

THE GENERAL ASSEMBLY OF PENNSYLVANIA

HOUSE BILL

No. 1106 Session of
2005

INTRODUCED BY COHEN, GEORGE, FABRIZIO, CURRY, CREIGHTON, TIGUE,
SHANER, BELFANTI, HALUSKA, BEBKO-JONES, YOUNGBLOOD,
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WALKO, McCALL, SOLOBAY, MUNDY, WHEATLEY, FRANKEL, FREEMAN,
JAMES, LEACH, WASHINGTON, KIRKLAND, PISTELLA, CRUZ,
CALTAGIRONE, BISHOP, CORRIGAN, LEDERER, W. KELLER, PALLONE
AND DALEY, MARCH 24, 2005

REFERRED TO COMMITTEE ON HEALTH AND HUMAN SERVICES,
MARCH 24, 2005

AN ACT

1 Reenacting and amending the act of September 26, 1951 (P.L.1539,
2 No.389), entitled, as amended, "An act defining clinical
3 laboratory; regulating the operation of the same; requiring
4 such laboratories to obtain permits, and to be operated under
5 the direct supervision of qualified persons; imposing certain
6 duties upon the Department of Health; and providing
7 penalties," providing for the accreditation and regulation of
8 forensic deoxyribonucleic acid laboratories.

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

11 Section 1. The title and act of September 26, 1951
12 (P.L.1539, No.389), known as The Clinical Laboratory Act,
13 amended or added August 4, 1961 (P.L.920, No.400) and December
14 6, 1972 (P.L.1388, No.297) and repealed in part April 28, 1978
15 (P.L.202, No.53), are reenacted and amended to read:

AN ACT

17 Defining clinical laboratory and forensic deoxyribonucleic acid
18 (DNA) laboratory; regulating the operation of [the same]

clinical laboratories and forensic DNA laboratories;
requiring such laboratories to obtain permits or
accreditation, 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
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 clinical
laboratory shall be permitted to supervise the work of such
laboratories.

CHAPTER 1

PRELIMINARY PROVISIONS

Section [1] 101. Short Title.--This act shall be known and
may be cited as "The Clinical and Forensic DNA Laboratory Act."

Section 102. Legislative Findings.--The General Assembly
finds as follows:

(1) The health and lives of the citizens of this
Commonwealth are endangered by incompetent supervision of
clinical laboratory tests.

(2) 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 clinical laboratory
shall be permitted to supervise the work of such laboratories.

(3) In a short period of time deoxyribonucleic acid (DNA)
evidence has become a significant element in many court cases.

1 In this Commonwealth and across the nation, DNA evidence has
2 proven to be the deciding factor in determining innocence or
3 guilt. Because of the increasing demand for this information,
4 the gathering, processing, handling and tabulating of DNA
5 materials in court cases and other areas has become an area of
6 great activity. There is often considerable pressure placed on
7 the few laboratories that process DNA materials. Processing and
8 handling DNA materials requires considerable expertise and
9 unique equipment. As is the case in this Commonwealth, most DNA
10 casework is carried out by large police departments and State
11 facilities. There are, however, some private labs conducting
12 this work. As DNA evidence continues to play an integral part in
13 determining the innocence or guilt of a person, it is vitally
14 important that laboratories conducting this type of analysis are
15 well regulated and accredited.

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

25 The term "Department" means the Department of Health.]

26 Section 103. Definitions.--The following words and phrases
27 when used in this act shall have the meanings given to them in
28 this section unless the context clearly indicates otherwise:

29 "ASCLD-LAB" means the American Society of Crime Laboratory
30 Directors/Laboratory Accreditation Board.

1 "Blind external proficiency testing" means a test sample that
2 is presented to a forensic laboratory for forensic
3 deoxyribonucleic acid (DNA) testing through a second agency, and
4 which appears to the analysis to involve routine evidence
5 submitted for forensic DNA testing.

6 "Board" means the Forensic DNA Accreditation Board
7 established in section 502.

8 "Bureau" means the Bureau of Laboratories in the Department
9 of Health of the Commonwealth.

10 "Clinical laboratory" means any place, establishment or
11 institution organized and operated primarily for the performance
12 of all or any bacteriological, biochemical, microscopical,
13 serological or parasitological tests by the practical
14 application of one or more of the fundamental sciences to
15 material originating from the human body, by the use of
16 specialized apparatus, equipment and methods, for the purpose of
17 obtaining scientific data which may be used as an aid to
18 ascertain the state of health.

19 "Department" means the Department of Health of the
20 Commonwealth.

21 "DNA" means the deoxyribonucleic acid which is located in the
22 cells and provides the personal genetic blueprint of each
23 individual through encoded genetic information that is the basis
24 of human heredity and forensic identification.

25 "DNA testing methodology" means the methods and procedures
26 used to extract and analyze deoxyribonucleic acid (DNA)
27 material, as well as the methods, procedures, assumptions and
28 studies used to draw statistical inferences from the test
29 results.

30 "FBI" means the Federal Bureau of Investigation.

1 "Forensic DNA laboratory" means any forensic laboratory
2 operated in this Commonwealth that performs forensic DNA testing
3 on crime scenes or for purposes of identification.

4 "Forensic DNA testing" means any test that employs techniques
5 to examine deoxyribonucleic acid (DNA) derived from the human
6 body for the purpose of providing information to resolve issues
7 of identification.

8 "Secretary" means the Secretary of Health of the
9 Commonwealth.

10 "State DNA identification record system" means the State DNA
11 Data Base reestablished under 42 Pa.C.S. § 4712 (relating to
12 State DNA Data Base) and the State DNA Data Bank reestablished
13 under 42 Pa.C.S. § 4713 (relating to State DNA Data Bank).

14 "Supreme Court" means the Supreme Court of the Commonwealth
15 of Pennsylvania.

16 CHAPTER 3

17 CLINICAL LABORATORIES

18 Section 301. Clinical Laboratory Permits.--The department
19 shall issue a permit for the operation of any clinical
20 laboratory which meets the requirements of this chapter and
21 complies with the regulations promulgated under this chapter.

22 Section [3. Limitations] 302. Supervision.--A clinical
23 laboratory shall be under the direct and personal supervision
24 of:

25 [1.] (1) A holder of a doctor of science degree or its
26 equivalent in the basic sciences, including professional degrees
27 in public health, medicine, osteopathy, pharmacy, dentistry and
28 veterinary medicine, from a college or university recognized by
29 the National Committee of Regional Accrediting Agencies or the
30 Department of Education, in chemistry, biology or microbiology,

1 and who has had two years of experience in a laboratory
2 acceptable to the department.

3 [2.] (2) The holder of a master of science degree or its
4 equivalent in the basic sciences from a college or university
5 recognized by the National Committee of Regional Accrediting
6 Agencies or the Department of Education, in chemistry, biology
7 or microbiology, and who has had a minimum of four years'
8 experience in a laboratory acceptable to the department.

9 [3.] (3) The holder of a bachelor of science degree or its
10 equivalent in the basic sciences from a college or university
11 recognized by the National Committee of Regional Accrediting
12 Agencies or the Department of Education, in chemistry, biology
13 or microbiology, and who has had a minimum of five years'
14 experience in laboratory work in a laboratory acceptable to the
15 department.

16 [4.] (4) From and after July 1, 1973, no clinical laboratory
17 shall be under the direction and personal supervision of any
18 person who does not meet the qualifications set forth in clause
19 [2] (2) of this section, and from and after July 1, 1974, no
20 clinical laboratory shall be under the direction and personal
21 supervision of any person who does not meet the requirements of
22 clause [1] (1) of this section[: Provided, however, That this].
23 This clause shall apply only to those laboratories for which an
24 application for a permit is made on or after the dates herein
25 specified[: And provided further, That this]. This provision
26 shall apply only to those clinical laboratories required to have
27 a permit pursuant to the provisions of this [act] chapter.

28 [5.] (5) The [foregoing] limitations in this section shall
29 not apply to those persons operating a clinical laboratory prior
30 to [the effective date of this act] January 1, 1952.

1 Section [3.1. Advisory Committee] 303. Advisory Committee
2 on Clinical Laboratories.--An advisory committee shall be
3 established for the purpose of advising the secretary in matters
4 relating to administration of [the act] this chapter. There
5 shall be seven members, each of whom is experienced in the
6 clinical laboratory field. At least one member shall be
7 qualified in the discipline of anatomic pathology and one in
8 clinical pathology and licensed to practice medicine in [the]
9 this Commonwealth or eligible for licensure, one shall be
10 qualified in the field of clinical chemistry, and one shall be
11 qualified in the field of clinical microbiology. Members of the
12 committee shall be appointed by the secretary.

13 Section [4] 304. Application for Clinical Laboratory
14 Permit.--All persons now operating or hereafter desiring to
15 operate an analytical-biochemical-biological laboratory shall
16 make written application to the department for a permit to
17 operate, which application shall be accompanied by [a fee of
18 twenty-five dollars (\$25)] an application fee, payable to the
19 department, and shall be retained by the department.

20 Section [5] 305. Contents of Application for Clinical
21 Laboratory Permit.--The application shall contain at least the
22 following:

23 [(a)] (1) The name and address of the persons owning the
24 place, establishment or institution in which the analytical-
25 biochemical-biological laboratory is to be or is operated.

26 [(b)] (2) The name and address of the persons operating or
27 to operate such laboratory.

28 [(c)] (3) The name and address of the qualified person under
29 whose direct and personal supervision such laboratory is to be
30 or is operated.

1 [(d)] (4) The kind and nature of the laboratory work to be
2 or is being done.

3 [(e)] (5) The description of the building, its location,
4 facilities, equipment, apparatus and appliances to be furnished
5 or used in the operation of such laboratory.

6 [(f)] (6) Such additional information as the department may
7 require by any rule or regulation.

8 The facts as set forth in the application shall be duly sworn to
9 or affirmed by one of the owners of such laboratory.

10 Section [6] 306. Revocation of Permit.--(a) Permits shall
11 become void upon change of director and also upon the removal of
12 the laboratory to other quarters. A new permit may be issued
13 without charge when the department has passed upon the
14 qualifications of the new director or upon the adequacy of the
15 new quarters and equipment.

16 (b) A permit may be revoked at any time for failure to
17 maintain proper standards of accuracy, for unethical practice or
18 for unethical advertising, or for any other cause deemed
19 adequate by the department.

20 Section [7] 307. Investigation by Department.--Upon the
21 filing of any application for a permit or for renewal, the
22 department shall investigate the facts set forth in the
23 application.

24 Section [8] 308. Issuance of Permit.--If the department
25 finds the statements contained in the application are true, the
26 [said] department shall issue a permit.

27 Section [9] 309. Contents and Signing of Permit.--(a) The
28 permits shall contain at least the following:

29 [(a)] (1) The name and address of the laboratory and of its
30 owner.

1 [(b)] (2) The name and address of the person charged with
2 the operation of the laboratory.

3 [(c)] (3) The name of the qualified person under whose
4 supervision the laboratory is operated.

5 [(d)] (b) All permits shall be signed or counter-signed by
6 the Secretary of Health.

7 Section [10] 310. Statement of Grounds for Denial of
8 Permits.--If the department does not, within six months after
9 the filing of the application, issue a permit, it shall state
10 the grounds and reasons for its refusal, in writing, furnishing
11 a copy to the applicant.

12 Section [11] 311. Inspection.--The department may at any
13 time visit, enter, examine and inspect the premises occupied,
14 maintained and conducted by any laboratory, and may examine all
15 matters in relation thereto. Periodically the department shall
16 verify the accuracy of the work of each laboratory using such
17 means and standards as the department shall specify by rule or
18 regulation.

19 [Section 11.1. Rules and Regulations.--The Department of
20 Health shall have the power, and its duty shall be, to adopt
21 rules and regulations for the proper enforcement of this act
22 with regard to the following:

23 (1) Contents of application;

24 (2) Adequacy of laboratory quarters and equipment;

25 (3) Means and standards of accuracy of laboratory
26 procedures;

27 (4) Definition of unethical practice and unethical
28 advertising;

29 (5) Any other matters it may deem advisable for the
30 protection of the public and for carrying out the provisions and

1 purposes of this act.

2 Section 12. Hearings and Appeals.--If an application for a
3 permit is denied, as provided in section ten hereof, the
4 applicant may request and be entitled to a hearing before the
5 Secretary of Health, if such request was made within thirty days
6 after the permit was denied. A permit issued under the
7 provisions of this act may be revoked or suspended by the
8 department for cause: Provided, That the permittee is permitted
9 to be heard by the department, either personally, by counsel, or
10 both: And provided further, That a written copy of the causes be
11 furnished him, by registered mail, ten days in advance of the
12 date set for hearing. Said notice shall fix the time and place
13 for said hearing, which shall not be more than thirty days from
14 the date of the mailing of said notice.

15 Any person who shall be aggrieved by any action of the
16 department under this act or by any rule or regulation
17 promulgated by the department shall have the right to file a
18 complaint with the Secretary of Health and to have a hearing
19 thereon before the Secretary of Health. Such hearing shall be
20 conducted and the decision of the Secretary of Health on the
21 issue involved shall be rendered in accordance with the
22 provisions of the Administrative Agency Law and its amendments,
23 approved June fourth, one thousand nine hundred forty-five
24 (Pamphlet Laws 1388), relating to adjudication procedure.

25 Section 13. Exemptions.--This act shall not include nor
26 apply to any laboratory or laboratories maintained and operated
27 by the Federal government; nor to any laboratory or laboratories
28 maintained and operated purely for research or teaching
29 purposes.]

30 Section [13.1] 312. Unlawful Conduct.--It shall be unlawful

1 for any person to solicit, receive, accept, deliver or transmit,
2 by mail or otherwise, material originating from the human body
3 on behalf of any person operating a clinical laboratory not in
4 possession of a permit under this [act] chapter regardless of
5 whether such laboratory is located in this Commonwealth. The
6 provisions of this section shall not apply to transactions with
7 any person operating a clinical laboratory located in another
8 state, which laboratory has been issued a license or permit in
9 conformity with the "Clinical Laboratories Improvement Act of
10 1967," and related statutes. Neither shall this section apply to
11 transactions with laboratories operated in this State which are
12 exempt from the permit requirements of this [act.] chapter.

13 Section 313. Rules and Regulations.--The department shall
14 have the power, and its duty shall be, to adopt rules and
15 regulations for the proper enforcement of this chapter with
16 regard to the following:

17 (1) Contents of application;

18 (2) Adequacy of laboratory quarters and equipment;

19 (3) Means and standards of accuracy of laboratory
20 procedures;

21 (4) Definition of unethical practice and unethical
22 advertising;

23 (5) Any other matters it may deem advisable for the
24 protection of the public and for carrying out the provisions and
25 purposes of this chapter.

26 CHAPTER 5

27 FORENSIC DNA LABORATORIES

28 Section 501. Accreditation of Forensic DNA Laboratories.--
29 The department shall accredit, regulate and oversee the
30 operations of forensic DNA laboratories in this Commonwealth

1 using the standards and system of accreditation established by
2 the board.

3 Section 502. Forensic DNA Accreditation Board.--(a) The
4 forensic science DNA accreditation board is established in the
5 department and shall consist of seven voting members and one ex-
6 officio member as follows:

7 (1) The Secretary of Health or a designee of the secretary,
8 who shall be chair of the board.

9 (2) The director of the Bureau of Laboratories or its
10 successor, who shall serve as an ex-officio member of the board.

11 (3) The Commissioner of the Pennsylvania State Police or a
12 designee.

13 (4) The Attorney General or a designee.

14 (5) One member to be appointed by the secretary for a term
15 of six years who shall be a scientist having experience in the
16 area of laboratory standards or quality assurance regulation and
17 monitoring.

18 (6) Two members to be appointed by the Governor for terms of
19 four years, one to be a prosecuting attorney, and one to be a
20 public defender.

21 (7) One member to be appointed by the Chief Justice of the
22 Supreme Court for a term of six years who shall be a judge or
23 attorney with a background in biomedical ethics and privacy
24 issues.

25 (b) The members of the Forensic DNA Accreditation Board
26 appointed by the Governor, the Chief Justice of the Supreme
27 Court and the secretary shall be confirmed by a majority vote of
28 the Senate.

29 (c) Any vacancy created other than by expiration of a term
30 shall be filled by the appointing authority for the unexpired

term of the member. Any vacancy shall be filled in the same manner as the original appointment. All members shall serve until successors are appointed.

(d) The accreditation board shall meet at least four times each year and may establish its own rules and procedures concerning the conduct of its meetings and other affairs not inconsistent with law.

(e) No member of the board shall be disqualified from holding any public office or employment, nor shall the member forfeit any such office or employment, by reason of appointment to the board. Members of the board shall not be required to take and file oaths of office before serving on the board.

(f) Members of the board shall receive no compensation for their services but shall be allowed their actual and necessary expenses incurred in the performance of their functions under this chapter.

Section 503. Powers and Duties of Board.--The board shall have the following powers and duties:

(1) To establish minimum standards for:

(i) Qualifications for forensic DNA laboratory directors and such other personnel as the board may determine to be necessary and appropriate.

(ii) The approval of forensic DNA laboratories for the performance of specific forensic methodologies.

(2) To adopt accreditation standards for forensic DNA laboratories which, at a minimum, include or require:

(i) Standards equivalent to or greater than standards promulgated by ASCLD-LAB.

(ii) Standards that require the applicant to comply with the standards issued by the FBI for forensic DNA laboratories.

1 (iii) Standards which meet the requirements of the
2 Pennsylvania State Police used for the State DNA Identification
3 Record System.

4 (3) The adoption and implementation of internal and external
5 proficiency testing programs, which may include a blind external
6 proficiency testing program for forensic laboratories performing
7 forensic DNA testing.

8 (4) The designation of one or more entities for the
9 performance of proficiency tests required under this chapter.

10 (5) The qualifications for and employment of forensic DNA
11 laboratory inspectors.

12 (6) To establish, appoint and set terms of members to as
13 many advisory councils as it deems necessary to provide
14 specialized expertise to the board with respect to new forensic
15 DNA technologies including testing methodologies.

16 (7) To designate one or more approved methodologies for the
17 performance of forensic DNA testing.

18 (8) To review and act upon applications by forensic DNA
19 laboratories for approval to perform forensic DNA testing.

20 (9) To assess and evaluate all DNA methodologies proposed to
21 be used for forensic analysis.

22 (10) To require a demonstration by an independent laboratory
23 of any proposed forensic DNA testing methodology proposed to be
24 used by a forensic laboratory.

25 (11) To develop an application for forensic DNA laboratory
26 accreditation.

27 Section 504. Objectives of Standards and Accreditation.--The
28 minimum standards and program of accreditation shall be designed
29 to accomplish all of the following objectives:

30 (1) Set minimum requirements for the effectiveness,

1 efficiency, reliability and accuracy of forensic DNA
2 laboratories.

3 (2) Recommend and assist the implementation of the highest
4 performance of DNA standards.

5 (3) Promote increased cooperation and coordination among
6 forensic DNA laboratories and other agencies in the criminal
7 justice system.

8 (4) Ensure compatibility, to the extent consistent with the
9 provisions of this chapter and any other applicable provision of
10 law pertaining to privacy or restricting disclosure or
11 redisclosure of information, with Federal and other state
12 forensic DNA laboratories to the extent necessary to share and
13 exchange information, data and results of forensic DNA analysis
14 and tests.

15 (5) Set forth minimum requirements for the quality and
16 maintenance of equipment.

17 Section 505. Requirements for Obtaining Accreditation.--The
18 program of forensic DNA laboratory accreditation shall include,
19 at a minimum, all of the following requirements:

20 (1) An initial laboratory inspection, and routine
21 inspections, as necessary, to ensure compliance with
22 accreditation requirements.

23 (2) Routine internal and external proficiency testing of all
24 laboratory personnel involved in forensic DNA analysis,
25 including blind external proficiency testing if the board
26 determines such a blind proficiency testing program is
27 practicable and appropriate, the board shall consider such
28 factors as accuracy and reliability of laboratory results, cost-
29 effectiveness, time, allocation of resources and availability.

30 (3) Quality control and quality assurance protocols, a

1 method validation procedure and a corrective action and remedial
2 program.

3 (4) Annual certification to the department by the forensic
4 DNA laboratories of their continued compliance with the
5 requirements of the accreditation program.

6 Section 506. Revocation and Suspension of Accreditation.--
7 The accreditation of a forensic DNA laboratory may be revoked,
8 suspended or otherwise limited, upon a determination by the
9 department that the laboratory or one or more persons in its
10 employ:

11 (1) Is guilty of misrepresentation in obtaining a forensic
12 DNA laboratory accreditation.

13 (2) Rendered a report on laboratory work actually performed
14 in another forensic DNA laboratory without disclosing the fact
15 that the examination or procedure was performed by such other
16 forensic DNA laboratory.

17 (3) Showed a pattern of excessive errors in the performance
18 of forensic DNA laboratory examination procedures.

19 (4) Failed to file any report required to be submitted
20 pursuant to this act or the rules and regulations promulgated
21 pursuant thereto.

22 (5) Violated in a material respect any provision of this
23 chapter or the promulgated rules and regulations.

24 Section 507. Cooperation with Department.--The department
25 may require and receive from any agency of the Commonwealth or
26 any political subdivision such assistance and data as may be
27 necessary to enable the department to administer the provisions
28 of this chapter. The department may enter into such cooperative
29 arrangements with the State Crime Laboratory, and any other
30 Commonwealth agency, each of which is authorized to enter into

such cooperative arrangements as shall be necessary or appropriate. Upon request of the department any Commonwealth agency may transfer to the department such officers and employees as the department may deem necessary from time to time to assist the department in carrying out its functions and duties. Officers and employees so transferred shall not lose their civil service status or rights, and shall remain in the negotiating unit, if any, established prior to such transfer.

Section 508. Subcontracting of DNA Testing.--Any Commonwealth accredited forensic DNA laboratory must require certification of compliance with the standards issued by the board when an out-of-state subcontractor performs forensic DNA analysis for the laboratory. The forensic DNA laboratory will establish and use appropriate review procedures to verify the integrity of the data received from the subcontractor.

Section 509. Confidentiality.--All records, findings, reports and results shall not be released to insurance companies, employers or potential employers, health providers, employment screening or personnel companies, agencies, or services, or private investigation services, and may not be disclosed upon request or order of any agency, authority, division, office, corporation, partnership or any other private or public entity or person. Nothing contained in this chapter shall prohibit disclosure in response to a subpoena.

Section 510. Unlawful Conduct.--It shall be unlawful for any person to intentionally disclose a DNA record, or the results of a forensic DNA test or analysis, to an individual or agency other than one authorized to have access to such records pursuant to this chapter or to intentionally use or receive DNA records, or the results of a forensic DNA test or analysis, for

1 purposes other than those authorized pursuant to this chapter.

2 Section 511. Compliance Schedule.--Upon enactment of this
3 chapter, the board shall have one year to establish and
4 promulgate minimum standards and a program of accreditation for
5 all forensic DNA laboratories in this Commonwealth. All DNA
6 laboratories shall apply for accreditation within six months of
7 the promulgation of the standards. Four years after the
8 effective date of this chapter, all forensic DNA labs in this
9 Commonwealth shall be in full compliance with this chapter. Any
10 forensic DNA laboratory not in full compliance after this time
11 shall be subject to penalties adopted by the department.

12 Section 512. Additional Research.--(a) Nothing in this
13 chapter shall be deemed to preclude forensic DNA laboratories
14 from performing research and validation studies on new
15 methodologies and technologies which may not yet be approved by
16 the board at that time.

17 (b) Regulation pursuant to this chapter shall not include
18 DNA testing on materials derived from the human body for the
19 purpose of determining a person's genetic disease or medical
20 condition.

21 CHAPTER 7

22 PROVISIONS OF GENERAL APPLICABILITY

23 Section 701. Exemptions.--This act shall not include nor
24 apply to any clinical or forensic DNA laboratory or laboratories
25 maintained and operated by the Federal government; nor to any
26 clinical or forensic DNA laboratory or laboratories maintained
27 and operated purely for research or teaching purposes.

28 Section 702. Hearings and Appeals.--(a) All adjudications
29 and final actions of the department under this act or the rules
30 and regulations promulgated under this act shall be subject to

1 appeal.

2 (b) All hearings on appeals and all procedures relating to
3 those hearing shall be conducted under the provisions of 2
4 Pa.C.S. Chs. 5 Subch. A (relating to practice and procedure of
5 Commonwealth agencies) and 7 Subch. A (relating to judicial
6 review of Commonwealth agency action).

7 Section [14. Penalty.--] 703. Penalties.--(a) Any person
8 operating a clinical laboratory without first having obtained a
9 permit from the [Department of Health] department or violating
10 the provisions of section [13.1 of the act] 312 shall, upon
11 conviction thereof, be sentenced to pay a fine not exceeding
12 [five hundred dollars (\$500)] \$500 or to imprisonment not
13 exceeding one [(1)] year, or both.

14 (b) (1) Any person operating a forensic DNA laboratory
15 without obtaining the accreditation required by this act, or
16 who, with the intent to mislead or deceive, misrepresents a
17 material fact to the department shall be subject to a civil
18 penalty not to exceed \$7,500 and such other penalties as are
19 prescribed by the law.

20 (2) Any person who:

21 (i) intentionally discloses a DNA record, or the results of
22 a forensic DNA test or analysis, to an individual or agency
23 other than one authorized to have access to such records
24 pursuant to this act; or

25 (ii) intentionally uses or receives DNA records, or the
26 results of a forensic DNA test or analysis, for purposes other
27 than those authorized pursuant to this act shall be guilty of a
28 felony, and upon conviction thereof, shall be subject to a fine
29 of not more than \$10,000 and such other penalties as are
30 prescribed by the law.

