

## DOCUMENT RESUME

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Report to Secretary, Department of Health, Education, and Welfare; by Gregory J. Ahart, Director, Human Resources Div.

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Organization Concerned: American Blood Commission.

Congressional Relevance: House Committee on Interstate and Foreign Commerce; Senate Committee on Human Resources.

The American Blood Commission was organized to carry out the National Blood Policy--a plan developed by the Department of Health, Education, and Welfare (HEW) for developing a safe, fast, and efficient blood collection and distribution system. The policy prescribed improvements in blood banking to include regionalized blood collection and distribution, transition to an all-voluntary blood donation system, and rational alinement of charges and costs for blood services. Findings/Conclusions: The Commission primarily develops and tests standards, guidelines, and procedures pertaining to blood banking. Factors which will make it difficult for the Commission to carry out its policy are: difficulties in obtaining funds to support its operations; disagreement between the two largest blood suppliers; possible opposition, especially from areas in which there are multiple suppliers of blood, to regionalized blood collecting and distributing; possible problems in obtaining data from blood banks by the National Blood Data Center; and lay members' lack of sufficient knowledge of blood banking. The Health Care Financing Administration (HCFA) has not yet developed a system to relate costs and charges for blood services.

Recommendations: The Secretary of HEW should: monitor closely the progress of the Commission toward carrying out the National Blood Policy and, if necessary, consider a legislative or regulatory approach; and instruct the Administrator, HCFA, to report on attempts to relate the costs of and charges for blood services. (Author/HTW)

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REPORT BY THE U.S.

# General Accounting Office

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## Problems In Carrying Out The National Blood Policy

The National Blood Policy is a plan established by HEW for developing a safe, fast, and efficient blood collection and distribution system. The progress of the American Blood Commission, which was organized to carry out this policy, has been hindered by

- a lack of funds,
- disagreement between the two largest blood suppliers,
- resistance to regionalization of blood collecting and distributing,
- problems in obtaining data from blood banks, and
- a lack of knowledge of blood banking by lay members of the Commission.

The Secretary of HEW should monitor the Commission's progress and, if necessary, consider a legislative or regulatory approach toward carrying out the policy. The Secretary should also instruct the Health Care Financing Administration to relate costs and charges for blood services.



HRD-77-150  
MARCH 7, 1978



**UNITED STATES GENERAL ACCOUNTING OFFICE**

**WASHINGTON, D.C. 20548**

**HUMAN RESOURCES  
DIVISION**

**B-164031(2)**

**The Honorable  
The Secretary of Health,  
Education, and Welfare**

**Dear Mr. Secretary:**

**This report makes recommendations to your Department concerning the implementation of the Department's National Blood Policy. The Department's tentative position in reply to our draft report represents, in our view, a favorable response to these recommendations.**

**As you know, section 236 of the Legislative Reorganization Act of 1970 requires the head of a Federal agency to submit a written statement on actions taken on our recommendations to the House Committee on Government Operations and to the Senate Committee on Governmental Affairs not later than 60 days after the date of the report and to the House and Senate Committees on Appropriations with the agency's first request for appropriations made more than 60 days after the date of the report.**

**We are sending copies of this report to the above-mentioned Committees; the House Committee on Interstate and Foreign Commerce; the Senate Committee on Human Resources; the Director, Office of Management and Budget; your Assistant Secretary for Health and Inspector General; the Director, National Institutes of Health; and the Administrator, Health Care Financing Administration.**

**Sincerely yours,**

  
**Gregory J. Ahart  
Director**

D I G E S T

The American Blood Commission was organized to carry out the National Blood Policy--a plan developed by the Department of Health, Education, and Welfare (HEW) for developing a safe, fast, and efficient blood collection and distribution system.

The policy prescribed specific improvements in blood banking to include

- regionalized blood collection and distribution,
- transition to an all-voluntary blood donation system, and
- rational alinement of charges and costs for blood services.

The commission primarily develops and tests standards, guidelines, and procedures pertaining to blood banking. However, several factors affecting the commission will make it difficult to carry out the policy. They are:

- Obtaining funds to support its operations. (See p. 14.)
- Disagreement between the two largest blood suppliers--the American National Red Cross and the American Association of Blood Banks. (See pp. 14 and 15.)
- Possible opposition, especially from areas in which there are multiple suppliers of blood, to regionalized blood collecting and distributing. (See p. 15.)
- Possible problems in obtaining data from blood banks by the National Blood Data Center. (See pp. 15 and 16.)

--Lay members' lack of sufficient knowledge of blood banking. (See p. 16.)

The Health Care Financing Administration, a component of HEW, has an important role in implementing the policy. It should relate costs and charges for blood services, an activity which it has yet to develop.

GAO recommends that the Secretary of Health, Education, and Welfare:

--Monitor closely the progress of the American Blood Commission toward carrying out the National Blood Policy and, if necessary, consider a legislative or regulatory approach toward this end.

--Instruct the Administrator, Health Care Financing Administration, to report on attempts to relate the costs of and charges for blood services. (See p. 23.)

HEW generally agreed with GAO's findings, conclusions, and recommendations. The actions proposed by HEW represent a favorable response to GAO's recommendations. (See pp. 23 and 24.)

The American Blood Commission offered several comments dealing with matters discussed throughout the report and presented information not available when the draft report was prepared. Where appropriate, such information has been included in the final report. (See pp. 24 and 25.)

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## ABBREVIATIONS

AABB	American Association of Blood Banks
ABC	American Blood Commission
ANRC	American National Red Cross
CCBC	Council of Community Blood Centers
FDA	Food and Drug Administration
GAO	General Accounting Office
HCFA	Health Care Financing Administration
HEW	Department of Health, Education, and Welfare
NHLBI	National Heart, Lung, and Blood Institute
SSA	Social Security Administration

## CHAPTER 1

### INTRODUCTION

In March 1972 the President asked the Department of Health, Education, and Welfare (HEW) to study and recommend to him a plan for developing a safe, fast, and efficient nationwide blood collection and distribution system. A task force, appointed by the Assistant Secretary for Health, undertook the study. Subsequently, on July 10, 1973, the Secretary of HEW announced the National Blood Policy. The policy identified four goals for developing an improved blood service system:

- (1) Supply. Providing an adequate supply of blood and blood products to meet the Nation's treatment and diagnostic needs.
- (2) Quality. Obtaining the highest standard of blood transfusion therapy through available scientific knowledge and additional scientific research.
- (3) Accessibility. Access to the national blood and blood products supply by everyone in need, regardless of economic status.
- (4) Efficiency. Efficient collecting, processing, storage, and use of the national blood and blood products supply.

To achieve these goals, the policy calls for attaining specific improvements in blood banking. Prominent among these goals are regionalized blood collection and distribution, adopting an all-voluntary blood donation system, and rationally coordinating charges and costs for blood services.

Regarding transition to an all-voluntary blood donation system, our report "Hepatitis From Blood Transfusions: Evaluation of Methods To Reduce the Problem" (Feb. 13, 1976, MWD-75-82), stated:

"Evidence clearly indicates, however, and HEW agrees, that some blood banks which pay their donors supply blood of relatively high quality and of a higher quality than others which rely fully on volunteer donors. This is particularly true of hospital-operated blood banks which obtain blood from well defined and controlled populations. We believe that the part of the National Blood Policy which calls for moving



toward an all-voluntary system should not arbitrarily call for eliminating paid blood from banks which can show a valid record of supplying high-quality blood, particularly if such action could jeopardize the adequacy of the blood supply or force a reliance on blood from other sources, from either paid or volunteer donors, which is or may be of lesser quality."

We recommended that the Secretary of HEW:

"Modify the National Blood Policy so [as not to eliminate] paid blood from banks which can show a valid record of supplying high-quality blood."

HEW did not agree with our recommendation and continues to support eliminating all paid blood.

Responding to a request by the Secretary of HEW, private sector organizations, involved in providing blood services, submitted a plan for implementing the National Blood Policy to the Secretary on January 31, 1974. This plan proposed creating an American Blood Commission (ABC). The plan further states that the ABC shall become largely self-supporting, although grants from private organizations and/or the Federal Government will be needed initially to help defray nonrecurring costs. The plan also suggests establishing 11 task forces to deal with

- blood inventory control,
- regional program development,
- data and statistical analysis,
- voluntary donor recruitment,
- blood utilization,
- research,
- education,
- cost evaluation and control,
- inspection and accreditation,
- standards, and

--plasma production and fractionation. 1/

The plan notes that this list is not all inclusive and that additional task forces may be needed.

In addition to private sector efforts, the Federal Government will also have an active role in implementing the National Blood Policy. According to an HEW report, which outlines the National Blood Policy, the Federal Government will be active in regulation, research, maintenance of needed data and information systems, and development of the relationship between costs and charges for blood services. In addition, the National Blood Policy states that if the private sector cannot satisfactorily progress toward implementing the National Blood Policy, a legislative or regulatory approach will have to be considered.

### SCOPE OF REVIEW

On July 7, 1976, a request from Members of Congress asked us to review progress by HEW and the ABC toward implementing the National Blood Policy. Because of this request, we met with officials from HEW, ABC, the American National Red Cross (ANRC), the American Association of Blood Banks (AABB), the Council of Community Blood Centers (CCBC), and the American Blood Resources Association. We also reviewed correspondence and records at ABC headquarters in Arlington, Virginia, and at the National Institutes of Health in Bethesda, Maryland.

We briefed congressional staff members on our review results on September 28, 1976. This report summarizes data gathered during our review and incorporates additional data collected since that time. We are providing this report as an informational source, which includes recommendations to the Secretary of HEW, concerning the Department's role in implementing the National Blood Policy.

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1/fractionation--chemically separating plasma into its component substances.

## CHAPTER 2

### AMERICAN BLOOD COMMISSION EFFORTS TO IMPLEMENT THE NATIONAL BLOOD POLICY

On March 25, 1975, the American Blood Commission was incorporated in the District of Columbia as a nonprofit corporation for implementing the National Blood Policy. The commission held its initial board of directors' meeting on April 3, 1975.

According to ABC's Articles of Incorporation, the commission will operate to promote the public welfare and to carry out scientific, educational, and other programs to develop an adequate, voluntary supply of blood to meet the Nation's health needs. The commission will monitor, promote, and coordinate activities involving donor recruitment and collecting, distributing, testing, preserving, storage, and transfusion of blood and will aid in developing future goals for (1) plasmapheresis <sup>1/</sup> and plasma fractionation activities, and (2) transplanting other human tissues.

ABC represents many diverse organizations concerned with the National Blood Policy (see app. III). ABC officials state that the commission must coordinate planning and develop consensus within all segments of the blood service community regarding ways and means of achieving the policy's goals. ABC officials further state that ABC will achieve its goals by gaining consensus. Furthermore, the commission will increase its influence by formulating standards and guidelines through a broadly based and powerful membership. Important to developing this consensus is establishing task forces composed of experienced individuals from all segments of society.

#### ABC TASK FORCE ACTIVITIES

As of November 1977, ABC had appointed members to 5 of the 11 initial task forces suggested by the implementing plan for the National Blood Policy. The task forces have received funds from contracts administered by the National Heart, Lung, and Blood Institute (NHLBI) of the National

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<sup>1/</sup>plasmapheresis--collecting blood followed by immediate separation and return of the red cells to the donor. Only the plasma is retained.

Institutes of Health, Department of Health, Education, and Welfare. The following sections discuss these five task forces and ABC activities relating to the other suggested task forces.

### Blood inventory control

The functions of the recommended blood inventory control task force are carried out by the Committee for Commonality in Blood Banking Automation (Commonality Committee). This committee was organized in June 1974, prior to establishment of the ABC. According to an ABC official, money for operating the Commonality Committee, which amounted to approximately \$45,000, came initially from the American National Red Cross, the American Association of Blood Banks, and the Council of Community Blood Centers. After incorporation of ABC, the Commonality Committee became a task force of the new commission. NHLBI assumed funding of the committee's activities under a contract for the period June 30, 1975, to August 27, 1976. <sup>1/</sup> Funding continued under a subsequent contract for \$112,526 to cover the period from August 30, 1976, to November 30, 1977.

An ABC publication stated that the Commonality Committee was established in response to safety and economic interests which have been exerting strong pressure to automate blood banking operations. Concern existed that various blood banks were automating their operations with incompatible systems. According to ABC, a variety of incompatible machine-readable coding structures could hinder the distribution of blood and blood products, and development and transferability of new automation techniques.

As part of its work, the committee has developed a blood bag label which it believes can be used by all blood banks, even those which are not automated. The label is both eye- and machine-readable. The machine-readable portion is a bar code similar to the one in use by the grocery industry. The task force is determining whether the new labels are usable by all blood banks through field tests at 16 blood

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<sup>1/</sup>The same contract funded task forces on the Regional Association of Blood Service Units and the National Blood Data Center. The total contract amount was \$261,644, which was not allocated to the various task forces. Subsequent contracts were awarded individually to each task force.

facilities. These facilities represent diverse blood service units, including 6 medium to large hospital blood banks and 10 blood centers that serve various hospitals. A series of final reports on the tests are to be completed by the task force.

### Regional program development

The Task Force on the Regional Association of Blood Service Units was authorized by the ABC board of directors on May 12, 1975, and as previously noted, was funded by a contract with NHLBI dated June 30, 1975. Funding has continued under a subsequent contract for an estimated \$351,423 to cover the period from August 30, 1976, to August 29, 1979. This contract calls for a task force to analyze the operating relationships among this country's blood banks, blood centers, and transfusion services. The contract further requires that the task force formulate guidelines for interrelating these facilities into a more effective blood service delivery system. The contract states that the task force will conduct further research on "regionalization," 1/ so that methods of implementing the regional association concept may be developed and accreditation or endorsement may be established.

Task force members represent a variety of blood service community and consumer interests. The task force includes representatives of each of the three major national blood banking organizations--AABB, ANRC, and CCBC. It also includes individuals associated with labor unions, medical schools, and commercial blood banks.

The task force believes that regionalization is the best way to achieve an effective and efficient blood service system. However, an NHLBI official told us that much opposition exists to regionalization, especially in areas with several blood suppliers.

According to the task force, approximately 7,000 copies of its draft entitled "Report of the Task Force on Regional Association of Blood Service Units," April 1, 1976, were distributed for review and comment to a variety of blood banking representatives and lay persons. On June 2, 1976, the task force reviewed the comments and revised the report to reflect constructive criticism.

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1/regionalization--coordinating efforts within a given geographical area.

The revised task force report of July 15, 1976, shows criteria for types and quality of blood services which should be provided by a regional association, and the criteria for organizing such an association (formation and functions). The report does not designate specific regions or region size as measured by area or population but rather states that a regional association should serve a geographically integrated area. The association should consider such factors as patient referral patterns, road networks, territory covered by various communications media, population density, seasonal shifts in population, and cultural considerations.

The report states that a regional association will be the locus of accountability for coordinating blood services among blood banks and centers, transfusion services, hospitals, patients, donors, and the general public. Also, the report provides that the regional plan will coordinate (1) recruiting donors, (2) collecting blood, (3) processing and distributing blood products and services, (4) managing the regional blood inventory, (5) collecting information, and (6) performing all other functions related to blood services.

An ABC official told us that under a current contract with NHLBI, the task force will test the criteria which it has developed for blood service regions. Another ABC official told us that as of November 1977, the task force had received requests from 46 regional associations which had requested review by the task force. She stated that the task force planned reviews of 10 regional associations. As of November 1977, six reviews were complete. She reaffirmed that these reviews are to test the criteria shown in their report for operating regional associations.

She also stated that in the future, the ABC plans to develop accreditation requirements for regional associations which meet ABC criteria.

#### Data and statistical analysis

This task force, officially named the National Blood Data Center Task Force, was authorized by the ABC board of directors on May 12, 1975, and, as previously noted, funded by a contract dated June 30, 1975, with NHLBI. Funding of \$396,890 under a subsequent contract is scheduled to expire on February 28, 1978. Task force members have expertise in both the clinical and management areas of blood service and in design and application of health care data systems.

The task force has reviewed existing and potential needs for data in the blood service complex and current data collection activities. The task force has also explored financial strategies required for developing and operating a data center. This center would have an estimated annual operating budget of \$993,609. Funds are expected from fees charged to Government and private users for services and data provided by the center. However, an ABC official said that as of November 1977, they had no firm commitments for the sale of these services and data, although negotiations are being held with HEW's Food and Drug Administration (FDA) and NHLBI.

The task force unanimously recommended establishing an independent National Blood Data Center. According to ABC literature, the proposed center could provide important information to a variety of users. The center will be a data repository and will have the capability to translate raw data into meaningful information.

In an August 1976 report, entitled "Toward a National Blood Data Center," ABC estimated that the data center will be partially operational by September 1978 and fully operational and independent by February 1979. In the interim, the task force will be (1) hiring staff, (2) negotiating with agencies which need blood data, (3) preparing a detailed system design, (4) designing forms, (5) designing a computer system, and (6) testing that system.

The report also states that National Blood Data Center participation will be voluntary. However, the task force has determined that several strong incentives exist for blood service organizations to supply the needed data. These incentives include (1) eliminating duplicative reporting, (2) providing comparative data for self-evaluation, and (3) retaining some control by the blood service community of its own reporting system. In addition, an ABC official informed us of his belief that peer pressure would force reluctant blood banks to provide data to the center. He stated that the strongest pressure would come from those reporting blood banks that have direct dealings with other blood banks which refuse to report.

An NHLBI official told us, however, that it will be difficult to convince all blood banks to participate in the National Blood Data Center. He said that some blood banks do not collect the kind of information such a system would require. Thus, accounting problems would occur as well as additional cost for gathering the data. According to this official, some blood banks guard the information the center

needs because such revelations might disclose inefficiency at a particular blood bank.

### Voluntary donor recruitment

A Task Force on Donor Recruitment was authorized by the ABC board of directors on May 12, 1975. This task force has received most of its funds under a contract with the NHLBI of June 30, 1976. This contract, which expired September 29, 1977, provided the task force with \$112,992. In addition to these NHLBI funds, the ABC board of directors approved the expenditure of \$17,000 in ABC funds for operating the task force. The task force includes representatives from the major organizations which provide blood, as well as consumer and donor groups, various scientific disciplines, and the health care professions.

The NHLBI task force contract stated that the task force would assess current blood procurement practices and prepare a description of these practices. The task force was also to examine currently operating blood procurement systems and develop the social policy for providing blood and blood products. This policy was to consider the feasibility of establishing an all voluntary blood system in view of social welfare, public health, and economic considerations. Donor appeal strategies to be reviewed include community responsibility, predeposit, replacement, assurance, insurance, and payment to donors.

The task force is drafting a definition of volunteer donor in social, economic, and health policy terms. Also, the task force has analyzed the use of the nonreplacement fee in blood banking.

On December 12, 1977, the ABC board of directors, acting on the task force recommendation, adopted as a principle and goal the obtainment of the Nation's blood supply through community responsibility without using a nonreplacement fee. The board also agreed that a task force should be established to recommend ways of implementing these objectives.

### Blood utilization

A fifth task force, the Committee on Utilization of Blood and Blood Components, was established to coordinate and to promote the improvement and development of scientific and administrative educational programs, and to encourage recognition of the most appropriate modes for using blood and blood components in transfusions.



The committee held its first meeting in October 1976. Subsequently, the committee's primary concern has been developing a proposal for financial support. Proposals were submitted in March 1977 to NHLBI and to a private foundation. The task force was awarded a \$14,700 contract by NHLBI for a 12-month period, beginning September 26, 1977, for a feasibility and planning study on blood component use.

### Research

ABC has a Research Review Committee which reviews all grant requests and proposals submitted by ABC. The committee is charged with considering the scientific and practical merit of proposals and the clarity with which they are presented, with providing constructive criticism of the proposals, and with making recommendations to the ABC board of directors.

### Education

The individual task forces are generally responsible for providing education in their areas of responsibility. In addition, ABC has begun a series of "Consumer-Donor Briefing Sessions." These sessions are the result of a request from members of the board of directors, who represent consumer-donor groups (lay members) so that they can become fully informed about the blood banking process from recruitment of the donor to patient infusion. This knowledge should help them to participate more actively and knowledgeably in ABC decisions.

### Cost evaluation and control

As part of its operations, the National Blood Data Center plans to collect and analyze data on the costs and charges for blood. Submission of such data, however, will be voluntary.

### Inspection and accreditation

ABC does not plan to inspect or accredit individual blood banks. ABC has been conducting site visits and will begin "recognizing" regional associations as part of the activities of the Task Force on the Regional Association of Blood Banks. ABC informed us, however, that it does not characterize such activities as inspection and accreditation.

## Standards

ABC officials told us that establishing operating standards for individual blood banks is not part of ABC's mission. They indicated that the American National Red Cross and the American Association of Blood Banks are more appropriate organizations for developing such standards. The task forces are, however, developing standards relative to the matters they each are working on. For example, the Task Force on the Regional Association of Blood Banks has established standards for the range and quality of services to be provided by regional associations of blood banks.

## Plasma production and fractionation

On September 28, 1977, ABC authorized the formation of a task force to address issues of blood, plasma, and plasma derivatives, particularly with regard to the scientific, economic, and social aspects of the supply of these products. This action resulted from recommendations presented by the Ad Hoc Committee on Plasma and Plasma Supply, which had been studying these issues during the preceding 6 months.

## FINANCIAL SUPPORT FOR ABC

The American Blood Commission has relied heavily on Federal Government contracts to support its operations. Five active task forces have been funded principally by contracts administered by NHLBI. ABC financial statements and reports indicate that as of March 31, 1977, or about 2 years after its inception, it had received total revenue of about \$916,000, of which about \$519,000 (57 percent) has been from Government contracts. Moreover, ABC officials and reports published by ABC estimate that for the fiscal year ending March 31, 1978, ABC will receive revenues totaling over \$741,000, with over \$596,000 (80 percent) from Government contracts. The following schedule summarizes the support and revenue that ABC (1) received during its fiscal years ended March 31, 1976, and 1977, and (2) estimated it will receive during the fiscal year ending March 31, 1978.

<u>Source</u>	<u>Support and revenue</u>		
	<u>FY 1976</u> <u>actual</u>	<u>FY 1977</u> <u>actual</u>	<u>FY 1978</u> <u>estimate</u>
Government contracts	\$128,923	\$390,384	\$541,729
Membership dues	141,375	143,562	145,000
Private foundation grants	100,000	-	40,000
Miscellaneous	4,125	7,409	39,000
<b>Total support and revenue</b>	<b><u>\$374,423</u></b>	<b><u>\$541,355</u></b>	<b><u>\$765,729</u></b>

The \$39,000 estimate included as miscellaneous revenue for fiscal year 1978 represents income from the ABC sponsorship program. This program was instituted in March 1977 to allow individuals and organizations which are ineligible for ABC membership to provide financial support to ABC and to be recognized as sponsors.

The Federal Government has awarded ABC more than \$1 million in contract funds; about one half of this amount has been for developing the National Blood Data Center. Originally, ABC had also planned to request contract funding for the center for an additional 2 years at an estimated \$1.7 million. However, HEW officials told us that the data center will probably not receive the projected amount. An NHLBI official indicated that the data center will probably receive funding for 1 more year at a level somewhat higher than the current contract of \$396,890. ABC has advised us that a more precise estimate is being made.

When fully operational, the National Blood Data Center is expected to be self-supporting. Annual operating expenses are estimated to be \$993,609 a year, which the task force expects will be funded through user fees. A task force report estimates that \$625,000 of this amount would be paid by Federal Government users--\$250,000 from NHLBI, \$250,000 from the Food and Drug Administration (FDA), \$50,000 from the Health Care Financing Administration (HCFA), \$50,000 from other Federal health agencies, and \$25,000 from miscellaneous other Federal agencies. Payments received from FDA are expected to be data for the center's use rather than cash.

With respect to NHLBI purchasing \$250,000 of services annually from the data center, an NHLBI official stated that he does not anticipate NHLBI needing that amount of data from the data center.

With respect to continuing the contract agreements between ABC and NHLBI, an NHLBI official told us that the Institute has received pressure from the scientific community--especially from persons associated with AABB--stating that too much Government money earmarked for research is going to ABC. Also, prior to awarding a contract for the initial NHLBI funding of three ABC task forces, the NHLBI Project Officer stated that monies for support of these specific proposals should be considered as "seed" money, providing early support to ABC while it develops its own resources. He stated that ABC will be expected to develop internal funding sources to implement the recommendations resulting from these activities.

ABC receives much of its financial support from NHLBI and has indicated its deep appreciation of this support. ABC has expressed its concern, however, that either a misunderstanding or lack of sympathy exists with representatives of NHLBI regarding the primary purpose of ABC. That purpose is to create a consensus among members of the private blood banking community as to how they will work together to implement the National Blood Policy. According to ABC this need for consensus has been reflected in contract proposals which called for regularly scheduled meetings of task force members to consider data, debate, and develop proposals for acceptance by blood banking communities. However, NHLBI has reduced moneys awarded for these meetings from the amounts originally requested.

An NHLBI official told us he believes that ABC is holding back and not moving forward. He stated that ABC is "muddling around" trying to bring together differing factions of the blood banking community and trying to promote good will among them.

### INHIBITING FACTORS

As part of our review, we discussed factors inhibiting the progress of ABC with officials from HEW, ABC, AABB, CCBC, and ANRC. These officials informed us of five factors which they believed may inhibit the progress of ABC. These include:

- Money to support operations.
- Disagreement between AABB and ANRC.
- Resistance to regionalization, especially by suppliers in areas which have more than one blood supplier.

--Problems in obtaining data from certain blood banks.

--Lay members' lack of knowledge regarding blood banking.

### Money

Obtaining money to support its operations has been difficult for ABC. The Federal Government has been, and ABC expects it to be, the primary source of funds. As stated on page 13, criticism has been expressed that too much Government money which was earmarked for research is going to ABC. We have also been informed by various officials that AABB was instrumental in limiting the maximum membership fee for ABC members to \$15,000 a year and in preventing the financing of ABC by means of a surcharge on each unit of blood. Members representing consumer groups also opposed using a surcharge.

In addition, we were informed that AABB is opposed to ABC's request for a Federal charter. According to ABC officials, a Federal charter should increase its chances to obtain funds from private foundations. An ABC Finance Committee member stated that without support, either from the Government or from a surcharge on blood collections, ABC will be weak.

### Disagreement between AABB and ANRC

An ABC official told us that disagreement between the two largest suppliers of blood--ANRC and AABB--is another inhibiting factor. ANRC philosophy is that providing blood is a community responsibility--that is, the community must supply enough blood to meet its own needs. The AABB concept is that providing blood is an individual responsibility, with each individual planning for his or her own blood needs through a predeposit donor group or replacing units used with donations from friends and relatives. These differing concepts and the resultant paperwork involved in accounting for individual blood debits and credits are among the reasons given us by ANRC for its withdrawal, effective October 19, 1976, from the AABB National Clearinghouse Program.

According to AABB, its National Clearinghouse Program is voluntary, thus enabling donors almost anywhere in the United States to voluntarily replace blood for patients who have been hospitalized in other areas. In addition,

the clearinghouse facilitates the "borrowing and lending" of blood between banks which have shortages and surpluses. By recording all inter-blood bank transactions, the clearinghouse can settle amounts due and amounts owed by the various blood banks.

### Resistance to regionalization

As noted on page 1, the National Blood Policy calls for attaining specific improvements in blood banking to achieve the policy's goals. One prominent improvement is the regionalization of blood collection and distribution. Also, as noted on page 6, the ABC Task Force on the Regional Association of Blood Banks believes that regionalization is the best way to achieve an effective and efficient blood service system.

An NHLBI official told us, however, that much opposition to regionalization exists, especially from areas containing multiple suppliers of blood.

An ABC official informed us that, in her opinion, areas with multiple suppliers of blood could regionalize. However, she did not believe that two different donor appeal strategies could be used within the same region. Apparently appeals for donations as part of community responsibility are incompatible in the same region as appeals for donations to cover individual needs, and vice versa.

### Problems with obtaining data from blood banks

A report of the American Blood Commission's National Blood Data Center Task Force states that the National Blood Data Center will succeed only with broad, voluntary participation by the blood service community. Statements by officials of HEW and NHLBI indicate, however, that the data center may not get sufficient participation to succeed.

As previously noted, an NHLBI official said that some information needed by the center is guarded by some blood banks because it could disclose their level of efficiency. He also stated that some blood banks do not collect the kind of information that would be needed by such a system. This would cause accounting problems and additional costs for blood banks to gather the data.

An HEW official informed us that AABB objects to FDA's collecting certain data that the Food and Drug Administration needs regarding blood banking facilities and personnel. If it is to be successful the data center will also

need the same data. He indicated that, in his opinion, AABB would also object to providing this data to the data center.

ABC said that the task force is conducting a feasibility study to consider the ability of blood banking establishments to provide data and ways the Center can enhance this ability. The study also will evaluate participation incentives and various means of maintaining privacy of data provided.

Lay members' lack of knowledge  
with regard to blood banking

An ABC official also said that the lay members' lack of knowledge regarding blood banking was an inhibiting factor. At the request of these members, ABC has started a series of special briefing sessions so that they can participate more actively and knowledgeably in commission decisions. (See p. 10.)

### CHAPTER 3

#### DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

##### EFFORTS TO IMPLEMENT THE NATIONAL BLOOD POLICY

Several elements of the Department of Health, Education, and Welfare are involved in implementing the National Blood Policy. These include:

- The Office of the Assistant Secretary for Health, which developed the policy.
- The National Heart, Lung, and Blood Institute, National Institutes of Health, which supports research pertaining to blood and blood banking.
- The Food and Drug Administration which regulates blood banks.

Also, the implementing strategy for the National Blood Policy states that the Federal Government will call on the Social Security Administration (SSA) to use its auditing and accounting procedures, developed under the Medicare program, to show the relationships between costs of and charges for blood services. The Health Care Financing Administration (HCFA), established on March 8, 1977, now has this responsibility. HEW and HCFA officials told us that neither SSA nor HCFA had started to develop this information. Also, HCFA officials told us that they were unaware of such a provision in the implementing strategy for the National Blood Policy, nor had they been called on to show the relationships between costs and charges for blood services.

##### OFFICE OF THE ASSISTANT SECRETARY FOR HEALTH

An official from the Office of the Assistant Secretary for Health informed us that currently the Office's role regarding the National Blood Policy is to convince the private sector to implement the policy. Recent projects in which the Office has been involved have included:

- Supporting the National Blood Policy against our recommendation that the policy be modified to allow blood banks to collect paid blood if they can show valid records of having supplied high quality blood. (See p. 2.)



--Defending the National Blood Policy against criticism from the Council of Wage and Price Stability regarding the policy's goal of eliminating all paid blood.

--Defending HEW and ABC against a lawsuit brought by the American Blood Resources Association seeking dissolution of the American Blood Commission. The General Counsel for the American Blood Resources Association informed us that the Association was not permitted to (1) participate in meetings of the ad hoc committee for establishing ABC or (2) see the minutes of those meetings or correspondence between an HEW official and the ad hoc committee. The U.S. District Court for the District of Columbia ruled in favor of HEW and ABC on June 21, 1976.

### NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

An official of NHLBI advised us that the Institute's principal responsibility in implementing the National Blood Policy has been supporting five American Blood Commission task forces. These task forces are discussed in chapter 2 of this report. In addition, NHLBI supports grants and contracts that indirectly impact on the National Blood Policy. For example, NHLBI is funding a project to develop a low cost procedure to obtain plasma from voluntary donors in a period equivalent to that required for whole blood donation. At present, plasma donation is a long, involved process, and it is difficult to get people to volunteer for it. Therefore, most plasma comes from donors who are paid by commercial establishments. Overall, such donors have a higher risk of transmitting hepatitis to recipients than do volunteer donors.

### FOOD AND DRUG ADMINISTRATION

Federal laws require blood and blood products to be safe, pure, potent, and effective. Responsibility for regulating blood and blood products has been delegated to FDA by the Secretary of HEW. Regulations require that blood banks which ship blood in interstate commerce or are located in the District of Columbia, be inspected at least once every year and that other blood banks be inspected every 2 years. These inspections generally include evaluating donor suitability, blood collecting techniques, and laboratory procedures.

FDA activities pertaining to implementing the National Blood Policy include (1) proposals made in the Federal Register to require that units of blood be labeled as coming

from paid or volunteer donors and (2) the design and implementation of a data collection and retrieval system pertaining to blood collection centers and transfusion services.

In the November 14, 1975, Federal Register (40 F.R. 53040), FDA proposed that a label be affixed to each unit of whole blood or red blood cells, stating the paid or voluntary status of the donor. Also, the label should include the statement: "Blood collected from paid donors is associated with a higher risk of transmitting hepatitis than blood from volunteer donors." According to the agency, no basis exists for outlawing paid donors. The proposal was aimed at reducing hepatitis by enlightening prescribing physicians and anticipating a reduction in paid donor blood use.

FDA received 342 letters commenting on this proposal. A majority of the comments recommended that the proposal be reissued to include a proposed definition for the terms "paid donor" and "volunteer donor." A number of comments also recommended that the proposed labeling requirement be extended to include all other blood components, source plasma (human), and plasma derivatives produced from such products.

Many comments objected to the proposed requirement concerning the warning statement that blood collected from paid donors provides a higher risk of transmitting hepatitis than blood from volunteer donors. These comments stated that blood from paid donors is not always associated with an increased risk of posttransfusion hepatitis.

In the February 25, 1977, Federal Register (42 F.R. 11018), FDA repropoed the regulation to require that each container of whole blood and blood component 1/ intended for transfusion shall bear the label statement, "paid donor" or "volunteer donor," as applicable. The reissued proposal did not provide for including the warning statement concerning blood from paid donors being associated with a higher risk of transmitting hepatitis.

The reissued proposal also included definitions for the terms "paid donor" and "volunteer donor." Paid blood donors were defined as donors who receive monetary payment for their donations. Benefits, such as time off from work, membership

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1/Blood components are listed in the February 25, 1977, Federal Register as red blood cells, cryoprecipitated antihemophilic factor, platelet concentrate, and single donor plasma.

in blood assurance programs, and cancellation of nonreplacement fees that are not readily convertible to cash were not considered monetary payment for blood donations. Volunteer blood donors do not receive monetary payment for blood donation. On January 6, 1978, FDA issued a final ruling enacting the reproposal (43 F.R. 2142). The regulation becomes effective May 15, 1978.

Another FDA activity pertaining to the National Blood Policy is the design and implementation of a data collection and retrieval system, made up of data related to the location, size, type, and function of all blood collection centers and transfusion services in this country and a file of deviations found during inspections carried out by FDA inspectors. This system is called the Blood Establishment, Inspection, and Registration System. One of the goals of the system is to provide local, regional, and national views of the adequacy of the existing blood supply and the blood service complex's ability to meet present and future needs.

ABC's National Blood Data Center Task Force believes that FDA's system will not collect all essential data for effectively planning the implementation of the National Blood Policy. The task force further believes the FDA system will not assess the performance of individual blood service units and the national blood service complex and will not adequately inform consumers. They noted that FDA's general counsel prohibited that agency from requiring submission of data on costs and charges for blood and blood products. Also, the task force believes that other important information, particularly regarding donor recruitment and motivation, would also be beyond the scope of FDA's legal charge. In addition, the ABC task force notes that FDA's system gathers data only from blood banks. Moreover, the chairman of the task force has indicated that it is beyond FDA's legislative authority to integrate data from other sources with FDA data or to perform the necessary analysis for identifying and applying measures so that an individual blood service establishment can compare its performance with comparable blood service establishments.

According to the task force chairman, the National Blood Data Center plans to obtain data from FDA, collect other necessary data, and provide the professional staff and analytical skills needed to provide information to blood service professional associations, consumers, and the Government.

HEW and American Blood Commission officials told us that needless duplication in the collecting and processing of data by the FDA system and the National Blood Data Center

will not exist. ABC plans call for information collected by the FDA system to be provided to the data center in exchange for services provided to FDA by the data center.

## CHAPTER 4

### CONCLUSIONS, RECOMMENDATIONS, HEW AND ABC

#### COMMENTS, AND OUR EVALUATION

##### CONCLUSIONS

At the time of our review, the American Blood Commission had been primarily involved in developing standards, guidelines, and procedures that pertain to blood banking, and to a limited extent, it had been testing these standards, guidelines, and procedures. ABC had also been involved in developing consensus among all segments of the blood service community. We believe that the effectiveness of efforts to implement these standards, guidelines, and procedures will be a good indication of ABC's ability to implement the National Blood Policy. However, it should be noted that several factors affecting ABC will make implementation difficult.

Principal among these is financing. The plan adopted for implementing the National Blood Policy states that ABC is to become largely self-supporting, although grants from private organizations or the Federal Government will be needed initially to help defray nonrecurring costs. As noted in chapter 2, ABC is largely being supported by the Federal Government at the present time. Also, efforts by ABC to increase its other sources of support either as a surcharge on each unit of blood or an increase to the maximum amount chargeable for membership in ABC, have been unsuccessful. Moreover, statements by HEW officials indicate that Federal funds for implementing these standards, guidelines, and procedures may not be provided or may be provided at a level below that anticipated by ABC officials.

Disagreement between the American National Red Cross and the American Association of Blood Banks may also inhibit the implementation of the recommendations developed by ABC and its task forces. For example, regionalization requires active participation of all blood suppliers within a region. Without such cooperation, it appears that regionalization will not be very effective. Other factors which are inhibiting the progress of ABC are (1) resistance to regionalization, especially by suppliers in areas with more than one supplier of blood, (2) problems in obtaining data from certain blood banks, and (3) lay members' lack of knowledge regarding blood banking.

According to an HEW report, the Federal Government's role in implementing the National Blood Policy includes regulation, research, maintenance of needed data and information systems, and development of the relationships between costs and charges for blood services. As noted in chapter 3, the Health Care Financing Administration has yet to develop the relationships between costs and charges for blood services. The report also notes that the rational alinement of charges and costs for blood services is one of the three prominent improvements needed in blood banking to achieve the goals of the National Blood Policy. Thus, it appears that HEW is not taking action in this area which it has identified as important to implementing the National Blood Policy, and for which it has identified one of its component agencies as having a major role. In addition, the National Blood Policy states that if the private sector is unable to progress satisfactorily toward implementing the National Blood Policy, a legislative or regulatory approach will have to be considered.

#### RECOMMENDATIONS TO THE SECRETARY OF HEW

We recommend that the Secretary:

- Closely monitor ABC's progress in implementing the National Blood Policy. If the Secretary is not satisfied with this progress, he should consider a legislative or regulatory approach to implementing the National Blood Policy.
- Instruct the Administrator, Health Care Financing Administration, to determine whether its auditing and accounting procedures can be used to develop the data necessary to show the relationships between costs of and charges for blood services, and if it can be done, to report the relationships to the Secretary of HEW. If such a determination cannot be made, he should report why it cannot. The report should be made within 6 months from the date of our report.

#### HEW COMMENTS AND OUR EVALUATION

By a letter dated November 18, 1977, HEW said it generally agreed with our findings, conclusions, and recommendations. (See app. I.)

HEW agreed with our recommendation for closer monitoring of ABC's progress in implementing the National Blood Policy and said it believed such evaluation should be feasible within the next year.

With regard to our recommendation for developing data on the relationships between costs and charges for blood services, HEW said that (1) it would direct HCFA to develop auditing and accounting procedures that show these relationships and (2) a report would be made to the Secretary as expeditiously as possible.

We believe that HEW's proposed actions represent a favorable response to our recommendations. We plan to monitor HEW's progress to assure that such action is taken in an expeditious manner.

#### ABC COMMENTS AND OUR EVALUATION

In a letter dated November 7, 1977, ABC commented on our draft report. (See app. II.) The Commission did not specifically address our recommendations, but offered several comments dealing with matters discussed throughout the report. ABC also presented information on activities that occurred after we submitted our draft report to the Commission on September 7, 1977. Where appropriate, we have incorporated such information in our final report.

Several of ABC's comments were directed toward our conclusions concerning factors which could inhibit ABC's effectiveness in implementing the National Blood Policy.

With regard to lay members' lack of knowledge of blood banking, ABC stressed the importance of such participation in providing a necessary balance and perspective to policy formulation. We recognize the value of such participation in ABC, and we have not concluded that ABC should not have such representation. Our comments relate to the need to educate such members so that they can participate more effectively. As noted on page 10 of our report, ABC has already recognized this need by starting a series of special briefing sessions to better educate lay members.

In commenting on efforts to build a national blood data system, ABC said that participation by every facility in the blood service community was an unsupported criterion for success. We are not suggesting that full participation is essential. Our discussion of factors inhibiting success is based on comments from HEW officials concerning potential problems in obtaining certain information from blood banks. In this regard, ABC noted in its comments that it had undertaken a study to address this issue.

ABC disagreed with our conclusion that the existence of differing donor appeal strategies in a region could inhibit the achievement of regionalization. ABC said that the task force on regionalization had recommended that each region develop a coordinated donor recruitment policy. According to ABC, this criterion for regionalization is aimed at eliminating any existing confusion between appeal strategies rather than calling for the elimination of different approaches to recruiting donors. In our opinion, the existence of different donor appeal strategies is in itself a significant cause of confusion by the public. In this regard the report of the task force on regionalization stated that:

"Although it may be appropriate for blood to be collected from donors in more than one blood service unit, the plan [for a regional association] should eliminate conflicting programs for donors by the collecting facilities."

In regard to our recommendation discussing HCFA's development of data on costs and charges for blood services, ABC noted that the National Blood Policy is of importance to still other agencies within HEW. We recognize that other agencies have responsibilities relating to the policy and have discussed these matters in our report. We have referred to HCFA in this instance solely because that agency is now the organization responsible for developing the needed data.





DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE  
OFFICE OF THE SECRETARY  
WASHINGTON, D.C. 20201

NOV 18 1977

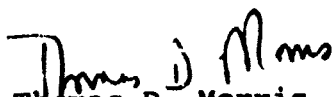
Mr. Gregory J. Ahart  
Director, Human Resources  
Division  
United States General  
Accounting Office  
Washington, D.C. 20548

Dear Mr. Ahart:

The Secretary asked that I respond to your request for our comments on your draft report entitled, "Department of Health, Education, and Welfare; and American Blood Commission Efforts to Implement the National Blood Policy." The enclosed comments represent the tentative position of the Department and are subject to reevaluation when the final version of this report is received.

We appreciate the opportunity to comment on this draft report before its publication.

Sincerely yours,

  
Thomas D. Morris  
Inspector General

Enclosure

COMMENTS OF THE DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE (DHEW)  
ON THE COMPTROLLER GENERAL'S DRAFT REPORT ENTITLED "DHEW AND AMERICAN  
BLOOD COMMISSION EFFORTS TO IMPLEMENT THE NATIONAL BLOOD POLICY"

GENERAL COMMENT

The Department is in general agreement with the findings, conclusions, and recommendations contained in the report. It accepts the report as a document developed from a different perspective and, therefore, it is an important source of assistance in evaluating the efforts to implement the National Blood Policy. To this extent it is also an important source of assistance in assuring the implementation of the Policy.

GAO RECOMMENDATION

We recommend that the Secretary closely monitor the progress being made by the ABC toward implementing the National Blood Policy. If the Secretary is not satisfied with the progress being made he should consider a legislative and/or regulatory approach to implementing the National Blood Policy.

DEPARTMENT COMMENT

The Department has been closely monitoring the progress of the American Blood Commission in implementing the National Blood Policy, but believes that the Commission has not been in existence long enough to allow a definitive judgment as to whether or not the Commission can achieve all that is expected of it without legislative and/or regulatory assistance. We believe that such evaluation should be feasible within the next year and shall be watching the activities of the Commission with this in mind.

GAO RECOMMENDATION

We recommend that the Secretary instruct the Administrator, Health Care Financing Administration to determine whether its auditing and accounting procedures can be used to develop the data necessary to show the relationships between costs of and charges for blood services, and if it can be done to report the relationships to the Secretary, HEW. If such a determination cannot be made he should report why such a determination cannot be made. The report should be made within six months.

DEPARTMENT COMMENT

The Department acknowledges that its auditing and accounting procedures have not been designed to show the relationships between costs of

and charges for blood services. It acknowledges also that public confidence in the relationship of charges to costs in this area is important to the assurance of an adequate supply of voluntary donors. . Because the health care financing authorities of the Department require that the charges paid be identifiable with costs incurred in the provision of health care and because the public's confidence in the relationships of charges to costs must be assured, the Health Care Financing Administration will develop auditing and accounting procedures that do indeed show these relationships for blood services. A report will be made to the Secretary as expeditiously as possible on the relationship between costs and charges for blood services.

# American Blood Commission

1901 North Ft. Myer Drive, Suite 300  
Arlington, Va. 22209  
(703) 522-8414

November 7, 1977

Dear Mr. Ahart:

On behalf of the American Blood Commission and as you requested, I am sending to your attention the following comments on the draft of a proposed GAO Report: "Department of Health, Education and Welfare; and American Blood Commission Efforts to Implement the National Blood Policy".

The Commission's comments are divided into two categories. Section I deals with the broader conclusions presented in the draft GAO Report (hereinafter referred to as the Report). Section II includes new information not available to GAO staff at the time they conducted their study, as well as refinements of information presented in the Report. These latter comments are provided to the GAO in the hope that GAO will find them useful in preparing as timely and accurate a report as possible, given the dynamic characteristics of the environment within which the National Blood Policy is being implemented.

## 1 - GENERAL COMMENTS ON GAO CONCLUSIONS

- (1) Page 1a of the Report addresses the National Blood Policy's call for the transition to an all-voluntary blood donation system, and the GAO's 1976 report calling for a modification of that objective. This section of the Report concludes with the statement that "HEW did not agree with our (GAO) recommendation and continues to support the position that all paid blood should be eliminated".

The Commission continues to have as a primary goal the full development of a volunteer blood donation system. The National Blood Policy called for an all-voluntary blood donor system for two reasons: it was felt this was necessary as the proper ethical climate for blood donation, and that the quality of blood would be improved as the amount of blood which was collected from paid donors decreased. While it is recognized that under certain circumstances, blood from compensated donors is as safe as that from volunteer donors, it is widely accepted that the safest blood generally is obtained from voluntary donors.

In support of these comments, I would respectfully draw your attention to the report submitted by the Acting Secretary of Health, Education, and Welfare to Congress on May 1, 1973, describing the plan for a National Heart, Blood Vessel, Lung and Blood Program.

[See GAO note, p. 36.]

TASK  
FORCES  
&  
COMMITTEES

Donor  
Recruitment  
522-8422

Regional  
Association of  
Blood Service  
Units  
522-8436

Commonality  
in Blood  
Banking  
Automation  
522-8430

National Blood  
Data Center  
522-8434

Utilization of  
Blood and  
Components  
522-8414

- (2) The Report (Pages iii, 22, 26, 35) concludes that "lay members' lack of knowledge with regard to blood banking" is an "inhibiting factor" in the progress of the Commission. An essential aspect of the ABC's philosophy is the importance of consumer involvement. By bringing together such groups as medical professionals, volunteers who donate blood, patients who use blood, and those who finance the use of health care services, the ABC is representative of the private sector. The Report's conclusion that the effectiveness of a broadly based coalition of medical professionals, and consumers and donors is inhibited precisely because of the participation of the consumers and donors, seems inconsistent with broader federal health policy that encourages active consumer involvement at local, state, and federal levels both in the formulation of health policy, and in the improvement of health care delivery.

It should be emphasized firmly and unequivocally that the Commission is the private sector's instrument for effecting the implementation of public policy. As such, the Commission emphatically must affirm its representativeness of the health care consumer and the population of blood donors, as well as of the scientific, medical, and financial communities. It cannot be over-emphasized that, in concert with the blood banking professionals, the consumer and donor member organizations of the Commission constitute the Commission's strength. And, in offering the lay viewpoint, they provide a necessary balance and perspective to policy formulation.

In addition, this conclusion of the Report is one instance of several throughout the document which apparently are based on comments by, and opinions of, unnamed individuals. Without refuting the validity of these individual opinions, it seems clear that further confirmation of many of these observations would be necessary to substantiate and support such comments and conclusions.

- (3) Included in the Report's observations of certain factors which are inhibitory to the Commission's progress is the existence of "bickering between the two largest suppliers of blood" (Pages iii, 24, 35).

While it is true that significant differences in philosophy exist in blood banking, and deeply held and opposing convictions are characteristic of the principal blood banking organizations, exception must be registered to the conclusion that such ideological disputes constitute "bickering". As the Report recognizes, the Commission is engaged in building consensus in the blood banking community, and this is often a difficult task in an environment of such profoundly held beliefs. While the Report conceivably may conclude that the Commission's progress in implementing the National Blood Policy might be swifter in the absence of such differences, the seemingly cavalier depiction of the motiva-

tions and positions of member organizations of the Commission is unsatisfactory, and the application of the concept of "bickering" to these consequential problems seems unwarranted.

It should be added that the issue representing the widest gulf between viewpoints within the Commission generally is acknowledged to concern the use and utility of the non-replacement fee in blood banking. If resolved within the Commission, the dissipation of this issue is likely to dispel for a considerable period any accuracy associated with the perception that discussion and resolution of issues constitutes "bickering".

- (4) In its discussion of the Commission's efforts to build a national blood data system, the Report (Pages 13 and 25) appears to assume that if participation in the proposed National Blood Data Center is voluntary, the Data Center will, therefore, only be partially successful. Participation in the data system by every facility and establishment in the blood service community is a rigid and unsupported criterion for the Data Center's success. The Commission's Task Force on a National Blood Data Center currently is engaged in a feasibility study to investigate just this issue. The design of the system will take into consideration the ability of the establishments to provide data, and ways in which the Center might enhance this ability. The study is also evaluating incentives for participation and the varied means of maintaining privacy of data for individual establishments.
- (5) The Report's observation (Page 17) that the "ABC has thus far ignored" the issues of plasma production and fractionation is misleading, in that it indicates that the Commission failed to address this important area.

In fact, the National Blood Policy clearly states that "Although this comprehensive policy (the National Blood Policy) accelerates the evolution of an all-voluntary supply of blood and blood components, it leaves untouched, for the time being, the commercial acquisition of plasma and the preparation and marketing of plasma derivatives, and the commercial acquisition of blood for preparation of diagnostic reagents. This distinction is necessary because of the enormous size and complexity of the plasmapheresis and plasmafractionation industry, and a lack of sufficient information and expertise upon which to make policy recommendations. The Policy will, however, promote the acquisition of information upon which future policy could be developed."

Rather than ignoring the complex issues related to the plasma supply, the Commission has attended the issue on an incremental and evolutionary basis. In point of fact, the Commission's Board of Directors, at its September 28, 1977 meeting, authorized the formation of a task force to address the issues of blood, plasma, and plasma derivatives, particularly with regard to the scientific, economic, and social aspects of the supply of these products. This action

by the Board of Directors resulted from recommendations presented to the Board by the Commission's Ad Hoc Committee on Plasma and Plasma Supply, which had been studying these issues during the preceding six months.

- (6) The Report observes (Pages 24a-25) that an example of possible "resistance to regionalization", appears to be that "appeals for donors to donate as a part of their community responsibility cannot be used in the same region as appeals for donors to donate in order to cover their individual needs, and vice versa". This observation follows the Report's statement that in the opinion of an ABC official, two different types of donor appeal strategies could not be used within the same region.

In order to eliminate competition for voluntary donors, the Report of the Task Force on Regional Association of Blood Service Units of the American Blood Commission, July 15, 1976, recommends that each region should "develop a coordinated donor recruitment policy". The Task Force Report continues to say that a coordinated policy for recruiting donors, as an integral part of a region's coordination of services provided by multiple functional units, will be an effective mechanism for eliminating confusion by the public over conflicting donor recruitment programs. The Task Force Report further states that "This does not mean that only one facility can collect blood from donors, but it does mean that all donor recruitment efforts must be coordinated to assure donors that their contributions will be used with maximum effectiveness".

Therefore, the criterion for regionalization should not in and of itself be met with opposition, "especially from areas in which there are multiple suppliers of blood", as the GAO Report suggests. The criterion aims at eliminating any existing confusion between the appeals and messages generated by community responsibility and individual responsibility recruitment systems, and any competition for donors, rather than calling for the elimination of different approaches to recruiting donors.

- (7) While in no sense disagreeing with the Report's recommendation that the Secretary should cause action to be taken by the Health Care Financing Administration to relate the costs of blood services to the charges for these services, it is felt that the point should be made that the National Blood Policy is of importance to still other agencies within HEW.

For example, the Commission is concerned with improving the management of the nation's blood services in order to achieve an adequate and safe blood supply. The Commission is, in addition, aware that effective methods of motivating the nation's blood donors are necessary to assure a sufficient supply of voluntarily donated blood, and that the development of regional organizational networks for the delivery of blood services, and the continued examination of management and technical issues are necessary for the successful implementation of the National Blood Policy. It is felt that, for these reasons, other agencies within HEW, such as the Health Resources Administration and the Health Services Administration, also have a responsibility in fulfilling HEW's commitment to achieving the goals of the National Blood Policy through support of planning and program development.

#### II - COMMENTS ON SPECIFIC ITEMS IN THE REPORT

- (1) The Report states (Page 6) that, as of September 14, 1976, the ABC had six task forces and refers (Page 18) to "four of the six active task forces". In fact, the ABC has had a total of five task forces and committees that are roughly equivalent to task forces: Task Force on Donor Recruitment, Task Force on Regional Association of Blood Service Units, Task Force on a National Blood Data Center, Committee for Commonality in Blood Banking Automation, and Committee on Utilization of Blood and Blood Components. The inaccuracy of the Report on this issue appears to be tied to a statement (Page 16) that "In addition to the above described task forces, the ABC has a Research Review Committee which reviews and oversees all grant requests and proposals submitted by ABC". The Research Review Committee is not a task force-equivalent committee, however. The distinction lies in the fact that committees of the Board, of which the Research Review Committee, the Nominating Committee, and the Bylaws Committee are examples, are created to carry out particular affairs of the Commission, under authority delegated by the Board. Task forces, on the other hand, are responsible for recommending plans and actions for the



implementation of the scientific and educational purposes of the Commission, pursuant to the goals of the National Blood Policy.

- (2) The Report states (Page 7a) that the Committee for Commonality in Blood Banking Automation (CCBBA) is field testing blood bag labels "at fifteen blood facilities". In fact, field testing of the blood bag labels was conducted at sixteen participating sites. Ten of the sites were blood centers, while six were hospitals.

It should be noted that at this time, research and development of a blood bag labeling system has been completed by CCBBA at the field sites. The contract in support of the CCBBA work has been extended (with no extension of funds) to November 30, 1977 to allow for completion of the CCBBA's series of final reports.

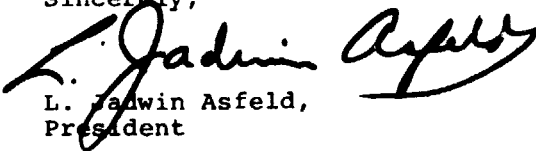
- (3) Concerning the composition of the first-year Task Force on Regional Association of Blood Service Units, the Report states (Pages 7b-C) that the membership included "providers of health insurance". One member of the Task Force was a former executive with Blue Cross/Blue Shield of Greater New York.
- (4) Since the Report was prepared, the Commission was awarded a contract from the National Heart, Lung, and Blood Institute in response to its renewal proposal, "Operating Relationship and Resource Sharing of Blood Banking Services on a Regional Basis". The two-year contract in the amount of \$192,204 went into effect on October 1, 1977.
- (5) Since the Report was prepared, the National Blood Data Center Task Force has received a no-cost extension of its contract to February 28, 1978. The Report (Page 10) states that this contract was scheduled to terminate on November 30, 1977.
- (6) The Report states (Page 11) that "The task force (on a National Blood Data Center) has unanimously recommended the establishment of an independent National Blood Data Center". It should be noted that the contract currently supporting the Task Force has as one of its objectives the development of plans for a governing body for the proposed Data Center. At this time, plans for the organization and characteristics of the Data Center and its eventual relationship with the Commission are being considered within the Commission.

- (7) As one of the activities of the National Blood Data Center Task Force, "designing a computer system" is a more accurate characterization of the work being performed than "selecting a computer system". (Page 12 of the Report)
- (8) Concerning the Task Force on Donor Recruitment (Pages 14-15 of the Report), it should be noted that the Task Force has analyzed the use of the non-replacement fee in blood banking. The Task Force's recommendations, accompanied by two minority reports, are now being considered by the members of the Commission, and will be placed before the Board of Directors for action on December 12, 1977.
- (9) Since the Report was prepared, the Committee on Utilization of Blood and Blood Components (Page 15 of the Report) has received funding from the National Heart, Lung, and Blood Institute for a feasibility and planning study in the area of blood component utilization. The \$14,700 contract is for a twelve-month period, beginning September 26, 1977. This planning process will concentrate specifically on the area of blood utilization. It is not expected that the Committee will give attention to the area of plasma production and fractionation at this time, as the Report indicates (Pages 17 and 18). Rather, the issues related to plasma are more appropriately under the purview of the recently authorized plasma task force, as indicated previously in this letter.
- (10) Concerning the Report's characterization (Page 16) of the duties of the Research Review Committee as involving an "overseeing" of "ABC proposals", a more accurate description of this Committee's responsibilities is that the Committee is charged with considering the scientific and practical merit of Commission proposals, and the clarity with which they are presented, with providing constructive criticism of the proposals, and with making recommendations to the Board of Directors.
- (11) The Report states (Page 16) that the Commission may "inspect and accredit regional associations". In connection with the Commission's ongoing interests and activities in the development and encouragement of regional associations of blood service units, the Commission has been conducting "site visits" and will begin "recognizing" associations. "Inspection and accreditation" are, therefore, misleading descriptions of the Commission's activities.

- (12) The Report refers (Pages 17 and 34) to the development of "standards" by Commission Task Forces. While it may seem a semantic battle, nevertheless, it is felt that "standards" are generally recognized as connoting a more technical function, and are established by authority as a rule to measure quality or performance. A more accurate description of the Commission's work is provided by the use of the word "criteria" rather than "standards".
- (13) The Report states (Page 20) that HEW officials have commented that the "data center will probably not receive the amount they are projecting". At the time the Report was prepared, the \$1.7 million referred to was a rough budgetary projection. At this time, more precise budget projections are being made by the Commission in conjunction with the development of a proposal for contract renewal for continued support of the development of the proposed Data Center.
- (14) Regarding the inference (Page 26) that the AABB would object to providing data on blood banking facilities and personnel because the "AABB is objecting to the collection by FDA of certain data that it needs on blood banking facilities and personnel", it is not clear that this statement is substantiated. The feasibility study being performed by the Commission's Task Force on a National Blood Data Center is addressing the attitude of this national organization and of its membership towards participating in the proposed Data Center.

It is hoped that the General Accounting Office will find the preceding comments to be useful in preparing its Report to the Secretary of Health, Education, and Welfare. Thank you for your courtesy in allowing the Commission to comment.

Sincerely,



L. Edwin Asfeld,  
President

Mr. Gregory Ahart  
Director  
Human Resources Division  
U. S. General Accounting Office  
Washington, D. C. 20548

GAO note: Page references in this appendix refer to the draft report and do not necessarily agree with the page numbers in final report.

MEMBERSHIP OF THE AMERICAN BLOOD COMMISSIONJULY 1977

American Association of Blood Banks  
 American Association for Clinical Chemistry  
 American Association of Foundations for Medical Care  
 American Association of Professional Standards Review  
     Organizations  
 American Cancer Society  
 American College of Emergency Physicians  
 American College of Physicians  
 American College of Surgeons  
 American Federation of Labor--Congress of Industrial  
     Organizations  
 American Heart Association  
 American Hospital Association  
 American Legion  
 American Medical Association  
 American National Red Cross  
 American Nurses' Association  
 American Osteopathic Association  
 American Osteopathic College of Pathologists  
 American Society for Medical Technology  
 American Society of Anesthesiologists  
 American Society of Clinical Pathologists  
 American Society of Hematology  
 American Surgical Association  
 Association of American Cancer Institutes  
 Association of Operating Room Technicians  
 Blue Cross Association  
 Catholic Hospital Association  
 College of American Pathologists  
 Communications Workers of America  
 Cooley's Anemia Foundation  
 Council of Community Blood Centers  
 International Union, United Automobile and Agricultural  
     Workers of America  
 Leukemia Society of America  
 National Association of Manufacturers  
 National Association of Patients on Hemodialysis and  
     Transplantation  
 National Association for Sickle Cell Disease  
 National Hemophilia Foundation  
 National Kidney Foundation  
 National Medical Association  
 National Retired Teachers Association--American Association  
     of Retired Persons  
 Pharmaceutical Manufacturers Association

Society for Cryobiology  
United Way of America  
Veterans Administration

PRINCIPAL DEPARTMENT OF HEALTH, EDUCATION,  
AND WELFARE OFFICIALS RESPONSIBLE FOR THE  
ACTIVITIES DISCUSSED IN THIS REPORT

	<u>Tenure of office</u>	
	<u>From</u>	<u>To</u>
<b>SECRETARY OF HEALTH, EDUCATION, AND WELFARE:</b>		
Joseph A. Califano	Jan. 1977	Present
David Mathews	Aug. 1975	Jan. 1977
Caspar W. Weinberger	Feb. 1973	Aug. 1975
Frank C. Carlucci (acting)	Jan. 1973	Feb. 1973
Elliot L. Richardson	June 1970	Jan. 1973
<b>ASSISTANT SECRETARY FOR HEALTH (note a):</b>		
Julius Richmond	July 1977	Present
James F. Dickson III (acting)	Jan. 1977	July 1977
Theodore Cooper (note b)	Feb. 1975	Jan. 1977
Charles C. Edwards	Mar. 1973	Jan. 1975
Richard L. Seggel (acting)	Dec. 1972	Mar. 1973
Merlin K. DuVal, Jr.	July 1971	Dec. 1972
<b>COMMISSIONER, FOOD AND DRUG ADMINISTRATION:</b>		
Donald Kennedy	Apr. 1977	Present
Sherwin Gardner (acting)	Dec. 1976	Apr. 1977
Alexander M. Schmidt	July 1973	Dec. 1976
Sherwin Gardner (acting)	Mar. 1973	July 1973
Charles C. Edwards	Feb. 1970	Mar. 1973
<b>DIRECTOR, NATIONAL INSTITUTES OF HEALTH:</b>		
Donald S. Fredrickson	July 1975	Present
R.W. Lamont-Havers (acting)	Feb. 1975	July 1975
Robert S. Stone	May 1973	Jan. 1975
John F. Sherman (acting)	Jan. 1973	May 1973
Robert Q. Marston	Sept. 1968	Jan. 1973
<b>COMMISSIONER OF SOCIAL SECURITY:</b>		
James B. Cardwell	Sept. 1973	Present
Arthur E. Hess (acting)	Mar. 1973	Sept. 1973
Robert M. Ball	Apr. 1962	Mar. 1973

ADMINISTRATOR, HEALTH CARE  
FINANCING ADMINISTRATION:  
Robert A. Derzon

Mar. 1977 Present

a/Until December 1972 the title of this position was Assistant Secretary (Health and Scientific Affairs).

b/Acting Assistant Secretary for Health from Feb. to May 1975.

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