

GRO-C



American Blood Resources Association  
PO Box 3346 • Annapolis MD 21403

RECEIVED

JAN 31 1983

January 28, 1983  
Reference No. A1475

Dear ABRA Member:

Acquired Immune Deficiency Syndrome (AIDS) has reached a level of public health concern and, more specific to ABRA members, product quality concern which has prompted the ABRA Board of Directors to prepare and approve the enclosed statement on AIDS and plasma donor deferral recommendations.

ABRA representatives have participated in a series of public and private meetings which have been taking place since July 1982. More recently, these meetings have been attempting to seek consensus on recommendations to reduce the risk of transmitting AIDS.

The ABRA statement has been prepared only after numerous discussions with informed representatives of the various interest groups. The chronology of these recent discussions to consider blood products and blood donor recommendations include:

November 7, 1982	ABRA - CDC Briefing of ABRA Members
December 4, 1982	FDA - Blood and Blood Products Advisory Committee
January 4, 1983	CDC - Conference on AIDS and Blood Product Concerns
January 6, 1983	AABB - Committee on Transfusion Transmitted Diseases
January 10, 1983	ABRA/FDA Liaison Committee
January 14, 1983	FMA - Biological Section Committee
January 14, 1983	National Hemophilia Foundation AIDS Conference

Also included in this mailing is a memorandum considering some of the possible legal issues associated with AIDS. The document was prepared by the Association's General Counsel, Richard Landfield.

The next issue of Plasma Quarterly, which you should be receiving in the next week to ten days, features a number of articles which should provide the membership with some data to permit you to begin ABRA recommended staff education programs.

Additional information on AIDS and the policies being proposed by other interested organizations will be detailed in our January - February ABRA Newsletter.

If you have any questions, please do not hesitate to call me.

Sincerely yours,

GRO-C

GRO-C

Robert W. Reilly  
Executive Director

RWR/ccr  
enclosures

02-001-00000000

100 3119

M004098 S

BAYP0004385\_0001

GRO-C

**ABRA**

American Blood Resources Association  
PO Box 3346 • Annapolis MD 21403

January 28, 1983

**ABRA RECOMMENDATIONS ON AIDS AND PLASMA DONOR DEFERRAL**

The American Blood Resources Association (ABRA) recommends that its member firms who are involved in the collection of plasma for the manufacture of certain products used in the treatment of hemophilia, a coagulation deficiency, take the following actions to eliminate plasma donors who may be in those groups identified as having a high risk to Acquired Immune Deficiency Syndrome (AIDS).

In the past two years, over 800 cases of AIDS have been reported in the United States. The disease is of unknown etiology, resulting in abnormal immune function, Kaposi's sarcoma and opportunistic infections with a high mortality rate. It appears most frequently in homosexuals, Haitians, and intravenous drug abusers. Several recent cases of AIDS in hemophiliacs and in recipients of various blood products, suggest that AIDS may be of infectious etiology.

The American Blood Resources Association represents the United States commercial plasmapheresis industry who performs 10 million plasmapheresis procedures each year, representing one-half of all donor collections in the United States. ABRA is concerned that steps be taken as soon as possible to screen plasma donors to minimize the possibility of transmitting AIDS. After extensive discussions with various organizations representing the Public Health Services, national blood banking groups and the National Hemophilia Foundation, the leadership of ABRA believes that the most significant action which can be taken, at this time, to reduce the potential risk of AIDS in certain plasma products, is to seek either voluntary donor exclusion or to modify the donor screening procedures to eliminate individuals from the plasma donor population who are in those groups identified as having a high risk to AIDS.

ABRA recommendations focus on three areas: 1) donor education, 2) donor screening, and 3) surrogate laboratory testing.

In the area of education, the Association recommends the preparation of an information document describing AIDS, including statements on how individuals in high risk groups may reduce their risk of exposure, and statements intended to discourage high risk individuals from donating plasma. In addition, the Association recommends that plasmapheresis center management initiate staff education programs on AIDS and its symptomatology.

020001 07-0000

100 3120

M004099 S

BAYP0004385\_0002

2  
ABRA RECOMMENDATIONS ON AIDS AND PLASMA DONOR DEFERRAL  
January 28, 1983  
Page 2

For donor screening, the Association recommends that donors be required to read the information about AIDS and acknowledge that they are not members of the high risk groups identified; and that individuals in high risk groups be excluded from donating plasma. Further, on a continuing basis, expand the medical history and examination to include the question, "Have you had AIDS or close contact with someone with AIDS?" All donors should be asked questions designed to elicit history of night sweats, unexpected weight loss, unexplained fevers, lymphadenopathy, or Kaposi's sarcoma. Anyone found to exhibit any of these symptoms should not be allowed to donate plasma without further medical studies.

For additional laboratory testing, the Association recommends that no large scale testing be initiated at this time. Assessment of issues such as the adequate availability of testing reagents and equipment of any of the several possible tests under consideration, their economic and logistical impact upon the plasma supply network, the efficacy of the test to exclude high risk individuals, and other potential consequences to plasma products resulting from the imposition of additional testing requirements is currently under study.

These ABRA recommendations are intended to apply to all plasma donors collected by plasmapheresis for use in the production of antihemophilic factor concentrate. The Association is forwarding these recommendations to other national and international organizations concerned with donor standards and blood and blood product quality. Each year, the blood banking community recovers plasma from several million voluntary blood donor units which are then used in the production of antihemophilic factor concentrate products used in the treatment of hemophiliacs. Therefore, it is the view of the ABRA leadership that all donors, whether they are participating on plasmapheresis programs or on voluntary blood donor programs, should be screened to eliminate individuals identified in the AIDS high risk groups.

ABRA will consider changing and updating these recommendations as more medical and scientific information becomes available. For more information, call the Association's National Office at (301) 263-8296.

UNCLASSIFIED

CONFIDENTIAL

100 3121

M004100 S