



SOUTHEASTERN
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Member of the
American Association
of Blood Banks,
the Florida Association
of Blood Banks and
America's Blood
Centers

June 22, 2000

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Jay S. Epstein, MD
Director, Office of Blood Research and Review
c/o Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20857

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

Dear Dr. Epstein:

I am writing on behalf of Southeastern Community Blood Center and the hospitals that we serve in North Florida and South Georgia to explain why it is important our blood center be allowed to continue to distribute blood derivatives under the Prescription Drug Marketing Act (PDMA). Besides providing blood products, we also distribute blood derivatives (under appropriate PDMA licenses in Georgia and Florida), store and distribute bone and tissue, perform therapeutic apheresis procedures and perform compatibility testing services.

Our blood center serves primarily a rural area of Florida and Georgia. Many of the hospitals are small and lack blood banking expertise. Our ability to centralize services and products assures the availability of expertise and of all blood products/derivatives to even the smallest hospital. Resources are conserved and waste is avoided.

It is not our intent to compete with traditional pharmaceutical providers on non-blood bank related products. Our mission is to assure access for our service area of vital blood bank related products.

It seems that being described as a "health care entity" and a "wholesale distributor" implies that we have a broad range of health care responsibilities and a vast drug wholesale business. This is not the case in blood center activities. Our role as health care providers is very focused to treatments or services that are directly blood bank related. The drugs or derivatives that we supply support these services and are also blood bank related. The derivatives are derived from blood products. Their appropriate use is an integral part of the area of expertise of our medical directors and technical staff.

In the early 1960s, we began our derivative distribution with Factor VIII for hemophiliacs and Rh Immune Globulin (RIG) for women. Our Factor VIII services provided easy access for our local hemophiliacs, without the red tape associated with hospital admissions. (This service was eventually transferred as reimbursement issues became too complicated through an independent blood center.)

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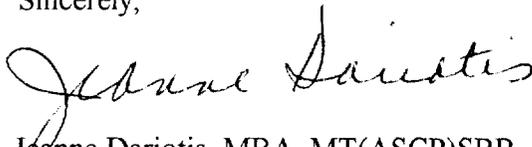
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Our distribution of RIG assures that the appropriate serological testing accompanies the derivative's issue. Appropriate and timely treatment with RIG is necessary to avoid antibody stimulation in mothers and fetal demise. Our control and issue of RIG avoids women not being properly treated because testing and product distribution are separated in time and space.

In addition to RIG, we provide human albumin when it is required for the therapeutic procedures that we perform. We experienced two separate dilutional errors by hospital pharmacies when the derivative was supplied through the hospital. By allowing our staff and medical director to oversee the distribution of the albumin directly, we have decreased potential life threatening errors for the patients we serve.

In summary, we believe that our ability to distribute blood derivatives under the PDMA reduces errors in patient treatment, assures fair distribution of valuable products, avoids waste of these products and allows an entity with experience in blood product and derivative treatments to provide control and valuable input to patient care. It does not appear to be the intent of Congress to change the role of blood centers in providing services and derivatives. By not allowing blood centers to continue in this dual role, patient treatment and care will suffer.

Sincerely,



Jeanne Dariotis, MBA, MT(ASCP)SBB
Executive Director

JD:kkf