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INTEROFFICE CORRESPONDENCE DATE: December 22, 1983

TO: To Members of the Operations Committee

Mr. B. Blomstrom	Dr. M. Kaiaki	Dr. C. Kwiatek
Mr. L. Coffey	Mr. W. Martin	Dr. S. Mealey
Dr. Z. Pedor	Mr. B. Latham	Mr. E. Olivarez
Dr. S. Funakoshi	Mr. K. Martinez	Mr. B. Thorne
Mr. D. Cury	Mr. E. Matveld	Mr. I. Yoshiro

RE: Blood Products Advisory Committee Meeting, December 15 and 16, 1983

Attached is a copy of the agenda for that Committee meeting. For those who are interested, I have requested a copy of the proceedings which we'll receive in the next few weeks, giving the detail of the presentations. Most important for Alpha is the outcome of the meeting. I will limit this memo to that. At the beginning of the meeting on December 15th, Dr. Donohue of the Office of Biologics Research and Review, in his introductory statements, advised the attendees of the need to consider the differences between the way plasma is collected, processed and distributed and how whole blood is collected, processed and transfused. This was in line with requests drafted by Dr. Donohue coming from FDA that have differentiated between recommendations addressed to plasmapheresis centers and recommendations addressed to the blood bank community. Note that PMA and ABRA have both objected to the differentiation. Dr. Donohue asked whether or not the time had come for one or more surrogate tests to be applied to source material for blood product.

Prior to deliberations by the panel at the end of the meeting, Dr. Donohue once again addressed the attendees. He stated that he wished the focus of the general discussion to separate whole blood and plasmapheresis as procedures. He referred to the July 19th meeting which resulted in a recommendation from the Advisory Panel that there not be a generalized mandatory procedure for recall because of a suspected diagnosis or a confirmed diagnosis of AIDS. He reviewed the recalls that had occurred because of suspected AIDS donors and confirmed AIDS donors and referred to the loss of the material for use and the cost in terms of loss of the product. He stated he had a proposition which had not been discussed at FDA prior to this meeting noting that he was looking for something that will define people exposed to infectious diseases. He referred to the multitudinous diseases of the gay population and of disease detection by anti-core testing. He noted that he felt this application of anti-core testing combined with heat treatment could possibly give us a safe Factor VIII product which could possibly eliminate consideration of market withdrawal and recall. He referred to the limited number of centers that would do the testing if this were applied only to plasmapheresis. Again, he requested discussion of this talking of the difference between whole blood and plasma collection.

Attached to this memo is a copy of the list of the members of the Advisory Committee and consultants. Note that Dr. Ronald Miller was not present. Dr. William Miller proceeded to poll the members of the Advisory Panel as

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to their opinions. Initially, Dr. Mosely, noted that anti-core testing could be used to identify the exchange of body fluids by certain individuals and that there was a significant difference in a 16% anti-core rate in plasmapheresis donors versus a 6% anti-core rate in whole blood donors and therefore believed that heat-treatment would be more successful if the contamination content of the original product was lower. In his mind it seemed a prudent measure to require anti-core testing. Dr. White immediately agreed with Dr. Mosley's position. At this point Dr. William Miller pointed out that recovered plasma would also be effected by such an opinion and noted that recovered plasma is processed by the manufacturers for the American Red Cross. Dr. Donohue countered with a proposal that the manufacturer could be made responsible for the testing of all ARC and blood bank plasma. Dr. Zucker Franklin and Dr. Sullivan of the Advisory Panel both totally agreed with Dr. Donohue and Dr. Mosley. At this point the discussion shifted to members from the audience.

There was input from Dr. Gerald Quinan of FDA and Dr. Robert Gerety of FDA, both of whom questioned the advisability of the test and noted problems associated with such a course of action. Note that this was the first they had heard of Dr. Donohue's proposal.

At this point Dr. Miller recognized Dr. Mike Rodell of Armour who had a proposal for a task force that had been generated by the fractionation manufacturers. Dr. Rodell proposed that a task force be formed representing all segments of the blood bank and plasmapheresis industries to examine the logistics, feasibility, impact on cost, donor populations, availability of reagents, etc.. and to report back in a very timely manner with recommendations. Further discussion occurred from the audience, notably Dr. Pindyck of New York City Blood Center, and Dr. Harvey Alter of the Clinical Center Blood Bank. Both stated that any such proposal applied to the plasma industry should also be examined for it's effect on the volunteer sector. Dr. Pindyck noted that "If it's good to do for plasma donors, then it's good to do for all donors", noting that the separation of the two may not be appropriate, further supporting Dr. Rodell's suggestion for formation of a task force. Dr. Alter reemphasized what Dr. Pindyck had said stating that it put him in an ethical dilemma. He noted that surrogate testing may be needed more for blood donors since blood cannot be heated. Dr. Perkins of Irwin Memorial Blood Bank argued also for the need for blood groups from different ethnic groups, many of which have a high incidence of anti-core antibody, also noting the amount of emotional trauma that could result from rejecting donors with anti-core antibody. The final results of the meeting were to accept the idea that a task force should be formed to further study the proposal.

Following the adjournment of the Advisory Panel a meeting was held between the PMA fractionators and Dr. Donohue. Dr. Donohue brought up a proposal stating that he felt perhaps all Hepatitis testing should be done centrally, i.e.. by the manufacturer and the same would be true for anti-core antibody testing. This was preparatory to his stating that this could be a solution to accepting material from the blood bank community and from ARC that had

not been core tested since manufacturer could pick up that testing. Eventually, we got down to the purpose of the meeting and decided it was important to select a chairman of the task force. Since it had been Dr. Rodell who had presented it to the Advisory Panel, he was elected chairman. We suggested participants to represent blood bank communities such as CDC, and the New York City Blood Center (Dr. Pindyck) and to represent further AIC and the Advisory Panel (Dr. William Miller). It was agreed that the task force needed to do it's work promptly and come back with recommendations, preferably by March of 1984. Subsequent to the meeting Dr. Rodell indicated to the responsible heads of the other manufacturers attending, that he intended that they also be members of the task force.

Dr. Donohue may have lost this particular battle, but I'm not sure he has lost the war. A great deal will depend upon the input of this task force and subsequent events. I think all of us attending felt that Dr. Donohue was attempting to cover a politically sensitive issue. He referred to the fact that he had mountains of mail from the representatives of the Moral Majority and the Gay Liberation Front. It's obvious he's under a tremendous amount of pressure to indicate to Secretary Brandt and probably the public that something is being done regarding this AIDS situation. Note that during the introductory remarks of Dr. Chernoff, Director of the National Heart, Lung and Blood Institute, he referred to 40 cases of transfusion associated AIDS with which 450 donors had been associated. This is the first time I've ever heard any figures like this and I'm still not sure what Dr. Chernoff meant. All reference I've heard of to the CDC article which will appear in the New England Journal of Medicine in January referred to 36 cases of transfusion associated AIDS and I have not heard of the number of donors associated with them other than to believe that it was probably 36 AIDS donors. In his remarks at the Fractionator's meeting, Dr. Donohue referred to another workshop that will be held in early 1984 with the blood bank community on the use of single donor plasma. It is his opinion that too much is being used and that there is no excuse for using it all, therefore, all of it should be used for fractionation. I think he was proposing this believing that this would make up on any short fall of donor loss from core testing.

Also attached to this memo is a copy of the slides and overheads used by Dr. Ojala in his presentation. These are included for your interest only.

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