

LDIR#101

MEDICAL

HEALTH

LABORATORIES

1966

February 6, 1967

STATEMENT BEFORE THE
SUBCOMMITTEE ON ANTITRUST AND MONOPOLY, Philip A. Hart, Chairman

by

Morris Schaeffer, Ph.D., M.D., Assistant Commissioner
and General Director of Laboratories
New York City Department of Health

WHAT IS WRONG WITH OUR CLINICAL LABORATORIES?

The problem

In the practice of medicine accurate diagnosis and proper treatment of disease is inextricably associated with the availability of competent clinical laboratories which are able and willing to provide prompt and reliable results.

Today, physicians and health officers require more and greater varieties of services from clinical and public health laboratories, than ever before, yet such laboratories generally have not kept pace, while the research laboratories have flourished beyond expectation in this era of extraordinary advancement in the sciences.

There are many reasons for the paradoxical and contradictory situation in this complex state of affairs. Among them may be included, the profound economic changes since World War II and the increasing attractiveness to college graduates of better paying industrial and federal research positions fostered by the vast growth of funds available for research. This, in turn, has caused a lack of trained and motivated personnel for the low salaried, less desirable clinical laboratory jobs. Many areas are, thus, without these important laboratory facilities and services. Where they are available, the performance, in a large proportion of the clinical laboratories, is largely substandard.

Studies in New York have shown that as many as 40% of over 350 laboratories tested are unable to isolate and identify bacteria which are commonly encountered in infectious diseases. Thirty to 50% of the laboratories fail in simple chemical tests and about 15% cannot type or crossmatch blood accurately. Yet thousands of such tests are performed daily and the results reported must so guide the action of the physician that the health or even the lives of certain patients are placed in jeopardy. (Appendix A attached).

In the "good old days" it was possible for a dedicated physician to learn all there was known about the laboratory and its application

Health Department's Role in Improving Operations of Clinical Laboratories

MORRIS SCHAEFFER, M.D., Ph.D.

WITHIN the past three decades, a curious and contradictory phenomenon has evolved in laboratory medicine. During an era of advancement in the biological and chemical sciences, research laboratories have flourished beyond expectation, but the service laboratories have not kept pace. This has occurred though physicians and health officers require more and greater varieties of services from clinical and public health laboratories.

What is the reason for this paradox? The factors are manifold and complex. Several are strikingly important common causes. These include the profound economic changes since World War II, increasing attractiveness of industrial and Federal research positions, vast growth of funds available for research, and lack of trained and motivated personnel.

In the management of infectious diseases, for example, the advent of one antibiotic after another, providing a false sense of therapeutic security, has all but eliminated the diagnostic microbiology laboratory. As if to compensate fundamental developments from the antibiotics, include tissue culture techniques and modern virus vaccines. Yet, applied medical microbiology is almost a lost art and few medical bacteriologists are being trained to replace the rapidly dwindling handful of old ones. The situation may not be quite as sad in other areas of clinical laboratory practice, but it is troublesome in many of them.

Dr. Schaeffer is director of the bureau of laboratories, New York City Department of Health.

Adequate medical care is impossible today without the prompt service of a reliable diagnostic laboratory. The proper choice and utilization of antibiotics in infections, control of electrolyte levels in the treatment of heart and kidney disease, restoration of normal function in metabolic and endocrine disorders, and the treatment of cancer in its earliest detectable stages, all depend upon the laboratory for diagnosis. Many other conditions are accompanied by increasing demands on the laboratory, including the extensive use of blood and blood products to permit the application of newer surgical techniques to the treatment of chronic heart and lung disease and the regulation of nutritional defects in aged patients and those with chronic gastrointestinal and liver disease.

The mounting complexity of these tests and growth in demands for direct patient service makes the good hospital laboratory of a decade ago obsolete today. Many administrators fail to recognize this situation and, indeed, many neither encourage nor permit their laboratories to improve physical facilities or obtain the adequately trained personnel needed to meet the challenges of advancing medical science.

The state of affairs is not limited to one city or State. Unfortunately it is a universal ill, which has been generally ignored by the individuals who should be most concerned, physicians, public health officials and educators.

New York City's pioneer efforts in the supervision of clinical laboratories took root nearly 50 years ago. Shortly after World War I the Sanitary Code of the City of New York was

THE CLINICAL LABORATORY IMPROVEMENT PROGRAM IN NEW YORK CITY

I. Current Methods of Evaluation and Performance Results

Morris Schaeffer, M.D., Daniel Widelock, Ph.D., Sylvia Blatt, M.S.
and Marion E. Wilson, Ph.D.

Bureau of Laboratories
Department of Health
City of New York

Delivered at the Laboratory Section
American Public Health Association

November 2, 1966
San Francisco

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Bureau of State Services.

LICENSURE OF CLINICAL LABORATORIES
AND PERSONNEL

A Suggested Guide For Preparation of
Enabling Legislation

Prepared By
Laboratory Branch
Communicable Disease Center
Public Health Service
U. S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
Atlanta, Georgia
November 28, 1966

REGISTRATION OF CLINICAL LABORATORIES,
COLLECTION STATIONS, BLOOD BANKS, AND SCHOOLS
OF MEDICAL TECHNOLOGY

A Suggested Guide for Preparation of
Enabling Legislation

Prepared by
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Season's

Greetings

december 1966

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from...

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WORLD

STATE OF RHODE ISLAND AND PROVIDENCE PLANTATIONS

DEPARTMENT OF HEALTH

Rules and Regulations

In accordance with the provisions of Section 5, Title 23, Chapter 39 of the general laws, the following rules and regulations are promulgated by the Director of Health.

CLINICAL LABORATORIES

23-39-2. Definitions. - When used in this chapter, (a) "Clinical Laboratory" means a place where microbiological, biochemical, hematological, cytological, pathological and serological tests of material taken from the human body are performed to obtain information for diagnosis, prophylaxis or treatment or where any examination, determination or test is made on any sample of food as a basis for advice as to the sanitary quality of such food or as to any possible danger to health involved, (b) "Director" means the director of the department of health.

23-39-3. Exceptions. - The provisions of this chapter shall apply to all clinical laboratories in this State except a clinical laboratory maintained by the State, any City or Town or the Federal Government, or by a hospital licensed under chapter 23-16 of the general laws, or by a licensed physician or a group of licensed physicians who make the tests referred to in section 23-39-2, personally or through employees, solely in connection with the treatment of their own patients; however, an independent laboratory which makes such tests on its own responsibility for a single physician or group of physicians is subject to this article.

July 6, 1965

FOR IMMEDIATE RELEASE

State control of medical laboratory testing has worked well in California for the last 25 years with one glaring exception, according to the California Association of Medical Laboratory Technologists. That is the loophole that allows medical specimens to be mailed to out-of-state labs for analysis by unlicensed personnel.

What this means to the welfare of a patient who expects the best kind of professional care as guaranteed by state laws has prompted Senator George Murphy of California to join with New York's Jacob Javits in sponsoring a bill to regulate clinical laboratories and personnel engaged in this sort of interstate commerce. Senator Murphy said, "I know all Americans are shocked to read and hear of the deplorable conditions in our medical laboratories across the country...there may very well be a weak link in an otherwise strong medical team." In explaining his support for nation-wide regulation, Senator Murphy pointed out, "I am naturally proud of the fact that the State of California is a pioneer in the regulation of the clinical laboratories. The first law in my state was passed in 1937." But, he continued, "Despite this pioneering effort, California citizens are not completely protected because there is no present way they can be protected from substandard out-of-state laboratories."

In documenting the seriousness of the problem before the Senate, he quoted Dr. Max Chapman of the California State Department of Public Health who recalled a case when an owner of a laboratory purchased from a salvage dealer a supply of supposedly new slides. One carton contained 500 slides each smeared with cells for a Pap examination and bearing the

AN APPROACH TO STANDARDS TO GUIDE THE HEALTH
DEPARTMENTS IN DEVELOPING CERTIFICATION OR
APPROVAL PROGRAMS FOR MEDICAL LABORATORIES

Each State should develop an acceptable program for certification or approval of medical laboratories. The State shall appoint an advisory committee including, but not limited to, individuals representing various professional and technical groups engaged in medical laboratory practice who will advise on establishment and enforcement of such a program.

The standards shall apply to all medical laboratories, except for the individual physician for work on his patients provided that he does not accept referred work from any other physician and provided that he is not in partnership with more than one other physician.

The director of a laboratory should be a pathologist certified in clinical pathology, a person with a doctoral degree, certified by the American Board of Microbiologists or the American Board of Clinical Chemistry or a qualified person licensed to practice medicine.

The State may license or give comparable authority to persons with lesser qualifications, if such is required to meet the needs of the State to provide laboratory services, provided, however, that no person shall be certified as a laboratory director unless he possesses a Bachelor's degree in a biological or chemical science and has had at least four years of experience in a medical laboratory acceptable to the State.

In laboratories where no individual meets the doctoral requirements for a director the laboratory may be required to use only those technical methods prescribed by the responsible State agency and technical personnel shall undertake additional training as may be prescribed. The State agency may restrict the type and complexity of procedures done in these laboratories but in each instance a hospital laboratory must be able to reliably perform at least the following procedures: (1) hemoglobin or hematocrit, (2) white cell count and differential, (3) urinalysis, (4) bloodgrouping and crossmatching, and (5) blood or serum glucose.

Each laboratory shall have a director who shall administer the technical and scientific operations of the laboratory, including the reporting of results of the laboratory tests. The laboratory director shall be employed full time in medical laboratory work, provided however, that

1. No person may direct the work of more than two medical laboratories.
2. A person directing only one laboratory engaged in a limited scope of medical laboratory work may be engaged only part time in directing the laboratory, but shall be present in the laboratory during each day of operation, and shall have a working knowledge of the work performed in the laboratory and shall be responsible for all of its operations.
3. In small hospital laboratories where limited laboratory work is performed and only one technologist is employed, the director shall be available for consultation during the hours

Revised: December 2, 1966

A BILL

A Bill to protect the public health; to provide for the licensing and supervision of public laboratories making laboratory tests to aid in the diagnosis, prevention or treatment of disease or the assessment of medical condition; to establish minimum standards for the performance of laboratory procedures; to prescribe penalties for the violation thereof; and to repeal Act 45, P.A. 1931 being sections 325.71 - 325.75 of the Compiled Laws of 1948.

The People of the State of Michigan enact:

Section 1. The Director of the Michigan Department of Public Health is hereby vested with the administration of the provisions of this Act and is authorized to incur such expenses as shall be authorized by the Legislature. It shall be the duty of the Director of the Michigan Department of Public Health, after seeking advice as indicated in Section 5 (d) of this Act, to make and declare such rules and regulations with reference to public laboratories as shall be necessary to accomplish the purposes of this Act.

Section 2. As used in this Act -

(a) The term "Director" means the Director of the Michigan Department of Public Health.

(b) The term "public laboratory" means a facility which may be patronized by any physician or physicians and/or health officer or health officers for the purposes of obtaining information for the diagnosis, prevention or treatment of disease or the assessment of medical condition by the microbiological, serological, chemical, hematological, biophysical, cytological or pathological examination of materials derived from the human body. The term "public laboratory" shall not apply to any laboratory operated by the Federal Government.

(c) The term "owner" means the person, partnership, association or corporation which owns and controls the public laboratory.

(d) The term "laboratory director" means the individual responsible for the administration of the technical and scientific operation of a public laboratory, including the supervision of procedures and reporting of findings.

Section 3. No public laboratory may solicit or receive any specimen for laboratory examination unless such laboratory has been issued a license as provided in this Act and such license has not been suspended or revoked. A license issued under this Act shall authorize the performance of laboratory procedures in one or more categories.

Section 4. (a) Application for a public laboratory license under this Act shall be made by the owner of the public laboratory and shall contain the name of the owner, the name of the laboratory director, the laboratory procedures and categories for which the public laboratory license is sought, the location and physical description of the facility at which tests are to be performed, and such other information as the Director may require.

MODEL BILL

An Act Relating to the Practice of Medical
Technology in the State of

Section 1. Board of Medical Technology. A State Board of Medical Technology and Clinical Laboratories is hereby created and will be referred to in this Act as "The Board". The Board shall assume and exercise all powers and perform all the duties conferred and imposed by the provisions of this Act. Said Board shall consist of fourteen (14) members who shall be citizens of the United States, and each of whom shall have engaged in the practice of medical technology or clinical pathology in this State for more than five years, and shall hold a certificate from the American Board of Clinical Pathology or shall have satisfied the educational requirements for licensure as a medical technologist or clinical laboratory technician as provided in this Act. The Board shall consist of four clinical pathologists, six medical technologists, and four clinical laboratory technicians, all of whom shall be actively engaged in the practice of their professions. The persons appointed as clinical laboratory technicians shall serve as members of the Board but only in relation to and for the purpose of administering the provisions of this Act as it relates to clinical laboratory technicians. The Governor shall appoint to such Board four persons to serve for a term of two years, four for a term of three years, six for a term of four years, and not less than one clinical pathologist, one medical technologist, and one clinical laboratory technician shall be appointed to each term. Thereafter, as the term of any member of the Board expires, a successor shall be appointed for a term of four years, and such appointee shall be a clinical pathologist, medical technologist, or clinical laboratory technician as the Board vacancy shall require. In the event of a vacancy before the expiration of a term the

NATIONAL REGISTRY IN CLINICAL CHEMISTRY

FOR IMMEDIATE RELEASE

For Information Contact:

D.A.H. Roethel
American Chemical Society
1155 16th Street, N.W.
Washington, D.C. 20036
202-RE 7-3337 Ext. 215

A National Registry in Clinical Chemistry has been organized and incorporated in Washington, D.C., to accredit professionally qualified clinical chemists and clinical chemistry technologists who perform chemical tests on materials from the human body at the request of physicians.

All U.S. chemical groups known to have an interest in the clinical laboratory field participated in creating the new Registry. The effort was spearheaded by the American Association of Clinical Chemists, and also involved the American Board of Clinical Chemistry, the American Chemical Society, the American Institute of Chemists, and the American Society of Biological Chemists.

The principal purpose of the new Registry, according to Dr. W.B. Mason, University of Rochester, chairman of the planning group responsible for its formation, is to examine the educational and professional competency of those individuals who render essential public health services, such as are specified under terms of the Medicare program.

Commenting on the need for a clinical chemistry registry, Doctor Mason said: "It is important that the public interest be safeguarded by assuring that all clinical chemistry workers satisfactorily can perform the chemical tests which have become increasingly important for the physician's diagnosis."

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**LABORATORY CONSULTATION
AND
DEVELOPMENT PROGRAM**

General Aims and Approaches

by

**M. M. Brooke, Sc.D., Chief
Laboratory Consultation and Development Section
Laboratory Branch
Communicable Disease Center**

**U. S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE**

Subdivision 4

LABORATORIES PERFORMING TESTS FOR COMMUNICABLE DISEASES

(ED. NOTE: Unless otherwise specified, sections 24-005 through 24-035 of this chapter of the Oregon Administrative Rules Compilation were adopted by the Board of Health January 11, 1955, and filed with the Secretary of State January 18, 1955, as Administrative Order HB 70.)

Statutory Authority: ORS 433.335

24-005 DEFINITIONS. (1) "Board or State Board of Health" means the Oregon State Board of Health.

(2) "Advisory Committee" means the Oregon State Advisory Committee on Laboratory Standards.

(3) "State Public Health Laboratory" means the Public Health Laboratory of the Oregon State Board of Health.

(4) "Health Officer" means the State Health Officer.

24-010 APPROVAL FOR SYPHILIS SEROLOGY. (1) Application. Application for approval will be made on forms provided by the Board. The director of the laboratory must agree to abide by any rules promulgated by the Board.

(2) Inspection. Inspection of the laboratory by a representative of the Board will be made and reported to the Advisory Committee prior to the granting of approval. Inspection shall cover the adequacy of facilities, light, and equipment. All deficiencies must be corrected before a certificate is granted.

(3) Personnel. Technicians performing syphilis serology tests must meet the minimum education and training standards as follows:

(a) Successful completion of at least 90 semester (or 135 quarter) hours, at a college or university accredited by a regional accreditation association recognized by the National Commission on Accrediting, including required courses in:

(A) Chemistry—minimum of 4 semesters or 16 semester hours. One full year of general college chemistry, which may include qualitative analysis, is required. The remaining courses may be in quantitative, organic, physical chemistry, or biochemistry.

(B) Biologic Sciences—minimum of 4 semesters or 16 semester hours. One full year lecture and laboratory course in general biology and/or zoology is required. The remaining biology courses may be in bacteriology, immunology, mycology, parasitology, histology, physiology, histologic technic, comparative anatomy, or genetics.

(C) Mathematics—3 semester hours of college mathematics.

(b) After completing the educational requirements set forth in Section 24-010, Subsection (3) (a), a student shall spend at least 12 consecutive months of training in a university, medical school, state department of health, or hospital school of medical technology which is under the direct supervision of a clinical pathologist licensed to practice medicine or osteopathy in the state in which he practices.

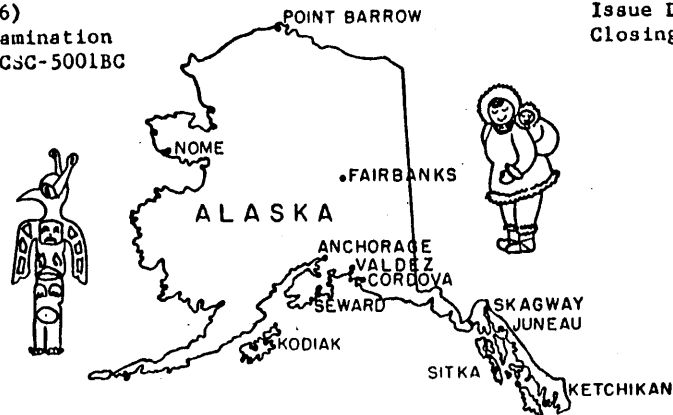
(A) The 12 month course of training shall include the following subjects: biochemistry, bacteriology, blood banking, basal metabolism, hematology, histologic technic, parasitology, serology, urinalysis and miscellaneous clinical microscopy. Such training shall include test assignments, lectures and discussions, demonstrations, supervised practice, quizzes and written, oral and practical examinations.

(c) Exemption. The provisions of Section 24-010, Subsection (3) (a), shall not apply to the following:

ANCHORAGE JOINT BOARD OF U. S. CIVIL SERVICE EXAMINERS
1034 FOURTH AVENUE
ANCHORAGE, ALASKA 99501

Announcement No. SE-101-5(66)
Unassembled - No Written Examination
Forms Required: SF-57 and CSC-5001BC

Issue Date: March 21, 1966
Closing Date: Open Until
Further Notice



Open Competitive Examination Announced for
Career-Conditional Appointment to the Following:

M E D I C A L T E C H N O L O G I S T

Grade: GS-5 ----- \$5181 per year Plus 25% Cost of Living Allowance
Grade: GS-7 ----- \$6269 per year Plus 25% Cost of Living Allowance

PLACES OF EMPLOYMENT: These positions are located throughout the state of Alaska in Public Health Service Hospitals, primarily in remote or outlying areas, and in various other Federal agencies serviced by the Anchorage Joint Board of U. S. Civil Service Examiners. A limited number of positions in other agencies throughout the state of Alaska also may be filled from this examination where no appropriate examination for the specific positions has been issued.

NOTE: Applicants who are willing to accept employment outside the locality of their residence must indicate the specific area or areas of availability.

REGISTERS: The registers established as a result of this examination will supersede similar registers established under Announcement 11-101-17(61). Persons who attained eligibility under Announcement 11-101-17(61) should apply for this new examination if they are still interested in receiving consideration for these positions. A separate register will be maintained for each grade of the position listed.

HOW TO APPLY: Obtain application forms Standard Form 57 and CSC-5001BC from the Anchorage Joint Board of U. S. Civil Service Examiners, 1034 Fourth Avenue, Anchorage, Alaska. Post Offices may also provide information as to where these forms may be obtained. File applications with the Anchorage Joint Board of U. S. Civil Service Examiners as soon as possible.

DESCRIPTION OF DUTIES: Medical technologists perform a variety of responsible professional duties in clinical, medical research, or regulatory control laboratories. They perform a variety of laboratory procedures and tests on samples of body fluids and tissues, and are responsible for accurate observations, accurate and valid results, recognition of irregularities and deviations from the normal, and accurate presentation of findings. They make use of a variety of complicated precision instruments, calibrate instruments and equipment, standardize solutions, and perform other related work as required. Technologists in the higher grades, depending upon the grade level of the position and the type of laboratory in which they work, perform the newer and more complex tests and procedures, contribute to the development and evaluation of improved tests, techniques, and procedures, assist in or direct training programs for medical technicians and medical technologists, evaluate and advise on blood bank or related procedures, and/or take charge of medical technology laboratories. Some medical technologists perform specialized medical laboratory work in a particular field only, such as bacteriology, chemistry, cytology, hematology, etc.

DEPARTMENT OF HEALTH

Amendments to New York City Health Code

AT A MEETING OF THE BOARD OF HEALTH OF THE DEPARTMENT OF Health held on February 4, 1963, the following resolution was adopted:

Resolved, that subsection (a) of section 5.07 of the New York City Health Code, as last amended by resolution adopted on the tenth day of January, nineteen hundred sixty-three and filed with the city clerk on the sixteenth day of January, nineteen hundred sixty-three, be and the same hereby is amended to read as follows:

(a) Application for permits and certificates of qualifications and for renewal thereof shall be accompanied by payment of fees prescribed by the following table. The Department may delay collection of the fee prescribed until the issuance of the permit or certificate of qualification. Permits and certificates of qualification shall expire and be renewed in accordance with the expiration date, if any, prescribed by such table:

Resolved further, that the column heading of the first column of the table set forth in subsection (a) of such section is hereby amended to read as follows:

DESCRIPTION OF ACTIVITY UNDER
PERMIT OR CERTIFICATE OF
QUALIFICATION

Resolved further, that the listing of "CLINICAL LABORATORY" permit appearing in the table set forth in such subsection be and the same hereby is amended to read as follows:

CLINICAL LABORATORY: Permit to maintain or operate a clinical laboratory, or to represent self as operating a clinical laboratory or to report or to undertake to report the result of microbiological, serological, chemical, hematological, biophysical, cytological or pathological tests made on material derived from the human body for the diagnosis, prevention or treatment of a disease or assessment of a medical condition	13.05(a)		NOVEMBER 30
—for a laboratory with five or more technicians exclusive of the director		\$50.00	
—for a laboratory with less than five technicians exclusive of the director		\$25.00	

Resolved further, that the table set forth in subsection (a) of such section be and the same hereby is amended by inserting therein between the listing for "CLINICAL LABORATORY" permit as hereby amended and the listing "DAY CARE SERVICE" permit the following listing:

CLINICAL LABORATORY: To act as director of	13.07	\$25.00 for original \$10.00 for renewal	NOVEMBER 30 BIENNIALY
CLINICAL LABORATORY: To act as supervisor of	13.09	\$5.00 for original \$5.00 for renewal	NOVEMBER 30 BIENNIALY
CLINICAL LABORATORY: To act as clinical laboratory technologist	13.11	\$5.00 for original \$5.00 for renewal	NOVEMBER 30 BIENNIALY
CLINICAL LABORATORY: To act as clinical laboratory technician	13.13	\$5.00 for original \$5.00 for renewal	NOVEMBER 30 BIENNIALY
CLINICAL LABORATORY: To act as clinical laboratory trainee	13.15	\$5.00	TWO YEARS FROM DATE OF ISSUANCE (UNLESS FURTHER EXTENDED)

Resolved further, that subsection (b) of such section be and the same hereby is amended to read as follows:

RECEIVED

DEC 14 1965

Alaska Dept. of Health
Southcentral Regional
Lab.

89TH CONGRESS
1ST SESSION

H. R. 9956

IN THE HOUSE OF REPRESENTATIVES

JULY 20, 1965

Mr. FARBERSTEIN introduced the following bill; which was referred to the Committee on Interstate and Foreign Commerce

FROM
RALPH J. RIVERS _____
CONGRESSMAN AT LARGE
ALASKA

A BILL

Establishing the Clinical Laboratory Licensing Act of 1965.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*
3 That this Act may be cited as the "Clinical Laboratory
4 Licensing Act of 1965".

5 SEC. 2. The Congress finds that clinical laboratories per-
6 form essential services necessary to the diagnosis and treat-
7 ment of human diseases and that such laboratories can, by
8 the improper performance of laboratory procedures, cause
9 unnecessary or improper medical treatment, prolonged ill-
10 ness, injury, or death. The Congress further finds that
11 clinical laboratories which transact business in interstate