Cutter

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TO Lee Hershberger
J. Hink

DATE 8/30/82

FROM

SUBJECT Immunodeficient Syndrome (IDS, AIDS, Kaposi Sarcoma, Pneumocistis Pneumonia, Pneumocistis Carini)

COPIES TO BSBU Members
Carol Moore
Dr. Fischer
Ed Potere
Terry Monroe
Otis Sangster
Lou Hal
Bob Barden

Dr. Donahue of FDA-BoB has asked you (Cutter) to voluntarily exclude plasma collected from known homosexuals from pools used in the production of Koate^{R} and presumably Konyne^{R}. He is not basing this request on scientific concerns that such plasma or coagulation by-product transmits AIDS but believes that the action is a political necessity to prevent national adverse publicity and (at this time) undue concerns in the hemophilic population. He has not requested such exclusion from material used in the production of ISG, IGIV, albumin or PPF. I have checked and determined that all of our anti-HB_s plasma is collected from centers using predominately homosexual donors. I have also canvassed several of our competitors to determine what action they have or plan to take on this matter and have learned the following:

Hyland (Mike Roedell) has had a policy that any plasma collected from a donor having a history of hepatitis (the disease, HB_sAg positive, or in close association with others having the disease) are excluded from use in the manufacture of AHF. Currently Hyland collects plasma from homosexuals for anti-HB_s but does not use it in their fractionation, it is sold to Alpha. Mike has told Donahue that he thinks Hyland excludes homosexual plasma from AHF but he wanted to check their procedures before making a solid voluntary commitment. My guess is that Hyland will make the commitment.

Alpha Therapeutics (Penny Carr) had just returned from Washington and had not met with her management (Hartin and Drees). She will make the recommendation that they voluntarily exclude all anti-HB_s plasma (almost exclusively collected from homosexuals) from coagulation components. Penny believes that the commitment should be "voluntary" rather than via a written request from BoB because the latter could have political reprocussions, could be difficult to ammend, and would ultimately create concerns and problems with both the homosexual and hemophilic populations. She also told me that FDA is looking carefully at Merck's HB_s vaccine (manufactured from HB_sAg positives collected principally from homosexuals) but does not expect that this chemically treated product will contain living virus.

Until recently Cutter's anti-HB_s plasma (all collected from centers dealing predominately with homosexuals) has been used in the manufacture of coagulation products. The cryo precipitate from the last fractionation made (late July) was used in scale up runs for HS-AHF and the Dilute Fill process. None of this experimental AHF will be released for human use. Under current plans we will fractionate less than 1500 liters anti-HBs for Cutter or Abbott for the remainder of this year. I plan to use all of the cryoprecipitate from these liters for "not for human use" AHF scale up runs. I will also place on the forthcoming 9/16 BSBU meeting agenda a recommendation that Cutter voluntarily exclude plasma collected from centers dealing primarily with known homosexuals or donors with a history of hepatitis from pools used in the manufacture of Koate^R or Konyne^R. I believe we must agree to a temporary exclusion for political, moral and liability reasons.

JHH:gma

GRO-C