

Cutter

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DEC 21 1982

TO: Those listed

Office of Dr. W. F. Schaeffler

DATE 12/21/82

FROM: S. J. Ojala

COMES TO:

SUBJECT: More AIDS and FDA

W. F. Schaeffler
J. Hink
K. Fischer
E. A. Cutter
C. Turner
J. Petersen

M. M. Sternberg
J. Ryan
J. Cherry
J. N. Ashworth
C. Patrick
C. Moore

M. Mozen
J. Hjorth
G. Nakamura
R. Schwartz
J. Sliwka
B. Cole

John Hink and I spoke with Dr. Donahue on Tuesday 12/21/82, regarding our proposed actions on eliminating high risk plasma from our coagulation products. We outlined our proposed education program to attempt to identify and exclude high risk donors. Donahue commented that we should also consider a program for sources of potential recovered plasma. Once again Irvin Blood Bank (which the CDC has reported obtains 30% of their collection from the homosexual population) and border locations in Texas were specifically mentioned.

We reviewed the use of source plasma collected in prisons and Donahue stated that the actual risk was less important than the perceived risk. He felt that pressure would be applied to insure that this source of plasma did not end up in the manufacturing process for coagulation products. He mentioned that we should very seriously consider excluding the prison derived plasma from AHF and Factor IX.

Donahue stated that Dr. Evatt of the CDC was conducting another meeting on AIDS on January 4 and strongly recommended that we be represented. He mentioned that one of the agenda items would be the demographics of the paid donors. I am recommending that John Hink and I represent Cutter at this meeting. (I had previously learned from the PMA and our competitors that they intend to send their "Responsible Heads" and experts in the plasma procurement area.)

Donahue requested that we send him some official notification of our plans so that he could use this as ammunition that voluntary efforts of the industry precluded the need for any further regulation or activities in the FDA compliance area. He reiterated his concern that emotional media presentations such as last Friday's "Nightline" would only make our jobs more difficult and could result in further pressure from various sources.

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He wished us all a Merry Christmas and closed by saying he would see us in Atlanta after his brief vacation in Seattle.

Our course of action at this point would appear to be:

- ✓ 1. Attend CDC meeting in January and see if we can further define our approach.
- ✓ 2. Continue work on education program for high risk donor.
- ✓ 3. Coordinate the same with the other fractionators.
- ✓ 4. Consider removing prison derived plasma from coagulation product production.
- ✓ 5. Develop a standard company response to concerned customers.
6. Wait for further developments.