THE NATIONAL
HEMOPHILIA FOUNDATION

THE NATIONAL HEMOPHILIA FOUNDATION/INDUSTRY

STRATEGY MEETING ON AIDS

January 14, 1983

Meeting Minutes

List of participants is attached.

Introduction:

Mr. Carman opened the meeting at 1:45 PM in his double role as Chairman of the NHF Board and Chairman of the NHF AIDS Task Force. He stressed that this meeting was open only to industry, voluntary blood agencies, government agencies and the NHF in order to promote free dialogue.

Review of January 4th, 1983 CDC Meeting:

Dr. Aledort reviewed the meeting with CDC in Atlanta on January 4th. He summarized the main issues addressed as: 1) Is AIDS transmissable? 2) Is it transmissable by blood products? and 3) Is it a virus? He reviewed the data showing identified AIDS cases as doubling every six months, and showing that of 843 cases reviewed 38% have died. Dr. Aledort reviewed the groups showing a high incidence of the disease, namely Haitians, homosexuals and IV drug users in addition to hemophiliacs, linking transmissability possibly with sexual contact or blood product use. He reported on an article in the NEJM showing that from 40-60% of patients on concentrates have a reverse ratio, and that though no data is conclusive, there appears a smaller incidence of reverse ratio of patients using cryoprecipitate.

Dr. Aledort concluded by raising the questions of whether eliminating certain high risk groups as donors will reduce risks of AIDS, of the efficacy of donor screening, and of the availability of cryoprecipitate, should the demand increase.

Dr. Hoyer than proceeded to review the recommendations that had been developed by the Medical and Scientific Advisory Council earlier in the day (see attached). The rest of the meeting focused on major issues concerning these recommendations as follows:

A. Donor Screening - Discussion Highlights:

Of the commericial agencies responding, Alpha indicated the most active screening process, through specific questioning of donors, which had been in effect for three weeks and had already excluded 308 people. Alpha further requires certification on each batch of product that each donor has responded to questions. The three other commerical agencies, Armour, Cutter

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and Hyland, reported educational screening methods would be in effect within two weeks, and would depend on voluntary self-exclusion methods. The voluntary blood banking community (The American Red Cross and Council of Community Blood Centers) questioned the efficacy of industry methods of screening, the adequacy of data, and the appropriateness of direct questioning regarding sexual preference. They mentioned the negative reactions that could accompany direct questioning of donors, such as reverse recruitment and overkill.

Speaking for NHF, Mr. Carman noted that the social lifestyle rights of the gay community should not impinge on the rights of hemophiliacs to seek maximum protection from the potential risk of AIDS and Dr. Hoyer summed up the discussion of MASAC's screening recommendations by saying that lacking definitive data, the position is based on logic.

B. Testing - Discussion Highlights:

Mr. Carman reported NHF's support of surrogate testing of donors to eliminate those at high risk and invited response:

Hyland gave a detailed reply saying that 12% might be rejected, based on data, which would entail substantial loss of revenue and thus raise the price of the product. After questioning, Hyland reported that it could abosorb a 10% rejection rate, and that a cost of $5 per test (anti core) would lead to an additional cost of 2.5¢ per unit.

Questions were raised as to the need for more information before testing.

Mr. Carman summarized the screening debate by a willingness on the part of the fractionation industry to use an appropriate test even with a 10% rejection rate, and despite an added price of 2.5¢ per unit. Additional effort is needed to address tests, which should be industry wide. NHF will urge third party payors to cover costs, despite increased prices, to ensure safety.

C. Geographic Exclusion:

Dr. Hoyer reported MASAC's recommendation to avoid collection in areas known to have a high incidence of AIDS cases, such as New York, the West Coast and prisons.

Alpha and Hyland both have such plans in effect at this time, as they reported, through prison exclusion by Hyland is recent. Hyland also believes that the same recommendation should be applied to the harvesting of cryoprecipitate.

Both the American Red Cross and the Council of Community Blood Centers registered dislike of geographic exclusion, which was felt might erode local support. Both reported preference to screen by groups and self-exclusion rather than by location.

Mr. Carman summarized the issue by citing attempts by all industry sources to eliminate collection from high risk areas, and the preference of voluntary groups to screen by groups, patient education and self-exclusion.

D. Miscellaneous Issues - DDAVP:

The FDA questioned the appropriateness of DDAVP use for donors, and said that more data was needed by FDA, which was reinforced by Immuno.

Size of Donor Pool:

A general discussion centered on the size of the donor pool, in which it was mentioned that one lot may have as many as 22,500 donors and that one infusion of cryoprecipitate may involve 25 to 60 donors. One problem in regard to reducing the size of the donor pool mentioned was the large number of containers that have to be retained in order to meet regulations. The issue was referred to Dr. Hoyer by Mr. Carman.

Research:

While Hyland reported working closely with researchers to clone factor VIII, none of the industry representatives foresaw an early breakthrough in substitute development.

Summary:

Mr. Carman summed up the meeting, citing the complicated issues involved, that no regulations would develop from the meeting, but that attendees would have expectations to walk away with. He stressed the need for caution in media contact, and promised that NHF would distribute minutes of the meeting to all participants. He indicated that the MASAC recommendations could be used to indicate the NHF position. He concluded by thanking all participants for attending and entering into an open and frank dialogue which could only be helpful in the present situation.

/mw

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HEMOPHILIA FOUNDATION

NHF/INDUSTRY STRATEGY MEETING ON AIDS

Friday, January 14, 1983

LIST OF PARTICIPANTS

NHF Board

*Nathan Smith, President
*Charles J. Carman, Chairman
*Donald Goldman

NHF Medical Co-Directors

*Louis M. Aledort, M.D.
*Marvin S. Gilbert, M.D.
MASAC Coordinator

NHF Medical and Scientific Advisory Council

*Leon W. Hoyer, M.D., Chairman
*Charles F. Abildgaard, M.D.
*David Agle, M.D.
*Willard Abe Andes, M.D.
*Franklin Desposito,M.D.
*Wahid Hanna, M.D.
*Peggy Heine, M.S. W.
*Margaret W. Hilgartner, M.D.
*Peter H. Levine, M.D.
*Jeanne M. Lusher, M.D.
*Kurt Niemann, M.D.
*John P. Olson, M.D.
*Harold R. Roberts, M.D.

Canadian Hemophilia Society Medical and Scientific Advisory Committee

*Hanna Strawczynski, Chairperson
Director, Montreal Helath Center

NHF Staff

*Alan P. Brownstein, Executive Director
*Patricia H. Webb, Director, Program and Chapter Development
Betty J. Greene, Admin. Assistant

Government Agencies

*Bruce L. Evatt, M.D., Director
Division of Host Factors
Center for Infectious Diseases
Centers for Disease Control
*Larry Zyla, M.P.H.
AIDS Project Coordinator
Center for Infectious Diseases
Centers for Disease Control

*Denotes those who participated at morning MASAC meeting on Friday, January 14.

continued . . .

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Government Agencies cont'd

*Amoz I. Chernoff, M.D.
Director, Division of Blood Diseases and Resources
National Heart, Lung and Blood Institute
National Insitutes of Health

*Dennis Donahue, M.D.
Director Division of Blood and and Blood Products
Office of Biologics
Food and Drug Administration

Merle McPherson, M.D.
Director, Habilitative Services Branch
Office of Maternal and Child Health

COMMERCIAL FRACTIONATORS

Alpha Therapeutic Company

Bruce Blomstrom, Senior Vice President
Sales and Marketing

Penny Carr, Vice President
Regulatory Affairs

William Hartin, Senior Vice President
Operations

Clyde McAuley, Medical Director

David R. Zimmerman
Public Relations

American Blood Resources Association

Robert W. Reilly, Executive Director

Joseph Rosen, Sera Tec Biologicals

Armour Pharmaceutical Company

Stephanie Beling, M.D.

Karl Hansen, M.D., Medical Director

Robert Johnson, Director
Regulatory Affairs

Stuart Samuels, Vice President
Marketing and Sales

Cutter Laboratories

Steve Ojala, M.D., Director
Regulatory Affairs

Charles Stewart, Eastern Regional
Sales Manager

Hyland Therapeutics Division Travenol Laboratories, Inc.

David Castaldi, President

John Bacich, Director
Biological Procurement

Mike Rodell, Ph.D., Vice President
Regulatory Affairs and Quality Control

Immuno, Vienna, Austria

Hans J. Eibl, Chief Executive

Eugene Timm, Ph.D.
Vice President

VOLUNTARY BLOOD INDUSTRY

American National Red Cross

Fred Katz, M.D., Executive Director, Blood Services

Doris Menache, M.D., Associate Director
Blood Services

Victor Schmidt, Associate Director
Blood Services

American Association of Blood Banks

Joseph Bove, M.D., Chairman
Committee on Transfusion Transmitted Diseases

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VOLUNTARY BLOOD INDUSTRY cont'd

American Blood Commission

Dr. John Gorman, Director of Blood Bank
New York University Medical Center

Canadian Red Cross

John Derrick, M.D., Advisor
Regulatory Affairs and Good Manufacturing Practices

Council of Community Blood Centers

Johanna Pindyck, M.D., Vice President
Greater New York Blood Program

Martin Stryker, Ph.D., Director Quality Control Laboratories, Blood Derivatives Program, New York Blood Center

GUESTS

*Richard A. Lipton, M.D., Director
Regional Comprehensive Hemophilia Diagnostic and Treatment Center
Long Island Jewish/Hillside Medical Center.

Chris Tsoukas, M.D., Clinical Immunologist
Montreal General Hospital

*James B. Bussell, M.D.
New York University
Medical Center

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