

GENERAL ASSEMBLY OF NORTH CAROLINA
SESSION 2003

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HOUSE BILL 1256
Committee Substitute Favorable 5/22/03

Short Title: Voluntary DNA Database.

(Public)

Sponsors:

Referred to:

April 24, 2003

A BILL TO BE ENTITLED

AN ACT TO DIRECT THE SECRETARY OF COMMERCE TO ESTABLISH A
DNA DATABANK FOR THE VOLUNTARY SUBMISSION BY INDIVIDUALS
OF DNA SAMPLES LINKED WITH THE INDIVIDUAL'S MEDICAL RECORD.

The General Assembly of North Carolina enacts:

SECTION 1. Article 10 of Chapter 143B of the General Statutes is amended
by adding the following new Part to read:

"Part 19. Voluntary DNA/Medical Records Database.

§ 143B-472.85. Voluntary DNA Database established; purpose.

(a) The Secretary of Commerce shall establish the Voluntary DNA Database for the recording of DNA data and related medical records submitted voluntarily by individuals for the purposes authorized in this Part. DNA data and related medical records stored in the database shall be stripped of all information that would personally identify the individual submitting the data. The Secretary may maintain the database in the Department of Commerce or another suitable location. The Secretary shall appoint the Director of the DNA database.

(b) The DNA database must be capable of classifying, matching, and storing the results of analyses of DNA and other biological molecules.

(c) The DNA database may contain DNA records and related medical records of individuals who have volunteered to provide the DNA sample and medical records. The Secretary may receive, analyze, store, and destroy a record, blood sample, or other specimen for the purposes described in subsection (d) of this section.

(d) The principal purpose of the Voluntary DNA Database is to advance scientific study of the links between genetics and common diseases in order to improve diagnosis and treatment of the diseases, provided that DNA samples and related medical records may only be stored in the database if all personal identifying information is removed. The information contained in the database may not be collected, analyzed, or stored to obtain information about human physical traits or predisposition for disease unless the purpose for obtaining the information is authorized by this subsection.

1 (e) The Director may publish educational materials on the Voluntary DNA
2 Database for dissemination to the general public. The materials shall describe the
3 purposes for which data in the database will be used, who will have access to the
4 database, the confidential nature of samples in the database, and other information.

5 **"§ 143B-472.86. Collection of DNA samples.**

6 (a) The Secretary shall adopt rules establishing procedures for the collection,
7 preservation, analysis, and use of blood samples or other specimens in a manner that
8 permits the exchange of DNA samples between DNA laboratories and the use of the
9 data for the purposes authorized under this section.

10 (b) The Director of the DNA database may conduct DNA analyses or contract
11 with a laboratory, other State agency, private entity, or institution of higher education
12 for services to perform DNA analyses.

13 (c) The Director of the DNA database may not accept a blood sample or other
14 specimen taken from a person that is submitted voluntarily unless the sample or
15 specimen is collected in a medically approved manner by a physician or registered nurse
16 or other person who is trained to properly collect samples or other specimens and
17 supervised by a licensed physician. A person collecting a blood sample or other
18 specimen under this section shall not be liable in any civil action if the person collects
19 the sample or specimen in a reasonable manner according to generally accepted medical
20 or other professional practices.

21 (d) The Director shall provide at no cost to the individual the specimen vials,
22 mailing tubes and labels, report forms, and other instructions for collection of blood
23 samples or other specimens from individuals voluntarily submitting DNA to the
24 database.

25 (e) A person who collects a blood sample or other specimen under this section
26 shall send the sample or specimen to the Director of the DNA database.

27 (f) A DNA laboratory may analyze a blood sample collected under this section
28 or other DNA specimen only for the purposes authorized under this section.

29 **"§ 143B-472.87. Collection of medical history.**

30 The Director of the DNA database shall make available on the Internet a medical
31 history questionnaire that shall be required as part of every voluntary submission to the
32 database. Information from the questionnaire shall be automatically entered into the
33 DNA database and shall be coded in a manner that links it to the DNA record of the
34 volunteer. The medical history questionnaire shall be developed by the Director, in
35 consultation with the following persons, or their designees:

36 (1) The Director of the Genomic Science Program, North Carolina State
37 University.

38 (2) The Chair of the Department of Genetics, University of North Carolina
39 School of Medicine.

40 (3) The Director of the Biomedical/Biotechnology Research Institute,
41 North Carolina Central University.

42 (4) The Chair of the Department of Pediatrics/Genetics, East Carolina
43 University School of Medicine.

1 (5) The Director of the Genomic Science Program, Western Carolina
2 University.

3 **"§ 143B-472.88. Access to Voluntary DNA Database information.**

4 (a) The Secretary shall adopt rules:

5 (1) To prevent unauthorized access to the DNA database.

6 (2) To release DNA records, specimens, or analyses from the DNA
7 database for authorized purposes.

8 (3) Relating to the internal disclosure, access, or use of a sample,
9 specimen, or DNA record in the Department of Commerce DNA
10 laboratory.

11 (b) The Director may release a DNA sample, analysis, or record, only if
12 personally identifiable information is removed, for:

13 (1) A population statistics database.

14 (2) Identification research and protocol development.

15 (3) Quality control.

16 (c) The Director may release a record of the number of requests made for a DNA
17 record and the name of the requesting person. The Director shall maintain a record of
18 requests made under this section.

19 **"§ 143B-472.89. Confidentiality of DNA records.**

20 (a) A DNA record stored in the Voluntary DNA Database is confidential and is
21 not subject to disclosure except for the purposes authorized in this Part.

22 (b) A person who knowingly discloses information in a DNA record or
23 information related to a DNA analysis of a blood specimen except as authorized by this
24 Part is guilty of a Class 1 misdemeanor.

25 (c) A violation of this section constitutes official misconduct.

26 **"§ 143B-472.90. Segregation of records.**

27 The Secretary shall adopt rules providing for the segregation of DNA records
28 created under this Part from records created under Article 13 of Chapter 15A of the
29 General Statutes.

30 **"§ 143B-472.91. Fees; other funds.**

31 The Director may collect a reasonable fee for providing population statistics data or
32 other research data as authorized by this Part. The Director shall charge to North
33 Carolina-based biotechnology corporations and research institutions an equal portion of
34 the cost to store and retrieve information in the database. The annual fee for each
35 biotechnology corporation or research institution shall be twenty-five thousand dollars
36 (\$25,000) for the first year of operating the database. Thereafter, the charge to each
37 corporation or research institution shall be based on the actual cost of maintaining the
38 system, divided by the number of biotechnology corporations and research institutions
39 that represents one-half of the total number of biotechnology corporations and research
40 institutions in the State. The Department of Commerce, on behalf of the Voluntary
41 DNA Database, may accept grants, contributions, devises, bequests, and gifts, which
42 shall be kept in a separate fund, which shall be nonreverting, and shall be used to fund
43 the implementation and continuing operation of the Voluntary DNA Database.

44 **"§ 143B-472.92. Definitions.**

1 As used in this Part, unless the context clearly requires otherwise:

2 (1) 'Database' or 'DNA database' means the Voluntary DNA Database
3 established under this Part for the recording of DNA samples and
4 related medical records voluntarily submitted by an individual.

5 (2) 'Director' means the Director of the Voluntary DNA Database
6 established under this Part.

7 (3) 'DNA' means deoxyribonucleic acid.

8 (4) 'DNA record' means DNA identification information stored in the
9 Voluntary DNA Database for the purposes stated in this Part.

10 (5) 'DNA sample' means a blood sample or other specimen voluntarily
11 submitted to the database by an individual."

12 **SECTION 2.** There is appropriated from the General Fund to the
13 Department of Commerce the sum of one hundred thousand dollars (\$100,000) for the
14 2003-2004 fiscal year. These funds shall be used to establish the Voluntary DNA
15 Database in accordance with Section 1 of this act. The Department shall establish a
16 schedule of implementation that ensures that the most cost-effective plan is pursued.
17 The following order of priorities shall serve as a guide for implementation of this act:

18 (1) Development and implementation of the medical history questionnaire,
19 test kits for volunteer submissions to the database, and collection and
20 storage of DNA samples.

21 (2) Computerization of DNA data submissions.

22 (3) Availability of DNA database for marketing to North Carolina
23 research institutions and biotechnology companies.

24 **SECTION 3.** This act becomes effective July 1, 2003. Section 1 of this act
25 becomes effective only if funds are appropriated to implement this act.