

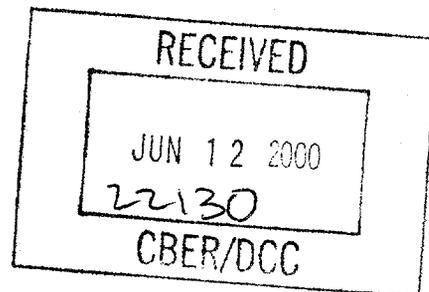
Northern California Community Blood Bank

A Non-Profit Corporation Serving Humboldt and Del Norte Counties Since 1951

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01 Jun 00

Jay S. Epstein, MD
Director
Office of Blood Research and Review (HFM-300)
Center for Biologics Evaluation and Research
1401 Rockville Pike
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Rockville, MD 20852-1448



Dear Dr. Epstein,

Please allow me to give you the picture from our local perspective regarding the threatened enforcement of current provisions of the 1987 PMDA.

The system now used by our blood bank, and I'm sure by a great many others across the nation, has evolved over several decades. We are the local repository for many manufactured products derived from plasma, i.e., IVIG, various coagulation factors, etc. We store enough to meet any expected need by any of our seven hospitals and can deliver to the hospitals usually within minutes. If we are forbidden to stock these products, it will require seven times as much storage, seven times the inventory management effort, and most importantly, seven times more volume of often scarce material out of circulation.

We are currently in a position to monitor and confer with those physicians in our community, who may not be experts, on choices, for example, between FFP and specific coagulation factors because we are aware when either is ordered.

We are one of the two smallest blood banks in California and one of the only two which have operated in black ink for the last two years. If we are unable to continue our distributor roll for "drugs" made from plasma, i.e., IVIG, Factors VIII, IX, etc. and others, we will join the majority of California blood banks in the red ink category. This occurs, in spite of our annual operations of about 1.8 million dollars, because our net income over expenses for total operations is almost exactly the difference between what we pay for "drugs" and what we sell them for, about \$10,000 to \$14,000 per year. Keep in mind that we sell these "drugs" for less than the hospitals can get them elsewhere, which is the only reason they buy from us rather than their own suppliers.

The system works. It has worked for years. It meets the medical needs of the community. It adds a small but currently important financial boost to our not-for-profit community blood bank. There have been no local complaints we are aware of.

IT'S NOT BROKEN! WHY ARE YOU FOOLING WITH IT?

Most sincerely,

Tate Minckler, MD
Medical Director

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