Cutter

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TO: Those listed GRO-C DATE: 6/1/83 *

FROM: S. J. Ojala COPIES TO:
SUBJECT: Potential AIDS Donor

W.F. Schaeffler
K. Fischer
J. Cherry
B. Modersbach
G. Nakamura
F. Geks
J. Hjerth
R. Rousell
M. Sternberg
J. Ryan
J. Russell
A. Leong
E. Cutter

We received notification from Jackie Parrish from the Orlando Blood Center that a donor bled on November 11, 1982 may have had AIDS. The plasma was processed into a lot of Koate® (NC 8454) and the 2783 vials were released on March 14, 1983. The product has been distributed to the field. Considering the recent Hyland recall of Autoplex and the adverse publicity relative to AIDS in the media, we met on May 31, 1983 to consider the course of action for this situation.

We agreed that further clinical information was required to assess the diagnosis of AIDS. Dr. Rousell contacted the county health authority and found that the donor was admitted to Lucerne Hospital on April 30, 1983. He was a sexually active homosexual and complained of dizziness, fever, sore throat and swollen glands. The examination revealed high fever, swollen regional lymph glands, acute and chronic rectal and abdominal bleeding, herpes I and II lesions and gonorrhea. He also had a yeast-like streptococcal throat infection and amebiasis. The laboratory tests were reported to be inconclusive for AIDS. He was discharged from the hospital on May 6, 1983 and has been classified as a permanent donor reject by the county health authorities and plasma centers. All contact with this donor has been lost and we could not confirm the rumor that he had subsequently died. We agreed that the diagnosis for AIDS could not be absolutely confirmed based on the available information.

I contacted Drs. Petricciani* and Donahue* of the FDA* to solicit their recommendations on this situation. Their suggestion was that we not take any action to recall this lot until after a meeting in Washington next week. They feel that the risk is not definable in these situations, and a precedent could be established whereby the supply of concentrates would be jeopardized because of the large number of potential AIDS donors. The meeting next week will involve the four manufacturers of concentrates, the FDA, the CDC, the Blood Advisory Panel and representatives from the user's (the National Hemophilia Foundation, for example). The purpose of this meeting would be to develop a working principle to use in these situations. The FDA is aware of the legal implications in these cases and will attempt to assist the industry via appropriate action. They are soliciting any recommendations that we might have on working principles.

Based on the recommendations of the FDA and the lack of absolute confirmation of a diagnosis of AIDS for the donor, we agreed to postpone any decision until next week.

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From: S.J. Ojala
Subject: Potential AIDS Donor Copies to:

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