105TH CONGRESS
1ST SESSION

S. 422

To define the circumstances under which DNA samples may be collected, stored, and analyzed, and genetic information may be collected, stored, analyzed, and disclosed, to define the rights of individuals and persons with respect to genetic information, to define the responsibilities of persons with respect to genetic information, to protect individuals and families from genetic discrimination, to establish uniform rules that protect individual genetic privacy, and to establish effective mechanisms to enforce the rights and responsibilities established under this Act.

IN THE SENATE OF THE UNITED STATES

MARCH 11, 1997

Mr. DOMENICI (for himself, Mr. JEFFORDS, and Mr. DODD) introduced the following bill; which was read twice and referred to the Committee on Labor and Human Resources

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A BILL

To define the circumstances under which DNA samples may be collected, stored, and analyzed, and genetic information may be collected, stored, analyzed, and disclosed, to define the rights of individuals and persons with respect to genetic information, to define the responsibilities of persons with respect to genetic information, to protect individuals and families from genetic discrimination, to establish uniform rules that protect individual genetic privacy, and to establish effective mechanisms to enforce the rights and responsibilities established under this Act.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the ''Genetic Confidentiality and Nondiscrimination Act of 1997''.

(b) TABLE OF CONTENTS.—The table of contents of this Act is as follows:

SEC. 2. FINDINGS AND PURPOSES.

(a) FINDINGS.—Congress finds the following:

(1) The DNA molecule contains the uniquely private and personal genetic information of an individual. This information is contained in a code that is rapidly being deciphered and understood.

(2) Research in human and medical genetics continues to provide and to predict immense health benefits to individuals and their families.

(3) Improper use and unauthorized disclosure of genetic information may cause significant social and psychological harm to individuals, including stigmatization and discrimination.

(4) Genetic analysis of the DNA of an individual provides information about the individual, and may provide information about the parents, siblings, and children of the individual.

(5) Existing legal protections for genetic information are inadequate to ensure genetic privacy and to prevent genetic discrimination.

(6) Uniform rules for the collection, storage, and use of DNA samples and genetic information, and for the disclosure of genetic information, will protect individual privacy, encourage genetic research, and prevent genetic discrimination.

(b) PURPOSES.—The purposes of this Act are—

(1) to define the circumstances under which—

(A) DNA samples may be collected, stored, and analyzed; and

(B) genetic information may be collected, stored, analyzed, and disclosed;

(2) to define the rights of individuals and persons with respect to genetic information;

(3) to define the responsibilities of persons with respect to genetic information;

(4) to protect individuals and families from genetic discrimination;

(5) to establish uniform rules that protect individual genetic privacy; and

(6) to establish effective mechanisms to enforce the rights and responsibilities established under this Act.

SEC. 3. DEFINITIONS.

As used in this Act:

(1) COLLECT.—The term ''collect'' means to obtain a DNA sample.

(2) COMPULSORY DISCLOSURE.—The term ''compulsory disclosure'' means any disclosure of genetic information required by Federal or State law for a judicial, legislative, or administrative proceeding.

(3) DISCLOSE.—The term ''disclose'', when used with respect to the genetic information of an individual, means to convey, or provide access to, the genetic information, to a person other than the individual.

(4) DNA.—The term ''DNA'' means deoxyribonucleic acid, which is a genetic material that is composed of a sequence of 4 kinds of molecular building blocks, called nucleotides, that encode genetic information.

(5) DNA MATCHING.—The term ''DNA matching'' means a scientifically and statistically reliable process for characterizing and comparing DNA samples, to determine if the DNA samples match and may therefore be presumed to originate from the same individual.

(6) DNA SAMPLE.—The term ''DNA sample'' means a human tissue sample from which DNA is

intended to be extracted, or DNA extracted from such tissue sample. The term ''DNA sample'' does not include a tissue sample that is taken—

(A) as a biopsy or an autopsy specimen, or as a clinical specimen solely for the purpose of conducting an immediate clinical or diagnostic test that is not a DNA test;

(B) as a blood sample solely for blood banking; or

(C) as a newborn screening specimen solely for determination of disease in the newborn, as required by law.

(7) EMPLOYER.—The term ''employer'' has the meaning given such term under section 3(5) of the Employee Retirement Income Security Act of 1974, except that such term shall include only employers of two or more employees.

(8) FAMILY.—The term ''family'' means the biological and legal relatives of an individual who may have a material interest in the genetic information of the individual.

(9) GENETIC ANALYSIS.—The term ''genetic analysis'' means the process of characterizing genetic information from a human tissue sample.

(10) GENETIC INFORMATION.—The term ''genetic information'' means information from a human DNA sample about molecular genotype, information from mutation analysis, or information about nucleotide sequence of a gene.

(11) INDIVIDUAL.—The term ''individual'' means the source of a human tissue sample from which DNA is extracted or molecular genetic information is characterized. The term ''individual'' includes a subject of genetic research, and where appropriate includes the parent, guardian or legal representative of the individual.

(12) INDIVIDUAL IDENTIFIER.—The term ''individual identifier'' means any information by which the identity of the individual can be ascertained. The term does not include codes that cannot be used singly to identify an individual.

(13) INSTITUTIONAL REVIEW BOARD.—The term ''Institutional Review Board'' means a board established in accordance with section 46.102(g) of title 45, Code of Federal Regulations (or any corresponding similar regulation or ruling).

(14) INSURER.—

(A) IN GENERAL.—The term ''insurer'' means an insurance company, insurance service,

or insurance organization (including a health maintenance organization, as defined in subparagraph (B)) which is licensed to engage in the business of insurance in a State and which is subject to State law which regulates insurance (within the meaning of section 514(b)(2) of the Employee Retirement Income Security Act of 1974). Such term does not include a group health plan.

(B) HEALTH MAINTENANCE ORGANIZATION.—The term ''health maintenance organization'' means—

(i) a Federally qualified health maintenance organization (as defined in section 1301(a));

(ii) an organization recognized under State law as a health maintenance organization; or

(iii) a similar organization regulated under State law for solvency in the same manner and to the same extent as such a health maintenance organization.

(15) PERSON.—The term ''person'' includes a family, corporation, partnership, association, joint venture, government, governmental subdivision or

agency, and any other legal or commercial entity. The term ''person'', used with respect to a human tissue sample, does not include the individual who is the source of the tissue sample.

(16) RESEARCH.—The term ''research'' means scientific investigation that includes systematic development and testing of hypotheses for the purpose of increasing knowledge.

(17) RESEARCHER.—The term ''researcher'' means a person who conducts research.

(18) RETAIN.—The term ''retain'' means to store a DNA sample or genetic information characterized from such a sample for an extended period of time after the initial testing conducted on the sample.

(19) SECRETARY.—The term ''Secretary'' means the Secretary of Health and Human Services.

(20) SUBJECT.—The term ''subject'', when used with respect to genetic research, means the source of a human tissue sample collected for molecular genetic analysis.

TITLE I—COLLECTION, STORAGE, AND ANALYSIS OF DNA SAMPLES

SEC. 101. COLLECTION OF SAMPLES.

(a) REQUIREMENT OF WRITTEN AUTHORIZATION.—Except as otherwise provided by law, a person may collect a DNA sample from an individual for genetic analysis only if the person—

(1) obtains the written authorization of the individual, as described in section 301;

(2) provides the information described in subsection (b) and the notice described in subsection (c); and

(3) collects the sample in accordance with the authorization and notice.

(b) REQUIRED INFORMATION.—Prior to the collection of a DNA sample from an individual for genetic analysis, the person who collects the sample shall inform the individual, in language understandable to the individual—

(1) that consent to the collection of the DNA sample is voluntary;

(2) about the genetic information that can reasonably be expected to be derived from the genetic analysis;

(3) about the implications of genetic information derived from the genetic analysis, for the individual and the family members of the individual;

(4) about the ways in which the genetic information derived from the genetic analysis will be used;

(5) about the information that the individual can expect to receive on completion of the genetic analysis;

(6) about the extent of the right of the individual to have the DNA sample removed from a research study and, if possible, to have the genetic information characterized from the DNA sample destroyed;

(7) about the right of the individual to revoke consent to the genetic analysis at any time prior to the commencement of the genetic analysis;

(8) that revocation of consent for genetic analysis does not absolve the individual of responsibility for all relevant costs of a clinical, diagnostic test;

(9) that the genetic analysis may yield information that should be communicated to a family member of the individual;

(10) about the existence of, and protections afforded by, this Act; and

(11) about the availability, or the lack of availability, of optional genetic counseling.

(c) NOTICE OF RIGHTS AND ASSURANCES.—The person who collects the DNA sample for genetic analysis shall provide the individual, prior to the collection of the DNA sample, and any other person upon request, with a written notice of rights and assurances that contains the following information and assurances:

(1) That the DNA sample will be used only as authorized in the written authorization, as described in section 301.

(2) That the individual has the right to order the destruction of an identifiable DNA sample at any time.

(3) That the DNA sample will be destroyed upon the completion of the genetic analysis or the genetic test, unless the individual has consented in writing to further use of the sample in accordance with section 301(a)(6).

(4) That the individual may designate another person as the person authorized to make decisions regarding disposition of the DNA sample after the death of the individual, and, if any person is so designated, that the individual should notify the facility in which the DNA sample is stored.

(5) That the individual has the right to examine clinical records containing genetic information, to obtain copies of such records, and to request amendment of such records.

(6) That researchers may be granted access to a DNA sample only as specified in the written authorization of the individual, in accordance with section 301(a)(6)(A).

(7) That the collection, storage, and analysis of the DNA sample and the genetic information characterized from the sample are protected by this Act, and that an individual whose rights under this Act are violated may seek civil remedies, including damages and attorney's fees, as provided for in this Act.

(8) That optional genetic counseling is, or is not, available as part of a research program.

SEC. 102. STORAGE AND GENETIC ANALYSIS OF DNA SAMPLES.

Except as otherwise required by Federal or State law, a person may store or conduct a genetic analysis of a DNA sample from an individual only if the person—

(1) confirms that the written authorization of the individual as described in section 301 has been obtained and the notice described in section 101(c) has been provided; and

(2) stores or conducts the analysis of the DNA sample in accordance with such authorization and notice.

TITLE II—DISCLOSURE OF GENETIC INFORMATION TO THIRD PERSONS

SEC. 201. DISCLOSURE OF GENETIC INFORMATION.

(a) REQUIREMENT OF WRITTEN AUTHORIZATION.—Except as otherwise required by Federal or State law, a person may disclose genetic information characterized from the DNA sample of an individual only with the written authorization of the individual, as described in section 302.

(b) REDISCLOSURE PROHIBITED.—Except to the extent reasonable in the exercise of judgment for professional medical consultation for the direct benefit of a patient, a person to whom genetic information has been disclosed may disclose the information only with the written authorization of the individual, as described in section 302.

SEC. 202. INSPECTION AND COPYING OF CLINICAL RECORDS CONTAINING GENETIC INFORMATION.

(a) INSPECTION OF CLINICAL RECORDS.—A person who retains the genetic information of an individual in

clinical records shall, on written request, permit the individual to inspect the records containing the genetic information and shall provide a copy of any such records to the individual.

(b) RESPONSE TO REQUEST FOR EXAMINATION AND COPYING OF INFORMATION.—A person described in subsection (a) who receives a written request from an individual to inspect or copy clinical records shall, not later than 20 business days after receiving the request, make the information available to the individual. The person may make the information available by permitting the individual to inspect the records at the storage site during regular business hours, or by delivering a copy of the records to the individual, using the mail or a private interstate document carrier.

(c) EXPLANATION OF TERMS AND CODES.—A person shall provide a nontechnical explanation of terms, and any codes or abbreviations, used in the records of the individual requesting the records.

(d) FEE.—The person may charge an individual (except an individual who participates as a subject in a research project) a reasonable fee, for copies of records that are provided under this section. The fee shall not exceed the actual duplication costs, including administrative costs, to the person providing the copies.

SEC. 203. AMENDMENT OF RECORDS.

(a) IN GENERAL.—Not later than 20 business days after receiving a written request by an individual to amend any clinical records containing genetic information, a person who retains the information in the records shall agree or refuse to add the written amendment to the clinical record. The person shall agree to make the amendment if such information is not accurate or complete for the purposes for which such information may be used or disclosed by the person.

(b) AGREEMENT.—If the person retaining the information agrees to make an amendment under subsection (a), the person shall, not later than 20 business days after such receipt—

(1) make the amendment requested;

(2) inform the individual that the amendment has been made; and

(3) make reasonable efforts to inform any other person to whom the information was previously disclosed of the amendment.

(c) REASONS FOR REFUSAL AND REVIEW PROCEDURES.—If the person retaining the information refuses to make an amendment under subsection (a), the person shall inform the individual in writing of—

(1) the reasons for the refusal of the person to make the amendment;

(2) the procedures for further review of the refusal; and

(3) the right of the individual to file with the person a concise written statement setting forth the requested amendment and the reasons of the individual for disagreeing with the refusal of the person to make the amendment.

(d) STATEMENT OF DISAGREEMENT.—After an individual has filed a statement of disagreement under subsection (c)(3), the person storing the records—

(1) shall make the statement part of the records of the individual; and

(2) in any subsequent disclosure of the disputed portion of the information, shall include a copy of the statement and may include a statement of the reasons for not making the requested amendment.

SEC. 204. DISCLOSURES PURSUANT TO COMPULSORY PROCESS.

(a) PROCEEDINGS IN WHICH AVAILABLE.—A person who stores genetic information in records may be compelled to disclose such information pursuant to a request for compulsory disclosure in any judicial, legislative, or administrative proceeding if—

(1) the request for compulsory disclosure is in accordance with Federal or State law requiring such disclosure;

(2) the individual whose genetic information is requested is a party to the proceeding and the content of the information is at issue; or

(3) the genetic information is requested for use in a law enforcement proceeding or investigation and the person storing the information is the subject of or a party to the proceeding or investigation.

(b) NOTICE.—A person requesting compulsory disclosure of genetic information under paragraph (2) or (3) of subsection (a) shall serve on the person storing the genetic information, and on the individual or the legal representative of the individual, the original or a copy of the compulsory disclosure request at least 30 days prior to the date on which the compulsory disclosure is requested. The request shall include a statement of the right of the individual, and of the person storing the genetic information, to have any objections to such compulsory disclosure heard by the court or governmental agency considering the request prior to the issuance of an order for compulsory disclosure, and a description of the procedure to be followed to have any such objections heard. Such service shall be made by certified mail, return receipt requested, or by

hand delivery, in addition to any form of service required by applicable Federal or State law.

(c) CERTIFICATION.—Service of compulsory disclosure (including discovery) requests on the person storing the genetic information shall be accompanied by a written certificate that—

(1) is signed by the person requesting disclosure of the genetic information or the authorized representative of the person;

(2) identifies the provision of subsection (a) under which the compulsory disclosure (including discovery) is being requested; and

(3) if disclosure of genetic information is requested under paragraph (2) or (3) of subsection (a), states that the requirements for notice under subsection (b) have been fulfilled.

The signature of a person on the certification shall be considered to be valid only if the person, at the time of signing, reasonably believed that the provision of subsection (a) that is identified in the certification provides an appropriate basis for compulsory disclosure (including discovery). The person shall store a copy of the written certification as a permanent part of the records containing the genetic information.

(d) STANDARD FOR ISSUANCE OF ORDER.—An order may only be entered under this section by a court or agency of competent jurisdiction after a hearing and determination that good cause exists for compulsory disclosure of genetic information. In making such a determination, the court or agency shall determine whether—

(1) other ways of obtaining the genetic information are available and would be effective; and

(2) there is a compelling need for the genetic information that outweighs the potential harm to the privacy interest of the individual whose genetic information is requested.

(e) CONTENT OF ORDER.—An order entered under this section that authorizes disclosure of genetic information shall—

(1) limit disclosure to the parts of records that contain the information and that are essential to fulfill the objective of the order;

(2) limit disclosure to the person whose need for the information is the basis of the order;

(3) require the deletion of individual identifiers from any documents that may be made available to the public; and

(4) include such other measures as are necessary to limit disclosure for the protection of the in-

dividual whose genetic information is requested, including sealing from public scrutiny the record or any portion of the record of any proceeding for which disclosure of the information has been ordered.

TITLE III—AUTHORIZATION BY WRITTEN INFORMED CONSENT

SEC. 301. AUTHORIZATION FOR COLLECTION AND STORAGE OF DNA SAMPLES FOR GENETIC ANALYSIS.

(a) WRITTEN AUTHORIZATION.—To be valid, the authorization by an individual required by sections 101 (for collection of a DNA sample) and 102 (for storage and genetic analysis of a DNA sample) shall comply with each of the following:

(1) WRITING.—The authorization shall be in writing, signed by the individual, and dated on the date of the signature.

(2) IDENTIFICATION OF COLLECTOR.—The authorization shall identify the person authorized to collect the DNA sample.

(3) DESCRIPTION OF COLLECTION.—The authorization shall state the tissue to be collected and the method of collection.

(4) AUTHORIZED USE.—The authorization shall include a description of all authorized uses of the DNA sample.

(5) STATEMENT REGARDING STORAGE AFTER COMPLETION OF ANALYSIS.—The authorization shall indicate whether the individual permits the sample to be retained after the analysis is completed.

(6) STATEMENT REGARDING USES OF DNA SAMPLES FOR RESEARCH OR COMMERCIAL PURPOSES.—The authorization shall include provisions that permit the individual to consent to—

(A) use of the DNA sample for research;

(B) commercial use of the DNA sample, with a waiver of, or a provision for, economic benefit to the individual;

(C) if the individual consents to use under subparagraph (A) or (B), use without identifiers, or use with individual identifiers or codes retained, of the DNA sample; and

(D) notification, if individual identifiers or codes are retained, about information resulting from such use that may have implications for the individual or a family member of the individual.

(7) ADDITIONAL LAWS.—The authorization shall comply with additional provisions of Federal or State law requiring informed consent by human subjects in research, including the provisions of part 46 of title 45, Code of Federal Regulations (or any corresponding similar regulation or ruling).

(b) RETENTION OF AUTHORIZATION.—The authorization shall be retained for the period during which the DNA sample is stored.

(c) COPY.—A copy of the completed authorization shall be provided to the individual.

SEC. 302. AUTHORIZATION FOR DISCLOSURE OF GENETIC INFORMATION.

(a) WRITTEN AUTHORIZATIONS.—To be valid the authorization by an individual required by section 201 (for disclosure of genetic information) shall comply with each of the following:

(1) WRITING.—The authorization shall be in writing, signed by the individual, and dated on the date of the signature.

(2) IDENTIFICATION OF PERSON MAKING DISCLOSURE.—The authorization shall identify the person authorized to make the disclosure.

(3) DESCRIPTION OF GENETIC INFORMATION.—The authorization shall describe the specific genetic information to be disclosed.

(4) RECIPIENT IDENTIFIED.—The authorization shall identify the person to whom the genetic information is to be disclosed.

(5) PURPOSE DESCRIBED.—The authorization shall describe the purpose for which the disclosure is being made.

(6) EXPIRATION DATE.—The authorization shall state the date upon which the authorization will expire.

(7) REVOCATION OR AMENDMENT STATEMENT.—The authorization shall include a statement that the authorization for disclosure of genetic information may be revoked or amended at any time prior to the disclosure.

(b) COPY.—A copy of the authorization shall be provided to the individual.

(c) REVOCATION OR AMENDMENT OF AUTHORIZATION.—An individual may revoke or amend the authorization at any time prior to the disclosure. The revocation or amendment shall be in writing and addressed to the person who stores the genetic information.

(d) IDENTIFICATION OF INFORMATION AS PROTECTED BY LAW.—Each disclosure made pursuant to the authorization shall be accompanied by the following written statement:

''This information is obtained from the DNA sample of an individual and has been disclosed to you from confidential records protected under the Genetic Confidentiality and Nondiscrimination Act of 1997. Any further disclosure of the information without specific written authorization of the individual is prohibited and is punishable under the provisions of title VII of such Act.''.

(e) EFFECT OF GENERAL AUTHORIZATION FOR RELEASE OF MEDICAL RECORDS.—A general authorization for the release of medical records or medical information shall not be construed to be an authorization for disclosure of genetic information about the molecular genotype of an individual with respect to any genetic trait. With respect to medical records that contain genetic information, the requirements for disclosure of genetic information that are described in this section shall be fulfilled prior to disclosure of the information.

TITLE IV—DISCRIMINATION PROHIBITED

SEC. 401. DISCRIMINATION BY EMPLOYERS OR POTENTIAL EMPLOYERS.

(a) IN GENERAL.—An employer shall not request, require, or use the genetic information of an employee or a prospective employee for the purpose of restricting any right or benefit otherwise due or available to the employee or the prospective employee. An employer may request or require or use the genetic information of an employee for the purpose of—

(1) permitting a genetically susceptible employee to avoid occupational exposure to substances with a mutagenic or teratogenic effect; or

(2) determining a genotype that is otherwise directly related to the work and is consistent with business necessity.

(b) ENFORCEMENT.—This section may be enforced in accordance with title VII.

SEC. 402. DISCRIMINATION BY HEALTH INSURERS.

(a) IN GENERAL.—An insurer offering health insurance coverage shall not—

(1) terminate, restrict, limit, refuse to renew, or otherwise apply conditions to the coverage of an individual or family member under the health policy or

plan involved, or restrict the sale of the health policy or plan to an individual or family member;

(2) deny coverage or exclude an individual or family member under the health policy or plan;

(3) impose a rider that excludes coverage for certain benefits or services under the health policy or plan for an individual or family member;

(4) establish differentials in premium rates or cost-sharing for coverage under the health policy or plan for an individual or family member; or

(5) otherwise discriminate against an individual or family member in the provision of health insurance coverage;

on the basis of any molecular genetic information about a healthy individual or a healthy family member, or on the basis of a request for or receipt of genetic services by an individual or family member.

(b) PROHIBITION ON TESTING OR QUESTIONING.—An insurer shall not require an applicant for health insurance coverage, or an individual or family member who is enrolled under a health insurance coverage policy or plan, to be subjected to a genetic test or to be questioned about genetic information.

(c) DISCLOSURE.—An insurer shall, in the application or enrollment information provided by the insurer

concerning health insurance coverage, provide the applicant or enrollee with a written statement disclosing the rights of the applicant or enrollee under this Act. Such statement shall be in a form and manner that is noticeable and understandable to an average applicant or enrollee.

(d) ENFORCEMENT.—

(1) PLANS OTHER THAN EMPLOYEE WELFARE BENEFIT PLANS.—The requirements established under subsections (a), (b), and (c) shall be enforced by the State insurance commissioner for the State involved or the official designated by the State, except that in no case shall a State enforce such requirements as the requirements relate to employee welfare benefit plans (as defined in section 3 of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1002)).

(2) EMPLOYEE WELFARE BENEFIT PLANS.—With respect to such employee welfare benefit plans, the Secretary shall enforce the requirements established under subsections (a), (b), and (c) in the same manner as the Secretary enforces requirements of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1001 et seq.) under sections 502, 504, 506, and 510 of the Employee Retirement In-

come Security Act of 1974 (29 U.S.C. 1132, 1134, 1136, and 1140).

(e) HEALTH INSURANCE COVERAGE.—In this section, the term ''health insurance coverage'' means benefits consisting of medical care (provided directly, through insurance or reimbursement, or otherwise and including items and services paid for as medical care) under any hospital or medical service policy or certificate, hospital or medical service plan contract, or health maintenance organization contract offered by an insurer.

TITLE V—RESEARCH ACTIVITIES

SEC. 501. RESEARCH INVOLVING GENETIC ANALYSIS.

(a) CONDITIONS FOR GENETIC ANALYSIS.—Except as provided in section 802(a), a DNA sample may be analyzed as part of a research project only if an Institutional Review Board, or similar board in the research industry, has determined that—

(1) use of DNA samples is essential to the research project;

(2) the potential benefit of the research project to society outweighs the potential risks to the research subjects, including psychosocial risks and intrusion into the privacy of the subjects that would result from genetic analysis of DNA samples; and

(3) the research protocol—

(A) contains adequate safeguards to protect against disclosure of genetic information that is generated by the research;

(B) requires that research subjects will be given the applicable information required under section 101;

(C) requires informed consent by the subjects, as provided in part 46 of title 45, Code of Federal Regulations (or any corresponding similar regulation or ruling);

(D) requires the written authorization of the subjects, that complies with the applicable requirements of section 301, and that describes the protocol and the intended uses of the DNA samples;

(E) prohibits inclusion of specific molecular genetic genotype information in clinical records unless the subjects authorize such inclusion in writing;

(F) with respect to protocols involving the use of DNA samples from subjects deceased prior to the effective date of this Act—

(i) provides a reasonable method for disclosing to the family members of a subject, the risks that—

(I) are associated with genetic information of the subject that is generated by the research; and

(II) in reasonable medical judgment can be effectively ameliorated, prevented, or treated; and

(ii) takes into account the right of family members to refuse learning about the genetic information; and

(G) describes the availability, or lack of availability, of genetic counseling related to the research project.

(b) SAFEGUARDS AGAINST DISCLOSURES OF GENETIC INFORMATION.—For purposes of subsection (a)(3)(A), adequate safeguards against disclosure of genetic information, at a minimum, include—

(1) obtaining an authorization from the Secretary as provided for in section 301(d) of the Public Health Service Act (42 U.S.C. 241(d));

(2) ensuring that research subjects will not be identifiable in any report or publication that results from the research; and

(3) having procedures to remove or destroy any individual identifiers at the earliest opportunity, con-

sistent with the purposes of the project and the terms of the consent of the subjects involved.

(c) DESTRUCTION OF DNA SAMPLES OF IDENTIFIERS.—If the DNA sample of a subject is collected, stored, or analyzed in connection with a research project, the researcher shall ensure the destruction of the DNA sample on the date of completion of the project or withdrawal of the subject from the project, whichever occurs first, unless the researcher obtains a specific authorization of the subject, as described in section 301, to store the sample after such date.

(d) PEDIGREE ANALYSIS AND FAMILY LINKAGE STUDIES.—If a research project includes genetic analysis of family members of a subject for pedigree analysis or linkage analysis—

(1) the Institutional Review Board, in addition to making the determinations required in subsection (a), shall also require that genotype records be stored in strict confidentiality; and

(2) the process for obtaining the informed consent and authorization of the subject, as described in subsection (a)(3)(C) and sections 301 and 302, shall include information about—

(A) the possibility that family members of the subject may learn genetic information about the subject as a result of a project;

(B) the possibility that the project may determine that some family members are not genetic relatives; and

(C) the disposition of records and data generated during the project.

(e) RIGHT OF SUBJECT TO OBTAIN INFORMATION.—A person who analyzes DNA samples as part of a research project described in subsection (d) shall provide a subject or family member with genetic information about another family member only with the written authorization of the subject or the other family member.

SEC. 502. DISCLOSURE OF GENETIC INFORMATION FOR RESEARCH PURPOSES.

(a) IN GENERAL.—Any person who stores molecular genetic information of a subject may allow access to such information to researchers only—

(1) if an Institutional Review Board has approved the protocol of the research project; and

(2) with the written authorization of the subject, as described in section 302.

Such information shall be provided with individual identifiers, or codes, or no identifiers, according to the written authorization of the subject.

(b) LIMITED ACCESS FOR STATISTICAL USE.—Notwithstanding subsection (a), a person who stores genetic information may grant access to such information solely for the purpose of inspection or review of the records containing the information if—

(1) the inspection or review is for the purpose of compiling data for statistical or epidemiological studies and genetic information that contains personal identifiers is not copied, removed from the records, or redisclosed in any way; and

(2) the person conducting the inspection or review certifies in writing—

(A) that the limitations in paragraph (1) will be complied with;

(B) that the person has complied with this Act; and

(C) to knowledge of liability for violations of this Act.

SEC. 503. EXCEPTION FOR DNA SAMPLES COLLECTED PRIOR TO THE EFFECTIVE DATE.

(a) IN GENERAL.—A DNA sample collected prior to the effective date of this Act may be analyzed as part of

a research project under a protocol approved by the Institutional Review Board, unless the individual involved, within 3 years of the effective date of this Act, submits a written request that such sample be withdrawn or destroyed; and

(b) DISCLOSURE.—Except as provided under section 502, genetic information collected as part of a research project described in subsection (a) may be disclosed only with the authorization of the individual involved or the individual's legal representative.

TITLE VI—MISCELLANEOUS PROVISIONS

SEC. 601. NOTIFICATION OF PRIVACY OBLIGATIONS.

Every person who collects, stores, or analyzes DNA samples or genetic information shall not less than annually notify the employees of the person of their responsibilities under this Act and of the penalties for violating the provisions of this Act.

SEC. 602. TRANSFER OF POSSESSION OF DNA SAMPLES AND GENETIC INFORMATION; DISCONTINUANCE OF SERVICES.

(a) ACTIVITIES INVOLVING DNA SAMPLES AND GENETIC INFORMATION.—Any person in possession of DNA samples and genetic information, who intends to transfer control of, or discontinue, activities or services related to

the analysis of DNA samples, shall inform the individual that the individual has the right to—

(1) consent to the transfer of the samples or records containing the genetic information;

(2) order that the samples or records be returned to the individual; or

(3) order that the samples or records be destroyed.

(b) NO RESPONSE.—If, within a period of 3 months after notification, the person identified in subsection (a) receives no response from the individual, the person—

(1) shall destroy the samples or the records if the activities or services are discontinued;

(2) may place the samples and research records, without personal identifiers, in a tissue sample archive, according to prior instructions of the individual; or

(3) may proceed with the intended transfer of the samples and records.

TITLE VII—ENFORCEMENT

SEC. 701. CIVIL REMEDIES.

(a) PRIVATE RIGHT OF ACTION.—Any individual whose rights under this Act (other than section 402) have been violated may maintain a civil action for damages or equitable relief, as provided for in this section.

(b) JURISDICTION.—The action may be brought under this section in a district court of the United States or a State court of competent jurisdiction.

(c) RELIEF.—In any action brought under this section, a court may order a person to comply with the provisions of this Act and may order any other appropriate equitable relief.

(d) LIABILITY FOR NEGLIGENT VIOLATIONS.—Any person who negligently collects, stores, or analyzes a DNA sample of an individual in violation of this Act, negligently discloses genetic information in violation of this Act, or negligently induces another person to conduct such collection, storage, analysis, or disclosure, shall be liable to the individual for each such violation in an amount equal to—

(1) any actual damages sustained as a result of the collection, storage, analysis, or disclosure, or $50,000, whichever is greater;

(2) in any case in which such violation has resulted in profit or monetary gain, treble damages; and

(3) in the case of a successful action under this section, the costs of the action and reasonable attorneys' fees as determined by the court.

(e) LIABILITY FOR WILLFUL VIOLATIONS.—Any person who willfully collects, stores, or analyzes a DNA sam-

ple of an individual in violation of this Act, willfully discloses genetic information of an individual in violation of this Act, or willfully induces another person to conduct such collection, storage, analysis, or disclosure, shall be liable to the individual for each such violation in an amount equal to—

(1) any actual damages sustained as a result of the collection, storage, analysis, or disclosure, or $100,000, whichever is greater;

(2) such punitive damages as the court may allow; and

(3) in the case of a successful action under this section, the costs of the action and reasonable attorneys' fees as determined by the court.

(f) LIABILITY FOR EMPLOYMENT DISCRIMINATION.—Any person who violates the rights of an individual under section 401 shall be liable to the individual for each such violation in an amount equal to—

(1) any actual damages sustained as a result of the violation, or $50,000, whichever is greater;

(2) in any case in which such violation has resulted in profit or monetary gain, treble damages; and

(3) in the case of a successful action under this section, the costs of the action and reasonable attorney's fees as determined by the court.

(g) STATUTE OF LIMITATIONS.—Except with respect to subsection (h), any action under this section shall be brought within 6 years after the date that the alleged violation was or should have been discovered.

(h) TOLLING OF LIMITATIONS.—If the person entitled to maintain an action under this section is unable to maintain the action because the individual is a minor, or is incapacitated by reason of mental illness, when the right to bring an action first occurs, the action may be commenced up to 10 years after the disability is removed.

SEC. 702. CIVIL PENALTIES AND INJUNCTIVE RELIEF.

(a) IN GENERAL.—If the Attorney General believes that any person is violating or is about to violate the provisions of this Act, and that proceedings would be in the public interest, the Attorney General may bring an action against such person to restrain the person by temporary restraining order or preliminary or permanent injunction from such violation.

(b) JURISDICTION.—The action may be brought in the district court of the jurisdiction in which the person resides or has a principal place of business.

(c) RELIEF.—The court may issue temporary restraining orders or preliminary or permanent injunctions and issue such other orders or judgments as may be necessary to prevent harm or to remedy harm suffered by any individual as a result of a violation of this Act.

(d) CIVIL PENALTY.—If the court finds that a person knew or should have known that the person was violating this Act, the court may require such person to pay a civil penalty of not more than $50,000 for each such violation and may also require such person to pay reasonable costs of investigation and litigation of such violation, including reasonable attorney's fees.

TITLE VIII—EFFECTIVE DATE; APPLICABILITY; AND RELATIONSHIP TO OTHER LAWS

SEC. 801. EFFECTIVE DATE.

This Act shall take effect on January 1, 1999.

SEC. 802. APPLICABILITY.

(a) RESEARCH ON DNA SAMPLES COLLECTED PRIOR TO EFFECTIVE DATE.—Notwithstanding the provisions of section 501, a DNA sample that was collected prior to the effective date of this Act may be analyzed as part of a research project under a protocol approved by the Institutional Review Board, if the researcher—

(1) withdraws or destroys the DNA sample if the subject makes a written request not later than 3 years after the effective date of this Act; and

(2) except as provided under section 502, discloses genetic information only with the written authorization of the subject or the legal representative of the subject, as described in section 302.

(b) AUTHORIZATIONS FOR DISCLOSURES.—An authorization for the disclosure of genetic information that is executed before January 1, 1999, and that does not meet the requirements of section 302, but which is valid under State law on January 1, 1998, shall remain valid until the expiration date specified in the authorization.

SEC. 803. RELATIONSHIP TO OTHER LAWS.

(a) IN GENERAL.—Nothing in this Act shall be construed to preempt any provision of State law or any privilege, whether derived from statute or common law, that—

(1) more completely protects the confidentiality or privacy of an individual with respect to genetic information about the individual than does this Act; or

(2) provides a greater right of access to genetic information to a subject of the information than does this Act.

(b) DISCLOSURE.—No State may establish or enforce any law (including a regulation) concerning the disclosure

of genetic information except to the extent that such law, conforms to the limitations contained in this Act.

(c) CONSTRUCTION.—Nothing in this Act shall be construed as limiting or prohibiting the pursuit of any other remedies available under common or statutory law in regard to the collection, storage, analysis of DNA samples, and the disclosure of genetic information.

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