

Cutter



PLAINTIFF'S
EXHIBIT
NO. 438

to John Sliwka
by J. J. Peterson
subject: Trip Report
AIDS Meeting - Orthopaedic Hospital, L.A. 1/3/83

date 1-5-83
cc: S. Ojala
C. Patrick
J. Ryan

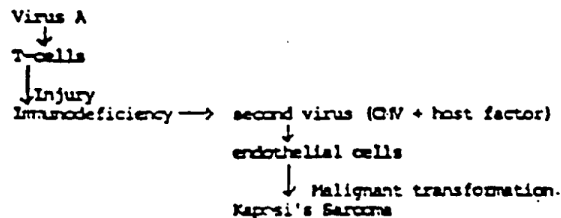
Due to the growing problem of AIDS as well as many news articles, physicians at Orthopaedic Hospital decided to have a patient/family meeting. Dr. Shelby Dietrich also stated that the meeting was being held in order to share the uncertainties and state of uncertainties that surround the problem.

The first speaker on the program was Dr. David Auerbach of the Epidemic Intelligence Service of the CDC in Los Angeles. He spoke of the differences between the Kaposi's Sarcoma and Pneumocystis Carinii. As of November 17, 1982, the following risk groups have been identified by the CDC:

74.5	Homosexuals
14.1	Illegal IV drug users
5.7	Haitians
0.7	Haemophiliacs
5.0	No applicable category

It appeared that the only commonality in these groups are that they are all at high risk for hepatitis B. Dr. Auerbach further hypothesized that AIDS could be a new hybrid virus, a new strain of a common virus, or, less likely, an unusual reaction to a common virus. He also felt that most people exposed to the causative agent have not contracted AIDS.

The second speaker was Dr. Michael Gottlieb, Assistant Professor of Medicine and Clinical Immunology and Allergy at UCLA. He basically explained the immune system and problems associated with it as a breakdown in the body's resistance to infection. The Pneumocystis Carinii is an opportunistic infection which if caught early can be treated with antibiotics. Dr. Gottlieb hypothesized that AIDS is a dual virus and proposed the following model:



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The attitudes and plans for Orthopedic Hospital were discussed by: Dr. Lois Boylan, Director of Adult Care, Dr. Nadia Dwing, Pediatrics, and Dr. Carol Kasper, Director of Coagulation Laboratory.

- A. For adults, the following treatment program has gone into effect:
1. Treat bleed early and take your concentrate with you.
 2. The amount of concentrate used is not to change; however, recommendations will be made in the future if there are any to be made.
 3. Any elective surgery will be deferred for a month until more is known about AIDS.
 4. If you are on prophylaxis use, use concentrate only when necessary. However, if you use less concentrate by prophylaxis, continue to do so.
 5. A mailing will be done if there is any new information.
 6. Above all, get proper rest, diet, manage stress, exercise and keep yourself in optimum health.
- B. For pediatric patients the following treatment program has gone into effect:
1. Treat bleeds.
 2. If AIDS is a virus, it would make sense to use product that comes from fewer donors, therefore:

Factor VIII children use cryo
Factor IX children use fresh frozen plasma

Although these products are not free of problems, (allergic reactions, not feasible for volumes) they seem a more reasonable choice for children.

- C. For infrequently treated patients such as mild, moderate and Von Willebrands, switch to cryo where possible.

Dr. Kasper also mentioned two investigational products that patients might want to try although there are long protocols involved. The first product is DDVP for mild, moderate and von Willebrands patients. This product is derived from a synthetic pituitary hormone. The second product is for inhibitor patients. It is a Porcine Factor VIII product derived from pigs.

While questions were collected from the audience for the panel and manufacturers' comments, Dr. Kasper asked Dr. Paul Thompson, Director of the Blood Bank of the Orange County Red Cross, what his centers

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plans were. He stated that they were awaiting results from the meeting at the CDC in Atlanta as well as from the Blood Transmission Committee of the AABB, both to be held this week. However, the Red Cross has had meetings with leaders of the gay community asking them to restrain from volunteering for blood donations. Dr. Kasper further asked if the use of cryo offers any less risk than concentrates. Thompson's response was that concentrates are made from a pool of donors and one donor can contaminate a whole pool. He also stated that the Red Cross is avoiding homosexual communities but does not turn down any donors at this point.

The written questions from the audience and responses were as follows:

- Q. Does taking concentrates transmit AIDS?
A. Dr. Auerbach: Presumably yes; however, an infant received a single donor blood transfusion in San Francisco and contracted AIDS.

Additional comments

Dr. Gottlieb: Certainly the paid blood donors are not adequately screened.

Dr. Thompson: The Red Cross requires a medical history interview regarding drug abuse. Also, immigrants who have been in the country less than 3 years are excluded.

- Q. In Haiti is there a prevalence of men over women getting AIDS?
A. Dr. Auerbach: Yes, however, further information on Haitians is not treated as complete or accurate due to the tenuous status of their immigration.

- Q. Does an immunological response ever revert to normal?
A. Dr. Gottlieb: It has happened, but not in a significant number of cases. Of 50 patients in a study only 2 spontaneously corrected. It has not happened with AIDS due to significant T-cell abnormality.

- Q. Is there an asymptomatic carrier state?
A. Dr. Gottlieb: Yes. Tests must be developed to see if there can be transmissions.

- Q. What safeguards, if any, should health professionals take and should family members take any particular precautions?
A. Dr. Gottlieb: Essentially Hepatitis B precautions should be taken. Avoid contact with blood and secretions. Do special hand washing. In all situations wear gloves.
Dr. Auerbach: It appears to resemble Hepatitis B; however, there are no known cases of hospital workers, unless they fell into previously designated categories.

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Dr. Kasper: Addressing the family situation, we have surveyed some hemophiliacs with lymphocyte abnormalities. While we look at the ratio of suppressor and helper cells this ratio does not equal AIDS. I am saying this because one of these patients asked if it was all right sleep with his wife or kiss his baby daughter.

Q. Are there any absolute diagnostic tests?

A. Dr. Gottlieb: No. However, the helper suppressor ratio is helpful.

Q. Is the plasma from homosexuals, prisoners, Haitians or other high risk persons being used in the manufacture of concentrates?

A. Alpha - Dr. Hainski: Alpha has talked to our centers and as of the last 3 weeks and in the future will not be taking their blood. Any donor suspected of having AIDS is not used either. Product manufactured from the plasma since these changes will take 2 to 3 months to reach the market.

Hyland - Dr. Gottlieb: Hyland is using a number of checks. Donors are asked if they ever injected a drug not prescribed. Donors are inspected 3 times for marks. We always eliminate a donor who has ever used self-injected non-prescribed drugs, not just current users. There has been no great change in the system, as this has always been in effect. We are changing the nature of questions to homosexuals to the best of our ability. We are asking of Haitians if they are residents or have visited Haiti within the past 5 years. (Dr. Evans says a 5 year limit is o.k.). We are asking questions regarding symptomatology such as fevers of unknown origin. Persons at the centers follow careful medical directions - looking at symptomatology. We look for lymphadenopathy - enlarged glands in more than one area of the body (neck, armpit, groin) and, if found, will need quite a significant explanation from the donor. There is a whole body check. There is a skin examination also looking at lower extremities for any early signs. We are doing everything that possibly can be of help. In fact, I am a member of a committee writing a new plasmapheresis manual.

Q. (Dr. Kasper) Will there be heat treated concentrates available that will be hepatitis safe or will not transmit other viruses?

A. Alpha - Dr. Hainski: We are making one.

Hyland - D. Castaldi: We have a license in Germany and an FDA

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application for licensure in the USA. We expect the
licensure to be complete in first quarter 1983.
Cutter - Dr. Ojala: We also have a product and expect to have
licensure in early 1983.

- Q. Dr. Kasper to Cutter - Are there any changes in donor selection and
is population distribution a problem?
- A. Cutter - Dr. Ojala: We are doing the same kinds of things as the
other companies to exclude high risk donors. We
have donor centers around the country and not a
preponderance in one area.
- Q. Dr. Kasper to Cutter - These centers seem to be in random centers
of town. Is there a move to move them to rural towns?
- A. Cutter - Dr. Ojala: Many of the centers are in smaller communities
and in towns such as Ypsilanti, Seattle, Clayton,
N.C., and San Diego. We do not have centers in L.A.
or San Francisco.

Dr. Kasper concluded the meeting by saying that patients need to stay in
optimum health to keep their immune systems healthy and if there is any
problem to seek early treatment. Dr. Hainiski of Alpha spoke for the
manufacturers by stating that the manufacturers are looking for the CDC
to form a conviction, that we are tied together and will ride another
crisis together.

By the way, Dr. Earl Hanson of Armour attended the meeting but did not
say a word.

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J. W. Peterson
Product Marketing Manager
Coagulation Therapeutics

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