

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
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: BLOOD PRODUCTS ADVISORY COMMITTEE :
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: MEETING: :
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: SAFETY AND PURITY OF PLASMA DERIVATIVES :
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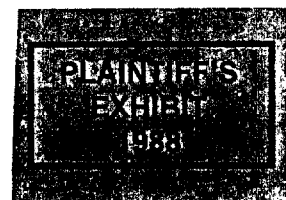
Tuesday, July 19, 1983

MEETING 8
(only 1 day)

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

This transcript has not been edited or
corrected, except, where relevant for the
OIA, to make it more understandable under
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1 Rodell, just mentioned to you. One, we would establish a
2 precedent leading to an eventual life-threatening short supply
3 of final product while, two, adding to the fear and concern in
4 the mind of the user. They would perceive that if the manufac-
5 turers are recalling product, the problem must be more serious
6 than previously thought. And, finally, the economic realities
7 associated with a policy of mandatory recall would cause the
8 industry to make a critical evaluation of whether it could
9 continue providing these products.

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

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

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

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

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

17 Does that strike you Committee folks as okay?

18 (Nods of assent)

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