HYLAND THERAPEUTICS DIVISION
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Paul Kaufman, M.D.
Pharmaceutical Manufacturers Association
1155 Fifteenth Street, N.W.
Washington, D.C. 20005

Dear Paul:

Following is a brief summary of the meeting on Acquired Immune Deficiency Syndrome (AIDS) held on July 27, 1982 at the Department of Health and Human Services.

Although the meeting was called by Dr. Brandt, Undersecretary for Health, it was chaired by Dr. Jeffrey Koplan of the Centers for Disease Control (CDC). Dr. Koplan called the meeting to order at 8:30 AM, stating that the purpose was to review the findings of CDC and NIH relative to the incidence and epidemiology of AIDS.

1. Kaposi's Sarcoma and Opportunistic Infection - James W. Curran (CDC)

   Dr. Curran reviewed the incidence of Kaposi's Sarcoma and Pneumocystis carinii pneumonia. The normal U.S. incidence of kaposi's sarcoma is 0.02 - 0.06/100,000 (50 to 150 cases per year), generally seen in older men. Exceptions to normal incidence in the U.S. population are transplant patients, immunosuppressed individuals, and homosexuals. P. carinii pneumonia incidence normally is 0.03/100,000, generally in immunocompromised patients. Exceptions to this frequency are seen in cases of protein-calorie malnutrition, drug addicts, and male homosexuals.

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Through July 6, 1982, the following incidence has been reported

Condition/No. of Patients	Alive	Dead	Total
Kaposi's Sacroma (KS)	112	30	142
P. carinii pneumonia (PCP)	132	101	233
KS plus PCP	13	21	34
Other Opportunistic Infections	18	25	43
Totals	275	177	452

Condition/Geographical Locale	NYC	LA	SF	Other
KS	70	17	10	45
PCP	108	23	13	89

Dr. Curran presented certain characteristics of the major groups identified as having high incidence of AIDS, to see if a common thread existed

Groups with AIDS	Increase in No. of Sex Partners	IV Drug Use	Nitrite Use	CMV Incidence	Sperm Exposure	HBV Risk
Male homosexuals	Yes	No	Yes	Yes	Yes	Yes
IV Drug Abusers	Doubtful	Yes	No	Doubtful	No	Yes
Haitian Refugees	Doubtful	No	No	Unknown	No	Yes
Others (?)	No	No	No	Unknown	No	Yes

2. Immunosuppression Associated with Kaposi's Sarcoma and Opportunistic Infections - Anthony Fauci (NIH)

Immunosuppresion in these patients is not associated with hypogammaglobulinemia; in fact, normal or elevated levels of circulating IgG are noted. The immunosuppression is cell mediated.

T-cells, via the involvement of T-cell mediators, normally form activated macrophage cells which provide protection against some bacterial infections and de novo tumors. In the case of patients with AIDS, T-cell incidence is markedly reduced, thereby lowering the number of cells capable of entering into defense mechanisms.

3. Hemophilia - Natural Course, Complications, Treatment - Louis Aledort, National Hemophilia Foundation (NHF)

Dr. Aledort presented a clear and concise description of hemophilia, its crippling and life threatening consequences, and acceptable modes of treatment. He pointed out quite emphatically that the great majority of treatment of severe hemophilics consists of the use of Factor VIII Concentrate (or Factor IX Complex for these with hemophilia B), and that great care must be exercised in order to avoid taking premature or precipitous action adversely affecting the availability of these products.

Subsequent to Dr. Aledort's review, questions arose regarding source material used in the manufacture of clotting factor concentrates, i.e., where are plasma centers located and what type of donors are involved. I attempted to answer specific questions as to whether any plasma centers were located in prisons (no more than 6 to 8 centers), how much plasma was produced at these centers (approximately 2% of total plasma collected in this country), and where non-prison centers were located (throughout the country in "inner city", suburban, and university locations). Discussion ensued relative to the potential for prison plasma to be a causative factor in transmission; I pointed out that the prisons are located in states where AIDS does not appear to be occurring in higher than normal incidence. I also pointed out that plasma from other sources, e.g., recovered plasma from whole blood collection, was involved in the manufacture of concentrates. Dr. Sandler (ANRC) commented that CDC has not yet proven that AIDS is transmissable by bloor or blood products, and that no donor population should be implicated at this time.

4. Description of Factor VIII Concentrates and Other Blood Components - Robert Gerety (NCDB, FDA)

Dr. Gerety reviewed information relative to collection and processing of plasma in manufacturing plasma derivatives, and data regarding hepatitis risk associated with each type of product (clotting factors, NSA, ISG, etc.).

5. Observations on Opportunistic Infections in Hemophilic Patients - Bruce Evatt (CDC)

Dr. Evatt reviewed findings in three hemophilics who are suspected or confirmed as having AIDS. Two of these patients (ages 62 and 59) have died; the third (age 27) is critical. Questioning of the widows of the two deceased patients excludes homosexuality and drug abuse; the surviving patient maintains that he is in fact a virgin, is not homosexual, and is not using illicit drugs.

6. General Round Table Discussion

The afternoon session was devoted to an open discussion during which those invited to the meeting could express their views and thoughts. Dr. Koplan requested that the discussion should be confined to suggesting what recommendations the Public Health Service should make to HHS.

Following is a sampling of some thoughts expressed during this session.

Donald Armstrong (N.Y. Group on KSOI) - an infectious agent must be involved; drug addicts and male homosexuals engaged in traumatic sexual practices give rise to this theory. Hemophilics appear to be the next generation of victims. Haitian refugee incidence cannot be readily explained.

Paul Holland (AABB) - although several patient populations have been identified (gays, drug abusers) what about those victims of AIDS not falling into these categories? [Response from Curran that CDC is investigating this]. Evidence of transmissable agent is lacking; implication of donors and blood products is far from proven.

Donald Francis (CDC-Arizona) - the suspicion of this syndrome being blood-borne thus far hinges on its appearance in 3 hemophilics. How strong are the facts regarding the backgrounds of these individuals? [Response from a member of CDC who was involved in family/patient interviews, eliminating homosexual or drug abuse possiblities].

Gerald Sandler (ANRC) - suggested that a group of hemophilics be tested for T-cell levels and T_4/T_8 cell ratios as an indicator of whether a problem really exists or if the 3 cases were random events. [Response from NIH and CDC that such tests were not entirely conclusive in nature]. Association of AIDS with blood and blood product utilization should be proven, rather than surmised.

Louis Aledort, Elaine Eyster (NHF) - strongly suggested that there is a need for hemophilic patient surveillance and prompt reporting by regional treatment centers to NHF, so that more definitive information can be obtained relative to incidence of AIDS with concentrate therapy.

David Sencer (NYC Health Dept.) - situation is urgent; AIDS is serious. Hemophilics must continue to be treated, but a risk/benefit statement may be in order. Efforts should be made to "clean up" clotting factor concentrates to minimize risk of disease transmission.

In view of the two main thoughts seeming to center about the need for proof of disease transmission and hemophilic patient surveillance, Dr. Koplan concluded the meeting with these points.

1. Activities will be initiated by CDC to seek out more information relative to incidence, immunologic definition, morbidity, etc.

2. Laboratory studies will be undertaken by CDC and NIH to attempt to identify the causative factor(s) as soon as protocols can be developed.

3. Hemophilia centers will be contacted by NHF to set up a surveillance and reporting system.

4. Consideration should be given to increase the safety of blood products, in the event that AIDS is blood-borne.

Dr. Koplan concluded the meeting, stating that this was an Ad Hoc committee, which possibly may not reconvene. He thanked everyone for their participation.

Attached is a list of those invited by HHS to attend the meeting.

Sincerely,

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

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Attachements

P.S.1 - During a private discussion with Dr. Donohue, he commented that the Division of Blood and Blood Products could find itself in the position of having to make a politically expedient decision to disapprove the operation of plasmapheresis centers specifically intended to collect anti-HBs plasma from homosexuals.

P.S.2 - Subsequent to the meeting, I received the attached letter from Charles J. Carman, President of NHF, soliciting the PMA for funds to staff a patient surveillance and monitoring program. During a recent conversation with him, he stated that he anticipates having to devote one-half person for 3 to 4 months, at a cost of $10,000.

cc: Penny Carr - Alpha Therapeutic
Robert Johnson - Armour Pharmaceutical
Lee Hershberger, Ph.D. - Cutter Laboratories, Inc.

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