

REPORT OF THE LEGISLATIVE RESEARCH COMMISSION
TO THE 1971 GENERAL ASSEMBLY

Feasibility and Advisability of
Licensing Commercial Donor Blood Banks
and Personnel Employed Therein

Raleigh, North Carolina

November 13, 1970

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REPORT OF THE LEGISLATIVE RESEARCH COMMISSION
TO THE 1971 GENERAL ASSEMBLY

Licensing of Commercial Donor Blood
Banks and Personnel Employed Therein

Introduction

Since the subject of this Resolution was of a highly technical nature, the Committee on Health called a public hearing March 27, 1970, to gain knowledge and understanding generally about blood banking and specifically about commercial blood banking. The following persons made presentations:

1. R. D. Langdell, M.C., Professor of Pathology, Memorial Hospital, Chapel Hill, and representative of the American Association of Blood Banks.
2. Inez Elrod, M.C., Chief of Red Cross Blood Banks for North Carolina.
3. Miss Marue Summerlin, North Carolina Society of Medical Technologists.
4. Charles F. Carroll, Jr., President, North Carolina Chapter of the National Society of Clinical Pathologists.
5. Lucille W. Hutaff, M.D., Professor of Preventive Medicine, Bowman Gray School of Medicine.
6. Edgar T. Beddingfield, M.D., President of the State Medical Society.
7. Lynn G. Maddry, Ph.D., Director, Laboratory Division, State Board of Health.
8. R. A. Groat, M.D., Ph.D., Pathologist.
9. William F. Henderson, Executive Secretary, Medical Care Commission.
10. Jacob Koomen, M.D., Director, State Board of Health.
11. Sidney Eagles, Assistant Attorney General.

Background

As medical care advances, there is a tremendous and increasing demand for blood for transfusions. Since there is no way to manu-

facture artificial blood, it is necessary for healthy people to supply the blood that is needed. An adequate supply of carefully collected, carefully stored, and carefully regulated whole blood is an absolute necessity to modern medical practice. To meet the need for blood, collection and/or distribution centers have come into existence which are commonly called blood banks and are of the following general types:

- A. Hospital Blood Banks: These blood banks are part of the hospital in which they are located. All functions of blood banking are done within the hospital.
- B. Hospital Blood Bank (Red Cross Participants): These blood banks are also part of the hospital in which they are located. Blood is supplied to these hospitals by a regional Red Cross Blood Center.
- C. Regional Blood Centers (American Red Cross): Blood collection and distribution of blood to participating hospitals is done by the regional center. The local Red Cross chapters are expected to provide a major role in recruitment of donors, all of whom are volunteers.
- C. Community Blood Bank: When several hospitals are in an area, they may elect to have a single blood bank to serve all hospitals in the local area.
- E. Plasmapheresis Center: In recent years there has been an increasing need for human plasma. Some of this plasma is used for transfusion purposes, but a large amount is used for commercially prepared reagents. If these centers collect blood which is not used for transfusion purposes, they are not subject to the same regulations as facilities collecting blood for human use.

F. Commercial Blood Bank: There is an ever growing deficit of blood being obtained on a voluntary basis. Therefore this deficit must be met by means other than the voluntary method. Blood banks under these circumstances must obtain blood from some outside source. There are blood banks that are organized primarily to provide blood to hospitals. These banks usually pay the blood donor and charge the hospital for the blood supplied--thus, the commercial aspect of the operation. Those commercial blood banks reported to be presently operating in North Carolina are:

Raleigh Blood Center, Inc.
200 E. Martin Street
Raleigh, N. C.
Mr. Tony Reaves, Manager
(Locally owned)

Durham Blood Center, Inc.
Durham, N. C.
Mr. Tony Reaves, Manager
(Same as Raleigh Blood Center)

National Blood Products, Inc.
Fayetteville, N. C.
Mrs. Anita Carter, Manager
(Parent Company-National Blood Bank of New York,
64 Second Ave., New York City)

National Blood Products, Inc.
218 S. Green Street
Greensboro, N. C.
Mrs. Gale Nelson, Assistant Manager
(Parent Company-National Blood Bank of New York,
64 Second Ave., New York City)

National Blood Bank of Philadelphia
217 N. Main Street
Winston-Salem, N. C.
Mr. James Pruett, Manager
(Parent Company-National Blood Bank of Philadelphia)

Central Blood Service, Inc.
417 S. Tryon Street
Charlotte, N. C.
Mrs. Dorothy Pannell, Manager
(Parent Company-Inter-State Blood Banks,
174 N. Third St., Memphis, Tenn.)

Unfortunately, it is difficult to control the quality of blood donated for transfusion. There are some tests that can be done to give partial protection to both donor and recipient, but they are limited to seeing if the prospective donor is anemic, is free of syphilis, and has normal temperature, pulse, blood pressure and weight. There is no effective and reliable method of determining if a person has recently been in a malarious area, has had hepatitis, or is taking drugs. The only available method for minimizing the frequency of these complications is carefully selecting the donors and taking medical histories of the donors from whom the blood is obtained. There are, however, hopeful signs that an effective and economical test may eventually be developed. Recent use of a new test (e.g. screening for hepatitis-associated antigen) has shown some promise.

Although there are published minimum standards for blood banks and transfusion services, there is at present no effective method to determine if these standards are being met. Partial inspection and accreditation of blood are carried out by several agencies. They are:

A. Division of Biologic Standards, N.I.H.

The sending or bringing of human blood from one state to another is regulated by the U. S. Public Health Service and may be done only by Federally licensed institutions. Licensure is based on Title 42 part 73 of the Code of Federal Regulations.

B. American Association of Blood Banks

A voluntary inspection and accreditation program is provided by the American Association of Blood Banks. The program is based upon the publication: "Standards for a

Blood Transfusion Service" currently in its 5th edition. All functions of blood banking are covered, and the program is described in the publication.

At the present time the following North Carolina Blood Banks are accredited by the American Association of Blood Banks:

Cabarrus Hospital Blood Bank, Concord
Cape Fear Valley Hospital Blood Bank, Fayetteville
Craven County Hospital Blood Bank, New Bern
Forsyth Memorial Hospital Blood Bank, Winston-Salem
Highsmith Rainey Hospital Blood Bank, Fayetteville
Memorial Hospital of Wake County Blood Bank, Raleigh
Moses H. Cone Memorial Hospital, Greensboro
New Hanover Memorial Hospital Blood Bank, Wilmington
Northern Surry Hospital Blood Bank, Mt. Airy
North Carolina Baptist Hospital Blood Bank, Winston-Salem
North Carolina Memorial Hospital, Chapel Hill
Rex Hospital Blood Bank, Raleigh
Rowan Memorial Hospital Blood Bank, Salisbury
Southeastern General Hospital Blood Bank, Lumberton
Stanly County Hospital Blood Bank, Albemarle
U. S. Naval Hospital Blood Bank, Camp Lejeune
Veterans Administration Hospital Blood Bank, Durham
Veterans Administration Hospital Blood Bank, Fayetteville
Watts Hospital Blood Bank, Durham
Wilson Memorial Hospital Blood Bank, Wilson

The hearings on the operation of commercial blood banks did not produce a consensus which the Committee might follow in making a

recommendation. Because of the complex nature of the question, the Committee asked Dr. Jacob Koomen, Director of the State Board of Health, to bring together knowledgeable persons with an interest in blood banking to make recommendations to the committee. He agreed and held a meeting on May 22, 1970. From this ad hoc group came many helpful recommendations which were studied by the Committee on Health. (See Appendix B)

Findings

Commercial donor blood banks are a relatively new venture in North Carolina, and they supply only a small percentage of the blood used in hospitals. Commercial operations are much more extensive in other states. There was a consensus among those participating in and contributing to this study that commercial operations did not at this time need to be separately dealt with in North Carolina.

The great majority of the blood used in North Carolina is collected from volunteers rather than paid donors.

Since there is no presently known effective and economical test for insuring that hepatitis is not transmitted in collected blood, blood collection centers must depend most heavily on the reliability of the medical history obtained from the donor. Because of this fact and the possibility of some emergency developing during the procedure, there seems to be considerable merit in requiring that a physician be responsible for the procedures used in blood banking operations and for taking necessary action in the event of medical problems arising.

Recommendations

The Commission recommends the enactment of the bill set forth in Appendix A of this report in order to implement the findings of the report.

The legislation would provide that all phases of the selection of blood donors and of the collection, storage, processing and transfusion of human blood shall be accomplished at the direction or under the supervision of a physician licensed in North Carolina. Further, the legislation would provide that due care shall be exercised in the selection of donors to minimize the risks of transmission of agents that may cause hepatitis or other diseases.

Appendix A

A Draft Bill

A BILL TO BE ENTITLED AN ACT RELATING TO THE SELECTION OF BLOOD DONORS
AND THE COLLECTION, STORAGE, PROCESSING AND TRANSFUSION OF BLOOD.

The General Assembly of North Carolina do enact:

Section 1. A new Article shall be added to Chapter 90 to be
entitled "Blood Banks" and shall read as follows:

"Article 15B

Blood Banks

§90-220.10. It shall be unlawful for any person, firm or corporation
to engage in the selection of blood donors or in the collection, storage,
processing, or transfusion of human blood, except at the direction or
under the supervision of a physician licensed in North Carolina. Any
person, firm or corporation convicted of the violation of this section
shall be guilty of a misdemeanor.

§90-220.11. In the selection of donors due care shall be exercised
to minimize the risks of transmission of agents that may cause hepatitis
or other diseases.

§90-220.12. Nothing in this article shall be construed to affect the
provisions of G.S. 20-16.2 and G.S. 20-139.1."

Sec. 2. All laws and clauses of laws in conflict with this Act are
hereby repealed.

Sec. 3. This Act shall become effective upon ratification.

Appendix B

Recommendations by Ad Hoc Committee on
Commercial Donor Blood Bank Operations
chaired by Jacob Koomen, M.D., State Health Director



James S Raper, M D
President
Asheville

Lenox D Baker, M D
Vice-President
Durham

Charles T. Barker, D D S.
New Bern

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Mount Airy

Jesse H Meredith, M. D.
Winston-Salem

June 16, 1970

Representative Kenneth C. Royall, Jr.
Chairman, Committee on Health
State of North Carolina
Legislative Research Commission
Legislative Building
Raleigh, North Carolina 27602

Dear Mr. Royall:

In your letter of April 10 you asked that I bring appropriate persons together to explore the possibility of making recommendations to your committee about commercial donor blood bank operations. I called a meeting on May 22 and the persons shown on the enclosed list graciously made time to attend. The meeting was marked by a spirit of good will and was productive of worthwhile discussion and a specific recommendation for legislative action.

The following motions were presented and adopted by the group:

A. "That this group recommend to the Legislative Research Commission that legislation be enacted so that all phases of the selection of blood donors and of the collection, storage, processing, and transfusion of blood shall be the responsibility of a physician licensed in North Carolina who has a thorough knowledge of blood bank methods and of transfusion principles and practices."

B. "That in consideration of the foregoing action of this group, this group goes on record deeming it unnecessary to enact any specific legislation to provide for the licensing of commercial donor blood banks and personnel employed therein who draw and handle human blood."

Note that the recommendation for a supervising physician applies to all blood bank operations and not only to commercial donor blood banks.

Two persons (Dr. Groat and Mr. Reaves) voted against the first motion, but Dr. Groat said he would have voted for it except for the phrase following the words "North Carolina". No one voted against the second motion.

Representative Kenneth C. Royall, Jr.
June 16, 1970
Page Two

There were a number of points raised during the meeting, some of which may be of interest to your committee:

1. One of the concerns of those involved with the collection of blood is the possibility of some emergency developing during the procedure. This is one of the reasons that supervision by a physician is required in the standards of the American Association of Blood Banks. The AAMB standards were the basis for the group's first motion.

2. Another concern is the reliability of the medical history obtained from the donor. This is another basis for recommending that all operations be under the supervision of a physician.

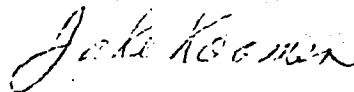
3. A third concern is the lack of an effective test for insuring that hepatitis is not transmitted in collected blood. No recommendation was made for legislation on this matter.

4. The great majority of the blood used in North Carolina is collected from volunteers rather than paid donors. It was stated that this is a tradition which has certain merits.

5. Commercial donor blood banks are a relatively new venture in North Carolina; there are six that have been identified and they supply only a small percentage of the blood used in hospitals. Commercial operations are much more extensive in other states. It was noted that Wisconsin has a law prohibiting the operation of a blood bank for commercial profit. There seemed to be a consensus that commercial operations did not at this time need to be separately dealt with in North Carolina.

I hope the actions of this ad hoc group of persons who were fairly representative of blood banking operations and concerns in the state will be useful to your committee in carrying out its study.

Sincerely,



Jacob Koomen, M.D., M.P.H.
State Health Director

JK/bam

cc: List attached

Dr. Robert W. Prichard
Department of Pathology
Bowman Gray School of Medicine
Winston-Salem, North Carolina 27103

Dr. Inez W. Elrod
Chief
Red Cross Blood Banks for the
State of North Carolina
Box 3507
Charlotte, North Carolina 28203

Mr. Dave Alexander
City Editor
The Greensboro Record
Greensboro, North Carolina

Miss Mary S. Britt
Registrar and Teaching Supervisor
School of Medical Technology
Duke University Medical Center
Durham, North Carolina

Mr. George M. Stockbridge
Health Planning Council for Central
North Carolina
Home Security Building
505 West Chapel Hill Street
Durham, North Carolina

Mr. Tony C. Reaves
Director, Raleigh Blood Center, Inc.
200 East Martin Street
Raleigh, North Carolina

Dr. R. D. Langdell
Department of Pathology
North Carolina Memorial Hospital
Chapel Hill, North Carolina 27514

Dr. Francis K. Widmann
Department of Pathology
University of North Carolina
Chapel Hill, North Carolina 27514

Dr. Albert L. Chason
Director, Blood Bank
Dex Hospital
Raleigh, North Carolina

Dr. R. A. Groat
Pathologist
321 North Elm Street
Greensboro, North Carolina

Mr. William F. Henderson *
Executive Director
North Carolina Medical Care Commission
Raleigh, North Carolina

Mr. Russell G. Walker, Jr. *
Assistant Revisor of Statutes
North Carolina Department of Justice
Raleigh, North Carolina

Mrs. Mildred A. Kerbaugh *
Assistant Director
Laboratory Division
State Board of Health
Raleigh, North Carolina

Mr. John Young *
Institute of Government
University of North Carolina
Chapel Hill, North Carolina

Mr. David G. Warren *
Institute of Government
University of North Carolina
Chapel Hill, North Carolina

Dr. Lynn G. Maddry *
Director, Laboratory Division
State Board of Health
Raleigh, North Carolina

Dr. Jacob Koomen *
State Health Director
N. C. State Board of Health
Raleigh, North Carolina

* Did not participate in voting

Appendix C

Materials on File with the Legislative
Research Commission

Materials on File with the Legislative
Research Commission

- (1) Remarks on Blood Banking by Charles F. Carroll, M.D., President, North Carolina Chapter of the National Society of Clinical Pathologist.
- (2) Map Showing Blood Supplied by Red Cross Blood Program.
- (3) "Recommendations of the Legislative Committee of the North Carolina Society of Medical Technologists Concerning the Licensing of Commercial Donor Blood Banks."
- (4) Letter from Stuart M. Sessoms, M.D., Director, Duke University Medical Center.
- (5) "Statement Regarding Proposed Commercial Blood Bank Law", by Lucille W. Hutaff, Professor of Preventive Medicine, Bowman Gray School of Medicine.
- (6) Letter from Lynn G. Maddry, Ph. D., Director, Laboratory Division, State Board of Health, to Jacob Koomen, M.D., M.P.H., State Health Director.
- (7) Remarks by Sidney S. Eagles, Jr., Assistant Attorney General.
- (8) Remarks by Edgar T. Beddingfield, M.D., President, State of North Carolina Medical Society.
- (9) Letter from R.A. Groat, Ph.D., M.D., Pathologist.
- (10) "Standards for a Blood Transfusion Service", American Association of Blood Banks, Committee on Standards, 30 North Michigan Avenue, Chicago, Illinois.

Appendix D

Resolution Directing the Study

NORTH CAROLINA
GENERAL ASSEMBLY

1969 SESSION

RATIFIED RESOLUTION
RESOLUTION 116

SENATE JOINT RESOLUTION 739

A JOINT RESOLUTION DIRECTING THE LEGISLATIVE RESEARCH COMMISSION
TO STUDY THE QUESTION OF THE LICENSING OF CERTAIN CLINICAL
LABORATORIES.

Be it resolved by the Senate, the House of Representatives
concurring:

Section 1. The Legislative Research Commission is
hereby directed to study the feasibility and advisability of the
enactment of legislation providing for the licensing of
commercial donor blood banks and personnel employed therein who
draw and handle human blood.

Sec. 2. The Legislative Research Commission shall
report its findings and any recommendations resulting from this
study to the 1971 General Assembly.

Sec. 3. This Resolution shall become effective upon its
ratification.

In the General Assembly read three times and ratified,
this the 1st day of July, 1969.

H. P. TAYLOR, Jr.

H. P. Taylor, Jr.
President of the Senate.

EARL W. VAUGHN

Earl W. Vaughn
Speaker of the House of Representatives.