

THE GENETIC PRIVACY ACT AND COMMENTARY

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INTRODUCTION

The Genetic Privacy Act is a proposal for federal legislation. The Act is based on the premise that genetic information is different from other types of personal information in ways that require special protection. The DNA molecule holds an extensive amount of currently indecipherable information. The major goal of the Human Genome

Project is to decipher this code so that the information it contains is accessible. The privacy question is, accessible to whom?

The highly personal nature of the information contained in DNA can be illustrated by thinking of DNA as containing an individual's "future diary."[\[1\]](#) A diary is perhaps the most personal and private document a person can create. It contains a person's innermost thoughts and perceptions, and is usually hidden and locked to assure its secrecy. Diaries describe the past. The information in one's genetic code can be thought of as a coded probabilistic future diary because it describes an important part of a unique and personal future.

Genetic information is powerful and personal. As the genetic code is deciphered, genetic analysis of DNA will tell us more and more about a person's likely future, particularly in terms of physical and mental well-being. The search for genetic information often involves locating predictors of undesirable and stigmatizing conditions - such as cancers, and conditions that lead to mental illness and dementia. This information is uniquely sensitive for a number of reasons. First, unlike ordinary diaries that are created by the writer, the information contained in the genetic code is largely unknown to the person in whose genetic material it is found. Therefore, if this information is obtained by someone else without the individual's permission, another person would learn intimate details of the individual's likely future life. A stranger could, in effect, read the future diary of an individual without the individual even knowing that the diary exists. There are many people, including insurers and employers, to whom information about an individual's likely health future would be useful.[\[2\]](#)

Second, deciphering an individual's genetic code also provides the reader of that code with probabilistic health information about that individual's family, especially parents, siblings and children. Third, since the DNA molecule is stable, once removed from a person's body and stored, it can become the source of an increasing amount of information as more is learned about how to read the genetic code. Finally, genetic information (and misinformation) has been used by governments to viciously discriminate against those perceived as genetically unfit.

DNA Databanks

We originally proposed drafting legislation to regulate DNA databanks. We thought of DNA databanks as entities that collected, stored, analyzed and controlled DNA samples and information derived from DNA samples, although the term could also include entities that either only stored DNA samples or only stored information derived from genetic analysis.[\[3\]](#) Thinking of such databanks as holders of genetic information, like computerized medical records, James Watson has said, "The idea that there will be a huge databank of genetic information on millions of people is repulsive."[\[4\]](#)

Dr. Watson's statement expresses the concern of many people who distrust both computer technology and large, bureaucratic record-keeping systems, and perceive private genetic information as uniquely personal. Such distrust also flows from the realization that current confidentiality policies and practices, which supposedly safeguard personal medical information, are inadequate to protect private genetic information.[\[5\]](#) New rules for DNA databanks are needed to minimize the potential harm to individual privacy and liberty that the collection, storage and distribution of genomic information could produce, and to foster personally and societally useful applications of genetic information. As the U.S. House of Representatives Committee on Government Operations rightly concluded in its study of genetic information, such rules "will be more effective and less expensive to implement if established in advance."[\[6\]](#)

Our own analysis of the privacy issues implicated by DNA databanks has persuaded us that it is not feasible to protect genetic privacy by limiting regulation to places called DNA databanks. One reason is that it is difficult even to define precisely a DNA databank. Entities that only store medical records seem to qualify, but are not the major focus of concern regarding the new genetics. There are already many entities that store genetic materials, including the FBI and individual state programs that store DNA samples from convicted sex offenders and other criminals, the U.S. Army's DNA sample storage program, and private medical research projects. The FBI is primarily interested in using DNA to identify criminal suspects, while medical research programs might conduct future analysis of DNA samples to further decipher the genetic code. Other entities could qualify as DNA banks because they collect and store large amounts of biological material, even though they have no current intent to conduct genetic analysis. Such programs include the Red Cross and other blood banks, private sperm, ovum and embryo banks, and state facilities that store blood samples

that have been used for phenylketonuria (PKU) testing.

Collection, Analysis and Storage of DNA and Genetic Information

Focusing solely on any or all of these types of DNA databanks assumes that the DNA samples have been legitimately obtained and analyzed, and the only issues are the proper storage of genetic information, and rules governing the disclosure of the genetic information by DNA databanks. But meaningful privacy protection must regulate the collection, analysis and storage of DNA **samples**, as well as the storage and disclosure of the genetic **information** derived from the analysis of these samples, no matter who performs that analysis. It is, after all, the DNA samples that contain the individual's private genetic information. Control of these samples enables the custodian to analyze and reanalyze them to derive increasing amounts of genetic information as new tests are developed. It is also possible to obtain biological material for the purpose of DNA analysis without the person knowing that such material was obtained or analyzed. For example, DNA can even be obtained from hair samples left on a barber's floor or from saliva found on a licked stamp.

Therefore, to effectively protect genetic privacy unauthorized collection and analysis of individually identifiable DNA must be prohibited. As a result, the overarching premise of the Act is that no stranger should have or control identifiable DNA samples or genetic information about an individual unless that individual specifically authorizes the collection of DNA samples for the purpose of genetic analysis, authorizes the creation of that private information, and has access to and control over the dissemination of that information.

The rules protecting genetic privacy must be clear and known to the medical, scientific, business and law enforcement communities and the public. The purpose of the Genetic Privacy Act is to codify these rules. It has been drafted as a federal statute to provide uniformity across state lines. However, the Act could be adopted by individual states and used as guidelines by professional societies, at least until such time as Congress acts.[\[7\]](#)

Under the Act, each person who collects a DNA sample (e.g., blood, saliva, hair or other tissue) for the purpose of performing genetic analysis is required to:

- provide specific information verbally prior to collection of the DNA sample;
- provide a notice of rights and assurances prior to the collection of the DNA sample;
- obtain written authorization which contains required information;
- restrict access to DNA samples to persons authorized by the sample source;
- abide by a sample source's instructions regarding the maintenance and destruction of DNA samples.

Special rules regarding the collection of DNA samples for genetic analysis are set forth for minors, incompetent persons, pregnant women, and embryos. DNA samples may be collected and analyzed for identification for law enforcement purposes if authorized by state law, and for identifying dead bodies, without complying with the authorization provisions of the Act. Research on individually identifiable DNA samples is prohibited unless the sample source has authorized such research use, and research on nonidentifiable samples is permitted if this has not been prohibited by the sample source. Pedigree research and research involving DNA from minors are also governed by specific provisions of the Act.

Individuals are prohibited from analyzing DNA samples unless they have verified that written authorization for the analysis has been given by the sample source or the sample source's representative. The sample source has the right to:

- determine who may collect and analyze DNA;
- determine the purposes for which a DNA sample can be analyzed;
- know what information can reasonably be expected to be derived from the genetic analysis;
- order the destruction of DNA samples;
- delegate authority to another individual to order the destruction of the DNA sample after death;
- refuse to permit the use of the DNA sample for research or commercial activities; and
- inspect and obtain copies of records containing information derived from genetic analysis of the DNA sample.

A written summary of these principles and other requirements under the Act must be supplied to the sample source by

the person who collects the DNA sample. The Act requires that the person who holds private genetic information in the ordinary course of business keep such information confidential and prohibits the disclosure of private genetic information unless the sample source has authorized the disclosure in writing or the disclosure is limited to access by specified researchers for compiling data.

The Genetic Privacy Act protects individual privacy while permitting medical uses of genetic analysis, legitimate research in genetics, and genetic analysis for identification purposes.

Acknowledgements

This project had its genesis at a meeting in Cold Spring Harbor in November 1989 at which one of the drafters (GJA) gave a presentation on the privacy issues involved in DNA banking. Fourteen months later, he and Dr. Sherman Elias co-hosted an NIH-sponsored workshop in Bethesda, Maryland the purpose of which was to suggest a prioritized research agenda for the Ethical, Legal & Social Implications (ELSI) program of the Human Genome Project. Protecting genetic privacy was ranked as one of the two highest priority issues at that workshop (regulating the introduction of new genetic tests into clinical practice was ranked slightly higher). Shortly thereafter the Director of the ELSI program for the U.S. Department of Energy, Michael Yesley, asked us to draft guidelines to protect the privacy of individuals whose DNA was stored at DNA banks. We agreed, and began this project in June of 1993, with Dr. Daniel Drell of the U.S. Department of Energy (Health Effects and Life Sciences Research Division, Office of Health and Environmental Research, Office of Energy Research) as the project monitor.

In the course of the first year of research we concluded that it was necessary to broaden the scope of the project, and presented the rationale for this change to the ELSI Working Group in June of 1994. They concurred. The first draft of the Genetic Privacy Act was completed in late September 1994, and presented to the ELSI Working Group in December 1994.

Many people, in addition to the members of the ELSI Working Group, contributed in substantial ways to the final product. These included our research assistants, Nan Elster, Sue Yeu, Chris Hager, and Alex Klickstein, as well as our support staff, especially the Administrative Coordinator of the Health Law Department, Marilyn Ricciardelli, and the Department's Secretary, Deborah Darling. The Director of the Boston University School of Public Health, Dr. Robert F. Meenan, was especially supportive of our work. We are grateful for the generous and thoughtful comments of our colleagues who reviewed drafts and provided needed insight to both legal and genetic issues. Sherman Elias was our primary genetics consultant, and his advice was invaluable. Robert Gellman's thoughtful comments and advice helped us to avoid many legislative drafting pitfalls. Lori Andrews worked especially hard to make sure we had taken all of the genetic privacy issues into account.

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II

THE GENETIC PRIVACY ACT

A BILL

To protect the genetic privacy of individuals.

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

Sec. 1. SHORT TITLE; TABLE OF CONTENTS

(a) SHORT TITLE. -- This act may be cited as the "Genetic Privacy Act."

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

Sec. 1. Short title; table of contents.

Sec. 2. Findings and purposes.

Sec. 3. Definitions.

PART A - - COLLECTION AND ANALYSIS OF DNA SAMPLES

Sec. 101. Collection of DNA samples.

Sec. 102. Analysis of DNA samples.

Sec. 103. Authorization for collection and storage of individually identifiable DNA samples for genetic analysis.

Sec. 104. Ownership and destruction of DNA samples.

Sec. 105. Notice of rights and assurances.

PART B - - DISCLOSURE OF PRIVATE GENETIC INFORMATION

Sec. 111. Disclosure of private genetic information.

Sec. 112. Authorization for disclosure of private genetic information.

Sec. 113. Inspection and copying of records containing private genetic information.

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Sec. 115. Disclosures pursuant to compulsory process.

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Sec. 131. Research involving genetic analysis.

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Sec. 142. Authorization for disclosure of private genetic information about individuals age 16 and 17.

Sec. 143. Authorization for collection and analysis of DNA samples from incompetent persons.

Sec. 144. Authorization for private genetic information about incompetent persons.

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Sec. 152. Authorization for disclosure of private genetic information about pregnant women and fetuses.

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PART G - - MISCELLANEOUS PROVISIONS

Sec. 161 Notification of privacy provisions.

Sec. 162 Transfer of ownership, discontinuation of services.

PART H - - ENFORCEMENT

Sec. 171 Civil remedies.

Sec. 172 Civil penalties and injunctive relief.

PART I - - EFFECTIVE DATE; APPLICABILITY; AND RELATIONSHIP TO OTHER LAWS

Sec. 181 Effective Date.

Sec. 182 Applicability.

Sec. 183 Relationship to other laws.

Sec. 2. FINDINGS AND PURPOSES

(a) **FINDINGS.** -- The Congress finds as follows:

- (1) The DNA molecule contains information about one's probable medical future, and this information is written in a code that is currently being broken at a rapid pace.
- (2) Genetic information has a history of being used by governments to harm individuals.
- (3) Genetic information is uniquely private and personal information that should not be collected or disclosed without the individual's authorization.
- (4) The improper use and disclosure of genetic information can lead to significant harm to the individual, including stigmatization and discrimination in areas such as employment, education, health care, and insurance.
- (5) An analysis of an individual's DNA provides information not only about an individual, but also about that individual's parents, siblings and children, thus implicating family privacy.
- (6) Genetic information is uniquely tied to reproductive decisions which are among the most private and intimate decisions that an individual can make.
- (7) Current legal protections for medical information, tissue samples, and DNA samples are inadequate to protect genetic privacy.
- (8) Uniform rules for the collection, storage and use of identifiable DNA samples and private genetic information obtained from them are needed both to protect individual privacy and to permit legitimate genetic research.

(b) **PURPOSES.** -- The purposes of this Act are as follows:

- (1) To define the circumstances under which DNA samples may be collected, stored and analyzed.
- (2) To define the circumstance under which private genetic information may be created, stored and disclosed.
- (3) To define the rights of individuals whose DNA samples are collected, stored, and analyzed.
- (4) To define the rights of individuals whose genetic information is stored and disclosed.
- (5) To define the responsibilities of persons who collect, analyze and use DNA samples and the genetic information derived from them.
- (6) To establish effective mechanisms to enforce the rights and responsibilities defined in this Act.

Sec. 3. DEFINITIONS

For purposes of this Act:

(a) **COMPULSORY DISCLOSURE.** -- The term "compulsory disclosure" means any disclosure of private genetic information mandated or required by federal or state law in connection with a judicial, legislative, or administrative proceeding, including but not limited to, disclosure required by subpoena, subpoena duces tecum, request or notice to produce, court order, or any other method of requiring a person maintaining private genetic information to produce private genetic information under the criminal or civil discovery laws of any state or the federal law.

(b) **DISCLOSE.** -- The term "disclose", when used with respect to private genetic information, means to provide access to the information, or the verification of the information, but only if such access or verification is provided to a person other than the sample source or the sample source's representative.

(c) **DISCLOSURE.** -- The term "disclosure" means the act or an instance of disclosing.

(d) **DNA.** -- The term "DNA" means deoxyribonucleic acid.

(e) **DNA SAMPLE.** -- The term "DNA sample" means any human biological specimen from which DNA can be

extracted, or DNA extracted from such specimen.

(f) DNA TYPING. -- The term "DNA typing" means a scientifically reliable method for characterizing and comparing sequences of DNA, and applying a statistical analysis of population frequency to determine that if the DNA sequences match, the probability that the match occurs by chance.

(g) IDENTIFIABLE INDIVIDUAL. -- The term "identifiable individual" means any individual whose name, address, Social Security number, health insurance identification number, or similar identifying information is known, available, or can be determined with reasonable accuracy either directly or by reference to other available information.

(h) INDIVIDUAL IDENTIFIER. -- The term "individual identifier" means a name, address, Social Security number, health insurance identification number, or similar information by which the identity of a sample source can be determined with reasonable accuracy, either directly or by reference to other available information. The term does not include characters, numbers, or codes assigned to an individual or a DNA sample which cannot be used to determine the identity of a sample source.

(i) INDIVIDUALLY IDENTIFIABLE DNA SAMPLE. -- The term "individually identifiable DNA sample" means any DNA sample linked to an individual identifier.

(j) INDIVIDUALLY IDENTIFIABLE RECORD. -- The term "individually identifiable record" means any record that contains private genetic information linked to an individual identifier.

(k) INSTITUTIONAL REVIEW BOARD. -- The term "Institutional Review Board" means a board established in accordance with 45 CFR 46.102(g)(1992) as such regulation may be amended.

(l) PERSON. -- The term "person" shall include an individual, a corporation, partnership, association, joint venture, government, governmental subdivision or agency, and other legal or commercial entity.

(m) PRIVATE GENETIC INFORMATION. -- The term "private genetic information" means any information about an identifiable individual that is derived from the presence, absence, alteration, or mutation of a gene or genes, or the presence or absence of a specific DNA marker or markers, and which has been obtained:

- (1) from an analysis of the individual's DNA; or
- (2) from an analysis of the DNA of a person to whom the individual is related.

(n) SAMPLE SOURCE. -- The term "sample source" means the individual from whose body the DNA sample originated.

(o) SAMPLE SOURCE'S REPRESENTATIVE. -- The term "sample source's representative" means any person who has the legal authority to make health care decisions concerning a minor or an incompetent person, or the administrator or executor of a deceased person's estate, if any, otherwise the next of kin of a deceased person.

PART A - - COLLECTION AND ANALYSIS OF DNA SAMPLES

Sec. 101. COLLECTION OF DNA SAMPLES

(a) REQUIREMENT OF WRITTEN AUTHORIZATION. -- Except as otherwise provided in sections 121, 122, and 123, no person may collect or cause to be collected an individually identifiable DNA sample for genetic analysis without the written authorization of the sample source or the sample source's representative.

(b) REQUIRED INFORMATION. -- Prior to the collection of a DNA sample from a sample source for genetic analysis, the person collecting the sample or causing the sample to be collected shall verbally inform the sample source or the sample source's representative:

- (1) that consent to the collection or taking of the DNA sample is voluntary;
- (2) that consent to the genetic analysis is voluntary;
- (3) of the information that can reasonably be expected to be derived from the genetic analysis;

- (4) of the use, if any, that the sample source or the sample source's representative will be able to make of the information derived from the genetic analysis;
- (5) of the right to inspect records that contain information derived from the genetic analysis;
- (6) of the right to have the DNA sample destroyed;
- (7) of the right to revoke consent to the genetic analysis at any time prior to the completion of the analysis;
- (8) that the genetic analysis may result in information about the sample source's genetic relatives which may not be known to such relatives but could be important, and if so the sample source will have to decide whether or not to share that information with relatives;
- (9) that in the future someone else may ask if the sample source has obtained genetic testing or analysis and condition a benefit on the disclosure of information regarding such testing or analysis;
- (10) that the collection and analysis of the DNA sample, and the private genetic information derived from the analysis is protected by this Act; and
- (11) of the availability of genetic counseling.

Sec. 102. ANALYSIS OF DNA SAMPLES

(a) **ANALYSIS PROHIBITED WITHOUT AUTHORIZATION.** -- Except as otherwise provided in sections 121, 122, and 123, genetic analysis of an individually identifiable DNA sample is prohibited unless specifically authorized in writing by the sample source or the sample source's representative.

(b) **ASCERTAINMENT OF AUTHORIZATION.** -- No person may analyze an individually identifiable DNA sample without ascertaining that written authorization for the analysis has been obtained.

Sec. 103. AUTHORIZATION FOR COLLECTION AND STORAGE OF INDIVIDUALLY IDENTIFIABLE DNA SAMPLES FOR GENETIC ANALYSIS

(a) **WRITTEN AUTHORIZATION.** -- To be valid, the authorization required by sections 101 and 102 must satisfy each of the following requirements:

- (1) **WRITING.** -- The authorization must be in writing, signed by the sample source or the sample source's representative, and dated on the date of such signature;
- (2) **COLLECTOR IDENTIFIED.** -- The authorization must identify the person who collects the DNA sample or causes the DNA sample to be collected;
- (3) **ANALYZER IDENTIFIED.** -- The authorization must identify the facility in which the analysis will be performed;
- (4) **STORAGE FACILITY IDENTIFIED.** -- The authorization must identify the facility in which the DNA sample will be stored;
- (5) **COLLECTION DESCRIBED.** -- The authorization must state the manner in which the sample is to be collected;
- (6) **AUTHORIZED USE.** -- The authorization must include a description of all authorized uses of the DNA sample;
- (7) **STATEMENT REGARDING STORAGE AFTER COMPLETION OF ANALYSIS.** -- The authorization must indicate whether or not the sample source permits the sample to be maintained or stored in an identifiable form after the analysis is completed;
- (8) **STATEMENT REGARDING USE OF UNIDENTIFIABLE DNA SAMPLES FOR RESEARCH OR COMMERCIAL PURPOSES.** -- The authorization form must include a provision that enables the sample source or the sample source's representative to prohibit the use of the DNA sample for research or commercial purposes even if the sample is not in an individually identifiable form.

(b) **RETENTION OF AUTHORIZATION.** -- The authorization for the collection and analysis of an individually identifiable DNA sample shall be retained at least as long as the DNA sample is retained.

(c) **COPY.** -- A copy of the authorization shall be provided to the sample source or the sample source's representative.

Sec. 104. OWNERSHIP AND DESTRUCTION OF DNA SAMPLES

- (a) **OWNERSHIP OF THE DNA SAMPLE.** -- An individually identifiable DNA sample is the property of the sample source.
- (b) **RIGHT TO ORDER DESTRUCTION OF THE DNA SAMPLE.** -- Except when a DNA sample has been collected pursuant to section 122 or 123 of this Act, the sample source or the sample source's representative shall have the right to order the destruction of the DNA sample.
- (c) **ROUTINE DESTRUCTION OF SAMPLES OR IDENTIFIERS.** -- An individually identifiable DNA sample must be destroyed on completion of genetic analysis unless:
- (1) the sample source or the sample source's representative, has directed otherwise in writing, or
 - (2) all individual identifiers linking the sample to the sample source are destroyed.

Sec. 105. NOTICE OF RIGHTS AND ASSURANCES

A person who collects or stores DNA samples for genetic analysis shall provide a sample source or a sample source's representative prior to the collection, storage, or analysis of a DNA sample, and any other person upon request, with a notice of rights and assurances that contains the following information and assurances that:

- (a) a DNA sample will only be used as authorized in the written authorization;
- (b) an individually identifiable DNA sample is the property of the sample source;
- (c) unless specifically prohibited by the sample source or sample source's representative, researchers may be granted access to DNA samples that cannot be linked to individual identifiers;
- (d) the sample source or the sample source's representative has the right to order the destruction of the individually identifiable DNA sample at any time;
- (e) the individually identifiable DNA sample will be destroyed on the completion of the analysis unless the sample source or the sample source's representative has previously directed otherwise in writing;
- (f) the sample source can designate another individual as the person authorized to make decisions regarding the individually identifiable DNA sample after the death of the sample source; and if any person is so designated, the sample source should notify the facility in which the DNA sample is stored;
- (g) the sample source or the sample source's representative has the right to examine the records containing private genetic information, to obtain copies of such records and to request correction or amendment of them;
- (h) private genetic information may be disclosed to researchers who qualify for such access under this Act;
- (i) the collection and analysis of the DNA sample and the private genetic information derived from the analysis is protected by this Act, and anyone whose rights under this Act have been violated can seek civil remedies, including damages, as provided in this Act; and
- (j) genetic counseling is available.

PART B - - DISCLOSURE OF PRIVATE GENETIC INFORMATION

Sec. 111. DISCLOSURE OF PRIVATE GENETIC INFORMATION

- (a) **REQUIREMENT OF WRITTEN AUTHORIZATION.** -- Except as provided in section 115 and section 132(b) no person who, in the ordinary course of business, practice of a profession, or rendering of a service, creates, stores, receives or furnishes private genetic information may by any means of communication disclose private genetic information except in accordance with a written authorization as provided for in section 112.
- (b) **REDISCLASURE PROHIBITED.** -- Redisclasure of private genetic information which has been disclosed to any

person pursuant to a valid written authorization is prohibited.

Sec. 112. AUTHORIZATION FOR DISCLOSURE OF PRIVATE GENETIC INFORMATION

(a) **WRITTEN AUTHORIZATIONS.** -- To be valid, an authorization for disclosure of private genetic information must satisfy each of the following requirements:

- (1) **WRITING.** -- The authorization must be in writing, signed by the sample source or the sample source's representative and dated on the date of such signature;
- (2) **SAMPLE SOURCE OR REPRESENTATIVE IDENTIFIED.** -- The authorization must identify the individual granting authorization and the individual's relationship to the sample source;
- (3) **PERSON MAKING DISCLOSURE IDENTIFIED.** -- The authorization must identify the person permitted to make the disclosure;
- (4) **INFORMATION DESCRIBED.** -- The authorization must describe the specific genetic information to be disclosed;
- (5) **RECIPIENT IDENTIFIED.** -- The authorization must identify the person to whom the information is to be disclosed;
- (6) **PURPOSE DESCRIBED.** -- The authorization must describe the purpose for which the disclosure is being made;
- (7) **EXPIRATION DATE.** -- The authorization must state the date upon which the authorization will expire, which in no event shall be longer than 30 days after the date of the authorization; and
- (8) **REVOCAION STATEMENT.** -- The authorization must include a statement that the authorization is subject to revocation at any time before the disclosure is actually made.

(b) **COPY.** -- A copy of the authorization shall be provided to the person making the authorization.

(c) **REVOCAION OR AMENDMENT OF AUTHORIZATION.** -- A sample source or the sample source's representative may revoke or amend the authorization, in whole or in part, at any time.

(d) **NOTICE OF REVOCATION.** -- A sample source may not maintain an action against a person for disclosure of private genetic information made in good faith reliance on a valid authorization if the person had no notice of the revocation of the authorization at the time the disclosure was made.

(e) **IDENTIFICATION OF INFORMATION AS PROTECTED BY LAW.** -- Each disclosure made with the written authorization described in subsection (a) must be accompanied by the following written statement:

"This information has been disclosed to you from confidential records protected under the Genetic Privacy Act and any further disclosure of the information without specific authorization is prohibited."

(f) **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 as an authorization for disclosure of private genetic information.

Sec. 113. INSPECTION AND COPYING OF RECORDS CONTAINING PRIVATE GENETIC INFORMATION

(a) **INSPECTION OF RECORDS.** -- Except as otherwise provided in section 131(c)(2) and 131(f), a person who maintains private genetic information shall upon written request permit the sample source or the sample source's representative to inspect records containing private genetic information and shall provide a copy of any such records upon request by the sample source or the sample source's representative.

(b) **RESPONSE TO REQUEST EXAMINATION AND COPYING OF INFORMATION.** -- Upon receipt of a written request from a sample source or the sample source's representative to inspect or copy all or part of records containing private genetic information, a person as promptly as required under the circumstances but no later than 30 business days after receiving the request, shall make the information available to the sample source or the sample source's representative for inspection during regular business hours or provide a copy, if requested, to the individual.

(c) EXPLANATION OF TERMS AND CODES. -- A person shall provide an explanation of terms and any code or abbreviations used in records containing the private genetic information upon request of the sample source or the sample source's representative.

(d) FEE. -- A person may charge a reasonable fee, not to exceed the person's actual duplication cost, for copies of records which are provided.

Sec. 114. AMENDMENT OF RECORDS

(a) IN GENERAL. -- Within 45 days of receipt of a written request by a sample source or a sample source's representative to correct or amend in whole or in part any record containing private genetic information, a person who maintains records containing private genetic information shall:

- (1) make the correction or amendment requested;
- (2) inform the individual that the correction or amendment has been made;
- (3) make reasonable efforts to inform any person to whom the uncorrected or unamended portion of the information was previously disclosed of the correction or amendment that has been made; and
- (4) at the request of the individual, make reasonable efforts to inform any known source of the uncorrected or unamended portion of the information about the correction or amendment that has been made.

(b) REASONS FOR REFUSAL AND REVIEW PROCEDURES. -- If correction or amendment is refused, the person maintaining the records shall inform the sample source or the sample source's representative of:

- (1) the reasons for the refusal of the person to make corrections or amendment;
- (2) any procedures for further review of such refusal; and

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

(c) STANDARDS FOR CORRECTION OR AMENDMENT. -- A person maintaining records containing private genetic information shall correct or amend information in accordance with a request made under subsection (a) if the information is not accurate or complete for the purposes for which the information may be used or disclosed by the person.

(d) STATEMENT OF DISAGREEMENT. -- After a sample source or a sample source's representative has filed a statement of disagreement under subsection (b)(3), the person, in any subsequent disclosure of the disputed portion of the information, shall include a copy of the individual's statement and may include a statement of the reasons for not making the requested correction or amendment.

Sec. 115. DISCLOSURES PURSUANT TO COMPULSORY PROCESS

(a) PROCEEDINGS IN WHICH AVAILABLE. -- No person who maintains private genetic information may be compelled to disclose such information pursuant to a request for compulsory disclosure in any judicial, legislative, or administrative proceeding, unless:

- (1) The person maintaining the genetic information has received the authorization of the sample source or the sample source's representative to release the information in response to such request for compulsory disclosure;
- (2) The sample source or the sample source's representative is a party to the proceeding and the private genetic information is at issue; or
- (3) The genetic information is for use in a law enforcement proceeding or investigation in which the person maintaining the information is the subject or party;

(b) NOTICE. -- If genetic information is sought under subparagraph (2) of subsection (a), or in a proceeding or investigation pursuant to subparagraph (3) of subsection (a), the person requesting compulsory disclosure shall serve upon the person maintaining the genetic information, and upon the sample source, the sample source's representative, or on the sample source's attorney, the original or a copy of the compulsory disclosure request at least thirty days in

advance of the date on which compulsory disclosure is requested, and a statement of the right of the sample source or sample source's representative, and of the person maintaining the genetic information, to have any objections to such compulsory disclosure heard by such court or governmental agency prior to the issuance of an order for such compulsory disclosure, and 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 state or federal law.

(c) **CERTIFICATION.** -- Service of compulsory process or discovery requests upon a person maintaining private genetic information must be accompanied by a written certification, signed by the person seeking to obtain the private genetic information or his or her authorized representative, identifying at least one subparagraph of subsection (a) under which compulsory process or discovery is being sought. The certification must also state, in the case of information sought under subparagraphs (2) or (3) of subsection (a), that the requirements under subsection (b) for notice have been met. A person may sign the certification only if the person reasonably believes that the subparagraph of subsection (a) identified in the certification provides an appropriate basis for the use of discovery or compulsory process. A copy of the written certification shall be maintained as a permanent part of the records of private genetic information.

(d) **STANDARD FOR ISSUANCE OF ORDER.** -- An order under this section may only be entered by a court of competent jurisdiction after a hearing and determination that good cause exists. To make this determination the court must find that:

- (1) other ways of obtaining the private genetic information are not available or would not be effective; and
- (2) there is a compelling need for the private genetic information which outweighs the potential harm to the privacy interest of the subject of the information.

(e) **CONTENT OF ORDER.** -- An order under this section which authorizes disclosure of private genetic information must:

- (1) limit disclosure to those parts of records containing such information which are essential to fulfill the objective of the order;
- (2) limit disclosure to those persons whose need for the information is the basis of the order;
- (3) require the deletion of individual identifiers from any documents made available to the public; and
- (4) include such other measures as are necessary to limit disclosure for the protection of the subject of the information including, but not be limited to, sealing from public scrutiny the record or any portion of the record of any proceeding for which disclosure of the information has been ordered.

THE GENETIC PRIVACY ACT

PART C - - EXCEPTIONS FOR IDENTIFICATION AND COURT-ORDERED GENETIC ANALYSIS

Sec. 121. IDENTIFICATION OF DEAD BODIES

Notwithstanding any other provisions of this Act, a person may provide access to an individually identifiable DNA sample, or to data derived from DNA typing, to assist in the identification of a dead body, provided further that the analysis of any sample so provided and the analysis of a DNA sample from the dead body is limited to that which is necessary to determine the identity of the dead body.

Sec. 122. IDENTIFICATION FOR LAW ENFORCEMENT PURPOSES

Nothing in this Act shall be construed to prohibit federal, state or local law enforcement authorities from collecting, storing or typing DNA samples, when:

- (a) the collection, storage and typing of DNA samples is authorized under federal or state law;
- (b) collection, storage and typing of such samples is limited to the purpose of matching DNA samples in criminal investigations; and

(c) access to such DNA samples is limited to authorized law enforcement agencies, prosecutors, defense counsel, defendants, accused individuals, suspects, and their authorized agents.

Sec. 123. COLLECTION AND ANALYSIS OF DNA SAMPLES PURSUANT TO COURT ORDERED ANALYSIS

(a) **IN GENERAL.**-- Nothing in this Act shall be construed to prohibit the collection or analysis of an individually identifiable DNA sample pursuant to Rule 35 of the Federal Rules of Civil Procedure or comparable rules of other courts or administrative agencies in connection with litigation or proceeding to which the sample source is a party and in which the genetic condition of the sample source has been placed at issue, provided that the conditions in section (b) have been met.

(b) **ISSUANCE OF ORDERS.** -- An order under Rule 35 of the Federal Rules of Civil Procedure or comparable rules may only be made:

(1) upon motion for good cause shown and upon notice to the sample source or the sample source's representative and all parties; and

(2) the order must specify:

(A) the manner of collection of the DNA sample;

(B) the person or persons authorized to collect and analyze the sample;

(C) the purpose of the genetic analysis;

(D) that the genetic analysis is limited to that which is necessary to fulfill the purpose of the order; and

(E) that the person conducting the analysis destroy the sample at the earliest possible opportunity consistent with the purpose of that order.

PART D - - RESEARCH ACTIVITIES

Sec. 131. RESEARCH INVOLVING GENETIC ANALYSIS

(a) **CONDITIONS FOR A GENETIC ANALYSIS.** -- Except as provided in section 133 no individually identifiable DNA sample shall be analyzed as part of a research project unless an Institutional Review Board has determined that:

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

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

(3) the research protocol

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

(B) requires that research subjects will be given the applicable information set forth in section 101 of this Act in addition to the informed consent requirements contained in 45 CFR 46.116 (1992) as such regulation may be amended;

(C) requires the written authorization of research subjects that includes the applicable requirements of section 103 of this Act; and

(D) prohibits inclusion of research records in medical records unless the sample source or the sample source's representative authorizes such inclusion in writing.

(b) **SAFEGUARDS AGAINST DISCLOSURES OF PRIVATE GENETIC INFORMATION.** -- For purposes of subparagraph (3)(A) of subsection (a) of this section, adequate safeguards against disclosure of private genetic information include but are not limited to:

(1) obtaining a certificate of confidentiality from the Secretary of Health and Human Services as provided in 42 U.S.C. 241(d) as such statute may be amended;

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

(3) having procedures to remove or destroy at the earliest opportunity consistent with the purposes of the project,

information that would enable a sample source to be identified.

(c) **FURTHER LIMITATIONS ON RESEARCH INVOLVING INDIVIDUALS UNDER 18.** -- No research shall be conducted on individually identifiable DNA samples when the sample source is under 18 years of age unless:

- (1) a parent or guardian is given the applicable information set forth in section 101 of this Act;
- (2) a parent or guardian executes an authorization that includes the applicable requirements of section 103 of this Act and which specifically states that the parent or guardian understands and agrees that unless the analysis reveals a genetic condition which in reasonable medical judgment can only be effectively ameliorated, prevented or treated while the sample source is under 18 years of age, the results of the analysis will not be disclosed to the parent or guardian of the sample source; and
- (3) any provisions for soliciting the assent of minors as contained in 45 CFR 46.408 as such regulation may be amended which the Institutional Review Board determines to be applicable are met.

(d) **DESTRUCTION OF DNA SAMPLES OR IDENTIFIERS.**

(1) **GENERALLY.**-- In the absence of a specific authorization to maintain an individually identifiable DNA sample, individually identifiable DNA samples collected, stored or analyzed in connection with a research project shall be destroyed upon completion of the project or withdrawal of the sample source from the project, whichever occurs first.

(2) **EXCEPTION.**-- Whenever the authorization for collection, storage or analysis of an individually identifiable DNA sample does not contain a prohibition against research use of the sample when it is no longer linked to any individual identifier, the person in possession of the sample may destroy all individual identifiers linking the sample to the sample source instead of destroying the sample as required by subsection (1).

(e) **PEDIGREE ANALYSIS AND FAMILY LINKAGE STUDIES.** -- When a research project includes analysis of DNA from family members for pedigree analysis or linkage analysis--

(1) the Institutional Review Board, in addition to making the determinations required in subsection (a) of this section, shall also require--

- (A) that education and counseling regarding how pedigree analysis is conducted and the kind of information that results from such analysis is provided to research subjects;
- (B) that as far as practicable separate records are maintained on each subject.

(2) Prior to their participation, and in addition to the disclosures required by section 101 of this Act, subjects shall be--

- (A) informed that one risk of their participation is that by the end of the project other family members may learn private genetic information about them;
- (B) informed of what will be done with records and data generated during the project;
- (C) informed that the project may determine that some members of their family are not genetic relatives.

(f) **SUBJECTS RIGHT TO OBTAIN INFORMATION.** -- When complying with the provisions of section 113 of this Act, no person shall provide an individual in the pedigree with private genetic information about another person without that other person's authorization.

(g) **USE OF UNIDENTIFIABLE DNA SAMPLES NOT PROHIBITED.** -- Nothing in this Act shall be construed as prohibiting or limiting research on a DNA sample that cannot be linked to any individual identifier.

Sec. 132. DISCLOSURE OF PRIVATE GENETIC INFORMATION FOR RESEARCH PURPOSES

(a) **IN GENERAL.** -- Any person who, in the ordinary course of business, practice of a profession, or rendering of a service, stores or maintains private genetic information is prohibited from allowing access to such information to researchers unless:

- (1) an Institutional Review Board has approved the conduct of the research program or study; and

(2) the sample source or the sample source's representative has specifically consented to the access or disclosure of such information in an authorization that meets the requirements of section 112 of this Act.

(b) **LIMITED ACCESS FOR STATISTICAL USE.** -- Notwithstanding the provisions of subsection (a), a person who stores or maintains private genetic information may grant access to such information solely for the purpose of inspection or review of records containing the information provided that

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

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

(A) that these limitations will be complied with; and

(B) to an awareness of their liability for violations of this Act.

Sec. 133. EXCEPTION FOR DNA SAMPLES PREVIOUSLY COLLECTED FROM DECEASED PERSONS

(a) **ANALYSIS PERMISSIBLE.** -- Notwithstanding the provisions of section 131, an individually identifiable DNA sample which was collected from a sample source who died prior to the effective date of this Act may be analyzed as part of a research project, but no individually identifiable genetic information may be disclosed without the authorization of the sample source's representative.

(b) **DISCLOSURE TO RELATIVES.** -- If the analysis of a DNA sample permitted by subsection (a) determines that a relative of a deceased sample source is at risk for a genetic disease which in reasonable medical judgment can be effectively ameliorated, prevented, or treated, nothing in this Act shall be construed as prohibiting researchers from contacting such relatives and informing them of such risk provided that private genetic information about the sample source is not disclosed.

PART E - - MINORS AND INCOMPETENT PERSONS

Sec. 141. AUTHORIZATION FOR COLLECTION AND ANALYSIS OF DNA FROM MINORS

(a) **INDIVIDUALS UNDER 16.** -- Except as provided in sections 131(c) and 151, the individually identifiable DNA sample of a sample source who is under 16 years of age shall not be collected or analyzed to determine the existence of a gene that does not in reasonable medical judgment produce signs or symptoms of disease before the age of 16, unless:

(1) there is an effective intervention that will prevent or delay the onset or ameliorate the severity of the disease; and

(2) the intervention must be initiated before the age of 16 to be effective; and

(3) the sample source's representative has received the disclosures required by section 101 of this Act and has executed a written authorization which meets the requirements of section 103 of this Act and which also limits the uses of such analysis to those permitted by this section.

(b) **INDIVIDUALS AGE 16 OR 17.** -- Except as otherwise provided in sections 131(c) and 143, the individually identifiable DNA sample of a sample source who is 16 or 17 years of age may be collected and analyzed provided that--

(1) the sample source receives the information required by section 101 of this Act while accompanied by a parent or other adult family member; and

(2) the sample source executes a written authorization which meets the requirements of section 103 of this Act.

(c) **DESTRUCTION OF DNA SAMPLES OF INDIVIDUALS UNDER 16.** -- A sample source's representative may, on behalf of a sample source who is under 16 years of age, order the destruction of a DNA sample collected pursuant to subsection (a) of this section.

Sec. 142. AUTHORIZATION FOR DISCLOSURE OF PRIVATE GENETIC INFORMATION ABOUT INDIVIDUALS AGE 16 OR 17

(a) AUTHORIZATION REGARDING INDIVIDUALS. -- Except as provided by section 144, private genetic information about an individual who is age 16 or 17 shall not be disclosed unless the sample source has executed a written authorization which meets the requirements of section 112.

(b) AUTHORIZATION REGARDING INDIVIDUALS UNDER 16. -- Except as provided in section 152, private genetic information about a minor who is under 16 years of age shall not be disclosed unless a parent or other sample source's representative has executed a written authorization that meets the requirements of section 112.

Sec. 143. AUTHORIZATION FOR COLLECTION AND ANALYSIS OF DNA SAMPLES FROM INCOMPETENT PERSONS

(a) LIMITATIONS ON COLLECTION AND ANALYSIS. -- The individually identifiable DNA sample of a sample source who lacks the ability to understand the information disclosed pursuant to section 101 and the information contained in an authorization under section 103 shall not be collected or analyzed unless--

(1) the analysis is necessary:

(A) to diagnose the cause of incompetence; or

(B) to diagnose a genetic condition which in reasonable medical judgment can only be effectively ameliorated, prevented or treated while the sample source is incompetent; or

(C) to diagnose a genetic disease of a parent, sibling, child or grandchild of the sample source provided that the disease in reasonable medical judgment can be effectively ameliorated, prevented, or treated;

(2) the analysis is limited to that which is necessary for such diagnosis; and

(3) the sample source's representative has executed an authorization which meets the requirements of section 103 of this Act.

(b) DESTRUCTION OF SAMPLES COLLECTED PRIOR TO INCOMPETENCY. -- Whenever a sample source while competent has, either in an authorization under section 103 of this Act, or in an exercise of the sample source's rights under section 104(b) of this Act, ordered the destruction of a DNA sample, and the sample source becomes incompetent before the occurrence of the date or event which was designated by the sample source to cause the destruction of such sample, the sample source's representative may order the earlier destruction of such sample, but is not empowered to cancel or override any such destruction unless the postponement of the destruction is to enable an analysis of the DNA sample for a purpose provided for in subsection (a) of this section.

Sec. 144. AUTHORIZATION FOR DISCLOSURE OF PRIVATE GENETIC INFORMATION ABOUT INCOMPETENT PERSONS

Private genetic information about an incompetent person shall not be disclosed unless:

(a) the information--

(1) is necessary for the diagnosis of a genetic condition which in reasonable medical judgment is effectively ameliorated, prevented or treated while the person is incompetent; or

(2) is necessary for the purpose of genetic counselling for a relative of the person;

(b) the information disclosed is limited to that which is necessary to conduct such treatment or counselling; and

(c) the sample source's representative executes an authorization that meets the requirements of section 112 of this Act.

PART F - - PREGNANT WOMEN, FETUSES, AND EXTRACORPOREAL EMBRYOS

Sec. 151. AUTHORIZATION FOR COLLECTION AND ANALYSIS OF DNA FROM PREGNANT WOMEN AND FETUSES

Regardless of her age, a pregnant woman shall have all the rights and authority of an adult sample source in regard to her DNA sample and the DNA sample of her fetus unless she is otherwise incompetent under the provisions of section 143.

Sec. 152. AUTHORIZATION FOR DISCLOSURE OF PRIVATE GENETIC INFORMATION ABOUT PREGNANT WOMEN AND FETUSES

Regardless of her age, a pregnant woman shall have all the rights of an adult sample source in regard to records containing private genetic information as provided in section 113, 114, and 115 of this Act, and in regard to disclosure of genetic information resulting from an analysis of her DNA sample or the DNA sample of her fetus, unless she lacks the ability to understand the information contained in an authorization under section 112.

Sec. 153. AUTHORIZATION FOR COLLECTION AND ANALYSIS OF DNA FROM EXTRACORPOREAL EMBRYOS

(a) **RELINQUISHMENT OF DONOR'S RIGHTS.** -- Whoever donates a gamete for the reproductive purposes of a person or persons other than the gamete donor relinquishes all rights regarding the collection and analysis of a DNA sample of an embryo subsequently created using the donated gamete.

(b) **CONDITIONS FOR COLLECTION AND ANALYSIS.** -- Prior to the collection and analysis of a DNA sample from an extracorporeal embryo created for reproductive purposes, the person collecting or causing to be collected the DNA sample of such embryo shall:

- (1) make the disclosures required by section 101 of this Act to the person or persons who intend to use the embryo for reproduction; and
- (2) shall obtain the written authorization of such person or persons that meets the requirements of section 103 of this Act.

(c) **DISCLOSURE OF RESULTS.** -- The results of a genetic analysis of a DNA sample of an extracorporeal embryo shall be disclosed to the person or persons who intend to use the embryo for reproductive purposes.

PART G - - MISCELLANEOUS PROVISIONS

Sec. 161. NOTIFICATION OF PRIVACY OBLIGATIONS

Not less than annually every person who maintains individual identifiable DNA samples or individual identifiable records containing private genetic information shall notify their employees of their responsibilities under this Act and the penalties for violating them.

Sec. 162. TRANSFER OF OWNERSHIP, DISCONTINUANCE OF SERVICES

(a) **ACTIVITIES INVOLVING DNA SAMPLES.** -- Any person in possession of individually identifiable DNA samples who intends to discontinue a program, business, enterprise, or service in which such DNA samples were collected, stored, or analyzed or who intends to transfer control of such program, business, enterprise, or service to a person who intends to use such DNA samples for a substantially different purpose than was authorized at the time of collection, storage, or analysis of such DNA samples must:

- (1) no less than 45 days prior to the effective date of the discontinuance or transfer of control, mail a notice to the last known address of each sample source or the sample source's representative informing such individuals of the intended change, and
 - (A) in the case of an intended discontinuance of activities, give the individual the opportunity to direct that the DNA sample be returned to the individual prior to the date on which the discontinuance is effective and informing them of the date on which such direction must be received to effectuate such request; or
 - (B) in the case of an intended transfer of control, give the individual the option of agreeing to the transfer, or requiring the destruction or return of the DNA sample prior to the effective date of the transfer, and

informing the individual of the date on which such a requirement must be received to be effectuated;

(2) In the event that no response is received from the individual by the date specified in the notice, the person in possession of such DNA sample:

(A) in the case of a discontinuance shall destroy such DNA samples; and

(B) in the case of transfer of control shall either;

(i) destroy such DNA samples, or

(ii) remove all individual identifiers from such DNA samples.

(b) RECORDS CONTAINING PRIVATE GENETIC INFORMATION. -- Any person in possession of individually identifiable records that contain private genetic information who intends to discontinue a program, business, enterprise, or service in which the private genetic information was created or obtained, and any person who maintains records other than medical records that contain private genetic information who intends to transfer control of a program, business, enterprise, or service in which the private genetic information was created or obtained shall:

(1) no less than 45 days prior to the effective date of the discontinuance or transfer of control, mail a notice to the last known address of each sample source or the sample source's representative informing such individuals of the intended change, and

(A) in the case of an intended discontinuance, inform the individual of

(i) their right to order return of the records prior to the discontinuance and informing them of the date on which such direction must be received to effectuate such order, or

(B) in the case of an intended transfer of control, provide the name of the person who will be in control of the records after the transfer, and inform the individual of their right to order return of the records to the individual or to a person designated by that individual, or to agree to the intended transfer.

(2) If no response is received from the individual by the date specified in the notice, the person in possession of such records:

(A) in the case of discontinuance, shall

(i) destroy the records, or

(ii) seal and securely store the records for no longer than 3 years; or

(B) in the case of an intended transfer, may proceed with transfer of control of the records.

PART H - - ENFORCEMENT

Sec. 171. CIVIL REMEDIES

(a) PRIVATE RIGHT OF ACTION. -- Any person whose rights under this Act have been violated may maintain a civil action for damages or equitable relief as provided for in this section.

(b) JURISDICTION. -- An action to enforce the liabilities under this section may be brought in the district courts 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 through negligence collects a DNA sample in violation of this Act, analyzes a DNA sample in violation of this Act, or discloses private genetic information in violation of this act, shall be liable to the sample source for each such violation in an amount equal to:

- (1) any actual damages sustained as a result of the collection, analysis, or disclosure, or \$25,000, whichever is greater; and
- (2) in any case where such violation has resulted in profit or monetary gain, treble damages; and
- (3) in the case of a successful action to enforce any liability under this section, the costs of the action together with reasonable attorneys' fees as determined by the court.

(e) **LIABILITY FOR WILLFUL VIOLATIONS.** -- Any person who--

(1) through a request, the use of persuasion, under threat, or with a promise of reward, willfully induces a person to collect a DNA sample in violation of this Act, analyze a DNA sample in violation of this Act, or disclose private genetic information in violation of this Act, or

(2) willfully collects a DNA sample in violation of this Act, willfully analyzes a DNA sample in violation of this Act, or willfully discloses private genetic information in violation of this Act, shall be liable to the sample source for each such violation in an amount equal to:

- (A) any actual damages sustained as a result of the collection, analysis, or disclosure, or \$50,000, whichever is greater;
- (B) punitive damages as the court may allow; and
- (C) in the case of a successful action to enforce any liability under this section, the costs of the action together with reasonable attorneys' fees as determined by the court.

(f) **STATUTE OF LIMITATIONS.** -- Except for subsection (g) any action under this section must be brought within two years of when the alleged violation was or should have been discovered.

(g) **TOLLING OF LIMITATIONS.** -- If the person entitled to an action under this section 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 2 years after the disability is removed.

Sec. 172. CIVIL PENALTIES AND INJUNCTIVE RELIEF

Whenever the attorney general has reason to believe that any person is using or is about to use any method, act or practice in violation of 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 by temporary restraining order or preliminary or permanent injunction the use of such method, act or practice. The action may be brought in the district court of the jurisdiction in which the person resides or has a principal place of business. The court may issue temporary restraining orders or preliminary or permanent injunctions and make such other orders or judgments as may be necessary to prevent harm or to remedy harm suffered by any person as a result of the use or employment of such method, act or practice in violation of this Act. If the court finds that a person has employed any method, act or practice which he knew or should have known to be in violation of 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 the said person to pay reasonable costs of investigation and litigation of such violation, including reasonable attorneys fees.

PART I - - EFFECTIVE DATES; APPLICABILITY; AND RELATIONSHIP TO OTHER LAWS

Sec. 181. EFFECTIVE DATES

This Act, and the amendments made by this Act, shall take effect on _____, 199__.

Sec. 182. APPLICABILITY

(a) **AUTHORIZATION FOR ANALYSIS OF DNA SAMPLES COLLECTED PRIOR TO EFFECTIVE DATE.** -- In order to comply with the provisions of this Act, any person who, prior to the effective date of this Act, is in possession of an individually identifiable DNA sample must, prior to performing any genetic analysis on the DNA samples:

- (1) make the disclosures required by section 101 (c); and obtain a written authorization that meets the requirements of section 112; or
- (2) take all steps necessary to ensure that the DNA sample is no longer linked to any individual identifier.

(b) **AUTHORIZATIONS FOR DISCLOSURES.** -- An authorization for the disclosure of private genetic information that is executed before _____, 199__ , and which does not meet the requirements of section 103, but which is valid under State law on _____, 199__ , shall remain valid until thirty days after the effective date of this Act, or the expiration date specified in the authorization, whichever occurs earlier.

Sec. 183. RELATIONSHIP TO OTHER LAWS

(a) No state may establish or enforce any law or regulation concerning the collection, storage, of analysis of DNA samples except to the extent that such law or regulation:

- (1) prohibits or further restricts the collection, storage, or analysis of DNA samples; or
- (2) provides additional protection to the privacy interests of the individual who is a sample source.

(b) Effective as of the effective date of this Act, no State may establish or enforce any law or regulation concerning the disclosure of private genetic information except to the extent that such law or regulation:

- (1) prohibits or further restricts the disclosure of such information;
- (2) prohibits or further restricts the use of such information; or
- (3) provides additional protection to the privacy interests of the individual who is a sample source or the subject of the genetic information.

(c) 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 private genetic information.

III

COMMENTARY

This commentary explains why and how decisions were made about provisions of the Genetic Privacy Act to help readers understand both its scope and the intent of the drafters. Those parts of the Act that are self-explanatory are not referenced in this section.

Sec. 3. DEFINITIONS

(m) PRIVATE GENETIC INFORMATION. - The term "private genetic information" means any information about an identifiable individual that is derived from the presence, absence, alteration, or mutation of a gene or genes, or the presence or absence of a specific DNA marker or markers, and which has been obtained:

- (1) from an analysis of the individual's DNA; or**
- (2) from an analysis of the DNA of a person to whom the individual is related.**

The term "Private Genetic Information" is the key to the Act because it defines the information that is protected by it. This definition recognizes that not all genetic information needs or warrants legal protection, and limits the Act's protection to information derived from DNA analysis. The Act, accordingly, does not protect genetic information derived from medical examinations, family histories, or pedigrees.

Like other kinds of personal information, some genetic information is more sensitive than other genetic information. Control of some genetic information is more critical for the exercise of personal autonomy, and publication or disclosure of some genetic information can be more damaging or stigmatizing than disclosure of other genetic

information. For instance, although height, eye and skin color, and other physical characteristics are inherited and therefore genetic information, such externally-expressed genetic information is not private. On the other hand, knowledge about the presence of a gene that makes it probable that the individual will suffer a debilitating disease later in life is private information, at least until a point in time when symptoms become manifest or the individual intentionally discloses the information.

We wanted to draft a definition that is based on a principled distinction between "private" and other genetic information, and at the same time susceptible to practical application. The manner in which genetic information is created contributes to its private nature. Genetic analysis of an individual's DNA, such as testing for a specific disease gene, particularly if signs and symptoms of the disease are not manifested, is an obvious source of such private information. Similarly, if an analysis reveals that an individual is the carrier of a recessive disease gene which could be passed on to offspring, this carrier status is private information if derived from a DNA analysis. Carrier status could also be inferred from a genetic condition in an individual's child. Therefore, another source of private genetic information about an individual is the analysis of the DNA of a close relative of the individual.

Private genetic information can also be obtained from a family history of a genetic disease. Physicians who inquire about the incidence of a particular condition in a patient's family acquire private genetic information on a regular basis. This source of private genetic information is the least susceptible to regulation and control because it is virtually impossible to distinguish such private genetic information from other family medical history in any principled way.

Development of a genetic medical history can be a complex process involving review of medical records of several family members, or it can result simply from asking the patient a few questions about specific relatives. Regardless of the nature of the inquiry, the purpose is the same: to determine an individual's risk of having inherited a gene. For example, developing a family pedigree or history can be used to determine whether or not a woman is likely to have inherited a breast cancer gene. The prediction that an individual family member has inherited the gene may be based solely on the patient's report of the age and relationship of other women in the family who have developed cancer. [\[8\]](#)

Although one process uses DNA analysis and the other does not, both lead to the creation of the same private genetic information: the prediction of a predisposition to disease. Nonetheless, distinguishing between "private genetic information" derived from a family history and other medical information derived from a family history is problematic. For example, it is difficult, if not impossible, to distinguish between the prediction of having inherited the breast cancer gene, based on disease occurrence in the family, and establishing a person's risk for other diseases, such as heart disease or diabetes, based on the prevalence of these diseases in a family.

Inclusion of family history-based risk information in the definition of "Private Genetic Information" would protect information that has historically been collected and disclosed as ordinary medical information, and virtually all medical records would be subject to the provisions of the Act. Extending the umbrella of protection through such an expansive definition would necessitate the overhaul of well established medical information practices and policies.

A similar analysis leads to the same conclusion regarding biochemical tests that detect the presence or absence of a protein that indicates the presence or absence of a particular gene. By not including genetic information derived from family histories, biochemical tests, or methods other than DNA analysis, we recognize that some genetic information will escape the protection of the Act. We have opted to exclude this type of genetic information to avoid the enormous practical problems presented by including it. Despite this underinclusiveness, we believe our definition is consistent with the goal of protecting information developed within the context of the Human Genome Project as a result of mapping the human genome: information derived from DNA analysis is subject to uniform and comprehensive privacy protection.

(n) SAMPLE SOURCE. - The term "sample source" means the individual from whose body the DNA sample originated.

(o) SAMPLE SOURCE'S REPRESENTATIVE. - The term "sample source's representative" means any person who has the legal authority to make health care decisions concerning a minor or an incompetent person, or the administrator or executor of a deceased person's estate, if any, otherwise the next of kin of a deceased person.

"Sample Source" refers to the individual from whom a DNA sample has been collected. It is necessary to have a term that distinguishes the individual from whom the DNA originates from other persons who may have possession of, or interest in, a DNA sample. We considered suggestions by reviewers of early drafts to utilize a term that was less dehumanizing, such as sample source person, human source, or source individual. However, despite the desirability of preserving the sense of person in regard to individuals who have DNA analyzed, alternatives were either awkward in the context of the statutory provisions, or did not maintain the connection between the DNA sample and the person from whom it originated in a clear and succinct way. We also considered using terms that were familiar from use in statutes like the Uniform Anatomical Gift Act and medical records acts. However, because only some genetic information is medically relevant, they were found to be of limited applicability in discussing DNA.

"Donor," a term associated with blood collection and organ harvesting, was also considered. However, it has not been used in conjunction with the collection of biological specimens for purposes other than selling them or giving them away, and consequently it would only be accurate if the DNA samples were intended to be used by others.

The term "depositor" was also considered, and would be consistent with the concept of DNA banking. While it is a term used by others such as the Ad Hoc Committee on DNA Technology of the American Society of Human Genetics,^[9] its relevance and utility are diminished when banking is not the focus of the activity that is to be regulated. "Depositor" is only accurate when referring to someone who leaves tangibles with another person for storage, safekeeping or transfer to a third party and it assumes that a voluntary act is involved. However, the Act regulates the collection and analysis of DNA whether or not it involves a voluntary act of depositing. While the term would be applicable to circumstances where DNA samples are temporarily stored or maintained "as is," and where the recipient only functions as a custodian, such storage alone is not the activity that we are primarily concerned with controlling. Furthermore, although suggesting a role of stewardship on the part of the recipient, it fails to acknowledge the connection that the depositor would still have with the information contained in the deposited DNA sample.

In comparison to these terms, "sample source" clarifies that the individual referred to is the one from whom the DNA has been extracted, without being unnecessarily wordy or conjuring up images and associations that are inconsistent with the nature of the sample itself or the information it contains. It avoids reference to how the person storing or analyzing the sample came into possession of the sample, and is the simplest term available.

If the sample source does not have the legal capacity to exercise the rights granted by this Act, they can be exercised by the "sample source's representative." This is the person who is legally authorized under state law to make health care decisions for such persons. For minors, the sample source's representative will usually be a parent or legally appointed guardian. For an incompetent person, the representative could be a guardian, or a person appointed under a health care proxy or similar legal instrument, to act on behalf of the incompetent person. The term also encompasses those who are authorized to make decisions regarding deceased persons or a deceased person's estate.

An executor or administrator, who is authorized to act on behalf of a decedent and the decedent's estate, could authorize disclosure of private genetic information about the sample source. Samples collected prior to death may, as property of the sample source, be included in his or her estate, and consequently, the executor or administrator would be responsible for authorizing the storage, transfer or destruction of such samples in accordance with the decedent's wishes.

(f) DNA TYPING. - The term "DNA Typing" means a scientifically reliable method for characterizing and comparing sequences of DNA, and applying a statistical analysis of population frequency to determine that if the DNA sequences match, the probability that the match occurs by chance.

"DNA typing" refers to what some commentators term "DNA profiling" or "DNA fingerprinting." "Typing" was selected because it is the most accurate term for identifying the process used in forensics to determine if one DNA sample "matches" another sample, and calculating the probability that a match is due to chance. It is our intent to clarify that this identification process, unlike other kinds of DNA analysis, yields genetic information that has no independent meaning and is only useful for matching purposes in much the same way that an individual's fingerprint provides no more information than the identity of the individual.^[10]

(g) IDENTIFIABLE INDIVIDUAL. - The term "identifiable individual" means any individual whose name,

address, Social Security number, health insurance identification number, or similar identifying information is known, available, or can be determined with reasonable accuracy either directly or by reference to other available information.

(h) INDIVIDUAL IDENTIFIER. - The term "individual identifier" means a name, address, Social Security number, health insurance identification number, or similar information by which the identity of a sample source can be determined with reasonable accuracy, either directly or by reference to other available information. The term does not include characters, numbers, or codes assigned to an individual or a DNA sample which cannot be used to determine the identity of a sample source.

(i) INDIVIDUALLY IDENTIFIABLE DNA SAMPLE. - The term "individually identifiable DNA sample" means any DNA sample linked to an individual identifier.

(j) INDIVIDUALLY IDENTIFIABLE RECORD. - The term "individually identifiable record" means any record that contains private genetic information linked to an individual identifier.

Throughout the Act the words "sample," "records," and "individual" are often modified by the terms "individually identifiable" or "identifiable." This is necessary to distinguish samples and records which are linked to individual identifiers from those which are not. The choice of "linked" to express the connection between the sample and the identifiers is meant to be as broad and inclusive as possible. No matter how loose or indirect the linkage may be, if there is a way to connect a sample to an individual, the sample is not anonymous. Only when the numbers or characters assigned to samples simply distinguish one sample from another, are otherwise meaningless, and **cannot** be matched with any identifiable person, are the samples no longer individually identifiable. The term "individual identifier" as defined here is intended to include **any** name, number or code that can be used to learn the identity of an individual.

This distinction between samples that are individually identifiable and those that are not is significant, since the goal of the Act is to protect the privacy interests of individuals. Unless DNA samples are linked to an individual, use of the samples and use of the information derived from the samples does not implicate informational privacy interests. Consequently, regulation of the use of such samples or information is not within the domain of the Act.

PART A

COLLECTION AND ANALYSIS OF DNA SAMPLES

Sec. 101. COLLECTION OF DNA SAMPLES

(a) REQUIREMENT OF WRITTEN AUTHORIZATION. -- Except as otherwise provided in sections 121, 122, and 123, no person may collect or cause to be collected an individually identifiable DNA sample for genetic analysis without the written authorization of the sample source or the sample source's representative.

(b) REQUIRED INFORMATION. -- Prior to the collection of a DNA sample from a sample source for genetic analysis, the person collecting the sample or causing the sample to be collected shall verbally inform the sample source or the sample source's representative:

- (1) that consent to the collection or taking of the DNA sample is voluntary;**
- (2) that consent to the genetic analysis is voluntary;**
- (3) of the information that can reasonably be expected to be derived from the genetic analysis;**
- (4) of the use, if any, that the sample source or the sample source's representative will be able to make of the information derived from the genetic analysis;**
- (5) of the right to inspect records that contain information derived from the genetic analysis;**

- (6) of the right to have the DNA sample destroyed;**
- (7) of the right to revoke consent to the genetic analysis at any time prior to the completion of the analysis;**
- (8) that the genetic analysis may result in information about the sample source's genetic relatives which may not be known to such relatives but could be important, and if so the sample source will have to decide whether or not to share that information with relatives;**
- (9) that in the future someone else may ask if the sample source has obtained genetic testing or analysis and condition a benefit on the disclosure of information regarding such testing or analysis;**
- (10) that the collection and analysis of the DNA sample, and the private genetic information derived from the analysis is protected by this Act; and**
- (11) of the availability of genetic counselling.**

This section sets forth the general prohibition against collection of identifiable DNA samples without the written authorization of the sample source or that person's representative. In addition, this section requires that particular information be verbally communicated before an authorization is obtained. These requirements are designed to foster a knowledgeable and voluntary decision to proceed with the collection and analysis of a DNA sample. A perfunctory recitation should be discouraged, despite the fact that mere delivery of the information would technically satisfy the requirement of this section. Those who collect DNA samples should be encouraged to expand upon the minimum information required by providing additional information they believe to be beneficial to individuals who plan to have their DNA analyzed.

The information that must be provided under this Act is similar to the kind of information that must be disclosed before obtaining consent for diagnostic tests that reveal highly private and sensitive information. For example, several state laws require that anyone undergoing an HIV test must first be told about the information that the test can yield, the reliability of the test, and how the information can be used by the individual that is tested, in addition to how the information may be used by others who become aware of it.^[11] Such requirements are warranted because, if disclosed, information on HIV status could result in economic, social or psychological harm. Similarly, genetic information may be used to preclude the sample source from obtaining an economic or social service benefit.

Disclosure of genetic information can also have a harmful effect because it can also indicate the presence or absence of a stigmatizing condition or disease. The sample source should therefore be told that others may ask if the sample source has had a DNA analysis, and the results obtained.

An additional disclosure, required by section 101(b)(8), is intended to address the fact that the results of genetic analysis can reveal that others are likely to be affected by the same genetic condition or disease as the individual whose DNA is to be analyzed. This section, therefore, also requires that the person be informed:

that the genetic analysis may result in information about the sample source's genetic relatives which may not be known to such relatives but could be important and if so the sample source will have to decide whether or not to share the information with relatives.

DNA analysis may reveal that other relatives are likely to be gene carriers, to have a gene that codes for disease, or to be predisposed to developing a particular disease or condition by reason of their genetic relationship to the sample source. In effect, the uncollected DNA of family members is indirectly analyzed. This aspect of genetic analysis raises questions about whether such family members should be told about their possible risks and if so, by whom and how? One suggestion is that access to genetic testing in some circumstances be made conditional on a prior agreement to disclose information to other family members who become identified as at risk.^[12] This suggestion, however, has not been widely supported for several reasons, including the fact that it would deter individuals from seeking information about themselves.^[13]

Creating either a contractual or statutory obligation for individuals to share such information with their family members would be not only unprecedented, but inadvisable. The creation of new substantive rights or duties of family members is not our intention and is beyond the scope of this Act. However, because the Act creates rules that govern the use and disclosure of information, it is imperative that individuals be informed of the fact that by seeking genetic

information about themselves through genetic analysis, they may also become privy to information about other family members who would also want and/or need such information. A person seeking genetic analysis will not always be able to anticipate the nature of the information that can result and must therefore be informed of this possibility before the analysis is authorized. While it will be an individual choice as to whether or not to share that information with others, this disclosure should instigate discussion between the sample source and the collector of the sample.

For example, if as a result of the analysis of the DNA of the sample source it could be determined that the person's sibling is also the carrier of a genetic condition, and could pass the condition to offspring, or could suffer in the future from a genetic condition that can be ameliorated or treated, the sample source must be informed that he or she will have to decide whether or not to share that information with the sibling once the results are known. Despite the absence of a legal obligation to do so, the sample source should be encouraged out of moral obligation to share as much of the information as would provide the sibling, or other relatives, with the opportunity to obtain information about their own condition or risk. Since this is a foreseeable and a relatively common burden resulting from DNA analysis, its disclosure is necessary. This issue is discussed in more detail in the Appendix.

Availability of genetic counseling can also provide the sample source with help in deciding how and when to initiate discussion with relatives, and in determining how much information about their own status they are comfortable sharing with others. Consequently, in addition to disclosing the nature and scope of the information that the analysis will produce, section 101(b)(11) requires that the person who collects the sample must provide information on the **availability** of such counseling. This requirement can be fulfilled by telling the individual about the existence of genetic counselors whose expertise is to help individuals understand what genetic information that can be derived from DNA analysis means, and plan in light of such information. The person could suggest how a genetic counselor could be located by those who decide a consultation would be desirable. The person collecting the sample is not, however, required to provide such counseling, nor would they be obligated to take any steps to ensure that the individual is referred to a specific counselor.

This limited requirement will not be burdensome, since it would be rare for anyone who regularly collects and analyzes DNA samples not to have information about genetic counseling services. Research and clinical programs that conduct DNA analysis often utilize such services, receive references from such services or at least recommend that subjects or patients take advantage of the assistance counselors can give. Anyone collecting and analyzing DNA samples as a regular part of their business or practice should have some awareness of this emerging field, and requiring some discussion about the availability of genetic counseling is consistent with present practices of many programs.

This requirement is supported by the recommendations of other experts who have studied the effects of genetic information.^[14] Research and experience with Huntington Disease linkage studies and other genetic testing has demonstrated that pre-test counseling as well as post-test counseling is needed for those who face the choice of having DNA analyzed and the possibility of sharing such information with others.^[15] Test results can have an impact, not only on the self perception of the individual who has been tested, but on family relationships as well. Particular attention has been focused on the effect of information about the inheritance of this disease on family relationships and personal identity.^[16] Although Huntington Disease is an extreme example because the disease itself is devastating, it presents issues that are typical in genetic testing and analysis.^[17]

Sec. 102. ANALYSIS OF DNA SAMPLES

(a) ANALYSIS PROHIBITED WITHOUT AUTHORIZATION. - Except as otherwise provided in sections 121, 122 and 123, genetic analysis of an individually identifiable DNA sample is prohibited unless specifically authorized in writing by the sample source or the sample source's representative.

(b) ASCERTAINMENT OF AUTHORIZATION. - No person may analyze an individually identifiable DNA sample without ascertaining that written authorization for the analysis has been obtained.

This section prohibits conducting any analysis of an individually identifiable DNA sample without specific written authorization. When DNA is collected in a clinical setting for diagnosis of disease or determination of an appropriate course of treatment, the collection process will not differ from taking blood or other specimens for other types of

testing or screening. Consequently, the collection of a sample may begin with a physician ordering that the sample be taken by other personnel, such as a phlebotomist, and sent to a lab for analysis. Under the provisions of the Act, even if the physician is the one responsible for informing the sample source and obtaining the written authorization, if he fails to do so, a laboratory may not proceed with conducting the analysis. This is because section 102(b) prohibits DNA analysis, unless the person conducting the analysis ascertains that the authorization has been obtained. If they fail to do so, they, as well as the person who initiated collection of the sample without written authorization, face the penalties for noncompliance with the statutory requirements. How this "person" verifies that the authorization has been obtained is, however, not dictated by the statute, but will be governed by the person's own administrative policies and procedures.

This section does not require the phlebotomist who draws blood under orders from a physician, or a lab technician who receives a sample for analysis to obtain the sample source's consent. This would be unrealistic and disruptive to established roles and protocols in which the collection or analysis of DNA might take place. Instead, the Act requires everyone to refrain from proceeding with their role in the process until proper authorization has been obtained.

This section does not describe these responsibilities as applying to specific personnel because, in the future, collection and analysis of DNA samples might take place outside a clinical setting, such as a commercial facility or free standing laboratory, where the person collecting samples is not a health care professional. DNA can be extracted from different kinds of specimens, including strands of hair, so collecting a DNA sample does not always involve technical medical skills or knowledge. These requirements are applicable to all collection situations and mandate that the necessary disclosures are made and written authorization is obtained from all sample sources. Since these responsibilities have been delegated to the "person" who collects the sample or causes the sample to be collected, and to the "person" who performs an analysis, regardless of whether the facility in which this takes place is a health care facility, this "person" will have to establish procedures and protocols to ensure compliance with these requirements. The effect of the Act should be the same in all instances and settings, regardless of who ultimately obtains the written authorization.

Compliance with the rules in sections 101 and 102 prevents secret collection and analysis of DNA and ensures that before an individual authorizes an analysis he or she should know: why the analysis is being suggested, required or recommended; what information will likely result from the analysis; how the information can be useful to them; and that genetic counselors can be consulted for help in making a decision to go ahead with an analysis, or in understanding the results of the analysis.

Sec. 103. AUTHORIZATION FOR COLLECTION AND STORAGE OF INDIVIDUALLY IDENTIFIABLE DNA SAMPLES FOR GENETIC ANALYSIS

(a)WRITTEN AUTHORIZATION. -- To be valid, the authorization required by sections 101 and 102 must satisfy each of the following requirements:

- (1)WRITING. -- The authorization must be in writing, signed by the sample source or the sample source's representative, and dated on the date of such signature;**
- (2)COLLECTOR IDENTIFIED. -- The authorization must identify the person who collects the DNA sample or causes the DNA sample to be collected;**
- (3)ANALYZER IDENTIFIED. -- The authorization must identify the facility in which the analysis will be performed;**
- (4)STORAGE FACILITY IDENTIFIED. -- The authorization must identify the facility in which the DNA sample will be stored;**
- (5)COLLECTION DESCRIBED. -- The authorization must state the manner in which the sample is to be collected;**
- (6)AUTHORIZED USE. -- The authorization must include a description of all authorized uses of the DNA sample;**
- (7)STATEMENT REGARDING STORAGE AFTER COMPLETION OF ANALYSIS. -- The authorization must indicate whether or not the sample source permits the sample to be maintained or stored in an identifiable form after the analysis is completed;**
- (8)STATEMENT REGARDING USE OF UNIDENTIFIABLE DNA SAMPLES FOR RESEARCH OR COMMERCIAL PURPOSES. -- The authorization form must include a provision that enables the sample**

source or the sample source's representative to prohibit the use of the DNA sample for research or commercial purposes even if the sample is not in an individually identifiable form.

(b)RETENTION OF AUTHORIZATION. -- The authorization for the collection and analysis of an individually identifiable DNA sample shall be retained at least as long as the DNA sample is retained.

(c)COPY. -- A copy of the authorization shall be provided to the sample source or the sample source's representative.

An authorization which includes the details set forth should facilitate compliance with the requirements and goals of section 101. Any forms which are drafted to meet the requirements of this section should contain clear language and not undermine the purposes or process of obtaining informed authorization.^[18] Those who develop authorization forms are urged to include additional details and information that they believe to be helpful.

The person who collects the sample, the person who will analyze the sample, and the person who will store the DNA sample, must all be identified in the authorization [section 103(a)(2)-(4)]. Because the individual has the right to order the destruction of a DNA sample that has been collected [section 104(b)] and to inspect records containing information that results from an analysis [section 113], it is important for the individual to know who is, or may be, in possession of the DNA sample and the information that is developed through analysis.

The form must also indicate the manner in which the sample will be collected, describe all authorized uses of the sample, and indicate whether or not the sample source permits storage of the individually identifiable sample after the analysis is completed. [section 103(a)(5)-(8)] These requirements are intended to give the individual maximum control over their DNA. They also provide a mechanism for documenting that authorization to conduct particular tests, or to store samples for a specific period of time, has been obtained.

Finally, the authorization must allow for the inclusion of a prohibition against use of the sample, even in non-identifiable form, for research or commercial use so that individuals who want to prohibit such use can do so. Because individuals have different attitudes toward supporting or participating in research or commercial ventures that utilize human DNA, this provision accommodates the expression of such differences. Admittedly, the Act does not restrict the use of DNA samples which are not linked to any individual identifiers and tracking the use of a sample which is no longer identifiable should be impossible. Consequently, it is not likely that a violation of this directive could be uncovered and inclusion of this item in an authorization form may be more symbolic than effective.

Sec. 104. OWNERSHIP AND DESTRUCTION OF DNA SAMPLES

(a)OWNERSHIP OF THE DNA SAMPLE. - An individually identifiable DNA sample is the property of the sample source.

(b)RIGHT TO ORDER DESTRUCTION OF THE DNA SAMPLE. - Except when a DNA sample has been collected pursuant to section 122 or 123 of this Act, the sample source or the sample source's representative shall have the right to order the destruction of the DNA sample.

(c)ROUTINE DESTRUCTION OR REMOVAL OF IDENTIFIERS. - An individually identifiable DNA sample must be destroyed on completion of genetic analysis unless:

- (1)the sample source or the sample source's representative has directed otherwise in writing, or**
- (2)all individual identifiers linking the sample to the sample source are destroyed.**

Some individuals will want to take maximum advantage of the evolving nature of knowledge about the human genome, and will welcome the opportunity to have their DNA collected, stored or analyzed. Others are wary of the potential harm that can result from information derived from genetic analysis, and will want reassurance that they alone control when their DNA is analyzed and who has access to their samples and information. The provisions of this section are intended to preserve the autonomy of all individuals regardless of their varying views on the benefits and dangers of genetic information.

Giving individuals control over their DNA is accomplished first by establishing that an individually identifiable DNA sample is the property of the sample source. Since the sample source has this property right, control of a sample can be transferred to another individual through a will or other legal instrument. Consequently, individuals who do not want their DNA analyzed during their own lifetime may nevertheless have a sample collected and stored for the benefit of others. Descendants to whom control over DNA samples is transferred could thus benefit from future developments in genetics which require analysis of DNA from multiple generations. Until the complete genome is mapped, locating genes through linkage analysis will be dependent upon the availability of such samples. This provision can promote this availability.

In addition to being able to transfer ownership of a sample, the sample source also has the right, except in limited circumstances, to order the destruction of a sample that has been collected. [section 104(b)] This gives those who want to limit the availability of such samples reassurance that once authorized analysis has been completed, the sample itself can be destroyed, preventing any additional unauthorized analysis. In some circumstances, a sample source's representative, such as the parent of a minor, can exercise this right on behalf of the individual from whom the sample has been collected. However, this right is not exercisable by either the sample source or a sample source's representative when samples have been collected for identification use in law enforcement (section 122), or when the sample has been collected pursuant to a court-ordered analysis (section 123). Requiring that the person analyzing such samples destroy them at the direction of a sample source would directly conflict with the compulsory nature of collection and analysis in these situations.

Finally, section 104 provides for routine destruction of DNA samples or removal of identifiers, after the completion of the authorized analysis. This routine destruction can be overridden by the explicit directions of the sample source or the sample source's representative. [section 104(c)] Routine destruction would not result in an irreplaceable loss, since each individual is the source of an abundant supply of DNA samples. If an individual anticipates having a series of analyses conducted, and wants to avoid what is perceived as the inconvenience of collecting multiple samples, the authorization for collection of a specimen containing DNA can include specific directions for storage of the sample for analysis in the future, provided, of course, that storage services are offered by the collector or analyzer.

Sec. 105. NOTICE OF RIGHTS AND ASSURANCES. -- A person who collects or stores DNA samples for genetic analysis shall provide a sample source or a sample source's representative prior to the collection, storage, or analysis of a DNA sample, and any other person upon request, with a notice of rights and assurances that contains the following information and assurances that:

(a) a DNA sample will only be used as authorized in the written authorization;

(b) an individually identifiable DNA sample is the property of the sample source;

(c) unless specifically prohibited by the sample source or sample source's representative, researchers may be granted access to DNA samples that cannot be linked to individual identifiers;

(d) the sample source or the sample source's representative has the right to order the destruction of the individually identifiable DNA sample at any time;

(e) the individually identifiable DNA sample will be destroyed on the completion of the analysis unless the sample source or the sample source's representative has previously directed otherwise in writing;

(f) the sample source can designate another individual as the person authorized to make decisions regarding the individually identifiable DNA sample after the death of the sample source; and if any person is so designated, the sample source should notify the facility in which the DNA sample is stored;

(g) the sample source or the sample source's representative has the right to examine the records containing private genetic information, to obtain copies of such records and to request correction or amendment of them;

(h) private genetic information may be disclosed to researchers who qualify for such access under this Act;

(i) the collection and analysis of the DNA sample and the private genetic information derived from the analysis is protected by this Act, and anyone whose rights under this Act have been violated can seek civil remedies, including damages, as provided in this Act; and

(j) genetic counseling is available.

Individuals who authorize the collection and analysis of their DNA may not be aware of their rights under this Act and therefore be unable to exercise them. To enhance the knowledge of one's rights, this section requires that persons who collect DNA samples provide written notice to the individual when authorization for collection, storage and analysis of the DNA sample is obtained. This notice is similar in function and content to notices of fair information practices required by other informational privacy statutes.^[19] However, since the Act has provisions relating to the collection and analysis of samples, in addition to provisions that govern the information that results from such activities, the notice required by section 105 is more inclusive than other information practices.

A notice prepared under this section does not contain contractual assurances, but will consist of a series of statements regarding the legal responsibilities of those who collect, store and analyze samples, and the legal rights of the sample source.

PART B

DISCLOSURES OF PRIVATE GENETIC INFORMATION

Sec. 111. DISCLOSURE OF PRIVATE GENETIC INFORMATION

(a) REQUIREMENT OF WRITTEN AUTHORIZATION. - Except as provided in section 115 and section 132(b) no person who, in the ordinary course of business, practice of a profession, or rendering of a service, creates, stores, receives or furnishes private genetic information may by any means of communication disclose private genetic information except in accordance with a written authorization as provided in section 112.

(b) REDISCLOSURE PROHIBITED. - Redisclosure of private genetic information which has been disclosed to any person pursuant to a valid written authorization is prohibited.

This section states the general rule that any person who creates, maintains or furnishes private genetic information as part of their ordinary business or professional activities may disclose such information only in accordance with written authorization. (Exceptions to this general rule are presented in sections 115 and 132(b) and are discussed below.) These provisions apply to health care providers, lab technicians, genetic counselors, researchers, insurers and anyone else whose activities fall within the description in this section, regardless of the number of individuals on whom they have information. Section 111 also prohibits redisclosure of information received pursuant to a valid authorization.

Not all disclosures of private genetic information are prohibited by this or any other section of the Act. For example, nothing in the language of this statute prohibits a friend, neighbor, relative or any other person not engaged in such business activities from repeating genetic information that is learned directly or indirectly from a sample source or someone knowledgeable about the sample source. Consequently, anyone who wants to recover for unauthorized disclosures of information by such individuals will have to look to common law torts or other statutes for a cause of action and a remedy.

The Act does not carve out an exception for disclosures of genetic information without the individual's authorization, as do some other statutes that deal with medical information. Where some statutes governing medical information permit breaches of confidentiality by professionals in emergency circumstances to prevent harm to another individual,^[20] the Act does not permit disclosure of private genetic information without authorization, regardless of how well-intentioned the purpose of the contact with another individual. A full discussion of the common law on this

issue appears in the Appendix.

Therefore, when it is anticipated that the analysis of one person's DNA will reveal that a second individual (usually a close relative) is or may be at risk, the individual who has authorized an analysis should be encouraged to share the information with other family members who might benefit from it.

Sec. 112. AUTHORIZATION FOR DISCLOSURE OF PRIVATE GENETIC INFORMATION

(a) WRITTEN AUTHORIZATIONS. -- To be valid, an authorization for disclosure of private genetic information must satisfy each of the following requirements:

(1) WRITING. -- The authorization must be in writing, signed by the sample source or the sample source's representative and dated on the date of such signature;

(2) SAMPLE SOURCE OR REPRESENTATIVE IDENTIFIED. -- The authorization must identify the individual granting authorization and the individual's relationship to the sample source;

(3) PERSON MAKING DISCLOSURE IDENTIFIED. -- The authorization must identify the person permitted to make the disclosure;

(4) INFORMATION DESCRIBED. -- The authorization must describe the specific genetic information to be disclosed;

(5) RECIPIENT IDENTIFIED. -- The authorization must identify the person to whom the information is to be disclosed;

(6) PURPOSE DESCRIBED. -- The authorization must describe the purpose for which the disclosure is being made;

(7) EXPIRATION DATE. -- The authorization must state the date upon which the authorization will expire, which in no event shall be longer than 30 days after the date of the authorization; and

(8) REVOCATION STATEMENT. -- The authorization must include a statement that the authorization is subject to revocation at any time before the disclosure is actually made.

(b) COPY. -- A copy of the authorization shall be provided to the person making the authorization.

(c) REVOCATION OR AMENDMENT OF AUTHORIZATION. -- A sample source or the sample source's representative may revoke or amend the authorization, in whole or in part, at any time.

(d) NOTICE OF REVOCATION. -- A sample source may not maintain an action against a person for disclosure of private genetic information made in good faith reliance on a valid authorization if the person had no notice of the revocation of the authorization at the time the disclosure was made.

(e) IDENTIFICATION OF INFORMATION AS PROTECTED BY LAW. -- Each disclosure made with the written authorization described in subsection (a) must be accompanied by the following written statement:

"This information has been disclosed to you from confidential records protected under the Genetic Privacy Act and any further disclosure of the information without specific authorization is prohibited."

(f) 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 as an authorization for disclosure of private genetic information.

This section sets forth the requirement for a valid authorization which must be specific and in writing. The purpose is to prevent disclosures of genetic information under blanket releases of information and overly broad and unnecessary access to highly personal information.

The individual who authorizes the disclosure may revoke it at any time. However, anyone who does not receive notice of a revocation, and who makes a disclosure in good faith reliance on the authorization, will not be liable for violating this Act [section 112(d)]. The individual may only be able to express a revocation orally, so a written revocation is not required. However, when possible and to prevent the holder of the authorization from denying awareness of revocation, it would make sense for any individual who intends to revoke authorization, or to amend the provisions of

an authorization, to do so in writing.

Those governed by the provisions of sections 111 and 112 would, at a minimum, include researchers, independent databanks, clinical laboratories, medical care providers and insurers. Although few insurers at the present time routinely request or require DNA analysis in the course of processing applications, some insurers are interested in obtaining access to private genetic information that already exists.^[21] They can do so by directly asking applicants if they have had genetic analysis and by obtaining information contained in medical records. While most applicants are not likely to have had any DNA analysis done prior to an application for insurance, this may change in the future. This change could be precipitated by several factors, including the identification of genes that predispose individuals to common diseases such as cancer and the development of readily available and cost effective predictive testing for such disorders.^[22]

When an individual has had a DNA analysis and the resultant private genetic information is entered into medical records, an authorization for disclosure that meets the requirements of this Act is required before such information can be disclosed. The Act specifically provides that a general authorization for disclosure of medical information does not fulfill this requirement [section 112(f)]. Consequently, a provider disclosing medical information to an insurer, an employer, or any other person, must be careful that private genetic information is not disclosed along with other information unless it has been specifically authorized. Those who maintain medical records that include private genetic information as defined by the Act, must develop record keeping policies and procedures that adequately guard against wrongful disclosures of such information under general releases of medical information.

A rule that would require complete segregation of private genetic information from medical records would facilitate compliance with these provisions. Nonetheless, we believe such a statutory requirement is neither practical nor advisable. At least some private genetic information may be necessary for the provision of adequate and appropriate medical treatment. Inclusion of such information in medical records is, therefore, left to the discretion of providers and the developing standards of care. Disclosure of such information, on the other hand, is not discretionary and can only be made when the individual specifically authorizes it, and when the purpose of the disclosure has been explicitly documented. Nothing in these provisions, however, would require that providers disclose private genetic information, if to do so would conflict with any other law or professional ethics.

Accommodating the provisions of these sections should not be burdensome on those who maintain such information whether or not it is incorporated in medical records. Developing authorization forms that meet these requirements should not be any more difficult than development of forms and procedures so as to comply with federal regulations governing the confidentiality of alcohol and substance abuse treatment, as well as other laws governing medical records.^[23] Since most medical records in the future are likely to be maintained in electronic format, it should be feasible to program record keeping so that private genetic information can be deleted from records prior to release under a general authorization.

Sec. 113. INSPECTION AND COPYING OF RECORDS CONTAINING PRIVATE GENETIC INFORMATION

(a)INSPECTION OF RECORDS. -- Except as otherwise provided in section 131(c)(2) and 131(f), a person who maintains private genetic information shall upon written request permit the sample source or the sample source's representative to inspect records containing private genetic information and shall provide a copy of any such records upon request by the sample source or the sample source's representative.

(b)RESPONSE TO REQUEST EXAMINATION AND COPYING OF INFORMATION. -- Upon receipt of a written request from a sample source or the sample source's representative to inspect or copy all or part of records containing private genetic information, a person as promptly as required under the circumstances but no later than 30 business days after receiving the request, shall make the information available to the sample source or the sample source's representative for inspection during regular business hours or provide a copy, if requested, to the individual.

(c)EXPLANATION OF TERMS AND CODES. -- A person shall provide an explanation of terms and any code or abbreviations used in records containing the private genetic information upon request of the sample source

or the sample source's representative.

(d)FEE. -- A person may charge a reasonable fee, not to exceed the person's actual duplication cost, for copies of records which are provided.

This section requires that anyone maintaining records that include private genetic information permit a sample source or that individual's representative to inspect and obtain copies of such records. These information practices echo the provisions of state laws governing access to medical records and proposed federal legislation.^[24] However, the Act differs from such models in one significant respect. Several laws grant health care providers discretion to deny inspection of medical information in particular circumstances. For instance, under some statutes, it is within the discretion of a provider to withhold inspection of records that include mental health or psychiatric information, and to provide a summary to the patient instead, or to allow inspection by a representative of the patient.^[25] The presumption behind such discretion is that the provider is able to determine if, and when, access to such information would be harmful to the patient.

In contrast, the Act's general obligation on the holder of private genetic information to permit a sample source or that individual's legal representative to inspect records containing such information, is modified by two narrow exceptions that apply only to research activities. These sections, 131(f) and 131(c)(2) are discussed below.

Sec. 114. AMENDMENT OF RECORDS

(a)IN GENERAL. -- Within 45 days of receipt of a written request by a sample source or a sample source's representative to correct or amend in whole or in part any record containing private genetic information, a person who maintains records containing private genetic information shall:

- (1)make the correction or amendment requested;**
- (2)inform the individual that the correction or amendment has been made;**
- (3)make reasonable efforts to inform any person to whom the uncorrected or unamended portion of the information was previously disclosed of the correction or amendment that has been made; and**
- (4)at the request of the individual, make reasonable efforts to inform any known source of the uncorrected or unamended portion of the information about the correction or amendment that has been made.**

(b)REASONS FOR REFUSAL AND REVIEW PROCEDURES. -- If correction or amendment is refused, the person maintaining the records shall inform the sample source or the sample source's representative of:

- (1)the reasons for the refusal of the person to make corrections or amendment;**
- (2)any procedures for further review of such refusal; and**
- (3)the individual's right to file with the person a concise statement setting forth the requested correction or amendment and the individual's reasons for disagreeing with the refusal of the person to make the correction or amendment.**

(c)STANDARDS FOR CORRECTION OR AMENDMENT. -- A person maintaining records containing private genetic information shall correct or amend information in accordance with a request made under subsection (a) if the information is not accurate or complete for the purposes for which the information may be used or disclosed by the person.

(d)STATEMENT OF DISAGREEMENT. -- After a sample source or a sample source's representative has filed a statement of disagreement under subsection (b)(3), the person, in any subsequent disclosure of the disputed portion of the information, shall include a copy of the individual's statement and may include a statement of the reasons for not making the requested correction or amendment.

This section includes provisions for processing requests for correction or amendment of information in records that contain private genetic information. The specific details in this section have been adapted from similar provisions in the Fair Health Information Practices Act of 1994.^[26] They require the holder of records to make corrections or inform the individual of any reason for refusal to do so. Records should be corrected if the information is not accurate or complete for the purposes for which it may be used or disclosed. When the holder refuses to amend or correct

records, the sample source must be informed of further procedures that are available for review of the refusal, and in the event that the dispute is not resolved subsequent disclosures of the information must be accompanied by a statement of the sample source's disagreement with the accuracy of the information.

Most people will not know enough about genetics or DNA analysis to be able to question the correctness of private genetic information. Awareness of an inaccuracy may occur when the sample source has had more than one genetic analysis done and the results of both are incompatible or contradictory, placing the accuracy of at least one test in question. Because others may make decisions regarding the sample source based on this information, and records containing private genetic information may not be governed by any other rules that require correction of information, it is important that mechanisms be in place to ensure the accuracy of such information and prevent hardships due to disclosure of inaccurate records.

Sec. 115. DISCLOSURES PURSUANT TO COMPULSORY PROCESS

(a)PROCEEDINGS IN WHICH AVAILABLE. -- No person who maintains private genetic information may be compelled to disclose such information pursuant to a request for compulsory disclosure in any judicial, legislative, or administrative proceeding, unless:

- (1)The person maintaining the genetic information has received the authorization of the sample source or the sample source's representative to release the information in response to such request for compulsory disclosure;**
- (2)The sample source or the sample source's representative is a party to the proceeding and the private genetic information is at issue; or**
- (3)The genetic information is for use in a law enforcement proceeding or investigation in which the person maintaining the information is the subject or party.**

(b)NOTICE. -- If genetic information is sought under subparagraph (2) of subsection (a), or in a proceeding or investigation pursuant to subparagraph (3) of subsection (a), the person requesting compulsory disclosure shall serve upon the person maintaining the genetic information, and upon the sample source, the sample source's representative, or on the sample source's attorney, the original or a copy of the compulsory disclosure request at least thirty (30) days in advance of the date on which compulsory disclosure is requested, and a statement of the right of the sample source or sample source's representative, and of the person maintaining the genetic information, to have any objections to such compulsory disclosure heard by such court or governmental agency prior to the issuance of an order for such compulsory disclosure, and 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 state or federal law.

(c)CERTIFICATION. -- Service of compulsory process or discovery requests upon a person maintaining private genetic information must be accompanied by a written certification, signed by the person seeking to obtain the private genetic information or his or her authorized representative, identifying at least one subparagraph of subsection (a) under which compulsory process or discovery is being sought. The certification must also state, in the case of information sought under subparagraphs (2) or (3) of subsection (a), that the requirements under subsection (b) for notice have been met. A person may sign the certification only if the person reasonably believes that the subparagraph of subsection (a) identified in the certification provides an appropriate basis for the use of discovery or compulsory process. A copy of the written certification shall be maintained as a permanent part of the records of private genetic information.

(d)STANDARD FOR ISSUANCE OF ORDER. -- An order under this section may only be entered by a court of competent jurisdiction after a hearing and determination that good cause exists. To make this determination the court must find that:

- (1)other ways of obtaining the private genetic information are not available or would not be effective; and**
- (2)there is a compelling need for the private genetic information which outweighs the potential harm to the privacy interest of the subject of the information.**

(e) CONTENT OF ORDER. -- An order under this section which authorizes disclosure of private genetic

information must:

- (1) limit disclosure to those parts of records containing such information which are essential to fulfill the objective of the order;**
- (2) limit disclosure to those persons whose need for the information is the basis of the order;**
- (3) require the deletion of individual identifiers from any documents made available to the public; and**
- (4) include such other measures as are necessary to limit disclosure for the protection of the subject of the information including, but not be limited to, sealing from public scrutiny the record or any portion of the record of any proceeding for which disclosure of the information has been ordered.**

Despite the fact that an individual discloses personal information to others with the expectation and intention that the recipient of the information will keep it confidential, the law may not recognize the information as privileged and therefore beyond compelled discovery in legal proceedings. Even communications to a physician, psychotherapist or other health care professionals which often fall under the protection of a state statutory privilege, are not absolutely protected from compelled disclosure. In some circumstances courts have determined that a litigant's need for medical information outweighs the patient's privacy interest, and that claims of privilege, even when they can be invoked, do not always protect records containing such information from discovery.[\[27\]](#)

Just as discovery of medical records has been sought in the past, there will be situations in which an individual or entity will seek to obtain records containing private genetic information through compulsory process. Under the Act, disclosure of private genetic information contained in any records, however, can be compelled only in limited circumstances. First, if the sample source has authorized release of the information in response to a request for the compulsory disclosure, the holder of the information can be compelled to comply with the request. [section 115(a)(1)] Additionally, when the sample source is a party to a proceeding and the private genetic information is at issue, the disclosure can be compelled.[section 115(a)(2)] For instance, in an action for medical malpractice or negligent DNA analysis, this information may be necessary to prove or disprove the validity of the claim.

Finally, the disclosure may be compelled if the person who holds the information is under investigation for committing a crime. [section 115(a)(3)] Fraud is the most likely crime in which the holder of private genetic information would be under investigation and prosecution. The standards applied by particular courts in Medicare and Medicaid fraud cases are helpful in developing an appropriate standard for compelled discovery of private genetic information and balancing the state's interest against the privacy interests of the individual subjects of the information.

Assertion of a statutory physician-patient privilege, or psychotherapist-patient privilege, so as to bar compelled production in fraud cases has had various degrees of success in protecting private patient information. A few courts that have determined that the state interest in preventing fraud warrants compelled disclosures of otherwise privileged information have also sought to protect patient privacy by limiting the specific information that must be disclosed, and rejected requests for entire records. Even in cases involving psychotherapy records, however, which are sometimes afforded special protection out of deference to the extremely personal nature of the communication, courts have not applied consistent and explicit standards to protect patient privacy.

In resolving the conflict between federal Medicaid law and the psychotherapist-patient privilege, a Massachusetts court held that production of psychotherapy records can be compelled in a prosecution for fraud, but only to the extent that they are "necessary fully to disclose the extent of the services provided."[\[28\]](#) Records that meet this criteria were further determined to include documentation of the time and lengths of appointments, fees, diagnoses, treatment plans, recommendations and somatic therapies. In contrast, records reflecting the patient's thoughts and feelings could not be compelled since they were of no concern to the legitimate investigation. Other courts have viewed the disclosure of patient records as an all or nothing matter, and not bothered to distinguish between kinds of information contained in the records sought.[\[29\]](#)

To avoid similar inconsistency and overly broad compulsory disclosure in cases where private genetic information is sought, the Act sets forth specific requirements for those seeking such disclosure, and the standard for courts to apply in considering objections to such disclosures. The provisions of section 115(b)-(e) establish notice procedures for those who seek disclosure of private genetic information through compulsory process for use in criminal investigations and for proceedings in which the genetic condition of a party is at issue. They are intended to ensure that the individual

who is the subject of the information has the opportunity to object to the disclosure and protect his or her individual interests. To avoid abrogation of the privacy interests of the sample source, the Act further requires that prior to compelled disclosure, the court must find that there is no other available and effective way to get the information that is sought, and that there is a compelling need for the information. [section 115(d)]

Additionally, even when such findings have been made, the subsequent order must direct that all individual identifiers be deleted from documents which will be available to the public and any other measures that the court determines are necessary to protect the privacy of the sample source. [section 115(e)]

PART C

EXCEPTIONS FOR IDENTIFICATION AND COURT-ORDERED GENETIC ANALYSIS.

Sec. 121. IDENTIFICATION OF DEAD BODIES

Notwithstanding any other provisions of this Act, a person may provide access to an individually identifiable DNA sample, or to data derived from DNA typing, to assist in the identification of a dead body, provided further that the analysis of any sample so provided and the analysis of a DNA sample from the dead body is limited to that which is necessary to determine the identity of the dead body.

Sec. 122. IDENTIFICATION FOR LAW ENFORCEMENT PURPOSES.

Nothing in this Act shall be construed to prohibit federal, state or local law enforcement authorities from collecting, storing or typing DNA samples, when:

- (a) the collection, storage and typing of DNA samples is authorized under federal or state law;**
- (b) collection, storage and typing of such samples is limited to the purpose of matching DNA samples in criminal investigations; and**
- (c) access to such DNA samples is limited to authorized law enforcement agencies, prosecutors, defense counsel, defendants, accused individuals, suspects, and their authorized agents.**

These sections contain two related exceptions to the general rule which requires written authorization prior to the collection, storage and analysis of DNA. Both exceptions are allowed because of the limitation on the kind of DNA analysis which can be conducted and consequently on the kind of information that is created. The genetic analysis which is permitted is referred to in the statute as "DNA typing" and has been discussed in the comments on the definitions used in this statute. DNA typing is a method used for purposes of identification and should not create any other information about the person who is the source of the DNA. Consequently, the privacy concerns raised by creation and disclosure of other genetic information do not apply to this specific type of analysis and the resultant profile.

Section 121, therefore, permits the performance of DNA typing on samples solely for the purpose of identifying a dead body. Reliance on this exception will rarely be necessary for practical reasons. First, it would only be applicable when there is reason to believe that the sample source is the decedent and a DNA sample had been collected from the suspected individual before discovery of the unidentified body. Secondly, it is likely that currently utilized methods of identification, such as matching of dental records with remains, will continue to be more readily available and cost effective than DNA typing. However, to accommodate those rare instances in which other methods are unavailable, not practicable, or more burdensome than DNA typing, the Act allows DNA typing for this purpose, and permits access to the results of DNA typing without individual authorization.

The second area in which DNA typing is permitted without the authorization of the sample source (or that person's

legal representative), is when the analysis is in relation to criminal law enforcement activities. As of the drafting of this Act, 19 states have enacted laws which authorize the creation of forensic DNA banks for storage of DNA samples and data. These laws vary, both in terms of the circumstances under which individuals can be required to submit to the collection of samples, and the evidentiary use of the genetic profiles that result. [\[30\]](#)

The public benefit versus the threat to individual privacy that will ultimately be realized from creation of DNA banks for such forensic use has been widely argued. Controversy surrounds not only the reliability of the technology involved, and the admissibility of evidence derived from such techniques, [\[31\]](#) but also the erosion of privacy that is seen as the inevitable creation of national DNA databanks. [\[32\]](#) Although such concerns may be well founded, it is not within the scope of this Act to resolve all the legal and policy issues presented by the provisions in a particular state statute or the concept of forensic DNA banking in general. The provisions contained in section 122 are, however, intended to specify when collection and analysis of DNA for forensic use does not implicate privacy interests, and consequently could be conducted without infringing on the individual rights created by this Act. Indeed, the fact that DNA in the custody of forensic DNA databanks cannot be lawfully analyzed except for identification purposes under the provisions of the Act, may make the existence of such forensic DNA data banks less troubling. In addition, the Violent Crime Control and Law Enforcement Act of 1994 (P.L.103-322, sec. 120305) prohibits the disclosure or obtaining of personally identifiable DNA information from samples held for law enforcement purposes, with a fine of up to \$100,000 for violations.

Although the word "fingerprinting" is often used in regard to the kind of analysis that is involved in law enforcement, it is misleading to perpetuate the use of this benign term in regard to genetic analysis. Consequently, we have intentionally chosen to use the term DNA typing in these provisions. Traditional fingerprinting consists of copying lines from fingertips and examining them to see if they match another print. There is no other use that can be made of the material that makes up the "print," and no other information except identification can be obtained from it. DNA typing, by contrast, is one of several kinds of analysis or methods for deciphering information encoded in the material that is collected. In regard to the privacy interests of the person whose DNA is collected, this distinction is of extreme significance. Fingerprinting is only useful for identification, whereas DNA can be analyzed for a multitude of purposes. [\[33\]](#)

In recognition of these distinctions, this section states that nothing in the Act shall be construed as prohibiting the collection, storage or typing of DNA samples when three criteria have been met. First, the collection, storage and typing of the DNA samples must be authorized by other federal or state law. This exception would therefore not be applicable to local law enforcement use in the approximately 30 states which have yet to authorize forensic DNA banking. Secondly, the purpose for which the applicable law authorizes such activities is restricted to the matching of samples in criminal investigations. Lastly, the access to collected samples must be limited to authorized law enforcement agencies, prosecutors, defense counsel, defendants, accused individuals, suspects, and their authorized agents.

These restrictions will prevent law enforcement authorities from obtaining private genetic information about individuals. A state law which is invoked as the basis for this exception cannot authorize a DNA analysis which reveals the presence of disease genes or markers associated with a disease. Nor could it permit use of DNA samples to create suspect profiles through use of probes for any other genetic characteristic. [\[34\]](#)

Sec. 123. COLLECTION AND ANALYSIS OF DNA SAMPLES PURSUANT TO COURT ORDERED ANALYSIS

(a) IN GENERAL.-- Nothing in this Act shall be construed to prohibit the collection or analysis of an individually identifiable DNA sample pursuant to Rule 35 of the Federal Rules of Civil Procedure or comparable rules of other courts or administrative agencies in connection with litigation or proceeding to which the sample source is a party and in which the genetic condition of the sample source has been placed at issue, provided that the conditions in section (b) have been met.

(b) ISSUANCE OF ORDERS. -- An order under Rule 35 of the Federal Rules of Civil Procedure or comparable rules may only be made:

(1) upon motion for good cause shown and upon notice to the sample source or the sample source's representative and all parties; and

(2) the order must specify:

(A) the manner of collection of the DNA sample;

(B) the person or persons authorized to collect and analyze the sample;

(C) the purpose of the genetic analysis;

(D) that the genetic analysis is limited to that which is necessary to fulfill the purpose of the order; and

(E) that the person conducting the analysis destroy the sample at the earliest possible opportunity consistent with the purpose of that order.

This section applies to situations in which the genetic condition of an individual has been raised as an issue in a court proceeding and the individual, who is a party to the proceeding, will not voluntarily submit to genetic analysis to resolve the disputed facts. When the physical or mental condition of a party to a proceeding is at issue, the authority of the court to order the individual to submit to an examination is governed by Rule 35 of the Federal Rules of Civil Procedure or a comparable state procedural rule. This section restates the provisions of the federal rule with some modification to accommodate the special privacy concerns that are raised by DNA analysis regardless of whether or not it is voluntarily undertaken.

A special section regarding paternity cases and court ordered genetic tests to determine paternity is unnecessary because section 123 applies to all cases in which the genetic condition of a party is at issue. If one or more of the parties to the action does not voluntarily submit to testing, then in the language of section 123 (a), "nothing in this Act shall be construed to prohibit the collection or analysis of an individually identifiable DNA sample pursuant to Rule 35 or the Federal Rules of Civil Procedure or comparable rules of other courts or administrative agencies... provided the conditions in section (b) have been met."[\[35\]](#)

Section 123(a) clarifies that genetic analysis can be ordered by a court in circumstances similar to those in which a physical examination can be ordered. However, an order that issues under this rule must be specific in regard to the manner of collection of the DNA sample, the person who is authorized to collect and analyze the sample, and the purpose of the genetic analysis. [section 123(b)(2)(A)-(C)] Additionally, to prevent creation and disclosure of irrelevant genetic information, the analysis that is ordered must be limited to that which is necessary to fulfill the purpose of the order [section 123(b)(2)(D)] and the person who is conducting the analysis must destroy the DNA sample at the earliest possible opportunity consistent with the purpose of the order.

It should be noted that these provisions do **not** authorize **compulsory** collection and analysis of DNA. Rather, failure to comply with court mandated DNA testing would lead to the dismissal of the lawsuit of the plaintiff who refuses testing or a finding against the defendant based on other available evidence and inference drawn from the refusal to comply.

A recent example of a case in which this section would have applied, if it had already been enacted, arose in California. A woman filed suit against a former employer claiming that her son's developmental disability stems from her workplace exposure during pregnancy to a solvent called methylethylketone (MEK). The defense has contended that a genetic condition, Fragile X syndrome, and not the exposure, is the cause of his difficulties, and the judge has ordered that the son undergo genetic tests to determine whether an inherited gene or her exposure to the solvent, caused his disability.[\[36\]](#) If the order had issued pursuant to section 123 of the Act, it would have specified that the purpose of the analysis was to determine the presence of Fragile X, and the analysis itself would have been limited to that which is necessary to determine the presence of the gene or gene markers responsible for Fragile X. The analysis could not, for example, have utilized any multiplex test which would produce information on any other gene or genetic condition. In addition, if the determination could have been made by chromosomal examination, without an actual DNA analysis, then it would have been limited to that process.

This is probably the first personal injury case in which a court has ordered genetic analysis. It is, however, likely that as more is known about the genetic component of diseases, particularly cancers that are also associated with exposure

to toxic substances, more defendants will seek genetic analysis of plaintiffs.

PART D

RESEARCH ACTIVITIES

Sec. 131. RESEARCH INVOLVING GENETIC ANALYSIS

(a) CONDITIONS FOR A GENETIC ANALYSIS. -- Except as provided in section 133 no individually identifiable DNA sample shall be analyzed as part of a research project unless an Institutional Review Board has determined that:

- (1) use of individually identifiable DNA samples is essential to the research project;**
- (2) the potential benefit of the research project outweighs the potential risks to the subjects including psychosocial risks and intrusion into the privacy of the subjects that would result from analysis of individually identifiable samples;**
- (3) the research protocol**
 - (A) contains adequate safeguards to protect against disclosure of private genetic information that is generated by the research;**
 - (B) requires that research subjects will be given the applicable information set forth in section 101 of this Act in addition to the informed consent requirements contained in 45 CFR 46.116 (1992) as such regulation may be amended;**
 - (C) requires the written authorization of research subjects that includes the applicable requirements of section 103 of this Act; and**
 - (D) prohibits inclusion of research records in medical records unless the sample source or the sample source's representative authorizes such inclusion in writing.**

(b) SAFEGUARDS AGAINST DISCLOSURES OF PRIVATE GENETIC INFORMATION. -- For purposes of subparagraph (3)(A) of subsection (a) of this section, adequate safeguards against disclosure of private genetic information include but are not limited to:

- (1) obtaining a certificate of confidentiality from the Secretary of Health and Human Services as provided in 42 U.S.C. 241(d) as such statute may be amended;**
- (2) ensuring that research subjects will not be identifiable in any report or publication which results from the research; and**
- (3) having procedures to remove or destroy at the earliest opportunity consistent with the purposes of the project, information that would enable a sample source to be identified.**

(c) FURTHER LIMITATIONS ON RESEARCH INVOLVING INDIVIDUALS UNDER 18. -- No research shall be conducted on individually identifiable DNA samples when the sample source is under 18 years of age unless:

- (1) a parent or guardian is given the applicable information set forth in section 101 of this Act;**

(2) a parent or guardian executes an authorization that includes the applicable requirements of section 103 of this Act and which specifically states that the parent or guardian understands and agrees that unless the analysis reveals a genetic condition which in reasonable medical judgment can only be effectively ameliorated, prevented or treated while the sample source is under 18 years of age, the results of the analysis will not be disclosed to the parent or guardian of the sample source; and

(3) any provisions for soliciting the assent of minors as contained in 45 CFR 46.408 as such regulation may be amended which the Institutional Review Board determines to be applicable are met.

(d) DESTRUCTION OF DNA SAMPLES OR IDENTIFIERS.

(1) GENERALLY.-- In the absence of a specific authorization to maintain an individually identifiable DNA sample, individually identifiable DNA samples collected, stored or analyzed in connection with a research project shall be destroyed upon completion of the project or withdrawal of the sample source from the project, whichever occurs first.

(2) EXCEPTION. -- Whenever the authorization for collection, storage or analysis of an individually identifiable DNA sample does not contain a prohibition against research use of the sample when it is no longer linked to any individual identifier, the person in possession of the sample may destroy all individual identifiers linking the sample to the sample source instead of destroying the sample as required by subsection (1)....

* * * *

[subpart on pedigree analysis discussed [below](#)]

(g) USE OF UNIDENTIFIABLE DNA SAMPLES NOT PROHIBITED. -- Nothing in this Act shall be construed as prohibiting or limiting research on a DNA sample that cannot be linked to any individual identifier.

The provisions included in this part are detailed, and modify and adapt the general rules about the collection, storage, and analysis of DNA in the research setting. By setting forth detailed rules that govern use of individually identifiable DNA samples in research, the Act takes some of the burden off researchers who would otherwise have to develop guidelines for individual projects on a case by case basis. Moreover, nothing in the Act prohibits or limits the use of non-identifiable DNA samples in research [see section 131(g)]. Minors are treated differently in the context of research than elsewhere. Parental authority to authorize analysis of a child's DNA, although not absolute in any circumstances (see discussion in regard to section 141), is restricted in the context of research in unique ways.

This section incorporates by reference and builds upon the requirements of the Federal Policy for the Protection of Human Subjects, which apply to 16 federal departments and agencies that conduct or support research involving human subjects.[\[37\]](#) The rules presented here, however, are applicable to research regardless of whether it is conducted under federal support and regulation, or is financed entirely by private sources.

The section requires as a condition to analysis of an individually identifiable DNA sample in research that an Institutional Review Board (IRB) must make certain determinations. First, use of such samples must be essential to the project. This creates an initial barrier against using genetic analysis unnecessarily. Furthermore, the potential benefit of the project must outweigh the risks to the subjects. Although this requirement is not novel, in weighing these risks, the IRB must consider the psychosocial risks and intrusion into the privacy of the subjects which would result from an analysis. [section 131(a)(2)] This consideration has been specifically included because the risk that might otherwise be focused on is that presented by the relatively non-invasive procedures used to collect specimens that contain DNA, such as taking of blood or extrapolation of hair or tissue samples. In this area of genetic research it is the information that results from the analysis itself, and not a procedure performed on the subjects, which presents the risk to an individual's privacy and well-being.

To guard against needlessly exposing subjects to these risks, the IRB must determine that the research protocol has adequate safeguards to protect against disclosure of private genetic information created as a result of an analysis. Although the statute does not contain an exhaustive list of safeguards, it notes three specifically: obtaining a certificate of confidentiality from the Secretary of Health and Human Services pursuant to 42 U.S.C. 241(d)(which would protect the identity of the subjects from any compelled disclosure); ensuring that subjects will not be identified in publications or reports; and limiting the length of time that identifying information is maintained by destroying identifiers at the earliest possible time consistent with the purpose of the project. [section 131(b)]

Samples which no longer exist pose no threat of unauthorized analysis, therefore section 131(d) also requires that individually identifiable samples be destroyed on completion of the project or withdrawal of the sample source from participation, or that all individual identifiers be removed. This requirement can only be modified by the specific authorization of a sample source. As a result, projects which intend or anticipate secondary use of samples must obtain authorization to store samples beyond the initial analysis for use in any follow-up studies.

Use of DNA samples is further restricted when it involves subjects who are under 18 years of age. Section 131(c) requires that prior to authorization for collection and analysis of the DNA of a minor under 18, the parent or guardian must receive the information in section 101 which is applicable to the circumstances. Furthermore, the statute contains a limitation in regard to the information that the parent or guardian who authorized the analysis of the child's DNA can obtain from the person who conducts the research. **This limitation is unique, and is one of the few exceptions to the general policy of giving the person who authorizes an analysis access to the all the information that results.** Pursuant to this rule, although the parent or guardian must execute an authorization that is similar to one that is required by the basic rules, the authorization itself must contain one additional limitation. That is, the parent or guardian must agree that the results of the analysis can be withheld from the parent under certain conditions. If the analysis reveals a genetic condition which "in reasonable medical judgment cannot be ameliorated, prevented or treated while the sample source is under 18" [Section 131(c)(2)] the parent or guardian has no right to access that information. (*See* discussion on children at page 110, *infra*.)

Section 131(c) authorizes both parents and guardians to provide permission for research with minors. There is some question whether guardians should have this authority. The reason for limiting such authority solely to parents is that genetic research may unveil information about other family members and therefore a parent would be in the best position to determine whether or not this ought to be done. Furthermore, as a result of their parental role, it is likely that parents would be best situated to protect the interests of their minor children. It is also not apparent that limiting research to that which could only be performed on children with parental permission would limit genetic research with children. While such a limitation would exclude some particular children from being research subjects, it is not clear that requiring parental permission would eliminate the possibility of conducting an entire research project. There are, therefore, good arguments that guardian permission should not be sufficient for authorizing genetic research with children. However, we have included guardian authorization for genetic research with children to be consistent with the federal rules and because we were not sure if excluding guardian permission would, in fact, cut off some avenues of important research. However, where a genetic research project can be conducted with children with an available parent we think it would be appropriate for IRBs to exclude as subjects children who have guardians.

Sec. 131. (e) PEDIGREE ANALYSIS AND FAMILY LINKAGE STUDIES. -- When a research project includes analysis of DNA from family members for pedigree analysis or linkage analysis--

(1) the Institutional Review Board, in addition to making the determinations required in subsection (a) of this section, shall also require--

- (A) that education and counseling regarding how pedigree analysis is conducted and the kind of information that results from such analysis is provided to research subjects; and**
- (B) that as far as practicable separate records are maintained on each subject.**

(2) Prior to their participation, and in addition to the disclosures required by section 101 of this Act, subjects shall be--

- (A) informed that one risk of their participation is that by the end of the project other family members may learn private genetic information about them;**

- (B) informed of what will be done with records and data generated during the project;**
- (C) informed that the project may determine that some members of their family are not genetic relatives.**

Genetics can be thought of as the study of family information, and this is evident in research involving pedigree analysis. Historically, this method has been used to search for a particular gene and often begins with the study of gene markers in families with members who have the condition or disease that is under investigation. Through the analysis of DNA of several individuals and across generations, inferences about the presence and transmission of genetic conditions are made. Huntington disease, adult polycystic kidney disease, and familial breast cancer, are examples of diseases that were thought to be caused by a gene, and those genes were eventually discovered through linkage analysis. Because of the design of such studies and the nature of the information that results, maintaining individual privacy and confidentiality of participants is particularly difficult. The rules set forth in section 131(e) are intended to address the peculiarities of these family studies and the preservation of individual privacy in this context. These rules fall into two general categories: those that require specific information be given to participants, and those that govern the manner in which the researcher maintains and discloses information that is developed.

When a research project will include pedigree or linkage analysis, in addition to all the other requirements contained in the previous sections, the IRB must also require that some education and counseling be provided to research subjects. This is intended to ensure that subjects are aware, before they agree to participate, of how pedigree analysis is conducted and the kind of information that it produces. [section 131(e)(1)(A)] Since results of such studies usually consist of statistical probabilities regarding whether or not the subject carries a gene, such information may result in a greater sense of uncertainty than would have been expected by participants. Counseling provides the opportunity for individuals to identify and deal with such uncertainties. [\[38\]](#)

In addition, they must be told that one risk of participation is that others in the family may learn private genetic information about them. [section 131(e)(2)(A)] During the course of such study it may be impracticable, if not impossible, for information about one individual to be conveyed to that person without information about another being inferred in the process. For example, if individuals are told they have a marker that is linked to a disease causing gene or the probability that they have a disease causing gene, ensuing discussion may educate them on the probable transmission of the gene and by inference, the status of another individual. Before agreeing to participate, subjects also must be made aware that misattributed paternity can be discovered through the results of the DNA analysis of several family members. Consequently section 131(e)(2)(C) requires that they be told that the project may determine that some members of their family may not be genetic relatives. [\[39\]](#)

Despite the fact that participants in pedigree analysis and linkage analysis cannot be given a guarantee that no other family member will find out information about them in the course of the project, this does not mean that researchers are excused from making maximum efforts to maintain the confidential nature of information that is created. To assist with that endeavor section 131(e)(1)(B) instructs the IRB to require that, as far as practicable, individual records be maintained on each subject. Regardless of this rule, since the purpose of the project is to study the transmission of genes among family members, some pooling or compilation of information about several individuals in some records may be necessary. A charted pedigree which contains a shorthand version of information that has been extrapolated from the analyses of individual subjects is the most likely example. Unlike the family tree used in other genealogies, this pedigree may have notations that refer to the genetic condition of particular individuals and not just graphically represent innocuous information known to all members.

The researcher that creates group records, such as the charted pedigree, will be faced with a dilemma if an individual participant requests inspection of records containing his or her private genetic information and pursuant to section 113. On the one hand, access to such records containing information on the individual is mandated; on the other hand they also contain someone else's private genetic information. Therefore section 131(f) states that when complying with such a request, no person shall provide an individual member of the pedigree with private genetic information about another person without that person's authorization. Consequently, individuals can be denied access to their charted pedigree on the basis of this rule. This should not, however, prevent the holder from providing the individual with his or her own private genetic information. If the information is contained in other records which may not be examined, the holder can convey the information verbally or rewrite it. Of course, if everyone in the pedigree authorizes the disclosure of the pedigree itself, that too would fulfill the prerequisites to disclosure. On a practical level, however, it could be

cumbersome and complicated for a researcher to obtain everyone's authorization. Rather than requiring that a researcher seek and obtain all participants' authorization, the Act permits the researcher to choose between denying inspection of the pedigree to participants or obtaining everyone's authorization.

Lastly, to enable subjects to exercise their rights regarding their private genetic information, they must be informed of what will happen to records and data generated during the project. [131(e)(2)(B)]

Sec. 132. DISCLOSURE OF PRIVATE GENETIC INFORMATION FOR RESEARCH PURPOSES

(a) IN GENERAL. -- Any person who, in the ordinary course of business, practice of a profession, or rendering of a service, stores or maintains private genetic information is prohibited from allowing access to such information to researchers unless:

- (1) an Institutional Review Board has approved the conduct of the research program or study; and**
- (2) the sample source or the sample source's representative has specifically consented to the access or disclosure of such information in an authorization that meets the requirements of section 112 of this Act.**

(b) LIMITED ACCESS FOR STATISTICAL USE. -- Notwithstanding the provisions of subsection (a), a person who stores or maintains private genetic information may grant access to such information solely for the purpose of inspection or review of records containing the information provided that:

- (1) the inspection or review is for the purpose of compiling data for statistical or epidemiological studies and private genetic information is not to be copied, removed from the records, or redisclosed in any way; and**
- (2) the person conducting the inspection or review certifies in writing:**
 - (A) that these limitations will be complied with; and**
 - (B) to an awareness of their liability for violations of this Act.**

Researchers' interest in private genetic information is not limited to information they create through DNA analysis, but includes information that already exists. Access to genetic disease information, for example, will be sought much in the same way that medical information has traditionally been accessed by researchers from patient records. In recognition of this interest, laws governing the confidentiality of such patient information instruct medical record keepers as to the conditions under which access to patient information can be granted. In deference to the societal benefits of medical research, such disclosures can be permissible without the patient's knowledge or authorization.^[40] One rationale for not requiring patient consent prior to disclosures to researchers is that lack of consent from some of the targeted patients could seriously bias the results of a research project, and raise questions as to the validity of conclusions drawn from the study.^[41] While this concern may have merit, removing control from the patients places the control of private information in the hands of the keeper of the information, who may or may not be capable of appreciating the risks to the subjects of the information and representing their interests. This can be especially problematic when the patients whose information is sought belong to a vulnerable population whose interests are not as well represented as those of the general population. The provisions of this section are, therefore, intended to strike a balance between such competing interests, and to maximize individual control over private genetic information. They also reflect the anticipation that genetic research will, more often than not, involve the analysis of DNA samples rather than the secondary use of information derived from such analysis.

Section 132(a) sets forth the general rule governing holders of private genetic information and states that access to researchers is prohibited unless an IRB has approved the conduct of the research and the sample source (or the sample source's representative) has authorized the access or disclosure. An exception to this general rule nevertheless permits access to records containing private genetic information when records are inspected for compiling data for statistical or epidemiological use only. In the process of compiling such data, however, no records containing identifiable private genetic information may be copied, and new records containing identifiable private genetic information cannot be created. [section 132(b)]

This exception accommodates the legitimate societal interest in such studies without risking unauthorized disclosure of information about an identifiable individual. To ensure that such access is not casually granted, the Act further requires that the person inspecting such records certify in writing that the limitations will be complied with, and that they are

aware of liability for violations of these rules. [section 132(b)(2)] Of course, nothing in these provisions obligates a person who, in the ordinary course of business maintains records containing private genetic information, to provide such access to researchers. Finally, this section does not limit access to records containing genetic information, if those records contain nonidentifiable genetic information only.

Sec. 133. EXCEPTION FOR DNA SAMPLES PREVIOUSLY COLLECTED FROM DECEASED PERSONS

(a) ANALYSIS PERMISSIBLE. -- Notwithstanding the provisions of section 131, an individually identifiable DNA sample which was collected from a sample source who died prior to the effective date of this Act may be analyzed as part of a research project, but no individually identifiable genetic information may be disclosed without the authorization of the sample source's representative;

(b) DISCLOSURE TO RELATIVES. -- If the analysis of a DNA sample permitted by subsection (a) determines that a relative of a deceased sample source is at risk for a genetic disease which in reasonable medical judgment can be effectively ameliorated, prevented, or treated, nothing in this Act shall be construed as prohibiting researchers from contacting such relatives and informing them of such risk provided that private genetic information about the sample source is not disclosed.

This section is needed because research affected by the Act may already be underway. Living sample sources can be contacted prior to analysis of their DNA samples for purposes of complying with this Act, deceased sources, of course, cannot.

Section 133(a) permits analysis of the DNA of an individual who died prior to the effective date of this Act, so long as no identifiable genetic information is disclosed by the researcher without the authorization of the sample source's representative, i.e, the executor or administrator of the decedent's estate. The executor of an estate has been recognized elsewhere as the person who can waive privilege when discovery of confidential communications of a decedent are sought.[\[42\]](#)

This section additionally permits a researcher who analyzes the deceased person's DNA and in so doing determines that a relative of that person is at risk, to contact such individuals to tell them of that finding. The researcher may not, however, disclose private genetic information about the decedent. [section 133(b)]

PART E

MINORS AND INCOMPETENT PERSONS

Sec. 141. AUTHORIZATION FOR COLLECTION AND ANALYSIS OF DNA FROM MINORS

(a) INDIVIDUALS UNDER 16. -- Except as provided in sections 131(c) and 151, the individually identifiable DNA sample of a sample source who is under 16 years of age shall not be collected or analyzed to determine the existence of a gene that does not in reasonable medical judgment produce signs or symptoms of disease before the age of 16, unless:

- (1) there is an effective intervention that will prevent or delay the onset or ameliorate the severity of the disease; and**
- (2) the intervention must be initiated before the age of 16 to be effective, and**
- (3) the sample source's representative has received the disclosures required by section 101 of this Act and has executed a written authorization which meets the requirements of section 103 of this Act and which also limits the uses of such analysis to those permitted by this section.**

(b) INDIVIDUALS AGE 16 OR 17. -- Except as otherwise provided in sections 131(c) and 143, the individually identifiable DNA sample of a sample source who is 16 or 17 years of age may be collected and analyzed

provided that--

- (1) the sample source receives the information required by section 101 of this Act while accompanied by a parent or other adult family member; and
- (2) the sample source executes a written authorization which meets the requirements of section 103 of this Act.

(c) DESTRUCTION OF DNA SAMPLES OF INDIVIDUALS UNDER 16. -- A sample source's representative may, on behalf of a sample source who is under 16 years of age, order the destruction of a DNA sample collected pursuant to subsection (a) of this section.

Sec. 142. AUTHORIZATION FOR DISCLOSURE OF PRIVATE GENETIC INFORMATION ABOUT INDIVIDUALS AGE 16 OR 17

(a) AUTHORIZATION REGARDING INDIVIDUALS. -- Except as provided by section 144, private genetic information about an individual who is age 16 or 17 shall not be disclosed unless the sample source has executed a written authorization which meets the requirements of section 112.

(b) AUTHORIZATION REGARDING INDIVIDUALS UNDER 16. -- Except as provided in section 152, private genetic information about a minor who is under 16 years of age shall not be disclosed unless a parent or other sample source's representative has executed a written authorization that meets the requirements of section 112.

The collection and genetic analysis of DNA from minors is governed by different standards depending on the circumstances, which fall into these general categories and are summarized in [Table 1](#).

1. Rules that govern genetic analysis in the context of research and which apply to all minors (previously discussed and set forth in section 131);
2. Rules that govern genetic analysis in a non-research context and which apply to minors under the age of 16 [section 141(a)];
3. Rules that govern genetic analysis in a non-research context and which apply to minors age 16 and 17 [section 141(b)]; and
4. Rules that govern genetic analysis of DNA of pregnant minors (sections 151, 152).

The Act forbids the genetic testing of children for conditions that will not be manifested until after the child becomes an adult. This accords with the positions of others who have commented upon this topic. For example, the Institute of Medicine's report on **Assessing Genetic Risks** states:

Children should generally be tested only for genetic disorders for which there exists an effective curative or preventive treatment that must be instituted early in life to achieve maximum benefit. Childhood testing is not appropriate for carrier status, untreatable childhood diseases, and late onset diseases that cannot be prevented or forestalled by early treatment. [\[43\]](#)

Similarly, other commentators have said, "The only justification for doing predictive testing in childhood is if an advantage can clearly be demonstrated for the child."[\[44\]](#) These statements and the prohibition of such childhood testing are controversial because they remove authority from parents who may wish to have their offspring tested.

There are two reasons for this prohibition on the exercise of parental discretion. First, if someone learns that the child is a carrier of a gene that disposes the child to some condition later in life, this finding may subject the child to discrimination and stigmatization by both the parents and others who may learn of this fact. Second, a child's genetic status is the **child's** private genetic information and should not be determined or disclosed unless there is some compelling reason to do so.

Parents have an enormous amount of discretion and authority when it comes to making child rearing decisions. Indeed,

such authority has constitutional dimensions.^[45] Parents are given this authority because it is assumed that they will act in the best interests of their children. However, there are social policies that deprive parents of discretion in a number of areas. For example, child labor laws and mandatory education laws forbid parents from sending their young children to work or from withholding basic educational opportunities from their children. Even in circumstances in which parents have a religious objection to mandatory education, the state may require that children receive enough instruction so that children learn basic reading, writing and math skills.^[46]

Parents have broad discretion, but not absolute discretion, in making health care decisions for their children. For example, the state may require that children receive certain services, such as vaccination, even over parental objections. When a child is ill parents can choose between alternative suggested remedies and can choose to use no remedies in most cases. However, parents may not refuse to provide children with care that is necessary to sustain the child's life, because in such an instance there can be no argument that the parent is acting in the child's best interest.

Parents also have access to their children's medical records and other medical information as a general rule. This is because parents need to have such access to make informed medical decisions about their children's care. But when parents are not in the position to make health care decisions for their children there is no justification for parents to have access to these records. Thus, when minor children are authorized to make treatment decisions for themselves as a result of emancipation or maturity, their medical records are confidential and their parents are not authorized to obtain access to this private medical information.^[47]

It is increasingly recognized that children have rights independent of parent's rights. Thus minor women have a constitutional right to obtain abortions without their parents' consent or knowledge because minors have a constitutional right to privacy.^[48] Likewise, minors have a constitutional right to obtain contraceptives without parental involvement.^[49] The exercise of these rights by minors is dependent upon their maturity to make the decisions necessary to use these services.

The Act's limitation of parental authorization for genetic testing does not provide minors with decisional rights, but rather provides them with protection from potential harm. In this regard it is similar to the prohibition on parents from consenting to research for their children in which the research presents a risk of harm to the child with no benefit. Not only is such research strictly regulated, there are those who argue that it should be absolutely banned.^[50] The further purpose of the limitation of parental authority to authorize collection and analysis is to protect the child's privacy interest in his or her own genetic information. This information will not only exist during the child's minority but will continue to exist when the child becomes an adult. As a result, a parent's curiosity about a child's genetic information should not be sufficient to breach the child's (and later the adult's) privacy interest in this genetic information. If, however, there is sufficient justification, a parent may authorize the collection and analysis of DNA samples. It is for this reason that the Act makes an exception for the collection and analysis of genetic material where it is necessary in order to ameliorate, prevent or treat a condition that will manifest itself prior to the time when the child is authorized to consent to such DNA collection and analysis. This exception enables parents to play their traditional protective role, and provides them with the authority to obtain necessary information when needed for them to act in their child's best interest.^[51]

Under the Act 16 and 17 year olds have the same rights as adults in nonresearch settings to authorize genetic analysis [section 141 (b)]. This accords with the increasing recognition that mature minors are entitled to make medical decisions for themselves. Consequently, if a 16 or 17 year old wanted information about carrier status, such screening could be conducted under his or her sole authorization. This information would mostly be relevant to decisions relating to reproduction. Although unlikely, a 16 or 17 year old could seek genetic analysis either prior to becoming pregnant, or in relation to the decision to continue with a pregnancy. Where the young woman is already pregnant, under the Act, no restrictions are placed on her pursuit of such analysis and genetic information regarding herself or her fetus. (sections 151, 152)

In all other nonresearch circumstances, however, the Act requires that the 16 or 17 year old be accompanied by an adult family member at the time that the information required by section 101 (b) is given to him or her. [section 141 (b)(1)] The decision to include an adult family member in this process is not up to the young person, as some state statutes provide regarding abortion counseling.^[52] The Act requires an adult's involvement. Although the decision to

undergo genetic analysis is a highly personal and private one, it is unlike the decision to continue a pregnancy in that requiring the involvement of a family member does not expose the minor to the same familial repercussions. The goal of this requirement is to provide family support for the minor who is faced with a novel situation which involves obtaining and processing complex information. Since the collector of the sample is likely a stranger, regardless of how skilled this person is in communicating information, he or she may not be aware of, or sensitive to, the burden that such information can place on even a mature minor. A family member will also have a shared interest in protecting family privacy and will be aligned with the minor if issues of disclosure to other family members arise or are anticipated.

The Act does not require the authorization of the adult family member prior to the collection of a sample for analysis. The role of the adult family member in the authorization process is limited to providing support and guidance. The decision not to require dual consent of parent and minor when the minor is 16 or 17 years old is intentional. We want to avoid giving greater deference to the interests of a parent or family member than to the autonomy of the mature minor who seeks genetic analysis. Actual exercise of this authority by a 16 or 17 year old will undoubtedly be rare. In general, those likely to seek such genetic analysis will do so out of a need to know if they are at risk for a specific genetic disease that is known to be present in the family. Unlike adults, 16 and 17 year olds do not generally seek genetic analysis and information in the context of reproductive planning, since few teenage pregnancies are the result of conscious and careful planning.

Sec. 143. AUTHORIZATION FOR COLLECTION AND ANALYSIS OF DNA SAMPLES FROM INCOMPETENT PERSONS

(a) LIMITATIONS ON COLLECTION AND ANALYSIS. -- The individually identifiable DNA sample of a sample source who lacks the ability to understand the information disclosed pursuant to section 101 and the information contained in an authorization under section 103 shall not be collected or analyzed unless--

(1) the analysis is necessary:

(A) to diagnose the cause of incompetence; or

(B) to diagnose a genetic condition which in reasonable medical judgment can only be effectively ameliorated, prevented or treated while the sample source is incompetent; or

(C) to diagnose a genetic disease of a parent, sibling, child or grandchild of the sample source provided that the disease in reasonable medical judgment can be effectively ameliorated, prevented, or treated;

(2) the analysis is limited to that which is necessary for such diagnosis; and

(3) the sample source's representative has executed an authorization which meets the requirements of section 103 of this Act.

(b) DESTRUCTION OF SAMPLES COLLECTED PRIOR TO INCOMPETENCY. -- Whenever a sample source while competent has, either in an authorization under section 103 of this Act, or in an exercise of the sample source's rights under section 104(b) of this Act, ordered the destruction of a DNA sample, and the sample source becomes incompetent before the occurrence of the date or event which was designated by the sample source to cause the destruction of such sample, the sample source's representative may order the earlier destruction of such sample, but is not empowered to cancel or override any such destruction unless the postponement of the destruction is to enable an analysis of the DNA sample for a purpose provided for in subsection (a) of this section.

The question of what tests or procedures can be authorized by a guardian or other legally authorized representative of an incompetent person is not unique to genetics. In the past courts have been asked to determine when consent of a guardian is legally effective in varying circumstances. Several courts have determined that the doctrine of substituted judgment should be applied to effectuate the intentions and preferences of the incompetent individual whenever possible. When such intentions are not known, a decision to authorize or refuse treatment is based on a determination of the best interests of the ward. The rules in this section are consistent with this approach and are intended to prevent

exploitation of incompetency to obtain private genetic information about a person.

A person is incompetent for purposes of the Act if the person lacks the ability to understand the information that must be provided under section 101 and the information contained in the authorization [section 143(a)]. The DNA of any individual who is incompetent cannot be collected or analyzed unless the conditions in this section have been met. Such conditions are similar to the restrictions placed on the collection and analysis of the DNA of children because there are similar privacy concerns involved in determining both the best interests of children and incompetent adults whose intentions are unknown.

Consequently, the analysis of the DNA of an incompetent person can only be conducted if it is for one of three permissible purposes. Two are related to the person: for the diagnosis of the cause of incompetence, or the diagnosis of a genetic condition that can be effectively ameliorated, prevented, or treated during the period of incompetency. [section 143(a)(1)(A)] This prevents testing for untreatable genetic conditions (which would have no benefit for the incompetent person), and testing for conditions that do not require intervention during a period of temporary incompetency (which could be postponed until the person can act for themselves).

The third permissible purpose for analysis conducted is for the diagnosis of a particular relative (parent, sibling, child or grandchild) for a disease that can be ameliorated, prevented or treated. [section 143(a)(1)(B)] This purpose was included after examination of instances where courts have applied the best interests standard but nevertheless permitted a guardian to consent to procedures which had no therapeutic benefit for the ward, but significant benefit to another individual. Although reluctant to use substituted judgment as a basis for permitting invasive procedures with no direct benefit to the incompetent person, a few courts have nonetheless done so when an indirect psychosocial benefit to the individual has been demonstrated. Such benefit is typically derived from the continuation of a relationship with an individual who has a significant role in the ward's life and when that individual needs something from the ward in order to survive. [53] This benefit has been identified in cases involving kidney transplants and donation of bone marrow from an incompetent person to a close relative. [54]

In contrast to the procedures involved in such situations, the collection of DNA from an incompetent person itself presents little physical risk and is relatively non-invasive. The risks involved the harm that can come from disclosure of highly personal information, and not risk to the physical well-being of the individual. Balanced against this low risk is the indirect benefit that the person may gain when a relative with whom they have a significant relationship needs the information contained in the DNA of the incompetent person and it can be effectively used to help them. To limit creation of private genetic information about the incompetent person to those circumstances where actual benefit will result, the rule specifies that the information must be needed for the diagnosis of a disease which in "reasonable medical judgment can be effectively ameliorated, prevented, or treated." [section 143(a)(1)(B)] Because this purpose is also only permissible when the individual who will benefit is a parent, sibling, child or grandchild of the incompetent person, the Act reflects a presumption that the person would, if competent, choose to help such individuals.

The Act does not take the more stringent approach of requiring a demonstration that no other alternative is available for the diagnosis of the relative. [55] Instead, the determination of the appropriateness of the use of genetic analysis for such diagnosis is left first to the standard of medical care for the relative, and secondly, to the discretion of the sample source's representative whose authorization is required before the analysis can proceed. Until the whole human genome is mapped, there may be no other alternative than linkage analysis which involves the analysis of several family members' DNA to develop reliable information on the inheritance of some genetic diseases. Rather than prohibit the participation of an incompetent person in such a process, this rule accommodates a legitimate need for such participation. The Act does not, however, obligate a sample source's representative to authorize any analysis which would not be appropriate under the doctrine of substituted judgment, either because it would be inconsistent with the prior wishes of the incompetent person, or because it presents a risk to their privacy which is not outweighed by other factors.

Although the incompetent person's representative generally has the same authority in regard to authorizing the collection and analysis of DNA that the sample source would have if competent, there is one additional restriction on what the representative of such a sample source can do. The representative cannot in most circumstances override an order of the sample source made during a period of competency which directs the destruction of a previously collected

DNA sample. If postponement of the destruction would, however, avoid collection of an additional sample for an analysis that is currently necessary and permissible, the sample source's representative can authorize such postponement. [section 143(b)] The representative of an incompetent person is obligated to first act in a manner consistent with the person's expressed wishes, and therefore is unlikely to rescind an order made by the person while competent. Nonetheless, this rule gives clear deference to decisions made while the person was competent and prevents a representative from taking advantage of the person's incompetency so as to discover private genetic information.

PART F

PREGNANT WOMEN, FETUSES, AND EXTRACORPOREAL EMBRYOS

Sec. 151. AUTHORIZATION FOR COLLECTION AND ANALYSIS OF DNA FROM PREGNANT WOMEN AND FETUSES

Regardless of her age, a pregnant woman shall have all the rights and authority of an adult sample source in regard to her DNA sample and the DNA sample of her fetus unless she is otherwise incompetent under the provisions of section 143.

Sec. 152. AUTHORIZATION FOR DISCLOSURE OF PRIVATE GENETIC INFORMATION ABOUT PREGNANT WOMEN AND FETUSES

Regardless of her age, a pregnant woman shall have all the rights of an adult sample source in regard to records containing private genetic information as provided in section 113, 114, and 115 of this Act, and in regard to disclosure of genetic information resulting from an analysis of her DNA sample or the DNA sample of her fetus, unless she lacks the ability to understand the information contained in an authorization under section 112.

These rules apply regardless of the age of the pregnant woman, and thus avoid a situation where a pregnant mature minor's independent decision regarding the continuation of her pregnancy would have legal effect, but she would be unable to independently obtain genetic information about herself or her fetus. It is also the woman alone who can consent to any intervention that might be available for a fetus who may have a particular genetic condition, and therefore she has a direct interest in the information that could be derived from the analysis.

Sec. 153. AUTHORIZATION FOR COLLECTION AND ANALYSIS OF DNA FROM EXTRACORPOREAL EMBRYOS

(a) RELINQUISHMENT OF DONOR'S RIGHTS. -- Whoever donates a gamete for the reproductive purposes of a person or persons other than the gamete donor relinquishes all rights regarding the collection and analysis of a DNA sample of an embryo subsequently created using the donated gamete.

(b) CONDITIONS FOR COLLECTION AND ANALYSIS. -- Prior to the collection and analysis of a DNA sample from an extracorporeal embryo created for reproductive purposes, the person collecting or causing to be collected the DNA sample of such embryo shall:

- (1) make the disclosures required by section 101 of this Act to the person or persons who intend to use the embryo for reproduction; and**
- (2) shall obtain the written authorization of such person or persons that meets the requirements of section 103 of this Act.**

(c) DISCLOSURE OF RESULTS. -- The results of a genetic analysis of a DNA sample of an extracorporeal embryo shall be disclosed to the person or persons who intend to use the embryo for reproductive purposes.

In vitro fertilization may take place with gametes from individuals other than the woman in whom the embryo may be implanted, or the male who is the prospective father. Whose authorization is necessary for collecting and analyzing DNA from the embryo? There are several possibilities. The rules could require authorization of the gamete sources, regardless of whether or not such individuals have any connection to use of the gamete for reproductive purposes. The argument could be made that the individuals who are the source of the gametes are genetically linked to the embryo and therefore have the greatest interest in the information contained in the DNA of the embryo. However, it is not necessarily those individuals who will ultimately be responsible for decisions regarding the fetus that the embryo develops into, or the child that is eventually born. Compared to a gamete donor, it is the prospective parents who have a need for genetic information about the embryo so that they can plan for its future development and the care which will be their responsibility. Consequently, the Act reflects the diminishing interests of a gamete donor once a donation is made, and the increasing interests of the persons who use the resultant embryo for reproduction. Section 153(a) provides that the gamete donor who donates a gamete for reproductive purposes relinquishes all rights regarding the collection and analysis of the DNA of an embryo that is subsequently created with that gamete.

This allocation of authority does not deprive gamete donors of any genetic information about themselves since they are free to have their own DNA tested. Nor does it deny them any information they would need in regard to the possible future development of the resultant embryo, since they would not otherwise have any authority or responsibility in regard to its future. Giving them rights to such information would create the only instance under the Act where an individual could know private genetic information of another simply for the sake of knowing, and without serving any beneficial purpose.

If the embryo is subsequently implanted and develops into a fetus, then any further collection or analysis of DNA is governed by the rules in section 151 and the authorization of the pregnant woman is required.

PART G

MISCELLANEOUS PROVISIONS

Sec. 162. TRANSFER OF OWNERSHIP, DISCONTINUANCE OF SERVICES

(a) ACTIVITIES INVOLVING DNA SAMPLES. -- Any person in possession of individually identifiable DNA samples who intends to discontinue a program, business, enterprise, or service in which such DNA samples were collected, stored, or analyzed or who intends to transfer control of such program, business, enterprise, or service to a person who intends to use such DNA samples for a substantially different purpose than was authorized at the time of collection, storage, or analysis of such DNA samples must:

(1) no less than 45 days prior to the effective date of the discontinuance or transfer of control, mail a notice to the last known address of each sample source or the sample source's representative informing such individuals of the intended change, and

(A) in the case of an intended discontinuance of activities, give the individual the opportunity to direct that the DNA sample be returned to the individual prior to the date on which the discontinuance is effective and informing them of the date on which such direction must be received to effectuate such request; or

(B) in the case of an intended transfer of control, give the individual the option of agreeing to the transfer, or requiring the destruction or return of the DNA sample prior to the effective date of the transfer, and informing the individual of the date on which such a requirement must be received to be effectuated;

(2) In the event that no response is received from the individual by the date specified in the notice, the

person in possession of such DNA sample:

(A) in the case of a discontinuance shall destroy such DNA samples; and

(B) in the case of transfer of control shall either;

(i) destroy such DNA samples, or

(ii) remove all individual identifiers from such DNA samples...

This section contains detailed provisions for facilities that discontinue services or transfer control of such services to someone who will use individually identifiable DNA samples or private genetic information for a substantially different purpose than that authorized by the sample source or sample source's representative. Therefore, a sale of a business or practice in which DNA samples have been collected or stored to an individual or facility that will engage in different activities would require compliance with these provisions. However, sales of clinical practices in which DNA samples are collected or records containing private genetic information are maintained to practitioners who will provide similar services would not be affected by these rules. Neither would mergers between entities such as hospitals or laboratories that result in management or personnel changes but not in changes in the business or services provided. However, if individually identifiable DNA samples were, for instance, collected and stored in a research program on a genetic disease, a commercial enterprise such as a pharmaceutical company could not acquire the DNA samples or data bank that contains private genetic information, without meeting these provisions.

In regard to discontinuation of services or activities in which records containing private genetic information have been maintained, the holder of such records who does not receive a response from the subject of the information has the option of sealing and storing records for up to 3 years. [section 162(b)(2)(A)(ii)] This provision is intended to satisfy the concerns of those who fear that mandatory destruction of such records would hinder the defense of subsequent claims such as malpractice brought against the keeper of such records.

These rules will accommodate the commercial interests of individuals or entities that collect, store or analyze DNA samples or private genetic information, and who want to profit from the sale or transfer of their endeavors, without compromising the rights and interests created under this Act of persons who are affected by such changes.

PART H

ENFORCEMENT

Sec. 171. CIVIL REMEDIES

(a) PRIVATE RIGHT OF ACTION. -- Any person whose rights under this Act have been violated may maintain a civil action for damages or equitable relief as provided for in this section...

(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 through negligence collects a DNA sample in violation of this Act, analyzes a DNA sample in violation of this Act, or discloses private genetic information in violation of this act, shall be liable to the sample source for each such violation in an amount equal to:

(1) any actual damages sustained as a result of the collection, analysis, or disclosure, or \$25,000, whichever is greater; and

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

(3) in the case of a successful action to enforce any liability under this section, the costs of the action together with reasonable attorneys' fees as determined by the court.

(e) LIABILITY FOR WILLFUL VIOLATIONS. -- Any person who--

(1) through a request, the use of persuasion, under threat, or with a promise of reward, willfully induces a person to collect a DNA sample in violation of this Act, analyze a DNA sample in violation of this Act, or discloses private genetic information in violation of this Act, or

(2) willfully collects a DNA sample in violation of this Act, willfully analyzes a DNA sample in violation of this Act, or willfully discloses private genetic information in violation of this Act, shall be liable to the sample source for each such violation in an amount equal to:

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

(B) punitive damages as the court may allow; and

(C) in the case of a successful action to enforce any liability under this section, the costs of the action together with reasonable attorneys' fees as determined by the court...

Under this section an aggrieved individual may maintain a cause of action for negligent or willful acts in violation of these rules. Where a person has acted negligently in the collection or analysis of a DNA sample, or in regard to disclosures of private genetic information, they will be liable for a minimum amount of \$25,000. Although the individual who is harmed does not have to suffer actual damages in order to recover, if they do sustain actual damages which exceed \$25,000, they can recover the greater amount. [section 171(d)(1)] The amount of actual monetary damages as a result of violations of these provisions may not be sufficient to motivate individuals to assert their rights. These liquidated damages have been made available so that injuries to personal privacy and dignity that result from violations can be prosecuted. The availability of treble damages in cases where the negligent person has profited from such unlawful actions is included to deter profiting from the invasion of another's privacy and as an incentive for individuals and entities governed by these rules to monitor their compliance and performance. Whether the person facing liability is an individual practitioner, an independent laboratory or a multi-service corporation, a \$75,000 minimum potential liability for each violation that results in their benefit should be incentive to invest in effective risk management measures.

Under section 171(e), individuals can also recover for willful violations of these rules by individuals who induce another to collect or analyze a DNA sample in violation of these provisions, or who induce another to wrongfully disclose private genetic information. Consequently, anyone who exerts influence over those who actually collect or analyze DNA samples to obtain or analyze a sample without authorization, is exposed to liability for actual damages, or a liquidated damage amount of \$50,000, whichever is greater. [sections 171(e)(1) and (2)]. Anyone who willfully collects or analyzes a DNA sample without proper authorization, or who willfully discloses private genetic information without authorization, is similarly liable.

Both the person who induces such action, and the person who engages in the unauthorized act, are liable for such punitive damages as the court may allow. [section 171(e)(2)(B)] As in negligence cases, if the individual who is harmed prevails, costs of the action and reasonable attorneys' fees shall also be awarded. Besides awarding monetary damages, courts are empowered to fashion equitable relief and remedies as necessary in particular circumstances. [section 171(c)] For example, a court can order destruction or return of DNA samples, purging of records, reinstatement of benefits or privileges denied through violations, and order a person or entity to comply with the provisions of the statute.

Sec. 172. CIVIL PENALTIES AND INJUNCTIVE RELIEF

Whenever the attorney general has reason to believe that any person is using or is about to use any method, act or practice in violation of 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 by temporary restraining order or preliminary or permanent injunction the use of such method, act or practice. The action may be brought in the district court of the jurisdiction in which the person resides or has a principal place of business. The court may issue temporary restraining orders or preliminary or permanent injunctions and make such other orders of judgments as may be necessary to prevent harm or to remedy harm suffered by any person as a result of the use or employment of such method, act or practice in violation in the Act. If the court finds that a person has employed any method, act or practice which he knew or should have known to be in violation of 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 the said person to pay reasonable costs of investigation and litigation of such violation, including reasonable attorneys fees.

One problem which faces individuals whose privacy rights have been violated is that pursuit of remedial actions may contribute to further publication of genetic information and erosion of privacy. It may be possible to sue for wrongful collection or analysis of DNA and present necessary evidence without revealing private genetic information. Nonetheless, it is more likely that this information will be revealed since an essential proof in the case is that the information falls within the statutory definition of private genetic information. It will be up to individuals to assess the relative risks and benefits of asserting their rights and pursuing legal action. If the risks of pursuing such remedies inhibit individual enforcement, thereby diminishing the effectiveness of the Act, inclusion of additional methods of enforcement must be considered. The two remaining possibilities are: criminal actions and/or civil penalties.

Criminal penalties through fines and imprisonment for violations of this Act are not included or recommended. Despite a desire to draft a law that gives protection to the privacy interests of individuals and that would adequately deter unauthorized collection of DNA samples and unauthorized disclosures of private genetic information, we decided that creation of a new federal crime would not necessarily serve such goals. Criminal sanctions are appropriate when other methods of inducing compliance are ineffective or when the interests served by the law are best promoted through pursuit of criminal actions.

There is no reason to assume that there will not be voluntary compliance with the Act. Granting broad powers of law enforcement investigation and prosecution in areas that contain highly sensitive and personal information, and the risks to privacy that such power presents, must be balanced against this assumed low rate of noncompliance. Unless or until it is demonstrated that violations of the privacy rights created under the Act are sufficient in number or in degree of harm so as to warrant creation of a new federal crime, we do not recommend the inclusion of criminal sanctions. Additionally, it is our belief that such prosecutions could not realistically be given priority over the myriad federal crimes that now exist; nor would there be a likelihood that the severity of sentences that are likely to be imposed or arrived at through plea arrangements would have a deterrent effect greater than is presented by the threat of civil liability.

In addition to providing private civil actions and criminal sanctions, other statutes containing fair information practices either look to an administrative agency for enforcement, or authorize the attorney general to pursue civil penalties for violations of fair practices. For instance, the Fair Credit Reporting Act (FCRA) [15 USC 1681 (a)] authorizes the Federal Trade Commission to use powers granted by the Federal Trade Commission Act to enforce the provisions of the FCRA, and to bring actions to redress consumer complaints.

In regard to oversight of compliance with the Act, it might be useful to give enforcement powers to an independent board or agency. Although no privacy protection board currently exists, the concept of a data protection board has been introduced and recommended to Congress repeatedly over the last 20 years. Since the introduction of the Privacy Act of 1974, the need for an independent board which would, among other things, monitor and evaluate laws designed to protect personal privacy has been identified. In recent years, the proliferation of computer generated personal information systems has led to a renewed interest in a board charged with developing model standards, proposing legislation, and investigating complaints about violation of privacy or data protection rights.[\[56\]](#)

Even if such proposals were heeded, and a board created, its effectiveness in protecting individual privacy interests would be negligible unless it was granted enforcement powers in addition to investigative and advisory functions.[\[57\]](#) If a board with such inclusive powers is established in the future, we recommend that it be given jurisdiction over the investigation and enforcement of violations of this Act. To effectuate such a mandate, the Genetic Privacy Act could be amended to include a provision for the reporting of violations to the Board which could impose civil penalties on persons found to be in violation. Given that establishment of such a board is unlikely in the near future, this leaves one additional alternative for enforcement of civil penalties on violators of the Act. That is to authorize the Attorney General to bring civil actions against violators and to enforce the rights created by the Act.

PART I

EFFECTIVE DATES; APPLICABILITY; AND RELATIONSHIP TO OTHER LAWS

Sec. 183. RELATIONSHIP TO OTHER LAWS

(a) No state may establish or enforce any law or regulation concerning the collection, storage, of analysis of DNA samples except to the extent that such law or regulation:

- (1) prohibits or further restricts the collection, storage, or analysis of DNA samples; or**
- (2) provides additional protection to the privacy interests of the individual who is a sample source.**

(b) Effective as of the effective date of this Act, no State may establish or enforce any law or regulation concerning the disclosure of private genetic information except to the extent that such law or regulation:

- (1) prohibits or further restricts the disclosure of such information;**
- (2) prohibits or further restricts the use of such information; or**
- (3) provides additional protection to the privacy interests of the individual who is a sample source or the subject of the genetic information.**

(c) 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 private genetic information.

This Act does not supersede or preempt any federal or state law that provides additional privacy protection to sample sources. Consequently, states that pass legislation restricting the use of genetic analysis for particular purposes may do so. For example, nothing in the Act would limit a state's authority to prohibit genetic testing by employers or insurance companies. States, however, may not take actions that conflict with the protection provided by this Act. State statutes, for example, that would mandate genetic screening or testing of identifiable newborns would be preempted by these provisions if they analyzed DNA analysis and did not require the prior authorization of the parent.

The actions available under the Act to address wrongful violations are limited to civil actions and civil penalties; nonetheless, the Act does not prevent states from providing additional remedies, such as making unauthorized collection or analysis of DNA samples a crime, or criminalizing unauthorized disclosures of private genetic information.

The provision of the right to bring a civil action for damages does not prevent pursuit of other tort claims where the facts would support such causes of action and when available under state common or statutory law. For example, an action for publication of private facts would not be precluded by the remedy available here. Information covered by this Act may also be covered by other confidentiality statutes. Such concurrent coverage is intended so as to maximize the protection of private information. State laws which prohibit obtaining genetic information in particular circumstances, or the use of such information for particular purposes, would not be superseded by the Act. Therefore, states which prohibit employers or insurers from requiring individuals to submit to genetic analysis^[58] could continue to enforce such prohibitions. States could also mandate requirements in regard to the consent process for genetic analysis in all or particular circumstances which go beyond those required by the Act.^[59]

[1] Annas GJ & Elias S, eds, *Gene Mapping: Using Law and Ethics as Guides*, New York: Oxford University Press, 1992, p.9.

[2] Council of State Governments, *Advances in Genetic Information: A Guide for State Policy Makers*, Lexington, Ky: Council of State Governments, 1992; Privacy Commissioner of Canada, *Genetic Testing and Privacy*, Ottawa, Ontario: Privacy Commissioner of Canada, 1992.

[3] Annas GJ, "Privacy Rules for DNA Databanks", 270 JAMA 2346 (1993).

[4] *Domestic and International Data Protection Issues*, Hearings before the Subcommittee on Government Information, Justice, and Agriculture of the Committee on Government Operations, U.S. House of Representatives, 102d Cong., 2d Sess. (1991).

[5] Current confidentiality protections are inadequate even to protect individual medical records, a circumstance widely recognized during the recent health care reform debate. *See, e.g.*, the medical records section of *The Health Security Act* as amended in the U.S. House of Representatives, *Report on the Health Security Act*, Committee on Government Operations, Aug. 12, 1994; and *Hearings on Health Reform, Health Records, Computers and Confidentiality*, Committee on Government Operations, U.S. House of Representatives, 103d Cong. 1st Sess., Nov. 4, 1993; and *Hearings on Fair Health Information Practices Act of 1994*, April 20, May 4-5, 1994. *See also*, Wilker NL, Stawski S, Lewontin R, Billings PR, "DNA Data Banking and the Public Interest", in Billings PR, ed, *DNA on Trial: Genetic Information and Criminal Justice*, Cold Spring Harbor, NY: Cold Spring Harbor Laboratory Press, 1992, pp. 141-149; Yates JRW, Malcom S, Read AP, "Guidelines for DNA Banking: Report of the Clinical Genetics Society Working Party on DNA Banking", 16 *J. Med. Genet.* 245 (1989); Ad Hoc Committee on DNA Technology, American Society of Human Genetics, *DNA Banking and DNA Analysis: Points to Consider*. 42 *Am. J. Hum. Genet.* 781 (1986); and Andrews LB, *DNA Testing, Banking and Individual Rights*, in Knoppers BM & Laberge GM, eds, *Genetic Screening: From Newborns to DNA Typing*, Amsterdam: Excerpta Medica, 1990, pp. 217-242.

[6] *Designing Genetic Information Policy: The Need for an Independent Policy Review of the Ethical, Legal and Social Implications of the Human Genome Project*, Committee on Government Operations, U.S. House of Representatives, 102d Cong, 2d Sess., Rep. No.16, April 2, 1992, p.25.

[7] Congress has recently acted to protect genetic information derived from DNA samples held by law enforcement agencies for identification purposes. *See*, Violent Crime Control and Law Enforcement Act of 1994, P.L. 103-322 210305. This law would not be affected by the Genetic Privacy Act.

[8] *See* discussion of the use of family history by physician to conclude that an individual suffered from breast-ovarian carcinoma syndrome despite no manifested symptoms of disease in *Katskee v. Blue Cross/Blue Shield of Nebraska*, 245 Neb. 808, 515 N.W.2d 645 (1994), discussed in Annas, GJ, "When Should Preventive Treatment be Paid for by Health Insurance?" 331 *New Eng. J. Med.* 1027 (1994).

[9] Ad Hoc Committee on DNA Technology, American Society of Human Genetics, "DNA Banking and DNA Analysis: Points to Consider," 42 *Am. J. Hum. Genetics* 781 (1988).

[10] Office of Technology Assessment, U.S. Congress, *Genetic Witness: Forensic Uses of DNA Tests*, Washington, D.C.: U.S. Government Printing Office, 1990, p.132.

For detailed descriptions of the process and procedures used in DNA typing see Thompson, WC, "Evaluating the Admissibility of New Genetic Identification Tests: Lessons form the 'DNA War'", 84 *J. Crim. L.* 22 (1993); Committee on DNA Technology in Forensic Science, "DNA Typing Technical Considerations" in *DNA Technology in Forensic Science*, National Academy Press, Washington, D.C., 1992, pp.51-73.

[11] *See, e.g.*, Cal. Ins. Code 799.03(Deering 1994) (requiring that prior to execution of consent for HIV related test, insurers must provide printed materials on HIV, information on what the subject can do with the results, a list of available counseling services and sources of additional help); N.Y. Pub. Health Law 2781 (Consol 1993) (requiring that person ordering an HIV related test explain the nature of the illness, and provide information about discrimination problems that might result); Pa. Cons. Stat. 7605 (1993) (requiring that explanation of HIV related test and information on the availability of information about exposure and transmission and suggestion that subject may desire pre-test counseling be communicated prior to test).

[12] President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, *Screening and Counseling for Genetic Conditions* Washington, D.C.: U.S. Government Printing Office, 1983, p.43.

[13] Chapman M, "Invited Editorial: Predictive Testing for Adult Onset Genetic Disease: Ethical and Legal Implications of the Use of Linkage Analysis for Huntington Disease", 47 Am. J. Hum. Genet. 1, 2 (1990).

[14] Chapman M, "Canadian Experience with Predictive Testing for Huntington Disease: Lessons for Genetic Testing Centers and Policy Makers", 42 Am. J. Hum. Genet. 491, 493 (1992); The Institute of Medicine's Committee on Assessing Genetic Risks recommends more stringent requirements in regard to genetic counseling and believes that "genetic counseling and education must be an integral part of genetic testing; anyone who is offering, or referring for, genetic testing must provide--or refer for --appropriate genetic counseling and education prior to testing and follow-up after testing." *Assessing Genetic Risks*, Andrews LB, Fullarton JE, Holtzman NA & Motulsky G, eds., Washington, D.C. National Academy Press, 1994, p.170. As more primary care physicians provide and use genetic tests, they are the likely candidates to perform such counseling. However, before they will be adequately prepared to do so effectively, research and education on appropriate counseling methods must be undertaken. *Id.* at 173.

[15] Chapman, *supra* note 7, at 492; For discussion of issues that arise in the different contexts in which genetic counseling takes place, including pre-natal testing and screening for late onset disorders *see* IOM Report on *Assessing Genetic Risks*, *supra* note 7, Chap. 4, "Issues in Genetic Counseling."

[16] Huggins M, *et al*, "Ethical and Legal Dilemmas Arising During Predictive Testing for Adult-Onset Disease: The Experience of Huntington Disease", 47 Am. J. Human Genet. 4 (1990); Chapman, *supra* note 7 at 493; *Assessing Genetic Risks*, *supra* note 7, at 88-89.

[17] *See* Chapman, *supra* note 7, at 492; Huggins M. *et al*, "Predictive Testing for Huntington Disease in Canada: Adverse Effects and Unexpected Results in Those Receiving a Decreased Risk", 42 Am. J. Med. Genet. 508, 514-515 (1992). These commentators view the role of genetic counseling as particularly warranted in predictive testing since results will be an expression of altered risk and the individual who is tested may not appreciate the significance, for example, between being at 11% as opposed to 50% increased risk of having a particular gene or disease and act on such misunderstanding with harmful results.

[18] If discussion and forms are to be understandable by the average individual, considerable effort should go into their development. As a recent study at Johns Hopkins Oncology Center in Baltimore revealed, the average form for experimental therapies required at least an 11th grade reading level, despite the fact that most specialists recommend that important documents should be written at or below an 8th grade level. McFarling UL, Medical Notebook, Cancer Consent Forms Found Difficult to Read, *Boston Globe*, October 13, 1994, p.3.

[19] *See, e.g.*, 42 CFR 2.22 (1993)(requiring that at the time of admission for alcohol or drug abuse treatment, patients receive notice of the federal law and regulations that protect the confidentiality of such treatment records); Uniform Health Care Information Act 5-101, 9 U. L. A. 509 (1988)(requiring that a health care provider post a notice of information practices); Health Information Model Legislation 106 (Am. H. Info. Manag. Assoc.) (requiring those who receive health care information from patients to provide patients with a statement of the recipient's fair information practices); Insurance Information and Privacy Model Act 4 (N.A.I.C. 1989)(requiring insurance institutions and agents to provide a notice of information practices to applicants).

[20] *See, e.g.*, The Health Security Act, H.R. 3600, 103d Cong. 2d Sess. 5137 (permitting disclosures without patient's authorization if it is believed that the disclosure will avoid or minimize imminent danger to the health or safety of any individual), Uniform Health-Care Act 2-104 (additionally permitting disclosures to immediate family members, unless prohibited by the patient); and 42 U.S.C. 290dd-2(b)(2)(permitting disclosures of substance abuse treatment information to medical personnel in bona fide emergencies). It should be noted that the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research also recognizes that a genetic counselor's ethical duty of confidentiality can be overridden if several conditions are met, including a determination of a high probability of harm from withholding of the information, that the information will actually be used to avert the harm, and that only genetic information necessary for diagnosis or treatment of disease is disclosed. *Screening and Counseling for Genetic Conditions*, *supra* note 5 at 44. This issue is discussed in detail in the Appendix.

[21] McEwen J, McCarty K & Reilly P, "A Survey of Medical Directors of Life Insurance Companies Concerning Use of Genetic Information", 53 Am. J. Hum. Genet. 33 (1993).

[22] Marshall E, "Genetic Testing Set for Takeoff", 265 Science 464 (1994).

[23] *See*, 42 CFR 2.31 (1993) for contents of written consent to disclosure of substance abuse treatment information under the regulations and a sample form.

[24] *See, e.g.*, Uniform Health Care Information Act 3-101, 3-102, 9 U. L. A. 499, 501 (1988)(requiring that health care providers permit patients examine and copy records except in particular circumstances); Health Information Model Legislation 106(b)(6) (Am. H. Info. Manag. Assoc.) (providing that patients may have access to health care information); Mass. Gen. Laws Ann. ch. 112 12CC (West 1993); Fair

[25] *See, e.g.*, Mass. Gen. Laws Ann. ch. 112 12CC (permitting provider to withhold inspection of psychotherapy records when in the exercise of reasonable professional judgment, seeing these records would adversely affect the patient's well being; on request of the patient, however, the total record is to be made available to an attorney or another therapist.) In its Report on the Health Security Act, H.R. 3600, the Committee on Government Operations recommended amendment to include provisions of H.R. 4077 which allow withholding of seven categories of information from patients who request record inspection, H.R. Rptr. No. 601, 103d Cong., 2d Sess. Pt. 5, pp.25-26 (1994).Health Information Practices Act 111,112, H. R. 4077 103Rd Cong. 2d Sess. (1994)(requiring health information trustees to permit individuals to inspect and copy most health information).

[26] H.R. 4077. After introduction by Rep. Gary Condit in March, 1994, hearings were held by the Subcommittee on Information, Justice, Transportation and Agriculture, Committee on Government Operations, U.S. House of Representatives. The provisions of this bill form the basis for the Fair Health Information Practices Part of amendments to the Health Security Act (H.R. 3600) as reported in H.R. Rep. No. 601, 103d Cong., 2d Sess., Pt. 5, p.101 (1994).

[27] *See, e.g.*, *Terre Haute Regional Hospital v. Trueblood*, 600 N.E.2d 1358 (Ind. 1992) (permitting discovery of medical records of non-party patients but nonetheless requiring that identity of patients be redacted from them).

[28] *Commonwealth v. Kobrin*, 479 N.E.2d 674 (Mass. 1985).

[29] Khajezadeh D, "Patient Confidentiality Statutes in Medicare and Medicaid Fraud Investigations", 13 Am. J. L. & Med. 105, 120-121 (1987) In some cases the court has simply noted that disclosures are limited to the purposes connected to the plan's administration without any specific guidance as to which informational components of patient records meet particular purposes of the plan.

[30] For description of the range of law enforcement activities in which collection and analysis is allowed under various state laws *see* McEwen J & Reilly P, "A Review of State Legislation on DNA Forensic Databanking," 54 Am. J. Hum Genet. 941 (1994).

[31] *See generally*, Thompson, *supra* note 3.

[32] Shapiro ED & Weinberg ML, "DNA Data Banking: The Dangerous Erosion of Privacy," 38 Cleve. St. L. Rev. 455, 477 (1990).

[33] *U.S. v. Laub Baking Company*, 283 F.Supp. 217 (1968) (rejecting claims that fingerprinting violates rights against self-incrimination, unreasonable search and seizure, and right of privacy).

[34] Private genetic information could be developed under such laws because state statutes that authorize the establishment of forensic DNA databanks differ in defining the scope of authority to conduct DNA analysis in connection with such banking. For example, while Michigan identifies the process that is authorized as "DNA identification profiling" which is a "validated scientific method of analyzing components of deoxyribonucleic acid molecules for the purpose of identifying the pattern of the components' chemical structure that is unique to an individual" Mich. Comp. Law 28.172 (1992), not all states are as specific. Alabama's statute, which authorizes the establishment of that state's forensic databank, states that "the Alabama Department of Forensic Sciences should be

authorized and empowered to analyze, type and record any and all genetic markers contained in or derived from DNA and to create a statewide DNA database system for collection, storage and maintenance of genetic identification information as the same may pertain to the identification of criminal suspects." Code of Ala. 36-18-20 (1994).

[35] The only circumstance in which paternity tests involving genetic analysis would fall outside of this provision, and this Act could be construed as prohibiting them, would be if an order for such tests was not issued under Rule 35 or what was considered a "comparable rule". Paternity actions are routinely brought as civil actions in most states. Even when paternity is one element to be proven in a criminal action for failure to pay support by an enforcement agency, the civil rules of procedure are often applied. Some states, such as Ohio, have specific statutes regarding authority to issue orders for paternity testing on motion to the court. For example, ORCA 2317.47 (referring to blood tests in paternity actions) and ORCA 3111.09 (containing similar provisions for genetic tests in paternity actions). The consequences of willful failure to obey a court order under these circumstances includes having the refusal disclosed in trial or permitting the court to issue an order determining paternity without genetic testing. ORCA 3111.09 Most DNA identification tests are currently done to determine paternity; more than 100,000 a year for paternity and less than 10,000 for use in a criminal proceeding. Bishop JE, How DNA Scientists Help Track Criminals and Clear the Innocent, *Wall St. J.*, Jan. 6, 1995, p.1.

[36] Lewis, Under a Genetic Cloud, *Boston Globe*, August 14, 1994, p.A1. The named plaintiff, Le Ann Severson, filed suit in Santa Clara against KTI Chemicals, Inc.

[37] The Common Rule, based on the regulations of the Department of Health and Human Services (*see* 45 CFR Part 46) has been adopted in whole or as modified by individual departments and agencies. For a particular agency's version, *see* 56 *Fed. Reg.* 28019-28031 (1991).

[38] This requirement coincides with the recommendations of the NIH Office for Protection from Research Risks that IRB make sure adequate counseling is provided to pedigree research participants on the meaning of the genetic information they receive so as to minimize the psychological risks of participation. National Institute of Health, *Protecting Human Research Subjects, Institutional Review Board Guidebook*, Washington, D.C.: U.S. Gov. Printing Office, 1993, pp. 5-54.

[39] Revelation during the authorization process that such information may result from participation is also recommended by OPRR. *Id.*

[40] Examples include the Uniform Health Care Information Act 52-104(a)(7), and H.R. 4077, 128 *supra* note 17. These acts contain similar provisions for access for research use to patient information without the authorization of patients if an IRB has determined that the project's importance outweighs the intrusion into the patient's privacy, and that it would be impracticable to conduct the project without such information. Although 42 U.S.C. 290dd-2(b)(2) is less restrictive and permits disclosures of information regarding substance abuse treatment without patient authorization to "qualified personnel for purposes of conducting research", regulations under the same statute require that an independent panel of three persons determine the welfare of the patients will be adequately protected and that the risks in disclosure of alcohol and substance abuse treatment information are outweighed by the benefits of the research. 42 CFR 2.51 (1993). None of these models is more specific in regard to what factors must be considered by the reviewer in conducting such balancing tests.

[41] H.R. Rep. No. 601, *supra* note 19, 124-125.

[42] Courts have held that an administrator of an estate can waive the attorney client privilege on behalf of the deceased in some instances. In the Matter of John Doe Grand Jury Investigation, 562 N.E.2d (Mass. 1990) Statutes can also vest authority in a decedent's personal representative to exercise the decisional right to waive psychiatrist-patient privilege. *See*, for example, Mont. Code Ann. 50-16-222 (1993) granting such authority in the personal representative, or if none available, in a surviving spouse, parent or adult child.

[43] *Assessing Genetic Risks, supra* note 7, at 10.

[44] Bloch M & Hayden MR, "Opinion: Predictive Testing for Huntington Disease in Childhood: Challenges and

Implications," 46 Am. J. Hum. Genet. 1-4 (1990).

[45] *Pierce v. Society of Sisters*, 268 U.S. 510 (1925).

[46] *Wisconsin v. Yoder*, 406 U.S. 205 (1972).

[47] *See, e.g.*, Mass. Gen. Laws Ch. 112 12F.

[48] *Planned Parenthood v. Danforth*, 428 U.S. 52 (1976); *Bellotti v. Baird*, 443 U.S. 622 (1979).

[49] *Carey v. Population Services International*, 431 U.S. 678 (1977).

[50] Ramsey P, "Children in Medical Investigation" in *The Patient as Person*, New Haven, Conn., Yale University Press, 1970, pp.11-17; and Ramsey P, "Children as Research Subjects: A Reply," 7(2) *Hastings Center Report* 40 (April, 1977).

[51] Bloch & Hayden, *supra* note 37 at 1-3. The authors acknowledge that most parents who request such tests are seeking a way to allay their own anxieties about the child's future. However, they caution that the results could have negative impact on the child's upbringing and relationship to siblings with a different risk. They recommend that predictive testing in childhood only be done when an advantage can be clearly demonstrated for the child.

[52] *See, e.g.*, Me. Rev. Stat., tit.22, 1597-A4, requiring that the physician or counselor who provides information to the pregnant minor explore with her whether or not involvement of a parent, guardian or adult family member in the decision making process would be in her best interests.

[53] *See, e.g.*, *Strunk v. Strunk*, 445 S.W.2d 145 (Ky. 1969) in which the court exercised its equitable power to permit transplantation of a kidney from an incompetent man to his brother who was dying.

[54] *Id.* *See also*, *Curran v. Bosze*, 566 N.E.2d 1319 (Ill. 1990). Although the principal issue in this case was whether or not it was in a child's best interests for a parent to withhold consent for a donation to a half-sibling, the court specifically held that a parent could consent to such donation only when it would be in the minor's best interests. *Id.* at 1331.

[55] In *In re Richardson*, 284 So. 2d 185, 188 (La. App. 1973) the court concluded that before application of the best interests standard was considered to determine if consent could be given for transplantation of a kidney from a brother to a sister, it must first be established that the surgical intrusion was urgent, there were no reasonable alternatives, and that the contingencies were minimal.

[56] S. 1735, 103d Cong., 1st Sess. (1993), The Privacy Protection Act of 1993 was introduced by Sen. Paul Simon to establish a Privacy Protection Commission. Like previous proposals, although granting investigative powers to the Commission, this bill contained no similar grant of enforcement powers to the Commission itself but charged it with reporting violations of the Privacy Act for which criminal but not civil penalties are available, to the president, Attorney General and Congress. It also leaves activities of the private sector outside the Commission's jurisdiction.

[57] Rotenberg M, "In Support of a Data Protection Board in the United States," 8 *Gov. Info. Q.* 79, 88 (1991).

[58] *See, e.g.*, Iowa Code Ann. 729.6 (1992) (prohibiting employers from requiring or administering genetic tests as a condition of employment); Wis. Stat. Ann. 631.89 (1994) (restricting the use of genetic tests and results of such tests by insurers), Cal. Ins. Code 10146 (1994) (establishing standards for underwriting life and disability insurance on the basis of tests for genetic characteristics) and Cal. Health & Safety Code 1374.7 (1994) (prohibiting health insurance plans from rejecting applicants, or setting higher rates for applicants, on the basis of genetic characteristics).

[59] For instance, in regard to genetic testing that is permissible by life and disability insurers, California requires that written informed consent for such test include, in addition to information that would also be required by this Act, the limitations of the test and procedures for notifying the applicant of the results. Cal. Ins. Code 10148 (1994).

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