DRAFT 2/11/85

Medical & Scientific Advisory Council Minutes
10/13/84
1:00 P.M. - 5:00 P.M.

Present:

MASAC: Leon Hoyer, MD, Chairman; Charles Abildgaard, MD; David Agle, MD; Abe Andes, MD; Louis Aledort, MD; Mary Lou Damiano, RN; Franklin Desposito, MD; Elaine Eyster, MD; Marvin Gilbert, MD; Wahid Hanna, MD; Peggy Heine, MSW; Margaret Hilgartner, MD; Peter Levine, MD; Jeanne Lusher, MD; Kurt Niemann, MD; John Olson, MD; Harold Roberts, MD.

GUESTS: Bruce Evatt, MD - CDC; Jay Toole, MD, Genetics Institute; David Aronson, MD, Office of Biologics.

NHF BOARD/STAFF: Alan Brownstein, Lisa Flam, Cynthia Kingsbury, Madeleine Singer.

OBSERVERS: Silvija Hoag, MD; David Jenkins, MD; Joel Spero, MD; Martin Stryker, Ph.D.

1. Minutes from meeting of 10/22 - were approved.

C. CDC Study-

"The Cohort Study of Recipients of Factor VIII and Factor IX lots containing Blood Products from a person with AIDS" questionnaire was reviewed and modified by the Mental Health Committee.

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Dr. Evatt also said that CDC had planned to make an announcement in the form of an article in the Morbidity and Mortality Weekly Report regarding the three cases and their connection to Armour. Drs. Evatt and Levine both agreed that the article should be aborted so as not to cause hysteria in the hemophilia community. Both felt, however, that voluntary action should be taken by Armour. Armour was contacted, and proposed the following:

- a direct communication should be sent to the hemophilia community regarding the three known cases and their association with the Armour product;
- a withdrawal of all lots of product manufactured from donors not screened for HTLV-III antibody should be implemented;
- any outdated lots should be distroyed or discarded; and
- a panel of hemophilia professionals should be developed to discuss any additional steps which need to be taken.

II. MASAC Recommendations

After hearing the background information, MASAC mebers were asked to express their views and reach a consensus on the advisability of Armour's plan of action.

It was suggested that a follow-up bulletin to Armour's announcement be sent by NHF to its constituencies to allay hysteria and commend Armour for their response. Dr. Levine stated that Armour had been in communication with other professionals in hemophilia (who were in Italy), namely Drs. Alecort, Hilgartner and Gomperts, who expressed their opposition to the bulletin being sent because they were wary of making any decision based on incomplete data, and were concerned about creating hysteria.

At 9:39 p.m. the call was interrupted to allow Mike Rodell, MD, from Armour Pharmaceutical Company to be placed on the call, to answer questions posed by MASAC members. After a brief introduction, the call continued.

Q: What further testing is being done on the efficacy of Armour's 10 hour heat-treating process?

A: Dr. Rodell stated that theirs was a 30 hour process, not a 10 hour process. Armour is presently developing a new, longer heat-treating process which still has to be approved. However, it will not be available for some time.

Q: Are the lots involved from unscreened donors?

A: Yes. It was also noted that during the last 4-6 months all product has been from screened donors. It is felt that there is a relatively small amount of non-

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Q: Can you contrast your process to other manufacturers?

A: Armour - 60 degrees for 30 hours - dry state
Travenol - 60 degrees for 72 hours - dry state
[illegible] - dry state
[illegible] - 60 degrees for 24 hours - dry state
Alpha - 60 degrees for 20 hours - wet state

Q: What is Armour's current plan of action?

A: A letter has been drafted for distribution, to which they would like to add a line stating that a test done in Sweden does not indicate further sero-conversion incidence. They would also like to offer an exchange program for withdrawn product. If there are no objections by HASAC they intend to send the letter within the week.

Since HASAC had no additional questions to pose, Dr. Rodell signed off the call. Dr. Levine indicated he would contact Dr. Rodell to express HASAC's views, after completion of the call.

III. Summary

After further discussion, HASAC unanimously resolved to inform Armour that HHF appreciated Armour's responsible action, i.e., to quickly notify the hemophilia community and withdraw the product. It will also be suggested that they continue to study methods of improving the efficacy of viral attenuation methods; this recommendation will be sent to all manufacturers.

Armour plans to send out an announcement as soon as possible, after which HHF plans to distribute a follow-up bulletin (to be drafted by Dr. Levine and Donald Goldman) to its constituencies.

The call ended at 10:20 p.m.

D. The Psychological Impact of the AIDS Risk-
The results of this NHF-sponsored study indicate that there is considerable emotional distress among some members of the hemophilic population. In the future, health care providers should place emphasis on prevention, identification, and treatment of psychological dysfunctions resulting from the AIDS risks.

E. NHF Treatment Center Survey of Psychosocial Services-
Dr. Agle presented some statistics which demonstrated that many treatment centers lack adequate staffing in the psychosocial areas. The social work subcommittee is compiling the results with the objective of creating a directory of Mental Health professionals in hemophilia.

F. The Psychosocial Workshop -
was held during the 1984 annual meeting in Rochester. The principal program planner was Pamela Nimorwicz. 85 persons registered including 40 nurses and 20 social workers. The participants responded positively to the formal paper presentations, poster sessions, and workshops.

G. Psychosocial Triage Manual -
This is a major ongoing SWC-MHC project to establish guidelines for psychosocial services related to chapter/treatment center activities. A chapter/treatment rep. workshop to finetune these materials is scheduled for November 8, 1984.

H. AIDS Training Project for Health Care Providers -
The MHC and SWC has submitted a proposal to the office of Maternal and Child Health. The proposal is for a training project for health care providers to assist patients and family members troubled by the AIDS stress. Suggestions were discussed re: the format, and content of the seminar.

J. Other Activities -
Include MHC participation with the Ad Hoc Advisory Panel to the Office of Maternal and Child Health concerning hemophilia center programs.
-contributions of MHC and SWC to AIDS questions and answers and HIE Bulletins regarding AIDS and sexual transmission.
A written report dated 10/84 was included in the NASAC agenda.

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F. Patient/Family Model -

- Growth and Development Module has been compiled and will be incorporated into the P/F model.
- Adolescent Module - same as Growth and Development module but requires funding.
- AIDS Module - educational materials on AIDS and hemophilia to be incorporated into the P/F model. Project will be funded by CDC with workshop to compile materials into February, 1985 and Provider/Education workshop in June, 1985.
- Provider/Education Workshops - This took place in 1983-84 in Sacramento and Atlanta. The attendance and evaluation of both was excellent. Two workshops are to be scheduled for 1985 in Boston and Chicago.

7. Research and Review Committee -

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Leon Hoyer, MD, reported on two JGP fellowships for 1984. They are the following:
1. Gordon L. Bray, MD, University of Washington, Seattle. Advisor: Arthur R. Thompson, MD.
2. Peggy S. Weintrub, MD, University of California, San Francisco. Advisor: Arthur J. Ammann, MD.

We hope to fund two scholarships in 1985.

8. Present Status of Efforts to Produce Factor VIII

By Recombinant DNA technology - Jay Toole, MD, from Genetics Institute, reported on the progress made with Recombinant DNA technology. The steps prior to commercial availability are the following:

1. devise methods of scaling up of genetic product of Factor VIII.
2. conduct trials needed for FDA approval.

9. Update on Regulatory Issues at Office of Biologics -

David Aronson, MD reported that there were insufficient funds to adequately staff the coagulation lab at OoB. Dr. Hoyer stated that he would send a letter urging support for sufficient staff at OoB.

11. Hemophilia Information Exchange

HIE - Jeanne Lusher, MD, reported on the HIE Communications Network, which is funded by the Office of Maternal and Child Health and initiated in January, 1984. There are 99 subscribers to date, including physicians and scientists who have a major interest in hemophilia. The subscription fee for the first year was $20/year. Network members are encouraged to submit preprinted manuscripts of interest. Two surveys have been distributed re: use of hepatitis B vaccine and orthopedic surgery. The HIE Advisory Committee consists of:

Jeanne Lusher, MD	Alan Brownstein, MSW, MPH
Marvin Gilbert, MD	Peter Levine, MD
Robert Montgomery	

They have met twice and had two conference calls to discuss policy and methods of improving format, active participation, membership policy and questionnaires. A written report was attached to the MASAC agenda.

12. Executive Session -

At this juncture, observers were requested to leave to allow for a MASAC Executive Session to discuss HTLV III/LAV properties and MASAC Recommendation about AIDS and hemophilia treatment. MASAC approved Attachment A as a revision of Attachment B.

13. AIDS-Related Complex -

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