Alpha THERAPEUTIC CORPORATION®
5555 Valley Blvd., Los Angeles, CA 90032

January 21, 1983

Dr. Steve Ojala
Director-Regulatory Affairs
Cutter Laboratories
808 Parker Street
Berkeley, Ca. 94710

Dear Steve:

The following are the minutes of PMA members involved in plasma fractionation held on Thursday, January 14, 1983 in New York.

Those in attendance at the meeting were Bill Martin, Penny Carr, Bruce Blomstrom and Clyde McAuley - Alpha, Bob Johnson - Armour, Steve Ojala - Cutter, Mike Rodell, John Bactich and Dave Castaldi - Hyland and Bob Reilly and Joe Rosen - ABRA.

The purpose of the meeting was to develop an industry position related to AIDS.
The following was agreed to:

1. Donor Screening - It was agreed that the industry would attempt to eliminate from their donor population individuals with AIDS. Since high risk groups have been rather clearly identified, it was also agreed that the industry would attempt to eliminate from their donor population these high risk groups. This will be accomplished by educating the donor population with a presentation on the AIDS problem including an explanation and description of the high risk groups. Then the donor will be asked to either eliminate themselves if they fall into the high risk categories or by directly asking the donors if they are in any of the high risk categories. It was also agreed that closer attention would be paid to screening and examinations with emphasis on history of unexpected weight loss, unexplained fevers, night sweats, lymph adenopathy, protein results, etc.

2. Donor Testing - It was agreed that at the present time there is insufficient information to warrant the incorporation of any new surrogate lab test into routine donor testing.

3. Manufacturing process - for quite some time research in the industry has been directed towards providing a better and safer A.H.F. Processing changes such as heat treating (pasteurization) or other methods which will inactivate hepatitis virus are in the process of receiving

FDA approval. A.H.F. processed in this manner is expected to be available this year. As more information becomes available regarding AIDS, it is believed that these efforts at manufacturing process changes could become the most effective means of reducing the risk of AIDS.

Any attempt to reduce batch sizes of A.H.F. was considered ineffective because Hemophiliacs receive product representing hundreds of thousands of donors during the year regardless of batch size. Also so little is known regarding the effect of dilution that a batch size reduction could conceivably have a detrimental effect. Finally, batch size reduction could have serious negative repercussion on productive availability and, most especially, on cost.

Cryoprecipitate which is the ultimate in batch size reduction is felt to be at best a delaying action since it can so substantially alter the life style of Hemophiliacs.

4. Common requirements for blood and plasma - The principal concern at the present time regards the possibility of a transmissible agent in the blood or plasma. It is felt therefore, by the industry that whatever measures are deemed appropriate for the collection of plasma should apply to the collection of blood. Obviously, it would be foolish to test plasma donations for the absence of hepatitis surface antigen and not test blood or plasma coming from Blood Banks for surface antigen. In addition, fresh frozen plasma from Blood Banks is currently used in the manufacturing process for A.H.F.

From these consensus agreements, I will draft an industry position paper on AIDS similar to the AABB position paper. I will circulate this draft to each of you for your comments and approval.

Sincerely,

GRO-C

William G. Martin
Sr. Vice President

cc:;s Dr. Paul Kaufman ABRA
Dr. Andrew Schmitz, Jr.

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