

No. 297

AN ACT

SB 1235

Amending the act of September 26, 1951 (P.L.1539), entitled "An act defining analytical-biochemical-biological laboratory; regulating the operation of the same; requiring such laboratories to obtain permits, and to be operated under the direct supervision of qualified persons; imposing certain duties upon the Department of Health; and providing penalties," changing the designation of laboratories under the act; changing requirements for directors; making unlawful certain transactions with laboratories not under permit; creating an advisory committee.

The General Assembly of the Commonwealth of Pennsylvania hereby enacts as follows:

Section 1. The title, preamble, and sections 1, 2 and 3, act of September 26, 1951 (P.L.1539), known as "The Analytical-Biochemical-Biological Laboratory Act," are amended to read:

AN ACT

Defining **[analytical-biochemical-biological]** *clinical* laboratory; regulating the operation of the same; requiring such laboratories to obtain permits, and to be operated under the direct supervision of qualified persons; imposing certain duties upon the Department of Health; and providing penalties.

Whereas, the health and lives of the citizens of this Commonwealth are endangered by incompetent supervision of **[analytical-biochemical-biological]** *clinical* laboratory tests; and

Whereas, a due regard for public health and preservation of human life demands that none but scientists competent and properly qualified by sufficient training in the fundamental sciences and experienced in their applications in the **[analytical-biochemical-biological]** *clinical* laboratory shall be permitted to supervise the work of such laboratories.

Section 1. Short Title.—This act shall be known and may be cited as "The **[Analytical-Biochemical-Biological]** *Clinical* Laboratory Act."

Section 2. Definitions.—The term "**[Analytical-Biochemical-Biological]** *Clinical* Laboratory" means any place, establishment or institution organized and operated primarily for the performance of all or any bacteriological, biochemical, microscopical, serological, or parasitological tests by the practical application of one or more of the fundamental sciences to material originating from the human body, by the use of specialized apparatus, equipment and methods, for the purpose of obtaining scientific data which may be used as an aid to ascertain the state of health.

The term "Department" means the Department of Health.

Section 3. Limitations.—**[An analytical-biochemical-biological]** A

clinical laboratory shall be under the direct and personal supervision of:

1. A holder of a doctor of science degree or its equivalent in the basic sciences, including professional degrees in public health, *medicine*, *osteopathy*, pharmacy, dentistry and veterinary medicine, from a college or university recognized by the National Committee of Regional Accrediting Agencies or the Department of [Public Instruction] *Education*, in chemistry, biology or [bacteriology] *microbiology*, and who has had two years of experience in a laboratory acceptable to the department.

2. The holder of a master of science degree or its equivalent in the basic sciences from a college or university recognized by the National Committee of Regional Accrediting Agencies or the Department of [Public Instruction] *Education*, in chemistry, biology or [bacteriology] *microbiology*, and who has had a minimum of four years' experience in a laboratory acceptable to the department.

3. The holder of a bachelor of science degree or its equivalent in the basic sciences from a college or university recognized by the National Committee of Regional Accrediting Agencies or the Department of [Public Instruction] *Education*, in chemistry, biology or [bacteriology] *microbiology*, and who has had a minimum of five years' experience in laboratory work in a laboratory acceptable to the department.

4. [An individual who holds no degree, but who has had a minimum of ten years of experience in an acceptable analytical-biochemical-biological laboratory and whose experience covers all of the fields of analytical-biochemical-biological laboratory work and whose individual qualifications are acceptable to the department. This clause shall remain effective until December thirty-first, one thousand nine hundred fifty-five.] *From and after July 1, 1973, no clinical laboratory shall be under the direction and personal supervision of any person who does not meet the qualifications set forth in clause 2 of this section, and from and after July 1, 1974, no clinical laboratory shall be under the direction and personal supervision of any person who does not meet the requirements of clause 1 of this section: Provided, however, That this clause shall apply only to those laboratories for which an application for a permit is made on or after the dates herein specified: And provided further, That this provision shall apply only to those clinical laboratories required to have a permit pursuant to the provisions of this act.*

5. The foregoing limitations shall not apply to those persons operating [an analytical-biochemical-biological] a *clinical* laboratory prior to the effective date of this act.

Section 2. The act is amended by adding a section to read:

Section 3.1. Advisory Committee.—An advisory committee shall be established for the purpose of advising the secretary in matters relating to administration of the act. There shall be seven members, each of whom is experienced in the clinical laboratory field. At least one member shall be qualified in the discipline of anatomic pathology and

one in clinical pathology and licensed to practice medicine in the Commonwealth or eligible for licensure, one shall be qualified in the field of clinical chemistry, and one shall be qualified in the field of clinical microbiology. Members of the committee shall be appointed by the secretary.

Section 3. Section 13 of the act, amended August 4, 1961 (P.L.920), is amended to read:

Section 13. Exemptions.—This act shall not include nor apply to any laboratory or laboratories maintained and operated by the Federal [,State, county or municipal] government; nor to any laboratory or laboratories maintained and operated purely for research or teaching purposes [nor shall it apply to a laboratory operated by a physician licensed to practice in this Commonwealth, provided such laboratory is operated solely in connection with the diagnosis and treatment of his own patients, or to laboratories maintained and operated in hospitals; nor shall it apply to a laboratory maintained and operated by any industrial organization, provided such laboratory be in charge of a duly licensed physician].

Section 4. The act is amended by adding a section to read:

Section 13.1. Unlawful Conduct.—It shall be unlawful for any person to solicit, receive, accept, deliver or transmit, by mail or otherwise, material originating from the human body on behalf of any person operating a laboratory not in possession of a permit under this act regardless of whether such laboratory is located in this Commonwealth. The provisions of this section shall not apply to transactions with any person operating a laboratory located in another state, which laboratory has been issued a license or permit in conformity with the "Clinical Laboratories Improvement Act of 1967," and related statutes. Neither shall this section apply to transactions with laboratories operated in this State which are exempt from the permit requirements of this act.

Section 5. Section 14 of the act is amended to read:

Section 14. Penalty.—Any person operating [an analytical-biochemical-biological] a *clinical* laboratory without first having obtained a permit from the Department of Health *or violating the provisions of section 13.1 of the act* shall, upon conviction thereof, be sentenced to pay a fine not exceeding five hundred dollars (\$500) or to imprisonment not exceeding one (1) year, or both.

Section 6. An annual registration fee shall be established by rule of the Department of Health, and shall be payable to the department. Funds obtained from registration fees shall be applied and used for the administration of the act.

Section 7. The sum of ten thousand dollars (\$10,000) is appropriated to the Department of Health to carry out the provisions of this act.

Section 8. This act shall take effect July 1, 1972.

APPROVED—The 6th day of December, A. D. 1972.

MILTON J. SHAPP

The foregoing is a true and correct copy of Act of the General Assembly
No. 297.

A handwritten signature in black ink, reading "C. McLaughlin Tucker". The signature is written in a cursive style with a large initial "C." and a long, sweeping underline.

Secretary of the Commonwealth.