

Cutter

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MILES

Office of V. H. J. Shalson

TO: S. Bhonsle, P. DeHart, W. Johnson,
S. Ojala, V. Shalson

DATE: May 1, 1985

FROM: J. Ryan

SUBJECT: Phone Conversation With Charles
Carmen and Peter Levine, April 29

COPIES TO: Dr. W. Schaeffler
Dr. K. Fischer
Dr. M. Sternberg

By way of a conference call, I informed Charles Carmen and Peter Levine of our planned efforts with the Bureau of Biologics (BOB) to cancel the "gentlemen's agreement" not to prepare coagulation products from prison plasma. Peter Levine spoke personally rather than as a spokesman for the NHF, but it's pretty clear to me that he believes he is correctly representing the NHF's point of view when he indicated that he did not want to see us return to prison plasma as a source for AHF. Although he accepts the HTLV-III inactivation data with heat treatment, he still feels that by returning prison plasma to the pool, we are taking risks that are not justified. Specifically, increased risks for hepatitis Non-A and Non-B, as well as hepatitis B.

I told him that we would be continuing our dialogue with the BOB in an effort to use the cryo from prison plasma because we felt it was safe, and we felt our request was justified. I also said we would continue our dialogue with him. Needless to say, this matter is not resolved and Dr. Levine still has to be convinced. He felt that treaters would pay up to 1¢ more to avoid prison plasma. Obviously, a very general comment that means nothing to us.

He did confirm that the NHF was cancelling its recommendation to recall product made from Aids confirmed donors. The NHF has notified the OOB of their change in the recommendation. He also indicated "a manufacturer" has \$1.5 million of heat-treat Factor VIII and IX from an Aids donor and with this new development, is not planning to recall.

GRO-C

J. Ryan

JR/nr

P.S. S. Bhonsle & S. Ojala

Would you look at the idea of my suggesting to Peter Levine that we agree to test all prison plasma for ALT and exclude all units with a level of five times normal or higher. Can we handle this? Would it make economic sense?

Prison Plasma

1
5
1

0
9
6
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0