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TO: Those Listed DATE: 1/17/83

FROM: S.J. Ojala GRO-C COPIES TO:

SUBJECT: National Hemophilia Foundation/Industry Strategy Meeting on AIDS, Jan. 14, 1983, New York City

W.F. Schaeffler	M.M. Sternberg	M. Mozen	R. Schwartz
J. Hink	J. Hjorth	J. Ryan	C. Patrick
K. Fischer	J. Cherry	G. Nakamura	[redacted]
E. Cutter	J.N. Ashworth	B. Barden	W. Johnson
R. Rousell	C. Turner	B. Cole	B. Modersbach

MORNING:

The major industry representatives collected prior to the meeting to determine a concensus strategy prior to the actual NHF meeting. Included were:

Bill Hartin - Alpha	Clyde McAuley - Alpha
Penney Carr - Alpha	Bruce Blomstrom - Alpha
Mike Rodell - Hyland	Dave Castaldi - Hyland
John Bacich - Hyland	Bob Johnson - Armour
Joe Rosen - Sera Tec	Bob Reilly - ABRA

Primary concern was the possibility of a recommendation for further testing of plasma particulary the anti-Hepatitis B Core Antigen (Anti-HBc). Rodell pointed out that this test would exclude approximately 10% of all potential donors based on a series of studies done at three of Hyland's centers (6% positive in Duluth, 14% in Spokane and 12% in San Bernadino). He also pointed out that we would also exclude all high titer donors useful for ISG. We agreed that we would support testing in concept, but defer until a more specific test was available. Donahue (FDA) is not particularly enthusiastic about the anti-HBc nor lymph counts because of the lack of specificity/selectivity.

The progress of the Alpha donor interrogation was reviewed. Hartin indicated that 308 homosexuals had admitted their identity during the last three weeks, and an even larger number had voluntarily excluded themselves. They will continue to "fine tune" their program. Hyland will have their screening program in place by the first of February and Armour currently has signs of reviewing the AIDS problem in all their centers and are working on the rest of their program.

We also agreed that the CDC was getting increasingly involved in areas beyond their area of expertise and whenever possible we would try to deflect activity to the NIH/FDA. Apparently there were some major differences of opinion voiced at the ABRA meeting last week between Evatt and Donahue. Brandt will be getting more authority in this area, now that Schweiker has resigned, but Schweiker's last briefing was on this subject.

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We discussed the ramifications of switching to small pools (which everyone agreed was of questionable benefit) and we ran through some hypotheticals. If you use a 10 donor pool, and some very effective manufacturing, one can produce about 8-12 vials of AHF. Subtracting 2 vials for potency/purity testing, 2 for sterility and 2 for retention and 2 for FDA testing leaves 0-4 salable product. The economics of this procedure are relatively discouraging.

One major item agreed upon was that whatever requirements recommended for plasmapheresis centers should also be applied to bloodbanks. The conceptual risks involved for plasma also apply to whole blood and cryo.

Rodell thinks the FDA will approve their heat treated product because the data indicates it will delay the onset of Hepatitis B by 4-10 months. Alpha has not started their chimp studies and Armour appears to be relying heavily on DDAVP. Both Alpha and Hyland are taking the AIDS problem very seriously.

AFTERNOON:

Attached is the agenda recommendations and list of participants for the formal meeting.

Lou Aledort reviewed the background, the non-results of the Atlanta meeting and pointed out that the blood banking industry has not chosen to exclude high risk groups (see attached AABB statement) and he was not sure the facts warranted a major change in lifestyle resultant from altering current therapy. He also questioned why AIDS cases have not appeared in hemophiliacs in Europe with their larger doses. Throughout the meeting Aledort, Carman and Hoyer were very supportive of the industry's positions, and had some very negative comments directed toward the blood banking community. Dave Castaldi summed it up later as "it is unusual for us to come away wearing the white hats while the "volunteer" sector wears the black".

The recommendations are mostly self-explanatory. I will attempt to highlight the discussion.

Johanna Pindyck, of the CCBC continuously ridiculed the industry efforts at donor screening as being "self-defeating". Peter Levine strongly supported these efforts as being "better than inaction". Both Pindyck (CCBC) and Fred Katz (ARC) indicated that they would "work with the Gay

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Right groups to achieve some kind of voluntary exclusion". Carman, Aledort and Levine were quick to point out that this nebulous approach was clearly unsatisfactory and would accomplish little. Carman specifically pointed out that the medical rights of the Hemophiliacs transcended the civil rights of the gay community on this issue.

The message came through loud and clear that whatever steps the industry took was expected of the volunteer sector, and lip service was insufficient. Both seemed a little taken back by the strong posture of the NHF.

Rodell and Donahue very effectively presented the viewpoint that surrogate testing was a positive step, but was only at the R&D stage currently. The NHF seemed to accept the approach that we would accelerate any and all efforts in this area. The numbers reviewed were at $5.00 test cost and an approximately 2.5¢/unit additional burden. Donahue stated that the aproach should be to develop tests, then validate and implement rather than to incorporate additional testing blindly and hastily. We pointed out that we would not be screening for AIDS, but merely high risk groups. It was generally agreed that a 10% exclusion of donors would be acceptable. The exclusion of plasma from "hot" areas was mentioned as a moving target. San Francisco, Los Angeles and New York were specifically identified as "hot" areas. Prisons were mentioned and Hyland reviewed their plans to discontinue collection over the next year.

Johanna Pindyck voiced the concern that this move would add discrimination by geographical area to moves against the gay community. Levine pointed out that this was probably the best approach at present, even though it might raise public concerns about New York and San Francisco whole blood collections. Carman pointed out that this was only a short term solution until further information was available. Aledort pointed out the cryo would be higher risk than concentrate if the CCBC, AABB and ARC rejected screening of high risk donors. Donahue pointed out that in addition to interrogation of donors, attention should be paid to looking for major weight loss (greater than 10 pounds), night sweats and lymphodenopathy.

Curiously, Alpha inquired whether chimp studies would be required for approval of a heat treated AHF product. Donahue indicated that they would probably approve the use of this procedure without chimp studies if the manufacturer could prove that it had no effect on the efficacy of the product. The message here is that Alpha is not very far along with their heat treated product program.

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I pointed out that the question relating to DDAVP should be appropriately addressed to the FDA, and Donahue responded that a great deal of data would be required before it was approved for donor stimulation of Factor VIII. Rodell commented that some work that they had done had indicated that the increase in Factor VIII might be an artifact or at least the complete entity wasn't present.

The subject of small pool products was reviewed with Eibl of Immuno pointing out that this was routine practice in Europe. We pointed out that this was not particularly successful in that the U.S. exported a substantial amount of concentrate to Europe. We left the issue with the understanding that industry would get back to Hoyer on the feasibility of smaller pools.

Biotechnology was briefly reviewed and my carefully worded response was that we were actively pursuing efforts in the area (Hyland and Alpha had previously said the same thing) but that it was a long-term solution to the current problem.

In general, I have the impression that the NHF was pleased with the rapid response by industry in the high risk donor screening area and was less satisfied with the response from the volunteer sector. A press release from the NHF was scheduled for today.

Following the meeting, I met privately with Donahue at his request. He indicated that a "classic case" of AIDS transmission via whole blood transfusion had been identified in Texas and that the donor had previously donated plasma at least 200 times and the source plasma had found its way into Alpha and Cutter inventories. He said that the CDC would be contacting us for further information. He also pointed out that if any AHF products are implicated in hemophiliac AIDS transmission, the manufacturer is notified. Therefore, none of our product has been implicated in the current 10 reported cases.

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