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PLAINTIFF'S EXHIBIT NO. 683

History file CSOA 248

Cutter

MILES

TO: Those listed

DATE: 4/15/85

FROM: S. J. Ojala

SUBJECT: Fractionator Meeting: April 12, 1985.

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Penny Carr (Alpha), Steve Holst (Hyland) and I met in the Osaka room at Alpha Headquarters from 9 to 12 on April 12, 1985. We followed this meeting with a 2 hour conference call to Bob Reilly (ABRA) and Mike Rodell (Armour), to confirm our plans for testing and the upcoming Blood and Blood Product Advisory panel meeting. The following are salient conclusions:

ALT Testing:

The Ojala script for an industry position was accepted with enthusiasm from Alpha and some reluctance from the others. Gerety (or someone) will express concern to the Advisory panel that use of ALT positive plasma in domestic products will change the character of those products. Our formal presentation will state that we are simply hand selecting (via ALT screening) special plasma for a particular customer (the German Market) and that all remaining plasma remains licensed source plasma which may be utilized in other products. The ALT test is not required by the FDA, nor do we want it to become so. We will state that any plasma 2 times normal will not be used for the particular customer. We will further offer that any plasma with 5 times the upper limit of normal will not be used in domestic product and the donor will be deferred until the ALT levels fall back to normal. We will use the argument that 5 times normal may indicate a donor health problem. This may not please all of you, but it was the only way to achieve industry concensus. Further, plasma in the over 2, but less than 5 range will be used randomly in production so as not to concentrate this plasma in any particular lots. All coagulation products will be heat-treated for an extra margin of safety. We will endeavor to call German plasma "special" or some other term to nullify the idea that greater than 2 times normal plasma is "positive" or other negative connotations.

In practice, Armour will discard all 2X cryo and Hyland will discard all 2X plasma from coagulation products and Fraction II products. We estimate that approximately 20% of total U.S. plasma will be screened, but will vary between manufacturers. Armour requirements are modest, and Hyland will screen all plasma for the interim to "fill the pipeline". Alpha will screen only A and B plasma from select centers. Hyland's conservative position is due to Armour's decision (i.e., they want to be perceived as conservative in any subsequent litigation) and because they had two patients develop Non A/Non B in a clinical trial of their IVIG in Seattle. Holst thinks it is because of procedures at the clinical site,

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but Penny thinks it is because of starting with 2+3 paste for the Hyland product. The FDA has summoned Hyland to Washington for a "summit conference" on the Seattle incident. This is delaying their IVIG approval, until resolved.

In summary, the minimum industry position is:

1) less than: 2 X Normal + German product
2) 2 X Normal + 5 X Normal + random distribution in domestic product
3) greater than 5 X Normal + discard plasma, defer donor

This hasn't been approved by FDA, and Hyland and Armour will react more conservatively. I suggest this item be reviewed at the next BMC. Bob Reilly also mentioned that we will need to make some provisions in our business arrangements with our contract centers to preclude them from dumping "high ALT" plasma on us.

Prison Plasma:

This subject illicits even more diverse viewpoints. Cutter and Alpha believe that science has progessed to the point that we can screen this plasma through testing (HTLV-III, etc.) and we now heat treat the products. Hyland says they have no current prison plasma sources (!) and Armour states they will never have any. Reilly is perpetually gloomy on the entire subject, and feels we are destined to fail. Nevertheless, we agreed to hang together for a try with the FDA. We will propose to begin using prison plasma cryo and abandon our "Gentleman's agreement" unless the FDA takes issue and threatens regulatory action. We will further agree to do whatever testing the FDA deems necessary to answer any academic concerns. Sam Anderson will contact the NHF to insure there are no major obstacles there, and I recommend Jack Ryan do likewise. It will not serve our purposes to effect change with the FDA and offend our customers. The argument for using prison plasma is the additional testing (HTLV-III) and heat treatment which provides product safety. Penny, Mike and I will try to discuss this with Petricciani in Atlanta this week, on a preliminary basis.

HTLV-III and State Regulations:

Various state legislations have resulted which share no common thread. Hyland is interpreting the 60 day effective date for California as permitting notifying donors for 60 days from the date of signature. They are deferring donors in California right now and explaining why. They have further established a moratorium on plasma donations from company personnel because "this is information we don't want right now". Cutter needs to think about how we handle antibody positive employees. This

subject will be reviewed by the FDA shortly. John Petricciani reported (not to be quoted) that early data shows approximately 40% of antibody positive individuals "spill virus" at any given time.

Reilly will collect all state legislation in summary form in the near future. Hyland and Armour plan to continue telling donors of test results for public health reasons and violate any state laws as necessary. This apparently is a directive from Baxter, Chicago.

Alpha has a plasma center employee (female, married, two children) who is HTLV positive. They have not decided on a course of action, and I pledged your silence on the subject.

FDA Letter (attached):

No one likes the FDA response to our meeting in February to review the position on recall. We will lobby for a change to 3 or 6 months for unpooled units (not 3 years), but in any event, the letter has not been officially sent to the manufacturers. N.Y. Blood is doing retrospective testing on all plasma samples, and we agreed it was a bad idea. (They will inform transfusion victims of the results.)

Changes in FDA Organization:

John Petricciani will go to WHO by July 1, 1985. Bob Gerety will go to Merck on the same date and is currently a "lame duck" (no regulatory involvment). Gene Murano has been named "Regulatory Expediter", which is a positive step. Tom Zuck is rumored to be the replacement for Petricciani. Any information on his personality/proclivities would be appreciated. Review/approval times are slower than ever. We will plan for another "gripe session" with Harry Meyer this summer. Esber is rumored to be "moving on". The more things change.....(etc.).

Our next meeting will be in Washington the night before the Advisory Panel Meeting (April 23) to rehearse our performance. Please contact me if I need to be aware of any change in our position.

Miscellaneous:

HTLV-III test reporting officially begins with the period April 22 - May 5, to be submitted on May 6. I would like to see our current results by center as soon as available. I need total units collected, total number tested, total reactive (2 out of 3 rule). Reilly will aggregate for FDA.

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Re: Fractionator Meeting, April 12, 1985

Steve Holst commented that Baxter would like to rid themselves of Hyland since they don't make any money and provide a negative image for the corporation. I told him Bayer was content with our performance and wanted to expand the Biological business. He gave me a strange look.

Many more Japanese are taking up residence at Alpha.

John Petricciani/Harry Meyer/Frank Young are very upset about the Peter Jones letter and have been in personal communication. An official FDA rebuttal is planned. Alpha has already sent in a rebuttal. ABRA may do the same, if it doesn't focus more attention on the subject.