DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

ORIGINAL

BLOOD PRODUCTS ADVISORY COMMITTEE

MEETING:

SAFETY AND PURITY OF PLASMA DERIVATIVES

Tuesday, July 19, 1983

MEETING 8
(only 1 day)

Auditorium, Lister Hill Center
National Institutes of Health
8000 Rockville Pike
Bethesda, Maryland

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Rodell, just mentioned to you. One, we would establish a precedent leading to an evantual life-threatening short supply of final product while, two, adding to the fear and concern in the mind of the user. They would perceive that if the manufacturers are recalling product, the problem must be more serious than previously thought. And, finally, the economic realities associated with a policy of mandatory recall would cause the industry to make a critical evaluation of whether it could continue providing these products.

I mention this only as it relates to our collective concern relating to product availability, and not to engender any sympathy from the audience. Remember, this is all based on the relatively inconclusive data that AIDS is, in fact, transmissible via blood and blood products.

Our industry recommendation is to continue the current screening program, discarding plasma from suspect donors, and in general doing whatever is possible to minimize potential risk to the user. We would prefer to continue approaching each event in the light of its individual circumstances, the current scientific knowledge, and we would like our final decision framed by our individual company philosbphies developed in conjunction with the Food and Drug Administration -- we won't do this by ourselves.

In summary, we in the industry believe that the current situation does not warrant a mandatory recall policy by the

federal government, at least at the present time. We in the industry are prepared to answer any specific questions or any concerns that you might have during the discussion period.

DR. W. MILLER: We are back on target --- it looks like the West Coast is going to do well. It occurs to me that it might be appropriate -- I know that the folks in the Hemophilia Foundation would like a little time to gather their thoughts after hearing the presentations of the manufacturers, and had asked for that -- I think we might move now to the open discussion and go to a period of open discussion, talking about some of the things we have heard this morning, talking about the presentations we just heard, which I would suggest we try to limit to something on the order of half-an-hour to 45 minutes, and then at that point hear the presentations from the Hemophilia Foundation and from the manufacturers, then let the Committee work on this a little bit.

Does that strike you Committee folks as okay?

(Nods of assent)

Well, then, I think why don't we open the floor for comments from the audience or from the Committee, or questions, in the whole arena. I would like to kick it off with a question to Mike Rodell. Mike, I am struck by the epidemiologic similarity of this agent to hepatitis B, and I wonder if you would review for the audience and for the Committee the current manufacturing practices with regard to pools which are known