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Short Title: Voluntary DNA Database.

(Public)

Sponsors:

Referred to:

April 24, 2003

A BILL TO BE ENTITLED

AN ACT TO DIRECT THE SECRETARY OF HEALTH AND HUMAN SERVICES
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 3 of Chapter 143B of the General Statutes is amended
by adding the following new Part to read:

"Part 34. Voluntary DNA/Medical Records Database.

"§ 143B-216.68. Voluntary DNA Database established; purpose.

(a) The Secretary 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 or another suitable location. The Secretary shall appoint the Director of the DNA database who shall be responsible for marketing the database to potential donors and companies that may wish to access the database. The Secretary shall select a public research institution to develop, implement, and maintain the 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

1 diagnosis and treatment of the diseases, provided that DNA samples and related medical
2 records may only be stored in the database if all personal identifying information is
3 removed. The information contained in the database may not be collected, analyzed, or
4 stored to obtain information about human physical traits or predisposition for disease
5 unless the purpose for obtaining the information is authorized by this subsection.

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

10 **"§ 143B-216.69. Collection of DNA samples.**

11 (a) The Secretary shall adopt rules establishing procedures in accordance with
12 this Part for the collection, preservation, analysis, and use of blood samples or other
13 specimens in a manner that permits the exchange of DNA samples between DNA
14 laboratories and the use of the data for the purposes authorized under this section.

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

18 (c) The DNA database may not accept a blood sample taken from a person that is
19 submitted voluntarily unless the sample is collected in a medically approved manner by
20 a physician or registered nurse or other person who is trained to properly collect
21 samples or other specimens and supervised by a licensed physician. A person collecting
22 a blood sample or other sample or specimen under this section shall not be liable in any
23 civil action if the person collects the sample or other specimen in a reasonable manner
24 according to generally accepted medical or other professional practices. A person
25 voluntarily submitting hair or saliva samples or specimens, or other samples or
26 specimens except for blood, may send the hair, saliva, or sample or specimen other than
27 blood directly to the research institution.

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

32 (e) A person who collects a blood sample or other specimen under this section
33 shall send the sample or specimen to the DNA database in accordance with instructions
34 provided by the Director.

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

37 **"§ 143B-216.70. Data collection.**

38 (a) The Director of the DNA database shall make available on the Internet or by
39 mail a medical history questionnaire that shall be required as part of every voluntary
40 submission to the database. Upon receipt of the completed questionnaire from the
41 donor, the Department shall provide for a donor test kit to be mailed to the donor. The
42 test kit, returned samples or specimens, and the completed questionnaire will be linked
43 and uniquely identified by a bar code or other unique number in order to preserve the
44 donor's anonymity. When a sample is mailed to the lab site for housing, the sample will

1 be transferred to a stain card for storage before any analysis of the sample is undertaken.
2 The transfer to a stain card shall be in a manner and time period that preserves the
3 integrity of the sample for future testing. The medical history questionnaire shall be
4 developed by the Director, in consultation with the following persons, or their
5 designees:

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

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

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

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

14 (5) The Director of the Genomic Science Program, Western Carolina
15 University.

16 (b) The completed medical questionnaire shall be maintained in the database.
17 After not fewer than one thousand samples have been collected, a medical marker DNA
18 test shall be performed, computerized, and attached to the original completed medical
19 questionnaire. Information from the completed medical questionnaire and the medical
20 marker test shall be linked using the unique bar code or identifying number assigned.
21 The Department may make available the information from each linked marker and
22 questionnaire to North Carolina based biotechnology companies and research
23 institutions.

24 **"§ 143B-216.71. Access to Voluntary DNA Database information.**

25 (a) The Secretary shall adopt rules:

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

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

29 (3) Relating to the internal disclosure, access, or use of a sample,
30 specimen, or DNA record in the Department of Health and Human
31 Services DNA laboratory.

32 (b) A DNA sample, analysis, or record, may be released only if personally
33 identifiable information is removed, for:

34 (1) A population statistics database.

35 (2) Identification research and protocol development.

36 (3) Quality control.

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

40 **"§ 143B-216.72. Confidentiality of DNA records.**

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

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

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

5 **"§ 143B-216.73. Segregation of records.**

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

9 **"§ 143B-216.74. Fees; other funds.**

10 The Director shall charge to participating North Carolina-based biotechnology
11 corporations and research institutions an equal portion of the cost to store and retrieve
12 information in the database. The annual fee for each biotechnology corporation or
13 research institution shall be twenty-five thousand dollars (\$25,000) for the first year of
14 operating the database. After the first year, the fee shall be adjusted based on the actual
15 cost of maintaining the system. The Department of Health and Human Services, on
16 behalf of the Voluntary DNA Database, may accept grants, contributions, devises,
17 bequests, and gifts, which shall be kept in a separate fund, which shall be nonreverting,
18 and shall be used to fund the implementation and continuing operation of the Voluntary
19 DNA Database. The Department may also accept donations of equipment and storage
20 facilities from a State, private, or public research institution to be used for the purposes
21 of the DNA Database.

22 **"§ 143B-216.75. Definitions.**

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

- 24 (1) 'Database' or 'DNA database' means the Voluntary DNA Database
25 established under this Part for the recording of DNA samples and
26 related medical records voluntarily submitted by an individual.
27 (2) 'Department' means the Department of Health and Human Services.
28 (3) 'Director' means the Director of the Voluntary DNA Database
29 established under this Part.
30 (4) 'DNA' means deoxyribonucleic acid.
31 (5) 'DNA record' means DNA identification information stored in the
32 Voluntary DNA Database for the purposes stated in this Part.
33 (6) 'DNA sample' means a blood sample or other specimen voluntarily
34 submitted to the database by an individual.
35 (7) 'Medical record' means the questionnaire completed and submitted by
36 the individual volunteering to participate in the database.
37 (8) 'Secretary' means the Secretary of Health and Human Services."

38 **SECTION 2.(a)** No funds from the General Fund shall be used to implement
39 this act. The Secretary of Health and Human Services shall ensure that start-up and
40 maintenance of the Voluntary DNA Database shall proceed only as authorized funds
41 become available for these purposes.

42 **SECTION 2.(b)** This act becomes effective October 1, 2003.