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THE BLOOD CENTER

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May 30, 2000

Jay S. Epstein, M.D., Director
Office of Blood Research & Review (HFM-300)
CBER
1401 Rockville Pike, Rm. 400N
Rockville, M.D. 20852-1448

Dear Dr. Epstein:

We are writing today to express our concerns regarding the Prescription Drug Marketing Act (PDMA), which becomes effective December 4, 2000. We are in support of the letter and comments sent to you by America's Blood Centers.

The act, in its current form, would jeopardize many services provided by blood collection agencies, increase cost, and reduce efficiency. A few examples are described below.

- Our "Transfusion Services" departments provide complete blood component services to Home Health Agencies, Dialysis Centers, and long term care hospitals. These facilities lack the means to refrigerate, crossmatch or store blood and blood components. If this service becomes unavailable, patients from these facilities would require transfer and admission to local hospitals for transfusion, increasing overall cost dramatically.
- Therapeutic phlebotomies are performed at our donor centers for less than \$40.00 (forty dollars). If we are unable to provide this service on an outpatient basis, hospital admission may be required. Most hospitals contract with an area blood provider for this service.
- Many blood centers maintain a moderate inventory level of basic blood bank reagents. Hospitals frequently rely on this stock as "back-up" should they have supply problems or elect NOT to stock seldom used items. An excellent example of this is "RhoGam". As it is very expensive and has a limited shelf date, many small facilities and doctor's offices do not wish to stock it, preferring to order it "as needed" from the blood supplier.
- Therapeutic apheresis procedures require the technical expertise of a qualified physician. Since most use blood components or derivatives as replacement fluids. Therapeutic apheresis is an excellent illustration of the combined benefits of a "health care entity and wholesale distributor".

In the best interest of public health and the communities we serve, we strongly recommend revision of this regulation.

Sincerely,


Brian Gannon
President & CEO

bcc: Steve Worley
Jim McPherson

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