the public health needs of our community that we are allowed to remain both a distributor of blood derivatives as well as a health care entity.

Our blood center provides therapeutic apheresis procedures for local hospitals. In addition we provide RhoGam to small clinics in our area. We have been requested to provide this derivative since the product is very costly and by buying for all of them we can purchase for a lower price.

Thank you for your consideration of this important issue.

Sincerely,

M. Allene Carr-Greer

M. Allene Carr-Greer
Director of Operations

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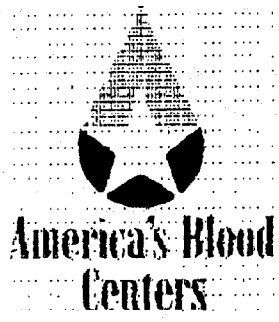

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OUR MEMBERS SERVE COMMUNITIES NATIONWIDE

May 19, 2000

TO: ABC Trustees

FROM: Celso Bianco, President, 212-570-3000, cbianco@nybc.org
Kristen Smith, Associate Director, Legislative & Public Affairs
Ext. 19, krsmith@americasblood.org

TCN 00-180 Request for Comments on PDMA Provisions

As many of you already know, FDA has delayed the effective date and reopened the administrative record regarding certain aspects of the final regulations implementing the Prescription Drug Marketing Act of 1987 (PDMA). Among other things, FDA has specifically invited comment on the economic and public health impact on blood centers of the provision in the Final Rule that provides "[a] person cannot simultaneously be a "health care entity" and a retail pharmacy or wholesale distributor."

While ABC will be submitting comments on behalf of its membership, we think it is critical at this juncture (since it represents what will likely be our last opportunity to obtain non-legislative relief from this prohibition) that individual blood centers take the time to provide FDA with as many concrete examples as possible from your own experiences that demonstrate the critical nature of being able to both provide health care services and act as wholesale distributors.

While we recognize that our request places the burden on you to devise your own comments, we are convinced that your submissions will be much more effective if they are blood center specific and offer more than a canned response provided by ABC for you to sign. In order to provide you with some guidance we are providing below a summary of the current legal analysis and points to consider that may suggest examples for you to include in your comments. We are also attaching a February 25, 2000, letter from ABC to Dr. Jay Epstein that you may want to consider for purposes of your submissions to FDA.

Brief Legal Analysis

FDA's Final Rule on PDMA defines a health care entity as: [a]ny 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.

The problem with the regulation's definition of a health care entity occurs in the context where blood centers, in addition to providing health care services, distribute blood derivatives (prescription drug products) in interstate commerce. Since FDA has exempted only blood and blood products intended for transfusion from PDMA, the distribution of blood derivatives has required blood centers to obtain wholesale distributor licenses in order to comply with FDA's earlier PDMA regulations governing the State licensing of wholesale drug distributors. 21 C.F.R. Part 205. However, as of the effective date of the final PDMA regulations (which has been delayed until October 1, 2001), blood centers that are licensed as wholesale drug distributors and that concurrently provide any health care services, will be in violation of PDMA. ABC has suggested that FDA revise the definition of "health care entity" so that the simultaneous acting as a wholesale distributor by a blood center is not precluded.

Points to Consider

Following is a list of critical health care services and other activities that may suggest examples for purposes of demonstrating the necessity of permitting blood centers to act as both health care entities and wholesale distributors.

Therapeutic hemapheresis
Therapeutic phlebotomies
Collection, processing and use of stem cells
Transfusion services
Distribution of products in short supply (e.g., IVIG)
Provision of consultative services regarding proper use of blood derivatives
Operation of hemophelia treatment centers

As an example of the types of concrete information that will be helpful in convincing FDA to take the action we have requested, ABC described the following scenarios in its February letter to Dr. Epstein:

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.

Comments are due to FDA by July 3, 2000. If you have any questions or need additional assistance please do not hesitate to contact Kristen Smith at the ABC office.