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TO Those listed

Office of Dr. W. F. Schaeffler

DATE 12/13/82

FROM Steven J. Ojala

COPIES TO

SUBJECT AIDS and FDA

W F Schaeffler	M M Sternberg	M Mozen
J Hink	J Hjorth	J Ryan
K Fischer	J Cherry	L Ambrus
E Cutter	J M Ashworth	G Nakamura
R Rousell	C Turner	D Schroeder

Dr. Donahue asked for an informal meeting with the four Blood Product Manufacturers following the PMA/FDA Liaison Committee Meeting on Friday to explore possible actions to minimize the risk of AIDS. Although the transmission of AIDS via blood products (and specifically AHF) has not been conclusively demonstrated, there is some evidence that a possibility does exist. Donahue wanted to know what we manufacturers could do immediately to minimize the risk of potential exposure.

Donahue specifically asked if we could simply exclude high risk plasma taken from areas such as New York, San Francisco and Hollywood from AHF production. Mike Rodell (Hyland) responded that he felt a more meaningful effort would be to attempt to educate the high risk populations (homosexuals, Haitians and drug users) and have them voluntarily exclude themselves from the plasmapheresis programs. Not everyone was convinced that a voluntary program would be completely successful, but it would be a first step. It was recommended that any educational program be coordinated between the manufacturers. Rodell made it clear that they intended to specifically ask their donors if they are high risk (i.e. homosexuals or drug users). He maintained that public health risks overode any concern with discrimination. The concensus was that the education program be formulated by a professional firm experienced in this kind of presentation.

Donahue then asked if we were willing to exclude plasma collected at prisons because of the homosexual link, and because it constituted only 2% of collected plasma. The other manufacturers had no problem with this suggestion, but it was pointed out that this was the source of our hyperimmunized donors. Donahue then suggested that we exclude this plasma from any AHF production. It is my opinion that they will remain relatively non-negotiable on this point. It was indicated that there had been no cases of AIDS reported from prison, and Donahue responded that was because of the etiology of the syndrome and insufficient time had transpired.

The final item of discussion related to recovered plasma. Donahue pointed out that we would have distinctly less leverage over any voluntary reduction of high risk donors in recovered plasma. He said that he felt we should consider very carefully if we should accept any recovered plasma collected from high risk populations. (He indicated the Irwin Blood Bank specifically.)

PLAINTIFF'S EXHIBIT 1

What did you tell the FDA? Pl. keep me posted! W/..

Although the discussion centered on AHF, it was mentioned that there was no evidence that heating of Fraction V products would inactivate any potential agent of AIDS transmission. I have the impression that while the agency is concerned about the question of AIDS, they are not going to overreact to the situation. Concerns have been expressed about the safety of "paid" donors versus voluntary sources and there are those who are championing the return to single donor cryo. I think the Bureau will take a more studied and scientific approach until sufficient information is available.

Donahue mentioned that about $50,000 would be necessary to perform some reasonable studies to indicate whether AIDS can be transmitted to Hemophiliacs via AHF, but that it would take the government a year or more to get around to funding it. He asked if the manufacturers might consider supporting a voluntary program to support these studies.

Dr. Donahue asked that I get back to him by Friday of this week (Dec. 17) with our company position on the following:

1. Voluntary education program to exclude high-risk donors.
2. Plasma collected at prisons.
3. Recovered plasma.
4. Financial support for study on AHF transmissions of AIDS.

In light of this development, I will attempt to convene a meeting this week of those concerned to review the current status of AIDS, and to frame our response to the FDA.