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18 July 1985

Robert W. Reilly, President
American Blood Resources Association
P.O. Box 3346
Annapolis, Maryland 21403

Dear Mr. Reilly:

I am writing concerning the letter of July 1, 1985, which you wrote to Alan Brownstein (Reference No. A3714). I was extremely dismayed to learn that you and your colleagues are considering abrogating the "gentlemen's agreement" between the U.S. Coagulation Product Manufacturers and the FDA that plasma from correctional institutions would not be used for the production of coagulation products.

I am also concerned with learning that a "limited study" comparing plasma donors from a prison setting to those in other locations might establish whether or not prison donors create a higher risk of the transmission of AIDS or other infectious agents. No such study is required.

Wearing my hat of Professor of Medicine at the University of Massachusetts Medical School, and having considerable experience and expertise in the region of blood derived infections, no additional study of this matter is required. If such a "limited study" demonstrated no increased risk of prison plasma, then the unescapable conclusion in the eyes of every American physician would be that the study were not properly done. We have ample high quality clinical and basic research to indicate the endemic nature of certain viral illnesses in prison populations. In addition we know very well that the larger the number of carriers of viruses in a donor pool, the larger the number which will escape detection by any screening tests.

I certainly have no problem with the use of prison plasma in creating products such as albumin which may be rendered free of the agents in question. Increasing the donor pool size of such high risk donors when it comes to coagulation products flies in the face of every bit of common sense and science now available to us. We already have excellent data to indicate that the hepatitis virus survives heat treatment, so that one cannot argue that heat treatment eliminates the risk. In addition, most of us who treat hemophiliacs continue to believe that, in spite of the current high level of anxiety concerning AIDS, hepatitis remains a larger risk to our patients over the long run than does HTLV-III-related disease.

I am aware of one major manufacturer in this country who has already publicaly taken the position that they will not return to the use of plasma from correctional institutions for production of coagulation products. A second manufacturer has made strong indications that they will also not abrogate the prior "gentlemen's

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agreement". It would be strongly to the detriment of other manufacturers to abrogate this agreement. More importantly, however, it would be to the great detriment of the recipients of such products.

Sincerely yours,

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cc Alan Brownstein
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