Cutter

TO: Those listed

DATE: 7/25/83

FROM: S. J. Ojala

COPIES TO:

SUBJECT: FDA Advisory Committee Meeting on AIDS/Recall
July 19, 1983

J Akers	J Hjorth	E Cutter
N Ashworth	M Hozen	C Patrick
J Cherry	M Sternberg	W Johnson
R Cole	J Hink	B Modersbach
W Ewald	W F Schaeffler	R Rousell
K Fischer	C Treppa	
J Ryan	C Turner	

Summary: The advisory committee for blood products met on July 19, 1983, and heard discussion from the government, industry and users of products relative to the need for an FDA policy on recall of product containing plasma from AIDS donors. The decision of the committee was that a recall policy was not warranted at this time.

Specifics: The audience consisted of nearly everyone concerned with plasma products from the FDA, including Meyer and Brandt, representatives from the CDC, the NIH, the Red Cross (U.S. and Canada) and fairly extensive media coverage.

Petricciani opened the meeting with a discussion of a series of hypothetical events that no one seemed to clearly understand (see attachment). Bruce Evatt of the CDC followed with a general discussion of the epidemiology which did not include much that was new. The current number discussed for AIDS in hemophiliacs was 17 and 8 deaths were reported. Four cases (3 deaths) outside the U.S. were mentioned in passing (these are in addition to the 17).

Apparently Evatt had some further unpublished information, but did not bring it up because of the media exposure. Donahue said he would try to ferret out this information after the meeting. (I think it may be related to the health-care personnel reported in the MMWR on July 15.) All the victims had used relatively high dosages (> 50,000 units/year) and no common lots of product were implicated.

Masur reviewed the clinical aspects of AIDS and Quinnan reviewed the possible virus links under investigation. These include CMV, EBV, Hepatitis, Parvovirus, Papovavirus and Petrovirus (HTLV). Most AIDS cases show a high EBV reactivation which Quinnan mentioned as an area for future research for meaningful screening testing.

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He also reviewed the T-cell maturation process and indicated where the IL-2 activity (widely reviewed in the lay press) influenced killer cell development. At this point, he feels that it is only an interesting observation, and not necessarily a basis for therapy.

The industry was represented by itself since the PMA was reluctant to add its approval without review by high levels within the trade association. Baxter sent Dale Smith and an attorney from Chicago, Dave Castaldi, Rich Srigley and Jack Goodman from Los Angeles; Alpha was represented by Penny Carr, Bill Martin, Dave Curry, and a couple of others I didn't meet, and Armour sent Mike Rodell, legal counsel and a clinician. Rodell and I were the only ones who spoke for industry. We presented the viewpoint that any action toward a mandatory recall policy would lead to an eventual shortage of final product based on some jointly derived data.

The only surprise for the day was when Lou Aledort stated that the concensus of the NHF was that recall should result from any positively identified or suspect donor plasma in the pool. Later during questioning, he mentioned that this was not his personal viewpoint.

During the committee discussion, it became apparent that there was concern about final product remaining in the field with positively identified AIDS plasma used in manufacturing, the situation did not justify a mandatory federal recall policy. Dr. Mosley did mention that a warning on the package insert might be appropriate for patients who did not routinely use the products. The concensus felt that most hemophiliacs were acutely aware of the AIDS risk.

I tape recorded the entire meeting (4 and 1/2 hours) for those who are interested in any further detail.

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