

GENETIC INFORMATION NONDISCRIMINATION ACT OF  
2007

MARCH 5, 2007.—Ordered to be printed

Mr. GEORGE MILLER of California, from the Committee on  
Education and Labor, submitted the following

R E P O R T

together with

MINORITY VIEWS

[To accompany H.R. 493]

[Including cost estimate of the Congressional Budget Office]

The Committee on Education and Labor, to whom was referred the bill (H.R. 493) to prohibit discrimination on the basis of genetic information with respect to health insurance and employment, having considered the same, report favorably thereon with an amendment and recommend that the bill as amended do pass.

The amendment is as follows:

Strike all after the enacting clause and insert the following:

**SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

(a) **SHORT TITLE.**—This Act may be cited as the “Genetic Information Non-discrimination Act of 2007”.

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

Sec. 1. Short title; table of contents.  
Sec. 2. Findings.

**TITLE I—GENETIC NONDISCRIMINATION IN HEALTH INSURANCE**

Sec. 101. Amendments to Employee Retirement Income Security Act of 1974.  
Sec. 102. Amendments to the Public Health Service Act.  
Sec. 103. Amendments to title XVIII of the Social Security Act relating to medigap.  
Sec. 104. Privacy and confidentiality.  
Sec. 105. Assuring coordination.  
Sec. 106. Regulations; effective date.

**TITLE II—PROHIBITING EMPLOYMENT DISCRIMINATION ON THE BASIS OF GENETIC INFORMATION**

Sec. 201. Definitions.  
Sec. 202. Employer practices.  
Sec. 203. Employment agency practices.  
Sec. 204. Labor organization practices.  
Sec. 205. Training programs.  
Sec. 206. Confidentiality of genetic information.

Sec. 207. Remedies and enforcement.  
 Sec. 208. Disparate impact.  
 Sec. 209. Construction.  
 Sec. 210. Medical information that is not genetic information.  
 Sec. 211. Regulations.  
 Sec. 212. Authorization of appropriations.  
 Sec. 213. Effective date.

TITLE III—MISCELLANEOUS PROVISION

Sec. 301. Severability.

**SEC. 2. FINDINGS.**

Congress makes the following findings:

(1) Deciphering the sequence of the human genome and other advances in genetics open major new opportunities for medical progress. New knowledge about the genetic basis of illness will allow for earlier detection of illnesses, often before symptoms have begun. Genetic testing can allow individuals to take steps to reduce the likelihood that they will contract a particular disorder. New knowledge about genetics may allow for the development of better therapies that are more effective against disease or have fewer side effects than current treatments. These advances give rise to the potential misuse of genetic information to discriminate in health insurance and employment.

(2) The early science of genetics became the basis of State laws that provided for the sterilization of persons having presumed genetic “defects” such as mental retardation, mental disease, epilepsy, blindness, and hearing loss, among other conditions. The first sterilization law was enacted in the State of Indiana in 1907. By 1981, a majority of States adopted sterilization laws to “correct” apparent genetic traits or tendencies. Many of these State laws have since been repealed, and many have been modified to include essential constitutional requirements of due process and equal protection. However, the current explosion in the science of genetics, and the history of sterilization laws by the States based on early genetic science, compels Congressional action in this area.

(3) Although genes are facially neutral markers, many genetic conditions and disorders are associated with particular racial and ethnic groups and gender. Because some genetic traits are most prevalent in particular groups, members of a particular group may be stigmatized or discriminated against as a result of that genetic information. This form of discrimination was evident in the 1970s, which saw the advent of programs to screen and identify carriers of sickle cell anemia, a disease which afflicts African-Americans. Once again, State legislatures began to enact discriminatory laws in the area, and in the early 1970s began mandating genetic screening of all African Americans for sickle cell anemia, leading to discrimination and unnecessary fear. To alleviate some of this stigma, Congress in 1972 passed the National Sickle Cell Anemia Control Act, which withholds Federal funding from States unless sickle cell testing is voluntary.

(4) Congress has been informed of examples of genetic discrimination in the workplace. These include the use of pre-employment genetic screening at Lawrence Berkeley Laboratory, which led to a court decision in favor of the employees in that case *Norman-Bloodsaw v. Lawrence Berkeley Laboratory* (135 F.3d 1260, 1269 (9th Cir. 1998)). Congress clearly has a compelling public interest in relieving the fear of discrimination and in prohibiting its actual practice in employment and health insurance.

(5) Federal law addressing genetic discrimination in health insurance and employment is incomplete in both the scope and depth of its protections. Moreover, while many States have enacted some type of genetic non-discrimination law, these laws vary widely with respect to their approach, application, and level of protection. Congress has collected substantial evidence that the American public and the medical community find the existing patchwork of State and Federal laws to be confusing and inadequate to protect them from discrimination. Therefore Federal legislation establishing a national and uniform basic standard is necessary to fully protect the public from discrimination and allay their concerns about the potential for discrimination, thereby allowing individuals to take advantage of genetic testing, technologies, research, and new therapies.

**TITLE I—GENETIC NONDISCRIMINATION IN  
HEALTH INSURANCE**

**SEC. 101. AMENDMENTS TO EMPLOYEE RETIREMENT INCOME SECURITY ACT OF 1974.**

(a) PROHIBITION OF HEALTH DISCRIMINATION ON THE BASIS OF GENETIC INFORMATION OR GENETIC SERVICES.—

(1) NO ENROLLMENT RESTRICTION FOR GENETIC SERVICES.—Section 702(a)(1)(F) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1182(a)(1)(F)) is amended by inserting before the period the following: “(including information about a request for or receipt of genetic services by an individual or family member of such individual)”.

(2) NO DISCRIMINATION IN GROUP PREMIUMS BASED ON GENETIC INFORMATION.—Section 702(b) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1182(b)) is amended—

(A) in paragraph (2)(A), by inserting before the semicolon the following: “except as provided in paragraph (3)”;

and

(B) by adding at the end the following:

“(3) NO DISCRIMINATION IN GROUP PREMIUMS BASED ON GENETIC INFORMATION.—For purposes of this section, a group health plan, or a health insurance issuer offering group health insurance coverage in connection with a group health plan, shall not adjust premium or contribution amounts for a group on the basis of genetic information concerning an individual in the group or a family member of the individual (including information about a request for or receipt of genetic services by an individual or family member of such individual).”.

(b) LIMITATIONS ON GENETIC TESTING.—Section 702 of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1182) is amended by adding at the end the following:

“(c) GENETIC TESTING.—

“(1) LIMITATION ON REQUESTING OR REQUIRING GENETIC TESTING.—A group health plan, or a health insurance issuer offering health insurance coverage in connection with a group health plan, shall not request or require an individual or a family member of such individual to undergo a genetic test.

“(2) RULE OF CONSTRUCTION.—Nothing in this part shall be construed to—

“(A) limit the authority of a health care professional who is providing health care services with respect to an individual to request that such individual or a family member of such individual undergo a genetic test;

“(B) limit the authority of a health care professional who is employed by or affiliated with a group health plan or a health insurance issuer and who is providing health care services to an individual as part of a bona fide wellness program to notify such individual of the availability of a genetic test or to provide information to such individual regarding such genetic test; or

“(C) authorize or permit a health care professional to require that an individual undergo a genetic test.

“(d) APPLICATION TO ALL PLANS.—The provisions of subsections (a)(1)(F), (b)(3), and (c) shall apply to group health plans and health insurance issuers without regard to section 732(a).

“(e) GENETIC INFORMATION OF A FETUS.—Any reference in this section to genetic information concerning an individual or family member of an individual shall, with respect to such an individual or family member of an individual who is a pregnant woman, include genetic information of any fetus carried by such pregnant woman.”.

(c) DEFINITIONS.—Section 733(d) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1191b(d)) is amended by adding at the end the following:

“(5) FAMILY MEMBER.—The term ‘family member’ means with respect to an individual—

“(A) the spouse of the individual;

“(B) a dependent child of the individual; and

“(C) any other individual who is a first-degree, second-degree, third-degree, or fourth-degree relative of an individual described in subparagraph (A) or (B).

“(6) GENETIC INFORMATION.—

“(A) IN GENERAL.—Except as provided in subparagraph (B), the term ‘genetic information’ means information about—

“(i) an individual’s genetic tests;

“(ii) the genetic tests of family members of the individual; or

“(iii) the occurrence of a disease or disorder in family members of the individual.

“(B) EXCLUSIONS.—The term ‘genetic information’ shall not include information about the sex or age of an individual.

“(7) GENETIC TEST.—

“(A) IN GENERAL.—The term ‘genetic test’ means an analysis of human DNA, RNA, chromosomes, proteins, or metabolites, that detects genotypes, mutations, or chromosomal changes.

“(B) EXCEPTIONS.—The term ‘genetic test’ does not mean—

- “(i) an analysis of proteins or metabolites that does not detect genotypes, mutations, or chromosomal changes; or  
 “(ii) an analysis of proteins or metabolites that is directly related to a manifested disease, disorder, or pathological condition that could reasonably be detected by a health care professional with appropriate training and expertise in the field of medicine involved.
- “(8) GENETIC SERVICES.—The term ‘genetic services’ means—  
 “(A) a genetic test;  
 “(B) genetic counseling (including obtaining, interpreting, or assessing genetic information); or  
 “(C) genetic education.”.
- (d) ERISA ENFORCEMENT.—Section 502 of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1132) is amended—  
 (1) in subsection (a)(6), by striking “(7), or (8)” and inserting “(7), (8), or (9)”;  
 and  
 (2) in subsection (c), by redesignating paragraph (9) as paragraph (10), and by inserting after paragraph (8) the following new paragraph:  
 “(9) SECRETARIAL ENFORCEMENT AUTHORITY RELATING TO USE OF GENETIC INFORMATION.—  
 “(A) GENERAL RULE.—The Secretary may impose a penalty against any plan sponsor of a group health plan, or any health insurance issuer offering health insurance coverage in connection with the plan, for any failure by such sponsor or issuer to meet the requirements of subsection (a)(1)(F), (b)(3), or (c) of section 702 or of section 714 in connection with the plan.  
 “(B) AMOUNT.—  
 “(i) IN GENERAL.—The amount of the penalty imposed by subparagraph (A) shall be \$100 for each day in the noncompliance period with respect to each participant or beneficiary to whom such failure relates.  
 “(ii) NONCOMPLIANCE PERIOD.—For purposes of this paragraph, the term ‘noncompliance period’ means, with respect to any failure, the period—  
 “(I) beginning on the date such failure first occurs; and  
 “(II) ending on the date such failure is corrected.  
 “(C) MINIMUM PENALTIES WHERE FAILURE DISCOVERED.—Notwithstanding clauses (i) and (ii) of subparagraph (D):  
 “(i) IN GENERAL.—In the case of 1 or more failures with respect to a participant or beneficiary—  
 “(I) which are not corrected before the date on which the plan receives a notice from the Secretary of such violation; and  
 “(II) which occurred or continued during the period involved;  
 the amount of penalty imposed by subparagraph (A) by reason of such failures with respect to such participant or beneficiary shall not be less than \$2,500.  
 “(ii) HIGHER MINIMUM PENALTY WHERE VIOLATIONS ARE MORE THAN DE MINIMIS.—To the extent violations for which any person is liable under this paragraph for any year are more than de minimis, clause (i) shall be applied by substituting ‘\$15,000’ for ‘\$2,500’ with respect to such person.  
 “(D) LIMITATIONS.—  
 “(i) PENALTY NOT TO APPLY WHERE FAILURE NOT DISCOVERED EXERCISING REASONABLE DILIGENCE.—No penalty shall be imposed by subparagraph (A) on any failure during any period for which it is established to the satisfaction of the Secretary that the person otherwise liable for such penalty did not know, and exercising reasonable diligence would not have known, that such failure existed.  
 “(ii) PENALTY NOT TO APPLY TO FAILURES CORRECTED WITHIN CERTAIN PERIODS.—No penalty shall be imposed by subparagraph (A) on any failure if—  
 “(I) such failure was due to reasonable cause and not to willful neglect; and  
 “(II) such failure is corrected during the 30-day period beginning on the first date the person otherwise liable for such penalty knew, or exercising reasonable diligence would have known, that such failure existed.  
 “(iii) OVERALL LIMITATION FOR UNINTENTIONAL FAILURES.—In the case of failures which are due to reasonable cause and not to willful neglect, the penalty imposed by subparagraph (A) for failures shall not exceed the amount equal to the lesser of—

“(I) 10 percent of the aggregate amount paid or incurred by the plan sponsor (or predecessor plan sponsor) during the preceding taxable year for group health plans; or

“(II) \$500,000.

“(E) WAIVER BY SECRETARY.—In the case of a failure which is due to reasonable cause and not to willful neglect, the Secretary may waive part or all of the penalty imposed by subparagraph (A) to the extent that the payment of such penalty would be excessive relative to the failure involved.

“(F) DEFINITIONS.—Terms used in this paragraph which are defined in section 733 shall have the meanings provided such terms in such section.”.

(e) REGULATIONS AND EFFECTIVE DATE.—

(1) REGULATIONS.—The Secretary of Labor shall issue final regulations not later than 1 year after the date of enactment of this Act to carry out the amendments made by this section.

(2) EFFECTIVE DATE.—The amendments made by this section shall apply with respect to group health plans for plan years beginning after the date that is 18 months after the date of enactment of this title.

#### SEC. 102. AMENDMENTS TO THE PUBLIC HEALTH SERVICE ACT.

(a) AMENDMENTS RELATING TO THE GROUP MARKET.—

(1) PROHIBITION OF HEALTH DISCRIMINATION ON THE BASIS OF GENETIC INFORMATION OR GENETIC SERVICES.—

(A) NO ENROLLMENT RESTRICTION FOR GENETIC SERVICES.—Section 2702(a)(1)(F) of the Public Health Service Act (42 U.S.C. 300gg–1(a)(1)(F)) is amended by inserting before the period the following: “(including information about a request for or receipt of genetic services by an individual or family member of such individual)”.

(B) NO DISCRIMINATION IN GROUP PREMIUMS BASED ON GENETIC INFORMATION.—Section 2702(b) of the Public Health Service Act (42 U.S.C. 300gg–1(b)) is amended—

(i) in paragraph (2)(A), by inserting before the semicolon the following: “, except as provided in paragraph (3)”; and

(ii) by adding at the end the following:

“(3) NO DISCRIMINATION IN GROUP PREMIUMS BASED ON GENETIC INFORMATION.—For purposes of this section, a group health plan, or a health insurance issuer offering group health insurance coverage in connection with a group health plan, shall not adjust premium or contribution amounts for a group on the basis of genetic information concerning an individual in the group or a family member of the individual (including information about a request for or receipt of genetic services by an individual or family member of such individual)”.

(2) LIMITATIONS ON GENETIC TESTING.—Section 2702 of the Public Health Service Act (42 U.S.C. 300gg–1) is amended by adding at the end the following:

“(c) GENETIC TESTING.—

(1) LIMITATION ON REQUESTING OR REQUIRING GENETIC TESTING.—A group health plan, or a health insurance issuer offering health insurance coverage in connection with a group health plan, shall not request or require an individual or a family member of such individual to undergo a genetic test.

(2) RULE OF CONSTRUCTION.—Nothing in this part shall be construed to—

“(A) limit the authority of a health care professional who is providing health care services with respect to an individual to request that such individual or a family member of such individual undergo a genetic test;

“(B) limit the authority of a health care professional who is employed by or affiliated with a group health plan or a health insurance issuer and who is providing health care services to an individual as part of a bona fide wellness program to notify such individual of the availability of a genetic test or to provide information to such individual regarding such genetic test; or

“(C) authorize or permit a health care professional to require that an individual undergo a genetic test.

“(d) APPLICATION TO ALL PLANS.—The provisions of subsections (a)(1)(F), (b)(3), and (c) shall apply to group health plans and health insurance issuers without regard to section 2721(a).”.

(3) REMEDIES AND ENFORCEMENT.—Section 2722(b) of the Public Health Service Act (42 U.S.C. 300gg–22(b)) is amended by adding at the end the following:

“(3) ENFORCEMENT AUTHORITY RELATING TO GENETIC DISCRIMINATION.—

“(A) GENERAL RULE.—In the cases described in paragraph (1), notwithstanding the provisions of paragraph (2)(C), the following provisions shall apply with respect to an action under this subsection by the Secretary with respect to any failure of a health insurance issuer in connection with a

group health plan, to meet the requirements of subsection (a)(1)(F), (b)(3), or (c) of section 2702.

“(B) AMOUNT.—

“(i) IN GENERAL.—The amount of the penalty imposed under this paragraph shall be \$100 for each day in the noncompliance period with respect to each individual to whom such failure relates.

“(ii) NONCOMPLIANCE PERIOD.—For purposes of this paragraph, the term ‘noncompliance period’ means, with respect to any failure, the period—

“(I) beginning on the date such failure first occurs; and

“(II) ending on the date such failure is corrected.

“(C) MINIMUM PENALTIES WHERE FAILURE DISCOVERED.—Notwithstanding clauses (i) and (ii) of subparagraph (D):

“(i) IN GENERAL.—In the case of 1 or more failures with respect to an individual—

“(I) which are not corrected before the date on which the plan receives a notice from the Secretary of such violation; and

“(II) which occurred or continued during the period involved;

the amount of penalty imposed by subparagraph (A) by reason of such failures with respect to such individual shall not be less than \$2,500.

“(ii) HIGHER MINIMUM PENALTY WHERE VIOLATIONS ARE MORE THAN DE MINIMIS.—To the extent violations for which any person is liable under this paragraph for any year are more than de minimis, clause (i) shall be applied by substituting ‘\$15,000’ for ‘\$2,500’ with respect to such person.

“(D) LIMITATIONS.—

“(i) PENALTY NOT TO APPLY WHERE FAILURE NOT DISCOVERED EXERCISING REASONABLE DILIGENCE.—No penalty shall be imposed by subparagraph (A) on any failure during any period for which it is established to the satisfaction of the Secretary that the person otherwise liable for such penalty did not know, and exercising reasonable diligence would not have known, that such failure existed.

“(ii) PENALTY NOT TO APPLY TO FAILURES CORRECTED WITHIN CERTAIN PERIODS.—No penalty shall be imposed by subparagraph (A) on any failure if—

“(I) such failure was due to reasonable cause and not to willful neglect; and

“(II) such failure is corrected during the 30-day period beginning on the first date the person otherwise liable for such penalty knew, or exercising reasonable diligence would have known, that such failure existed.

“(iii) OVERALL LIMITATION FOR UNINTENTIONAL FAILURES.—In the case of failures which are due to reasonable cause and not to willful neglect, the penalty imposed by subparagraph (A) for failures shall not exceed the amount equal to the lesser of—

“(I) 10 percent of the aggregate amount paid or incurred by the employer (or predecessor employer) during the preceding taxable year for group health plans; or

“(II) \$500,000.

“(E) WAIVER BY SECRETARY.—In the case of a failure which is due to reasonable cause and not to willful neglect, the Secretary may waive part or all of the penalty imposed by subparagraph (A) to the extent that the payment of such penalty would be excessive relative to the failure involved.”.

(4) DEFINITIONS.—Section 2791(d) of the Public Health Service Act (42 U.S.C. 300gg–91(d)) is amended by adding at the end the following:

“(15) FAMILY MEMBER.—The term ‘family member’ means with respect to an individual—

“(A) the spouse of the individual;

“(B) a dependent child of the individual, including a child who is born to or placed for adoption with the individual; and

“(C) all other individuals related by blood to the individual or the spouse or child described in subparagraph (A) or (B).

“(16) GENETIC INFORMATION.—

“(A) IN GENERAL.—Except as provided in subparagraph (B), the term ‘genetic information’ means information about—

“(i) an individual’s genetic tests;

“(ii) the genetic tests of family members of the individual; or

“(iii) the occurrence of a disease or disorder in family members of the individual.

“(B) EXCLUSIONS.—The term ‘genetic information’ shall not include information about the sex or age of an individual.

“(17) GENETIC TEST.—

“(A) IN GENERAL.—The term ‘genetic test’ means an analysis of human DNA, RNA, chromosomes, proteins, or metabolites, that detects genotypes, mutations, or chromosomal changes.

“(B) EXCEPTIONS.—The term ‘genetic test’ does not mean—

“(i) an analysis of proteins or metabolites that does not detect genotypes, mutations, or chromosomal changes; or

“(ii) an analysis of proteins or metabolites that is directly related to a manifested disease, disorder, or pathological condition that could reasonably be detected by a health care professional with appropriate training and expertise in the field of medicine involved.

“(18) GENETIC SERVICES.—The term ‘genetic services’ means—

“(A) a genetic test;

“(B) genetic counseling (such as obtaining, interpreting, or assessing genetic information); or

“(C) genetic education.”

(b) AMENDMENT RELATING TO THE INDIVIDUAL MARKET.—

(1) IN GENERAL.—The first subpart 3 of part B of title XXVII of the Public Health Service Act (42 U.S.C. 300gg–51 et seq.) (relating to other requirements) is amended—

(A) by redesignating such subpart as subpart 2; and

(B) by adding at the end the following:

**“SEC. 2753. PROHIBITION OF HEALTH DISCRIMINATION ON THE BASIS OF GENETIC INFORMATION.**

“(a) PROHIBITION ON GENETIC INFORMATION AS A CONDITION OF ELIGIBILITY.—A health insurance issuer offering health insurance coverage in the individual market may not establish rules for the eligibility (including continued eligibility) of any individual to enroll in individual health insurance coverage based on genetic information (including information about a request for or receipt of genetic services by an individual or family member of such individual).

“(b) PROHIBITION ON GENETIC INFORMATION IN SETTING PREMIUM RATES.—A health insurance issuer offering health insurance coverage in the individual market shall not adjust premium or contribution amounts for an individual on the basis of genetic information concerning the individual or a family member of the individual (including information about a request for or receipt of genetic services by an individual or family member of such individual).

“(c) GENETIC TESTING.—

“(1) LIMITATION ON REQUESTING OR REQUIRING GENETIC TESTING.—A health insurance issuer offering health insurance coverage in the individual market shall not request or require an individual or a family member of such individual to undergo a genetic test.

“(2) RULE OF CONSTRUCTION.—Nothing in this part shall be construed to—

“(A) limit the authority of a health care professional who is providing health care services with respect to an individual to request that such individual or a family member of such individual undergo a genetic test;

“(B) limit the authority of a health care professional who is employed by or affiliated with a health insurance issuer and who is providing health care services to an individual as part of a bona fide wellness program to notify such individual of the availability of a genetic test or to provide information to such individual regarding such genetic test; or

“(C) authorize or permit a health care professional to require that an individual undergo a genetic test.”

(2) REMEDIES AND ENFORCEMENT.—Section 2761(b) of the Public Health Service Act (42 U.S.C. 300gg–61(b)) is amended to read as follows:

“(b) SECRETARIAL ENFORCEMENT AUTHORITY.—The Secretary shall have the same authority in relation to enforcement of the provisions of this part with respect to issuers of health insurance coverage in the individual market in a State as the Secretary has under section 2722(b)(2), and section 2722(b)(3) with respect to violations of genetic nondiscrimination provisions, in relation to the enforcement of the provisions of part A with respect to issuers of health insurance coverage in the small group market in the State.”

(c) ELIMINATION OF OPTION OF NON-FEDERAL GOVERNMENTAL PLANS TO BE EXCEPTED FROM REQUIREMENTS CONCERNING GENETIC INFORMATION.—Section 2721(b)(2) of the Public Health Service Act (42 U.S.C. 300gg–21(b)(2)) is amended—

(1) in subparagraph (A), by striking “If the plan sponsor” and inserting “Except as provided in subparagraph (D), if the plan sponsor”; and

(2) by adding at the end the following:

“(D) ELECTION NOT APPLICABLE TO REQUIREMENTS CONCERNING GENETIC INFORMATION.—The election described in subparagraph (A) shall not be available with respect to the provisions of subsections (a)(1)(F) and (c) of section 2702 and the provisions of section 2702(b) to the extent that such provisions apply to genetic information (or information about a request for or the receipt of genetic services by an individual or a family member of such individual).”.

(d) REGULATIONS AND EFFECTIVE DATE.—

(1) REGULATIONS.—Not later than 1 year after the date of enactment of this title, the Secretary of Health and Human Services shall issue final regulations to carry out the amendments made by this section.

(2) EFFECTIVE DATE.—The amendments made by this section shall apply—

(A) with respect to group health plans, and health insurance coverage offered in connection with group health plans, for plan years beginning after the date that is 18 months after the date of enactment of this title; and

(B) with respect to health insurance coverage offered, sold, issued, renewed, in effect, or operated in the individual market after the date that is 18 months after the date of enactment of this title.

**SEC. 103. AMENDMENTS TO TITLE XVIII OF THE SOCIAL SECURITY ACT RELATING TO MEDIGAP.**

(a) NONDISCRIMINATION.—

(1) IN GENERAL.—Section 1882(s)(2) of the Social Security Act (42 U.S.C. 1395ss(s)(2)) is amended by adding at the end the following:

“(E)(i) An issuer of a medicare supplemental policy shall not deny or condition the issuance or effectiveness of the policy, and shall not discriminate in the pricing of the policy (including the adjustment of premium rates) of an eligible individual on the basis of genetic information concerning the individual (or information about a request for, or the receipt of, genetic services by such individual or family member of such individual).

“(ii) For purposes of clause (i), the terms ‘family member’, ‘genetic services’, and ‘genetic information’ shall have the meanings given such terms in subsection (x).”.

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall apply with respect to a policy for policy years beginning after the date that is 18 months after the date of enactment of this Act.

(b) LIMITATIONS ON GENETIC TESTING.—

(1) IN GENERAL.—Section 1882 of the Social Security Act (42 U.S.C. 1395ss) is amended by adding at the end the following:

“(x) LIMITATIONS ON GENETIC TESTING.—

“(1) GENETIC TESTING.—

“(A) LIMITATION ON REQUESTING OR REQUIRING GENETIC TESTING.—An issuer of a medicare supplemental policy shall not request or require an individual or a family member of such individual to undergo a genetic test.

“(B) RULE OF CONSTRUCTION.—Nothing in this title shall be construed to—

“(i) limit the authority of a health care professional who is providing health care services with respect to an individual to request that such individual or a family member of such individual undergo a genetic test;

“(ii) limit the authority of a health care professional who is employed by or affiliated with an issuer of a medicare supplemental policy and who is providing health care services to an individual as part of a bona fide wellness program to notify such individual of the availability of a genetic test or to provide information to such individual regarding such genetic test; or

“(iii) authorize or permit a health care professional to require that an individual undergo a genetic test.

“(2) DEFINITIONS.—In this subsection:

“(A) FAMILY MEMBER.—The term ‘family member’ means with respect to an individual—

“(i) the spouse of the individual;

“(ii) a dependent child of the individual, including a child who is born to or placed for adoption with the individual; or

“(iii) any other individuals related by blood to the individual or to the spouse or child described in clause (i) or (ii).

“(B) GENETIC INFORMATION.—

“(i) IN GENERAL.—Except as provided in clause (ii), the term ‘genetic information’ means information about—

“(I) an individual’s genetic tests;

“(II) the genetic tests of family members of the individual; or  
 “(III) the occurrence of a disease or disorder in family members  
 of the individual.

“(ii) EXCLUSIONS.—The term ‘genetic information’ shall not include  
 information about the sex or age of an individual.

“(C) GENETIC TEST.—

“(i) IN GENERAL.—The term ‘genetic test’ means an analysis of human  
 DNA, RNA, chromosomes, proteins, or metabolites, that detects  
 genotypes, mutations, or chromosomal changes.

“(ii) EXCEPTIONS.—The term ‘genetic test’ does not mean—

“(I) an analysis of proteins or metabolites that does not detect  
 genotypes, mutations, or chromosomal changes; or

“(II) an analysis of proteins or metabolites that is directly related  
 to a manifested disease, disorder, or pathological condition that  
 could reasonably be detected by a health care professional with ap-  
 propriate training and expertise in the field of medicine involved.

“(D) GENETIC SERVICES.—The term ‘genetic services’ means—

“(i) a genetic test;

“(ii) genetic counseling (such as obtaining, interpreting, or assessing  
 genetic information); or

“(iii) genetic education.

“(E) ISSUER OF A MEDICARE SUPPLEMENTAL POLICY.—The term ‘issuer of  
 a medicare supplemental policy’ includes a third-party administrator or  
 other person acting for or on behalf of such issuer.”

(2) CONFORMING AMENDMENT.—Section 1882(o) of the Social Security Act (42  
 U.S.C. 1395ss(o)) is amended by adding at the end the following:

“(4) The issuer of the medicare supplemental policy complies with subsection  
 (s)(2)(E) and subsection (x).”.

(3) EFFECTIVE DATE.—The amendments made by this subsection shall apply  
 with respect to an issuer of a medicare supplemental policy for policy years be-  
 ginning on or after the date that is 18 months after the date of enactment of  
 this Act.

(c) TRANSITION PROVISIONS.—

(1) IN GENERAL.—If the Secretary of Health and Human Services identifies a  
 State as requiring a change to its statutes or regulations to conform its regu-  
 latory program to the changes made by this section, the State regulatory pro-  
 gram shall not be considered to be out of compliance with the requirements of  
 section 1882 of the Social Security Act due solely to failure to make such change  
 until the date specified in paragraph (4).

(2) NAIC STANDARDS.—If, not later than June 30, 2008, the National Associa-  
 tion of Insurance Commissioners (in this subsection referred to as the “NAIC”)  
 modifies its NAIC Model Regulation relating to section 1882 of the Social Secu-  
 rity Act (referred to in such section as the 1991 NAIC Model Regulation, as sub-  
 sequently modified) to conform to the amendments made by this section, such  
 revised regulation incorporating the modifications shall be considered to be the  
 applicable NAIC model regulation (including the revised NAIC model regulation  
 and the 1991 NAIC Model Regulation) for the purposes of such section.

(3) SECRETARY STANDARDS.—If the NAIC does not make the modifications de-  
 scribed in paragraph (2) within the period specified in such paragraph, the Sec-  
 retary of Health and Human Services shall, not later than October 1, 2008,  
 make the modifications described in such paragraph and such revised regula-  
 tion incorporating the modifications shall be considered to be the appropriate  
 regulation for the purposes of such section.

(4) DATE SPECIFIED.—

(A) IN GENERAL.—Subject to subparagraph (B), the date specified in this  
 paragraph for a State is the earlier of—

(i) the date the State changes its statutes or regulations to conform  
 its regulatory program to the changes made by this section, or  
 (ii) October 1, 2008.

(B) ADDITIONAL LEGISLATIVE ACTION REQUIRED.—In the case of a State  
 which the Secretary identifies as—

(i) requiring State legislation (other than legislation appropriating  
 funds) to conform its regulatory program to the changes made in this  
 section, but

(ii) having a legislature which is not scheduled to meet in 2008 in  
 a legislative session in which such legislation may be considered, the  
 date specified in this paragraph is the first day of the first calendar  
 quarter beginning after the close of the first legislative session of the  
 State legislature that begins on or after July 1, 2008. For purposes of

the previous sentence, in the case of a State that has a 2-year legislative session, each year of such session shall be deemed to be a separate regular session of the State legislature.

**SEC. 104. PRIVACY AND CONFIDENTIALITY.**

(a) RULES FOR PUBLIC HEALTH SERVICE ACT AND INTERNAL REVENUE CODE OF 1986.—

(1) APPLICABILITY.—Except as provided in paragraph (4), the provisions of this subsection shall apply to group health plans (other than group health plans to which section 714 of the Employee Retirement Income Security Act of 1974 applies), health insurance issuers (including issuers in connection with group health plans or individual health coverage), and issuers of medicare supplemental policies, without regard to—

(A) section 2721(a) of the Public Health Service Act (42 U.S.C. 300gg-21(a)); and

(B) section 9831(a)(2) of the Internal Revenue Code of 1986.

(2) COMPLIANCE WITH CERTAIN CONFIDENTIALITY STANDARDS WITH RESPECT TO GENETIC INFORMATION.—

(A) IN GENERAL.—The regulations promulgated by the Secretary of Health and Human Services under part C of title XI of the Social Security Act (42 U.S.C. 1320d et seq.) and section 264 of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d-2 note) shall apply to the use or disclosure of genetic information.

(B) PROHIBITION ON UNDERWRITING AND PREMIUM RATING.—Notwithstanding subparagraph (A), a group health plan, a health insurance issuer, or issuer of a medicare supplemental policy shall not use or disclose genetic information (including information about a request for or a receipt of genetic services by an individual or family member of such individual) for purposes of underwriting, determinations of eligibility to enroll, premium rating, or the creation, renewal or replacement of a plan, contract or coverage for health insurance or health benefits.

(3) PROHIBITION ON COLLECTION OF GENETIC INFORMATION.—

(A) IN GENERAL.—A group health plan, health insurance issuer, or issuer of a medicare supplemental policy shall not request, require, or purchase genetic information (including information about a request for or a receipt of genetic services by an individual or family member of such individual) for purposes of underwriting, determinations of eligibility to enroll, premium rating, or the creation, renewal or replacement of a plan, contract or coverage for health insurance or health benefits.

(B) LIMITATION RELATING TO THE COLLECTION OF GENETIC INFORMATION PRIOR TO ENROLLMENT.—A group health plan, health insurance issuer, or issuer of a medicare supplemental policy shall not request, require, or purchase genetic information (including information about a request for or a receipt of genetic services by an individual or family member of such individual) concerning a participant, beneficiary, or enrollee prior to the enrollment, and in connection with such enrollment, of such individual under the plan, coverage, or policy.

(C) INCIDENTAL COLLECTION.—Where a group health plan, health insurance issuer, or issuer of a medicare supplemental policy obtains genetic information incidental to the requesting, requiring, or purchasing of other information concerning a participant, beneficiary, or enrollee, such request, requirement, or purchase shall not be considered a violation of this paragraph if—

(i) such request, requirement, or purchase is not in violation of subparagraph (A); and

(ii) any genetic information (including information about a request for or receipt of genetic services) requested, required, or purchased is not used or disclosed in violation of paragraph (2).

(4) APPLICATION OF CONFIDENTIALITY STANDARDS.—The provisions of paragraphs (2) and (3) shall not apply—

(A) to group health plans, health insurance issuers, or issuers of medicare supplemental policies that are not otherwise covered under the regulations promulgated by the Secretary of Health and Human Services under part C of title XI of the Social Security Act (42 U.S.C. 1320d et seq.) and section 264 of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d-2 note); and

(B) to genetic information that is not considered to be individually-identifiable health information under the regulations promulgated by the Secretary of Health and Human Services under part C of title XI of the Social

Security Act (42 U.S.C. 1320d et seq.) and section 264 of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d–2 note).

(5) ENFORCEMENT.—A group health plan, health insurance issuer, or issuer of a medicare supplemental policy that violates a provision of this subsection shall be subject to the penalties described in sections 1176 and 1177 of the Social Security Act (42 U.S.C. 1320d–5 and 1320d–6) in the same manner and to the same extent that such penalties apply to violations of part C of title XI of such Act.

(6) PREEMPTION.—

(A) IN GENERAL.—A provision or requirement under this subsection or a regulation promulgated under this subsection shall supersede any contrary provision of State law unless such provision of State law imposes requirements, standards, or implementation specifications that are more stringent than the requirements, standards, or implementation specifications imposed under this subsection or such regulations. No penalty, remedy, or cause of action to enforce such a State law that is more stringent shall be preempted by this subsection.

(B) RULE OF CONSTRUCTION.—Nothing in subparagraph (A) shall be construed to establish a penalty, remedy, or cause of action under State law if such penalty, remedy, or cause of action is not otherwise available under such State law.

(7) COORDINATION WITH PRIVACY REGULATIONS.—The Secretary shall implement and administer this subsection in a manner that is consistent with the implementation and administration by the Secretary of the regulations promulgated by the Secretary of Health and Human Services under part C of title XI of the Social Security Act (42 U.S.C. 1320d et seq.) and section 264 of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d–2 note).

(8) DEFINITIONS.—In this subsection:

(A) GENETIC INFORMATION; GENETIC SERVICES.—The terms “family member”, “genetic information”, “genetic services”, and “genetic test” have the meanings given such terms in section 2791 of the Public Health Service Act (42 U.S.C. 300gg–91), as amended by this Act.

(B) GROUP HEALTH PLAN; HEALTH INSURANCE ISSUER.—The terms “group health plan” and “health insurance issuer” include only those plans and issuers that are covered under the regulations described in paragraph (4)(A).

(C) ISSUER OF A MEDICARE SUPPLEMENTAL POLICY.—The term “issuer of a medicare supplemental policy” means an issuer described in section 1882 of the Social Security Act (42 U.S.C. 1395ss).

(D) SECRETARY.—The term “Secretary” means the Secretary of Health and Human Services.

(b) AMENDMENTS TO ERISA.—

(1) IN GENERAL.—Subpart B of part 7 of subtitle B of title I of the Employee Retirement Income Security Act of 1974 is amended by adding after section 713 (29 U.S.C. 1185b) the following new section:

**“SEC. 714. PRIVACY AND CONFIDENTIALITY OF GENETIC INFORMATION.**

“(a) APPLICABILITY.—Except as provided in subsection (d), the provisions of this section shall apply to group health plans, and health insurance issuers offering health insurance coverage in connection with such plans, without regard to section 732(a).

“(b) PROHIBITION ON UNDERWRITING, ELIGIBILITY TERMINATION, PREMIUM RATING, AND PLAN FORMULATION.—Notwithstanding section 104(a)(2)(A) of the Genetic Information Nondiscrimination Act of 2007, a group health plan, or a health insurance issuer offering health insurance coverage in connection with such a plan, shall not use or disclose genetic information (including information about a request for or a receipt of genetic services by an individual or family member of such individual) for purposes of underwriting, determinations of eligibility to enroll, premium rating, or the creation, renewal, or replacement of a group health plan or health insurance coverage offered in connection with such a plan.

“(c) PROHIBITION ON COLLECTION OF GENETIC INFORMATION.—

“(1) IN GENERAL.—A group health plan, or a health insurance issuer offering health insurance coverage in connection with such a plan, shall not request, require, or purchase genetic information (including information about a request for or a receipt of genetic services by an individual or family member of such individual) for purposes of underwriting, determinations of eligibility to enroll, premium rating, or the creation, renewal or replacement of a plan, contract or coverage for health insurance or health benefits.

“(2) LIMITATION RELATING TO THE COLLECTION OF GENETIC INFORMATION PRIOR TO ENROLLMENT.—A group health plan, or a health insurance issuer offering health insurance coverage in connection with such a plan, shall not request, require, or purchase genetic information (including information about a request for or a receipt of genetic services by an individual or family member of such individual) concerning a participant or beneficiary prior to the enrollment, and in connection with such enrollment, of such participant or beneficiary under the plan or coverage.

“(3) INCIDENTAL COLLECTION.—Where a group health plan, or a health insurance issuer offering health insurance coverage in connection with such a plan, obtains genetic information incidental to the requesting, requiring, or purchasing of other information concerning a participant or beneficiary, such request, requirement, or purchase shall not be considered a violation of this subsection if—

“(A) such request, requirement, or purchase is not in violation of paragraph (1); and

“(B) any genetic information (including information about a request for or receipt of genetic services) requested, required, or purchased is not used or disclosed in violation of subsection (b).

“(d) APPLICATION OF CONFIDENTIALITY STANDARDS.—The provisions of subsections (b) and (c) shall not apply—

“(1) to group health plans, or health insurance issuers offering health insurance coverage in connection with such plans, that are not otherwise covered under the regulations promulgated by the Secretary of Health and Human Services under part C of title XI of the Social Security Act (42 U.S.C. 1320d et seq.) and section 264 of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d–2 note); and

“(2) to genetic information that is not considered to be individually-identifiable health information under the regulations promulgated by the Secretary of Health and Human Services under part C of title XI of the Social Security Act (42 U.S.C. 1320d et seq.) and section 264 of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d–2 note).

“(e) DEFINITIONS.—In this section:

“(1) GENETIC INFORMATION; GENETIC SERVICES.—The terms ‘family member’, ‘genetic information’, ‘genetic services’, and ‘genetic test’ have the meanings given such terms in section 733(d).

“(2) GROUP HEALTH PLAN; HEALTH INSURANCE ISSUER.—The terms ‘group health plan’ and ‘health insurance issuer’ include only those plans and issuers that are covered under the regulations described in subsection (d)(1).”

(2) PREEMPTION.—Section 731 of such Act (29 U.S.C. 1191) is amended—

(A) by redesignating subsections (c) and (d) as subsections (d) and (e), respectively;

(B) in subsection (a)(1), by striking “subsection (b)” and inserting “subsections (b) and (c)”; and

(C) by inserting after subsection (b) the following new subsection:

“(c) SPECIAL RULES RELATING TO PRIVACY AND CONFIDENTIALITY OF GENETIC INFORMATION.—

“(1) IN GENERAL.—A provision or requirement under section 714 or a regulation promulgated under such section shall supersede any contrary provision of State law unless such provision of State law imposes requirements, standards, or implementation specifications that are more stringent than the requirements, standards, or implementation specifications imposed under such section or such regulations. No penalty, remedy, or cause of action to enforce such a State law that is more stringent shall be preempted by such section.

“(2) RULE OF CONSTRUCTION.—Nothing in paragraph (1) shall be construed to establish a penalty, remedy, or cause of action under State law if such penalty, remedy, or cause of action is not otherwise available under such State law.”

(3) CONFORMING AMENDMENT.—The table of contents in section 1 of such Act is amended by inserting after the item relating to section 713 the following new item:

“Sec. 714. Privacy and confidentiality of genetic information.”.

**SEC. 105. ASSURING COORDINATION.**

(a) IN GENERAL.—Except as provided in subsection (b), the Secretary of Health and Human Services, the Secretary of Labor, and the Secretary of the Treasury shall ensure, through the execution of an interagency memorandum of understanding among such Secretaries, that—

(1) regulations, rulings, and interpretations issued by such Secretaries relating to the same matter over which two or more such Secretaries have responsi-

bility under this title (and the amendments made by this title) are administered so as to have the same effect at all times; and

(2) coordination of policies relating to enforcing the same requirements through such Secretaries in order to have a coordinated enforcement strategy that avoids duplication of enforcement efforts and assigns priorities in enforcement.

(b) **AUTHORITY OF THE SECRETARY.**—The Secretary of Health and Human Services has the sole authority to promulgate regulations to implement section 104(a).

**SEC. 106. REGULATIONS; EFFECTIVE DATE.**

(a) **REGULATIONS.**—Not later than 1 year after the date of enactment of this title, the Secretary of Health and Human Services, the Secretary of Labor, and the Secretary of the Treasury shall issue final regulations to carry out this title.

(b) **EFFECTIVE DATE.**—Except as provided in section 103, the amendments made by this title shall take effect on the date that is 18 months after the date of enactment of this Act.

## **TITLE II—PROHIBITING EMPLOYMENT DISCRIMINATION ON THE BASIS OF GENETIC INFORMATION**

**SEC. 201. DEFINITIONS.**

In this title:

(1) **COMMISSION.**—The term “Commission” means the Equal Employment Opportunity Commission as created by section 705 of the Civil Rights Act of 1964 (42 U.S.C. 2000e–4).

(2) **EMPLOYEE; EMPLOYER; EMPLOYMENT AGENCY; LABOR ORGANIZATION; MEMBER.**—

(A) **IN GENERAL.**—The term “employee” means—

(i) an employee (including an applicant), as defined in section 701(f) of the Civil Rights Act of 1964 (42 U.S.C. 2000e(f));

(ii) a State employee (including an applicant) described in section 304(a) of the Government Employee Rights Act of 1991 (42 U.S.C. 2000e–16c(a));

(iii) a covered employee (including an applicant), as defined in section 101 of the Congressional Accountability Act of 1995 (2 U.S.C. 1301);

(iv) a covered employee (including an applicant), as defined in section 411(c) of title 3, United States Code; or

(v) an employee or applicant to which section 717(a) of the Civil Rights Act of 1964 (42 U.S.C. 2000e–16(a)) applies.

(B) **EMPLOYER.**—The term “employer” means—

(i) an employer (as defined in section 701(b) of the Civil Rights Act of 1964 (42 U.S.C. 2000e(b)));

(ii) an entity employing a State employee described in section 304(a) of the Government Employee Rights Act of 1991;

(iii) an employing office, as defined in section 101 of the Congressional Accountability Act of 1995;

(iv) an employing office, as defined in section 411(c) of title 3, United States Code; or

(v) an entity to which section 717(a) of the Civil Rights Act of 1964 applies.

(C) **EMPLOYMENT AGENCY; LABOR ORGANIZATION.**—The terms “employment agency” and “labor organization” have the meanings given the terms in section 701 of the Civil Rights Act of 1964 (42 U.S.C. 2000e).

(D) **MEMBER.**—The term “member”, with respect to a labor organization, includes an applicant for membership in a labor organization.

(3) **FAMILY MEMBER.**—The term “family member” means with respect to an individual—

(A) the spouse of the individual;

(B) a dependent child of the individual; and

(C) any other individual who is a first-degree, second-degree, third-degree, or fourth-degree relative of an individual described in subparagraph (A) or (B).

(4) **GENETIC INFORMATION.**—

(A) **IN GENERAL.**—Except as provided in subparagraph (B), the term “genetic information” means information about—

(i) an individual’s genetic tests;

- (ii) the genetic tests of family members of the individual; or
- (iii) the occurrence of a disease or disorder in family members of the individual.

(B) EXCEPTIONS.—The term “genetic information” shall not include information about the sex or age of an individual.

(5) GENETIC MONITORING.—The term “genetic monitoring” means the periodic examination of employees to evaluate acquired modifications to their genetic material, such as chromosomal damage or evidence of increased occurrence of mutations, that may have developed in the course of employment due to exposure to toxic substances in the workplace, in order to identify, evaluate, and respond to the effects of or control adverse environmental exposures in the workplace.

(6) GENETIC SERVICES.—The term “genetic services” means—

- (A) a genetic test;
- (B) genetic counseling (including obtaining, interpreting or assessing genetic information); or
- (C) genetic education.

(7) GENETIC TEST.—

(A) IN GENERAL.—The term “genetic test” means the analysis of human DNA, RNA, chromosomes, proteins, or metabolites, that detects genotypes, mutations, or chromosomal changes.

(B) EXCEPTION.—The term “genetic test” does not mean an analysis of proteins or metabolites that does not detect genotypes, mutations, or chromosomal changes.

#### SEC. 202. EMPLOYER PRACTICES.

(a) DISCRIMINATION BASED ON GENETIC INFORMATION.—It shall be an unlawful employment practice for an employer—

(1) to fail or refuse to hire or to discharge any employee, or otherwise to discriminate against any employee with respect to the compensation, terms, conditions, or privileges of employment of the employee, because of genetic information with respect to the employee (or information about a request for or the receipt of genetic services by such employee or family member of such employee); or

(2) to limit, segregate, or classify the employees of the employer in any way that would deprive or tend to deprive any employee of employment opportunities or otherwise adversely affect the status of the employee as an employee, because of genetic information with respect to the employee (or information about a request for or the receipt of genetic services by such employee or family member of such employee).

(b) ACQUISITION OF GENETIC INFORMATION.—It shall be an unlawful employment practice for an employer to request, require, or purchase genetic information with respect to an employee or a family member of the employee (or information about a request for the receipt of genetic services by such employee or a family member of such employee) except—

(1) where an employer inadvertently requests or requires family medical history of the employee or family member of the employee;

(2) where—

(A) health or genetic services are offered by the employer, including such services offered as part of a bona fide wellness program;

(B) the employee provides prior, knowing, voluntary, and written authorization;

(C) only the employee (or family member if the family member is receiving genetic services) and the licensed health care professional or board certified genetic counselor involved in providing such services receive individually identifiable information concerning the results of such services; and

(D) any individually identifiable genetic information provided under subparagraph (C) in connection with the services provided under subparagraph (A) is only available for purposes of such services and shall not be disclosed to the employer except in aggregate terms that do not disclose the identity of specific employees;

(3) where an employer requests or requires family medical history from the employee to comply with the certification provisions of section 103 of the Family and Medical Leave Act of 1993 (29 U.S.C. 2613), such requirements under State family and medical leave laws;

(4) where an employer purchases documents that are commercially and publicly available (including newspapers, magazines, periodicals, and books, but not including medical databases or court records) that include family medical history; or

(5) where the information involved is to be used for genetic monitoring of the biological effects of toxic substances in the workplace, but only if—

(A) the employer provides written notice of the genetic monitoring to the employee;

(B)(i) the employee provides prior, knowing, voluntary, and written authorization; or

(ii) the genetic monitoring is required by Federal or State law;

(C) the employee is informed of individual monitoring results;

(D) the monitoring is in compliance with—

(i) any Federal genetic monitoring regulations, including any such regulations that may be promulgated by the Secretary of Labor pursuant to the Occupational Safety and Health Act of 1970 (29 U.S.C. 651 et seq.), the Federal Mine Safety and Health Act of 1977 (30 U.S.C. 801 et seq.), or the Atomic Energy Act of 1954 (42 U.S.C. 2011 et seq.); or

(ii) State genetic monitoring regulations, in the case of a State that is implementing genetic monitoring regulations under the authority of the Occupational Safety and Health Act of 1970 (29 U.S.C. 651 et seq.); and

(E) the employer, excluding any licensed health care professional or board certified genetic counselor that is involved in the genetic monitoring program, receives the results of the monitoring only in aggregate terms that do not disclose the identity of specific employees;

(c) PRESERVATION OF PROTECTIONS.—In the case of information to which any of paragraphs (1) through (5) of subsection (b) applies, such information may not be used in violation of paragraph (1) or (2) of subsection (a) or treated or disclosed in a manner that violates section 206.

#### SEC. 203. EMPLOYMENT AGENCY PRACTICES.

(a) DISCRIMINATION BASED ON GENETIC INFORMATION.—It shall be an unlawful employment practice for an employment agency—

(1) to fail or refuse to refer for employment, or otherwise to discriminate against, any individual because of genetic information with respect to the individual (or information about a request for or the receipt of genetic services by such individual or family member of such individual);

(2) to limit, segregate, or classify individuals or fail or refuse to refer for employment any individual in any way that would deprive or tend to deprive any individual of employment opportunities, or otherwise adversely affect the status of the individual as an employee, because of genetic information with respect to the individual (or information about a request for or the receipt of genetic services by such individual or family member of such individual); or

(3) to cause or attempt to cause an employer to discriminate against an individual in violation of this title.

(b) ACQUISITION OF GENETIC INFORMATION.—It shall be an unlawful employment practice for an employment agency to request, require, or purchase genetic information with respect to an individual or a family member of the individual (or information about a request for the receipt of genetic services by such individual or a family member of such individual) except—

(1) where an employment agency inadvertently requests or requires family medical history of the individual or family member of the individual;

(2) where—

(A) health or genetic services are offered by the employment agency, including such services offered as part of a bona fide wellness program;

(B) the individual provides prior, knowing, voluntary, and written authorization;

(C) only the individual (or family member if the family member is receiving genetic services) and the licensed health care professional or board certified genetic counselor involved in providing such services receive individually identifiable information concerning the results of such services; and

(D) any individually identifiable genetic information provided under subparagraph (C) in connection with the services provided under subparagraph (A) is only available for purposes of such services and shall not be disclosed to the employment agency except in aggregate terms that do not disclose the identity of specific individuals;

(3) where an employment agency requests or requires family medical history from the individual to comply with the certification provisions of section 103 of the Family and Medical Leave Act of 1993 (29 U.S.C. 2613) or such requirements under State family and medical leave laws;

(4) where an employment agency purchases documents that are commercially and publicly available (including newspapers, magazines, periodicals, and books,

but not including medical databases or court records) that include family medical history; or

(5) where the information involved is to be used for genetic monitoring of the biological effects of toxic substances in the workplace, but only if—

(A) the employment agency provides written notice of the genetic monitoring to the individual;

(B)(i) the individual provides prior, knowing, voluntary, and written authorization; or

(ii) the genetic monitoring is required by Federal or State law;

(C) the individual is informed of individual monitoring results;

(D) the monitoring is in compliance with—

(i) any Federal genetic monitoring regulations, including any such regulations that may be promulgated by the Secretary of Labor pursuant to the Occupational Safety and Health Act of 1970 (29 U.S.C. 651 et seq.), the Federal Mine Safety and Health Act of 1977 (30 U.S.C. 801 et seq.), or the Atomic Energy Act of 1954 (42 U.S.C. 2011 et seq.); or

(ii) State genetic monitoring regulations, in the case of a State that is implementing genetic monitoring regulations under the authority of the Occupational Safety and Health Act of 1970 (29 U.S.C. 651 et seq.); and

(E) the employment agency, excluding any licensed health care professional or board certified genetic counselor that is involved in the genetic monitoring program, receives the results of the monitoring only in aggregate terms that do not disclose the identity of specific individuals;

(c) PRESERVATION OF PROTECTIONS.—In the case of information to which any of paragraphs (1) through (5) of subsection (b) applies, such information may not be used in violation of paragraph (1) or (2) of subsection (a) or treated or disclosed in a manner that violates section 206.

**SEC. 204. LABOR ORGANIZATION PRACTICES.**

(a) DISCRIMINATION BASED ON GENETIC INFORMATION.—It shall be an unlawful employment practice for a labor organization—

(1) to exclude or to expel from the membership of the organization, or otherwise to discriminate against, any member because of genetic information with respect to the member (or information about a request for or the receipt of genetic services by such member or family member of such member);

(2) to limit, segregate, or classify the members of the organization, or fail or refuse to refer for employment any member, in any way that would deprive or tend to deprive any member of employment opportunities, or otherwise adversely affect the status of the member as an employee, because of genetic information with respect to the member (or information about a request for or the receipt of genetic services by such member or family member of such member); or

(3) to cause or attempt to cause an employer to discriminate against a member in violation of this title.

(b) ACQUISITION OF GENETIC INFORMATION.—It shall be an unlawful employment practice for a labor organization to request, require, or purchase genetic information with respect to a member or a family member of the member (or information about a request for the receipt of genetic services by such member or a family member of such member) except—

(1) where a labor organization inadvertently requests or requires family medical history of the member or family member of the member;

(2) where—

(A) health or genetic services are offered by the labor organization, including such services offered as part of a bona fide wellness program;

(B) the member provides prior, knowing, voluntary, and written authorization;

(C) only the member (or family member if the family member is receiving genetic services) and the licensed health care professional or board certified genetic counselor involved in providing such services receive individually identifiable information concerning the results of such services; and

(D) any individually identifiable genetic information provided under subparagraph (C) in connection with the services provided under subparagraph (A) is only available for purposes of such services and shall not be disclosed to the labor organization except in aggregate terms that do not disclose the identity of specific members;

(3) where a labor organization requests or requires family medical history from the members to comply with the certification provisions of section 103 of

the Family and Medical Leave Act of 1993 (29 U.S.C. 2613) or such requirements under State family and medical leave laws;

(4) where a labor organization purchases documents that are commercially and publicly available (including newspapers, magazines, periodicals, and books, but not including medical databases or court records) that include family medical history; or

(5) where the information involved is to be used for genetic monitoring of the biological effects of toxic substances in the workplace, but only if—

(A) the labor organization provides written notice of the genetic monitoring to the member;

(B)(i) the member provides prior, knowing, voluntary, and written authorization; or

(ii) the genetic monitoring is required by Federal or State law;

(C) the member is informed of individual monitoring results;

(D) the monitoring is in compliance with—

(i) any Federal genetic monitoring regulations, including any such regulations that may be promulgated by the Secretary of Labor pursuant to the Occupational Safety and Health Act of 1970 (29 U.S.C. 651 et seq.), the Federal Mine Safety and Health Act of 1977 (30 U.S.C. 801 et seq.), or the Atomic Energy Act of 1954 (42 U.S.C. 2011 et seq.); or

(ii) State genetic monitoring regulations, in the case of a State that is implementing genetic monitoring regulations under the authority of the Occupational Safety and Health Act of 1970 (29 U.S.C. 651 et seq.); and

(E) the labor organization, excluding any licensed health care professional or board certified genetic counselor that is involved in the genetic monitoring program, receives the results of the monitoring only in aggregate terms that do not disclose the identity of specific members;

(c) **PRESERVATION OF PROTECTIONS.**—In the case of information to which any of paragraphs (1) through (5) of subsection (b) applies, such information may not be used in violation of paragraph (1) or (2) of subsection (a) or treated or disclosed in a manner that violates section 206.

**SEC. 205. TRAINING PROGRAMS.**

(a) **DISCRIMINATION BASED ON GENETIC INFORMATION.**—It shall be an unlawful employment practice for any employer, labor organization, or joint labor-management committee controlling apprenticeship or other training or retraining, including on-the-job training programs—

(1) to discriminate against any individual because of genetic information with respect to the individual (or information about a request for or the receipt of genetic services by such individual or a family member of such individual) in admission to, or employment in, any program established to provide apprenticeship or other training or retraining;

(2) to limit, segregate, or classify the applicants for or participants in such apprenticeship or other training or retraining, or fail or refuse to refer for employment any individual, in any way that would deprive or tend to deprive any individual of employment opportunities, or otherwise adversely affect the status of the individual as an employee, because of genetic information with respect to the individual (or information about a request for or receipt of genetic services by such individual or family member of such individual); or

(3) to cause or attempt to cause an employer to discriminate against an applicant for or a participant in such apprenticeship or other training or retraining in violation of this title.

(b) **ACQUISITION OF GENETIC INFORMATION.**—It shall be an unlawful employment practice for an employer, labor organization, or joint labor-management committee described in subsection (a) to request, require, or purchase genetic information with respect to an individual or a family member of the individual (or information about a request for the receipt of genetic services by such individual or a family member of such individual) except—

(1) where the employer, labor organization, or joint labor-management committee inadvertently requests or requires family medical history of the individual or family member of the individual;

(2) where—

(A) health or genetic services are offered by the employer, labor organization, or joint labor-management committee, including such services offered as part of a bona fide wellness program;

(B) the individual provides prior, knowing, voluntary, and written authorization;

(C) only the individual (or family member if the family member is receiving genetic services) and the licensed health care professional or board certified genetic counselor involved in providing such services receive individually identifiable information concerning the results of such services; and

(D) any individually identifiable genetic information provided under subparagraph (C) in connection with the services provided under subparagraph (A) is only available for purposes of such services and shall not be disclosed to the employer, labor organization, or joint labor-management committee except in aggregate terms that do not disclose the identity of specific individuals;

(3) where the employer, labor organization, or joint labor-management committee requests or requires family medical history from the individual to comply with the certification provisions of section 103 of the Family and Medical Leave Act of 1993 (29 U.S.C. 2613) or such requirements under State family and medical leave laws;

(4) where the employer, labor organization, or joint labor-management committee purchases documents that are commercially and publicly available (including newspapers, magazines, periodicals, and books, but not including medical databases or court records) that include family medical history; or

(5) where the information involved is to be used for genetic monitoring of the biological effects of toxic substances in the workplace, but only if—

(A) the employer, labor organization, or joint labor-management committee provides written notice of the genetic monitoring to the individual;

(B)(i) the individual provides prior, knowing, voluntary, and written authorization; or

(ii) the genetic monitoring is required by Federal or State law;

(C) the individual is informed of individual monitoring results;

(D) the monitoring is in compliance with—

(i) any Federal genetic monitoring regulations, including any such regulations that may be promulgated by the Secretary of Labor pursuant to the Occupational Safety and Health Act of 1970 (29 U.S.C. 651 et seq.), the Federal Mine Safety and Health Act of 1977 (30 U.S.C. 801 et seq.), or the Atomic Energy Act of 1954 (42 U.S.C. 2011 et seq.); or

(ii) State genetic monitoring regulations, in the case of a State that is implementing genetic monitoring regulations under the authority of the Occupational Safety and Health Act of 1970 (29 U.S.C. 651 et seq.); and

(E) the employer, labor organization, or joint labor-management committee, excluding any licensed health care professional or board certified genetic counselor that is involved in the genetic monitoring program, receives the results of the monitoring only in aggregate terms that do not disclose the identity of specific individuals;

(c) PRESERVATION OF PROTECTIONS.—In the case of information to which any of paragraphs (1) through (5) of subsection (b) applies, such information may not be used in violation of paragraph (1) or (2) of subsection (a) or treated or disclosed in a manner that violates section 206.

#### SEC. 206. CONFIDENTIALITY OF GENETIC INFORMATION.

(a) TREATMENT OF INFORMATION AS PART OF CONFIDENTIAL MEDICAL RECORD.—If an employer, employment agency, labor organization, or joint labor-management committee possesses genetic information about an employee or member (or information about a request for or receipt of genetic services by such employee or member or family member of such employee or member), such information shall be maintained on separate forms and in separate medical files and be treated as a confidential medical record of the employee or member. An employer, employment agency, labor organization, or joint labor-management committee shall be considered to be in compliance with the maintenance of information requirements of this subsection with respect to genetic information subject to this subsection that is maintained with and treated as a confidential medical record under section 102(d)(3)(B) of the Americans With Disabilities Act (42 U.S.C. 12112(d)(3)(B)).

(b) LIMITATION ON DISCLOSURE.—An employer, employment agency, labor organization, or joint labor-management committee shall not disclose genetic information concerning an employee or member (or information about a request for or receipt of genetic services by such employee or member or family member of such employee or member) except—

(1) to the employee or member of a labor organization (or family member if the family member is receiving the genetic services) at the written request of the employee or member of such organization;

(2) to an occupational or other health researcher if the research is conducted in compliance with the regulations and protections provided for under part 46 of title 45, Code of Federal Regulations;

(3) in response to an order of a court, except that—

(A) the employer, employment agency, labor organization, or joint labor-management committee may disclose only the genetic information expressly authorized by such order; and

(B) if the court order was secured without the knowledge of the employee or member to whom the information refers, the employer, employment agency, labor organization, or joint labor-management committee shall inform the employee or member of the court order and any genetic information that was disclosed pursuant to such order;

(4) to government officials who are investigating compliance with this title if the information is relevant to the investigation; or

(5) to the extent that such disclosure is made in connection with the employee's compliance with the certification provisions of section 103 of the Family and Medical Leave Act of 1993 (29 U.S.C. 2613) or such requirements under State family and medical leave laws.

**SEC. 207. REMEDIES AND ENFORCEMENT.**

(a) **EMPLOYEES COVERED BY TITLE VII OF THE CIVIL RIGHTS ACT OF 1964.—**

(1) **IN GENERAL.**—The powers, remedies, and procedures provided in sections 705, 706, 707, 709, 710, and 711 of the Civil Rights Act of 1964 (42 U.S.C. 2000e-4 et seq.) to the Commission, the Attorney General, or any person, alleging a violation of title VII of that Act (42 U.S.C. 2000e et seq.) shall be the powers, remedies, and procedures this title provides to the Commission, the Attorney General, or any person, respectively, alleging an unlawful employment practice in violation of this title against an employee described in section 201(2)(A)(i), except as provided in paragraphs (2) and (3).

(2) **COSTS AND FEES.**—The powers, remedies, and procedures provided in subsections (b) and (c) of section 722 of the Revised Statutes of the United States (42 U.S.C. 1988), shall be powers, remedies, and procedures this title provides to the Commission, the Attorney General, or any person, alleging such a practice.

(3) **DAMAGES.**—The powers, remedies, and procedures provided in section 1977A of the Revised Statutes of the United States (42 U.S.C. 1981a), including the limitations contained in subsection (b)(3) of such section 1977A, shall be powers, remedies, and procedures this title provides to the Commission, the Attorney General, or any person, alleging such a practice (not an employment practice specifically excluded from coverage under section 1977A(a)(1) of the Revised Statutes of the United States).

(b) **EMPLOYEES COVERED BY GOVERNMENT EMPLOYEE RIGHTS ACT OF 1991.—**

(1) **IN GENERAL.**—The powers, remedies, and procedures provided in sections 302 and 304 of the Government Employee Rights Act of 1991 (42 U.S.C. 2000e-16b, 2000e-16c) to the Commission, or any person, alleging a violation of section 302(a)(1) of that Act (42 U.S.C. 2000e-16b(a)(1)) shall be the powers, remedies, and procedures this title provides to the Commission, or any person, respectively, alleging an unlawful employment practice in violation of this title against an employee described in section 201(2)(A)(ii), except as provided in paragraphs (2) and (3).

(2) **COSTS AND FEES.**—The powers, remedies, and procedures provided in subsections (b) and (c) of section 722 of the Revised Statutes of the United States (42 U.S.C. 1988), shall be powers, remedies, and procedures this title provides to the Commission, or any person, alleging such a practice.

(3) **DAMAGES.**—The powers, remedies, and procedures provided in section 1977A of the Revised Statutes of the United States (42 U.S.C. 1981a), including the limitations contained in subsection (b)(3) of such section 1977A, shall be powers, remedies, and procedures this title provides to the Commission, or any person, alleging such a practice (not an employment practice specifically excluded from coverage under section 1977A(a)(1) of the Revised Statutes of the United States).

(c) **EMPLOYEES COVERED BY CONGRESSIONAL ACCOUNTABILITY ACT OF 1995.—**

(1) **IN GENERAL.**—The powers, remedies, and procedures provided in the Congressional Accountability Act of 1995 (2 U.S.C. 1301 et seq.) to the Board (as defined in section 101 of that Act (2 U.S.C. 1301)), or any person, alleging a violation of section 201(a)(1) of that Act (42 U.S.C. 1311(a)(1)) shall be the powers, remedies, and procedures this title provides to that Board, or any person, alleging an unlawful employment practice in violation of this title against an

employee described in section 201(2)(A)(iii), except as provided in paragraphs (2) and (3).

(2) **COSTS AND FEES.**—The powers, remedies, and procedures provided in subsections (b) and (c) of section 722 of the Revised Statutes of the United States (42 U.S.C. 1988), shall be powers, remedies, and procedures this title provides to that Board, or any person, alleging such a practice.

(3) **DAMAGES.**—The powers, remedies, and procedures provided in section 1977A of the Revised Statutes of the United States (42 U.S.C. 1981a), including the limitations contained in subsection (b)(3) of such section 1977A, shall be powers, remedies, and procedures this title provides to that Board, or any person, alleging such a practice (not an employment practice specifically excluded from coverage under section 1977A(a)(1) of the Revised Statutes of the United States).

(4) **OTHER APPLICABLE PROVISIONS.**—With respect to a claim alleging a practice described in paragraph (1), title III of the Congressional Accountability Act of 1995 (2 U.S.C. 1381 et seq.) shall apply in the same manner as such title applies with respect to a claim alleging a violation of section 201(a)(1) of such Act (2 U.S.C. 1311(a)(1)).

**(d) EMPLOYEES COVERED BY CHAPTER 5 OF TITLE 3, UNITED STATES CODE.—**

(1) **IN GENERAL.**—The powers, remedies, and procedures provided in chapter 5 of title 3, United States Code, to the President, the Commission, the Merit Systems Protection Board, or any person, alleging a violation of section 411(a)(1) of that title, shall be the powers, remedies, and procedures this title provides to the President, the Commission, such Board, or any person, respectively, alleging an unlawful employment practice in violation of this title against an employee described in section 201(2)(A)(iv), except as provided in paragraphs (2) and (3).

(2) **COSTS AND FEES.**—The powers, remedies, and procedures provided in subsections (b) and (c) of section 722 of the Revised Statutes of the United States (42 U.S.C. 1988), shall be powers, remedies, and procedures this title provides to the President, the Commission, such Board, or any person, alleging such a practice.

(3) **DAMAGES.**—The powers, remedies, and procedures provided in section 1977A of the Revised Statutes of the United States (42 U.S.C. 1981a), including the limitations contained in subsection (b)(3) of such section 1977A, shall be powers, remedies, and procedures this title provides to the President, the Commission, such Board, or any person, alleging such a practice (not an employment practice specifically excluded from coverage under section 1977A(a)(1) of the Revised Statutes of the United States).

**(e) EMPLOYEES COVERED BY SECTION 717 OF THE CIVIL RIGHTS ACT OF 1964.—**

(1) **IN GENERAL.**—The powers, remedies, and procedures provided in section 717 of the Civil Rights Act of 1964 (42 U.S.C. 2000e–16) to the Commission, the Attorney General, the Librarian of Congress, or any person, alleging a violation of that section shall be the powers, remedies, and procedures this title provides to the Commission, the Attorney General, the Librarian of Congress, or any person, respectively, alleging an unlawful employment practice in violation of this title against an employee or applicant described in section 201(2)(A)(v), except as provided in paragraphs (2) and (3).

(2) **COSTS AND FEES.**—The powers, remedies, and procedures provided in subsections (b) and (c) of section 722 of the Revised Statutes of the United States (42 U.S.C. 1988), shall be powers, remedies, and procedures this title provides to the Commission, the Attorney General, the Librarian of Congress, or any person, alleging such a practice.

(3) **DAMAGES.**—The powers, remedies, and procedures provided in section 1977A of the Revised Statutes of the United States (42 U.S.C. 1981a), including the limitations contained in subsection (b)(3) of such section 1977A, shall be powers, remedies, and procedures this title provides to the Commission, the Attorney General, the Librarian of Congress, or any person, alleging such a practice (not an employment practice specifically excluded from coverage under section 1977A(a)(1) of the Revised Statutes of the United States).

(f) **DEFINITION.**—In this section, the term “Commission” means the Equal Employment Opportunity Commission.

**SEC. 208. DISPARATE IMPACT.**

(a) **GENERAL RULE.**—Notwithstanding any other provision of this Act, “disparate impact”, as that term is used in section 703(k) of the Civil Rights Act of 1964 (42 U.S.C. 2000e–2(k)), on the basis of genetic information does not establish a cause of action under this Act.

(b) COMMISSION.—On the date that is 6 years after the date of enactment of this Act, there shall be established a commission, to be known as the Genetic Non-discrimination Study Commission (referred to in this section as the “Commission”) to review the developing science of genetics and to make recommendations to Congress regarding whether to provide a disparate impact cause of action under this Act.

(c) MEMBERSHIP.—

(1) IN GENERAL.—The Commission shall be composed of 8 members, of which—

(A) 1 member shall be appointed by the Majority Leader of the Senate;

(B) 1 member shall be appointed by the Minority Leader of the Senate;

(C) 1 member shall be appointed by the Chairman of the Committee on Health, Education, Labor, and Pensions of the Senate;

(D) 1 member shall be appointed by the ranking minority member of the Committee on Health, Education, Labor, and Pensions of the Senate;

(E) 1 member shall be appointed by the Speaker of the House of Representatives;

(F) 1 member shall be appointed by the Minority Leader of the House of Representatives;

(G) 1 member shall be appointed by the Chairman of the Committee on Education and Labor of the House of Representatives; and

(H) 1 member shall be appointed by the ranking minority member of the Committee on Education and Labor of the House of Representatives.

(2) COMPENSATION AND EXPENSES.—The members of the Commission shall not receive compensation for the performance of services for the Commission, but shall be allowed travel expenses, including per diem in lieu of subsistence, at rates authorized for employees of agencies under subchapter I of chapter 57 of title 5, United States Code, while away from their homes or regular places of business in the performance of services for the Commission.

(d) ADMINISTRATIVE PROVISIONS.—

(1) LOCATION.—The Commission shall be located in a facility maintained by the Equal Employment Opportunity Commission.

(2) DETAIL OF GOVERNMENT EMPLOYEES.—Any Federal Government employee may be detailed to the Commission without reimbursement, and such detail shall be without interruption or loss of civil service status or privilege.

(3) INFORMATION FROM FEDERAL AGENCIES.—The Commission may secure directly from any Federal department or agency such information as the Commission considers necessary to carry out the provisions of this section. Upon request of the Commission, the head of such department or agency shall furnish such information to the Commission.

(4) HEARINGS.—The Commission may hold such hearings, sit and act at such times and places, take such testimony, and receive such evidence as the Commission considers advisable to carry out the objectives of this section, except that, to the extent possible, the Commission shall use existing data and research.

(5) POSTAL SERVICES.—The Commission may use the United States mails in the same manner and under the same conditions as other departments and agencies of the Federal Government.

(e) REPORT.—Not later than 1 year after all of the members are appointed to the Commission under subsection (c)(1), the Commission shall submit to Congress a report that summarizes the findings of the Commission and makes such recommendations for legislation as are consistent with this Act.

(f) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to the Equal Employment Opportunity Commission such sums as may be necessary to carry out this section.

**SEC. 209. CONSTRUCTION.**

(a) IN GENERAL.—Nothing in this title shall be construed to—

(1) limit the rights or protections of an individual under any other Federal or State statute that provides equal or greater protection to an individual than the rights or protections provided for under this title, including the protections of an individual under the Americans with Disabilities Act of 1990 (42 U.S.C. 12101 et seq.) (including coverage afforded to individuals under section 102 of such Act (42 U.S.C. 12112)), or under the Rehabilitation Act of 1973 (29 U.S.C. 701 et seq.);

(2)(A) limit the rights or protections of an individual to bring an action under this title against an employer, employment agency, labor organization, or joint labor-management committee for a violation of this title; or

(B) provide for enforcement of, or penalties for violation of, any requirement or prohibition applicable to any employer, employment agency, labor organization, or joint labor-management committee the enforcement of which, or penalties for which, are provided under the amendments made by title I;

(3) apply to the Armed Forces Repository of Specimen Samples for the Identification of Remains;

(4) limit or expand the protections, rights, or obligations of employees or employers under applicable workers' compensation laws;

(5) limit the authority of a Federal department or agency to conduct or sponsor occupational or other health research that is conducted in compliance with the regulations contained in part 46 of title 45, Code of Federal Regulations (or any corresponding or similar regulation or rule);

(6) limit the statutory or regulatory authority of the Occupational Safety and Health Administration or the Mine Safety and Health Administration to promulgate or enforce workplace safety and health laws and regulations; or

(7) require any specific benefit for an employee or member or a family member of an employee or member under any group health plan or health insurance issuer offering group health insurance coverage in connection with a group health plan.

(b) **GENETIC INFORMATION OF A FETUS.**—Any reference in this title to genetic information about or with respect to an employee, individual, or family member of an individual shall, with respect to such an employee, individual, or family member of an individual who is a pregnant woman, include genetic information of any fetus carried by such pregnant woman.

**SEC. 210. MEDICAL INFORMATION THAT IS NOT GENETIC INFORMATION.**

An employer, employment agency, labor organization, or joint labor-management committee shall not be considered to be in violation of this title based on the use, acquisition, or disclosure of medical information that is not genetic information about a manifested disease, disorder, or pathological condition of an employee or member, including a manifested disease, disorder, or pathological condition that has or may have a genetic basis.

**SEC. 211. REGULATIONS.**

Not later than 1 year after the date of enactment of this title, the Commission shall issue final regulations to carry out this title.

**SEC. 212. AUTHORIZATION OF APPROPRIATIONS.**

There are authorized to be appropriated such sums as may be necessary to carry out this title (except for section 208).

**SEC. 213. EFFECTIVE DATE.**

This title takes effect on the date that is 18 months after the date of enactment of this Act.

## **TITLE III—MISCELLANEOUS PROVISION**

**SEC. 301. SEVERABILITY.**

If any provision of this Act, an amendment made by this Act, or the application of such provision or amendment to any person or circumstance is held to be unconstitutional, the remainder of this Act, the amendments made by this Act, and the application of such provisions to any person or circumstance shall not be affected thereby.

### **I. PURPOSE**

The purpose of this legislation is to protect individuals from discrimination in health insurance and employment on the basis of genetic information. Establishing these protections will allay concerns about the potential for discrimination and encourage individuals to participate in genetic research and to take advantage of genetic testing and new therapies. The legislation will provide substantive protections to those individuals who may suffer from actual genetic discrimination now and in the future. These steps are essential to fulfilling the promise of the human genome project and improving the health and longevity of the American people.

## II. COMMITTEE ACTION INCLUDING LEGISLATIVE HISTORY AND VOTES IN COMMITTEE

### 104TH–108TH CONGRESSES

Congresswoman Louise Slaughter introduced the first genetic information bill during the 104th Congress. The Genetic Information Nondiscrimination in Health Insurance Act of 1995, H.R. 2748, garnered 76 cosponsors.

During the 104th, the Senate Committee on Health, Education, Labor and Pensions began to hold hearings on the topic. The first hearing examined the public policy implications of advances in genetics research. In 1996, the Congress took a first step toward passing comprehensive genetic nondiscrimination legislation as part of the Health Insurance Portability and Accountability Act (HIPAA). HIPAA was signed into law in 1996 (P.L. 104–191; August 21, 1996). It prohibits discrimination against an individual in a group based on health status, including genetic information, and it primarily applies to group health plans and health insurance issuers in the group market.

Congresswoman Slaughter reintroduced the Genetic Information Nondiscrimination in Health Insurance Act in the 105th Congress as H.R. 306 with 213 cosponsors. Mrs. Slaughter filed a Motion to Discharge Committee on 6/11/1998 (Petition No: 105–4), but the motion was not considered.

In the 106th Congress, Congresswoman Slaughter introduced the Genetic Nondiscrimination in Health Insurance and Employment Act of 1999, H.R. 2457, on July 1, 1999 and garnered 164 cosponsors. The bill was reintroduced in the 107th Congress on February 13, 2001, as H.R. 602 with 266 cosponsors.

### 108TH CONGRESS

The Genetic Nondiscrimination in Health Insurance and Employment Act, H.R. 1910, was introduced by Congresswoman Slaughter on May 1, 2003 and garnered 242 cosponsors. The bill was referred to the Committees on Education and the Workforce, Energy and Commerce and Ways and Means. The Subcommittee on Employer-Employee Relations of this Committee held a hearing on “Genetic Non-Discrimination: Examining the Implications for Workers and Employers” on July 22, 2004. Witnesses testifying included: Dr. Kathy Hudson, Director, The Genetic and Public Policy Center, Johns Hopkins University, Washington, DC; Dr. Jane Massey Licata, partner, Licata & Tyrell, Marlton, New Jersey; Lawrence Lorber, partner, Proskauer Rose, on behalf of the US Chamber of Commerce, Washington, DC; and Tom Wildsmith, chairman, Genetic Testing Taskforce, American Academy of Actuaries, Washington, DC.

### 109TH CONGRESS

The Genetic Information Nondiscrimination Act of 2005, H.R. 1227, was introduced by Congresswoman Judy Biggert on March 10, 2005 and garnered 244 cosponsors. No action was taken in the House during the 109th Congress.

## 110TH CONGRESS

The Genetic Information Nondiscrimination Act of 2007, H.R. 493, was introduced by Congresswoman Slaughter on January 16, 2007. The bill has 205 cosponsors. The bill was referred to the Committees on Education and Labor, Energy and Commerce and Ways and Means. The Subcommittee on Health, Employment, Labor and Pensions held a hearing on January 30, 2007. The witnesses included: Congresswoman Louise Slaughter; Congresswoman Judy Biggert; Karen Rothenberg, Dean and Marjorie Cook Professor of Law, University of Maryland School of Law, Baltimore, MD; David Escher, former employee, Burlington Northern Santa Fe Railroad, Reno, NV; Harriet Pearson, Vice President, Corporate Affairs and Chief Privacy Officer, IBM Corporation, Washington, DC; and Burton J. Fishman, Partner, Fortney Scott, Genetic Information Nondiscrimination in Employment (GINE) Coalition, Washington, DC.

## FULL COMMITTEE MARK-UP OF HR. 493

On February 14, 2007, the Committee on Education and Labor convened to markup H.R. 493, the Genetic Information Nondiscrimination Act. An amendment in the nature of a substitute was offered by Chairman Miller. An amendment to coordinate the recordkeeping requirements for genetic information with other laws was offered by Mr. Kline and accepted by unanimous consent. An amendment to specify application of the bill to a “child to be born” offered by Reps. Wahlberg and Hoekstra was defeated by a vote of 20 to 27. The Committee voted to report favorably H.R. 493 by voice vote.

## III. SUMMARY OF THE BILL

## THE GENETIC INFORMATION NONDISCRIMINATION ACT OF 2007

## Title I—Genetic Nondiscrimination in Health Insurance

The legislation applies to employer-sponsored group health plans, health insurance issuers in the group and individual markets, Medigap insurance, and State and local non-federal governmental plans.

*Nondiscrimination in enrollment and group premiums**Group health plan protections*

The Employee Retirement and Security Act (ERISA) currently prohibits a group health plan or health insurance issuer offering coverage in connection with a group health plan from discriminating against an individual in the group in setting eligibility or premium or contribution amounts based on the individual’s genetic information.

This legislation clarifies that genetic information includes “information about a request for or a receipt of genetic services by an individual or family member of such individual.” It also prohibits a health insurance issuer offering health coverage in connection with a group health plan from adjusting premium or contribution amounts for a group on the basis of genetic information concerning an individual in the group or a family member of the individual.

*Individual health insurance market protections*

The bill prohibits health insurance issuers in the individual market from using genetic information about enrollees or their family members to adjust premium or contribution amounts, using genetic information as a condition of eligibility for insurance coverage.

*Medicare supplemental protections*

The bill prohibits an issuer of a Medicare supplemental policy from denying or conditioning the issuance of a policy, or discriminating in the price of the policy, based on genetic information.

*Limitation on requesting or requiring genetic testing*

Group health plans, health insurance issuers in the group and individual market, and issuers of Medicare supplemental policies covered under this Title are prohibited from requesting or requiring an individual to take a genetic test. The legislation makes it clear that this provision is not intended to interfere with the delivery of health care services. For instance, the provision does not limit the authority of the treating health care professional to request that an individual or family member undergo a genetic test. Nor does it limit the authority of a health care professional who is employed by or affiliated with a health plan or issuer from notifying an individual about genetic tests or providing information about a genetic test, if such actions are carried out as part of a bona fide wellness program. However, the legislation does prohibit a health care professional from requiring that an individual undergo a genetic test.

*Privacy and confidentiality of genetic information*

The HHS Standards for Privacy of Individually Identifiable Health Information (medical privacy regulations) (45 CFR Parts 160 and 164; final rule) protect the use and disclosure of all individually-identifiable health information, including genetic information. However, a permitted “use” of health information under the privacy rules (i.e., a specific item under “health care operations”) is underwriting, a practice that is inherently discriminatory. HR 493 expressly bans the use or disclosure of genetic information for purposes of underwriting. In addition, the bill bans health plans and insurance issuers from collecting (i.e., requesting or requiring) genetic information in the first place for purposes of underwriting.

The bill further protects the privacy of genetic information by prohibiting plans and insurance issuers from collecting (i.e., requesting, requiring, or purchasing) genetic information prior to enrollment under the plan.

*Enforcement*

Title I generally uses the same mechanisms to enforce the protections established under this legislation as apply to other violations of these underlying statutes (i.e. the Employee Retirement Income Security Act (ERISA), Public Health Service Act (PHSA), and Social Security Act). In addition, the bill ensures that similarly situated individuals are provided the same protection under the law, regardless of whether they are currently sick or disabled, or currently healthy. All individuals (healthy and sick) have genetic information that could be used to discriminate against them.

With respect to the nondiscrimination requirements, the bill is based on the same penalty and enforcement structure as Title I of HIPAA, which addresses insurance portability and discrimination based on health-status. Aggrieved participants may seek redress either from the Secretary of Labor or the courts.

In addition, for group health plans and health insurance issuers in the individual and group markets, the appropriate Secretary may impose penalties of \$100 per day/per person, with a minimum penalty of \$2,500—up to \$15,000 for multiple violations that are more than de minimis with an outside cap of up to \$500,000 for a violation of the protections against genetic discrimination.

With regard to the privacy provisions established by this legislation, the same enforcement structure and penalties created by the Social Security Act for the HHS privacy standards. Under this legislation, the genetic privacy provisions are enforced by the HHS Office of Civil Rights. The Secretary of HHS may impose civil monetary penalties of \$100 per violation—up to \$250,000 and 10 years in prison for violations committed for commercial advantage, personal gain, or malicious harm.

## Title II—Prohibiting Employment Discrimination on the Basis of Genetic Information

### *Prohibition on discrimination*

The legislation prohibits the use of genetic information in employment decisions, such as hiring, firing, job assignments, and promotions. This prohibition extends to employers, unions, employment agencies, and labor-management training programs.

### *Limitation on acquisition*

Employers, labor organizations, employment agencies, and joint labor-management committees are prohibited from requesting, requiring, or purchasing genetic information about an employee or family member, except for the following legitimate reasons: (1) for genetic monitoring of biological effects of toxic substances in the workplace, (2) if the employer provides genetic services, such as through a wellness program, with the employee's prior consent, or (3) for compliance with the certification provision of the Family and Medical Leave Act or its state equivalent. The purchase of commercially and publicly available documents or inadvertently requesting or requiring family medical history would not violate this title. Under each of these exceptions, however, the genetic information still could not be used or disclosed.

### *Confidentiality protections*

The legislation safeguards the confidentiality of genetic information in the employment setting. If an employer (acting as an employer) acquires genetic information, such information shall be treated and maintained as part of the employee's confidential medical records. Moreover, such information shall not be disclosed except in limited situations, such as to the individual or in order to comply with the certification provisions of Federal or State family and medical leave laws, or a court order.

*Enforcement*

The legislation protects applicants or employees of employers defined under the Civil Rights Act of 1964 (42 U.S.C. 2000e(f)), State employees, Federal employees, Congressional employees, and employees as defined in 3 U.S.C. 411(c)0. Aggrieved individuals are required to file a charge with the appropriate enforcement agency within a certain time period, prior to filing a suit in court. The bill provides for the same compensatory and punitive damages available to prevailing plaintiffs under 42 U.S.C. 1981a.

*Disparate impact*

The bill does not cover claims based on disparate impact and establishes a commission to review the science of genetics and advise the Congress on the need for establishing a separate disparate impact cause of action in the future.

## DEFINITIONS—(GENERALLY APPLY TO BOTH TITLE I AND TITLE II)

Genetic information is defined to include information about an individual's genetic tests; the genetic tests of family members of the individual; or the occurrence of a disease or disorder in family members of the individual. Genetic information does not include information about the sex or age of an individual for purposes of this legislation.

Genetic test is defined as an analysis of DNA, RNA, chromosomes, proteins, or metabolites, that detects genotypes, mutations, or chromosomal changes. A genetic test does not mean an analysis of (1) proteins or metabolites that does not detect genotypes, mutations, or chromosomal changes; or (2) an analysis of proteins or metabolites that is directly related to a manifested disease, disorder, or pathological condition that could reasonably be detected by a health care professional with appropriate training and expertise in the field of medicine involved. The second exception to genetic test only applies to Title I of the legislation.

Genetic Services is defined as a genetic test; genetic counseling (including obtaining, interpreting, or assessing genetic information), or genetic education.

Family Member includes the spouse of an individual, a dependent child, and any other individual who is a first degree, second degree, third degree or fourth degree individual described above.

## Title III—Severability

If a court strikes down a provision of the bill, it shall not affect the legality of other provisions of the bill.

## IV. STATEMENT AND COMMITTEE VIEWS

## SEQUENCING THE HUMAN GENOME

Although genetic science has been developing rapidly over the past 20 years, one of the most prominent symbols of our newfound understanding of genetics was the announcement in April 2003 that a vast team of scientists had determined the exact sequence of the human genetic code and placed that information in public databases. Each day, the practice of medicine is benefiting from

new discoveries about the links between genetic mutations and particular diseases.

This new understanding of the genetic basis of disease holds dangers as well as opportunities. The knowledge that a person carries a mutation in a disease-related gene may be used to inform future medical treatment or as a stimulus to seek preventive care; that same knowledge, however, could also be used for harmful purposes. A health insurance company might wrongly view the presence of the gene mutation to mean that the person would definitely contract the disease with which that gene is associated and improperly deny that person insurance coverage. An employer might use information about an employee's genetic profile to deny employment to an individual who is healthy and able to perform the job.

With these misconceptions so prevalent, employers may come to rely on genetic testing to "weed out" those employees who carry genes associated with diseases. Similarly, genetic traits may come to be used by health insurance companies to deny coverage to those who are seen as "bad genetic risks." Enabling employers, health insurers and others to base decisions about individuals on the characteristics that are assumed to be their genetic destiny would be an undesirable outcome of our national investment in genetic research, and may significantly diminish the benefits that this research offers.

#### CONCERNS ABOUT MISUSE OF GENETIC INFORMATION

The appropriate use of genetic information offers enormous opportunities to save lives and prevent the onset of disease. However, the medical progress made possible by genetic research is dependent on the willingness of study volunteers and patients to undergo genetic testing. Yet, such consent may be difficult to obtain today. Fears about the possible misuse or unauthorized disclosure of genetic information appear to adversely impact the desire of individuals to participate in genetic research. Such fears also extend to clinical practice, discouraging both patients and providers from taking full advantage of genetic tests and technologies.

A study conducted from 2001 to 2003, by Mr. Mark Hall and published in *Genetic Med.*, surveyed 86,859 adults about their willingness to undergo genetic testing. The results revealed that 40 percent felt genetic testing was not a good idea for fear that health insurance companies might deny or drop them from their insurance plan.

The Genetics and Public Policy Center at Johns Hopkins University conducted similar surveys. In 2002, 85 percent of those surveyed did not want employers to have access to their genetic information. By 2004, that number had risen to 92 percent. In 2002, 68 percent of those surveyed said their genetic information should be kept private from health insurers; by 2004, it had increased to 80 percent.

A 2003 study of 470 people with a family history of colorectal cancer showed that nearly half rated their level of concern about genetic discrimination as "high." Those individuals with high levels of concern indicated that they would be significantly less likely to consider meeting with a health care professional to discuss genetic testing, or to undergo testing, thus jeopardizing their ability to pre-

vent this deadly disease (Mr. D.W. Hadley, et. al., *Journal of Clinical Oncology*).

In a recent 2006 Cogent Research poll, 66 percent of respondents said they had concerns about how their genetic information would be stored and who would have access. Sixty-five percent said they were concerned about health insurance companies, and 54 percent were concerned with employers gaining unauthorized access. Seventy-two percent agreed that the government should establish laws and regulations to protect the privacy of individuals' genetic information. And 85% said that without amending the law, employers would discriminate.

Health care professionals are also hesitant to make their genetic information available. In one survey of genetic counselors, 108 out of 159 indicated that they would not submit charges for a genetic test to their insurance companies primarily because of the fear of discrimination. Twenty-five percent responded that they would use an alias to obtain a genetic test so as to reduce the risk of discrimination and maximize confidentiality. And 60 percent indicated they would not share the information with a colleague because of the need for privacy and fear of job discrimination. (E.T. Matloff, et. al., *Journal of Clinical Oncology*, 2000.)

#### FEDERAL LAW ON GENETIC DISCRIMINATION IN HEALTH INSURANCE

The Health Insurance Portability and Accountability Act (HIPAA) affords some protection against discriminatory practices in health insurance based on an individual's genetic information. In general, HIPAA ensures that individuals who change health insurance carriers (usually after switching jobs or losing employment) do not have their coverage denied or unduly restricted because of pre-existing medical conditions. HIPAA also prohibits a health insurance carrier from charging one individual within a group higher rates than other "similarly situated" individuals in the same group or determining eligibility to enroll in health insurance coverage, based on a health status-related factor. HIPAA includes genetic information as part of its definition of a "health status-related factor" which cannot be used to deny coverage, and excludes genetic information (in the absence of a diagnosis) from its definition of a pre-existing medical condition. Nonetheless, the Act has several important limitations in protecting Americans against genetic discrimination in health insurance. First, its protections against denying coverage on the basis of factors related to health status apply only to the group insurance market. HIPAA does not address discrimination in the individual market, and state laws vary considerably with regard to restrictions on using genetic information to set premiums or determine eligibility. In addition, HIPAA does not prohibit an insurance company from raising the premiums for the group health plan as a whole, based on the genetic information of an individual in that group.

#### FEDERAL PROTECTIONS AGAINST GENETIC DISCRIMINATION IN EMPLOYMENT

Federal employees have considerable protection against genetic discrimination under the terms of Executive Order 13145 issued on February 10, 2000, 65 CFR 6877. Under this order, Federal employees may not be discharged or otherwise subjected to restric-

tions in their employment or their employment-related benefits on the basis of protected genetic information. The Executive Order also provides protections against improper collection of employees' genetic information and against unauthorized disclosure of that information. Despite these protections, the Executive Order has no enforcement provisions.

Most employees in the private sector, however, enjoy no similar protections. In hearings, the Committee heard testimony that existing Federal employment laws, the Americans with Disabilities Act (ADA) and Title VII of the Civil Rights Act of 1964 (Title VII) provide limited or uncertain protections against the discriminatory use of genetic information in the workplace.

#### TITLE VII OF THE CIVIL RIGHTS ACT OF 1964

Title VII of the Civil Rights Act of 1964 makes it illegal for an employer, labor organization, employment agency, or training program to "discriminate against any individual \* \* \* because of such individual's race, color, religion, sex, or national origin." While this law provides express guarantees against discrimination on the basis of these characteristics, its applicability to genetic discrimination is limited. The plain language of the statute provides no obvious protection against genetic discrimination. Still, Title VII may indirectly offer some protections against discrimination on the basis of a person's genetic makeup when that discrimination disproportionately affects individuals on the basis of one of the characteristics specified in the Act.

For example, the genetic mutation associated with Tay-Sachs Disease is found most commonly in persons with an Eastern European Jewish ethnic background. If an employer were to selectively refuse to hire carriers of the Tay-Sachs mutation, this action would have a disproportionate effect on people with a specific national or ethnic origin. In this limited circumstance, the individuals experiencing such discrimination might have a claim under Title VII. However, for acts of genetic discrimination that do not have a discriminatory effect on members of class of individuals named in the Civil Rights Act, Title VII would provide no apparent protection.

#### STATE LAW ON GENETIC DISCRIMINATION

To fill the void created by the absence of clear protections at the Federal level, many states have enacted laws that seek to prohibit genetic discrimination in health insurance and/or employment. To date, 34 states have passed laws on genetic discrimination in employment and 46 have passed laws on genetic discrimination in health insurance (see, National Conference of State Legislatures Genetic Technologies Project). Among the states that prohibit discrimination in the issuing of health insurance, many cover only the group health insurance market and exclude individual health insurance policies, while others do the reverse. Many states exclude family medical histories from their definition of genetic information or include only the results of tests that are performed with announced intention of detecting genetic mutations.

Title I—Genetic Nondiscrimination in Health Insurance  
 AMENDMENTS TO EMPLOYEE RETIREMENT INCOME SECURITY ACT OF  
 1974

The Committee recognizes that ERISA Section 702(a)(1)(F) and 702(b) currently prohibit a group health plan and a health insurance issuer offering group health insurance coverage in connection with a group health plan from discriminating—in eligibility for enrollment or premium contributions—against an individual in the group based on the individual’s health status-related factors, including genetic information. With this section, the Committee intends to clarify and expand these protections, and the remedies and enforcement provided for these protections, for group health plan participants and beneficiaries governed by ERISA.

GENETIC SERVICES

The Committee believes that, in addition to discrimination based on actual genetic information, there is potential for discrimination based on the mere action of requesting or receiving a genetic service. For example, a health plan could potentially assume that a participant has a genetic disorder, such as Huntington’s disease, because the participant, or his or her family member, requested or received a genetic test for the disease. This provision clarifies, within the existing prohibition banning discrimination in enrollment against an individual in the group, that the term genetic information includes “information about a request for or receipt of genetics services by an individual or family member of such individual.”

The Committee’s interpretation regarding the inclusion of “information about a request for or receipt of genetics services by an individual or family member of such individual” applies in each section in which this provision appears, including Sec. 102(a)(1)(B) with respect to health insurance issuers offering coverage in connection with a group health plan, Sec. 2753(a) with respect to a health insurance issuer in the individual market, Section 103(a)(2) with respect to group health plans governed by the Internal Revenue Code, and Section 104 with respect to an issuer of a Medicare supplemental policy.

The Committee believes that fear of discrimination in health insurance and employment is causing large numbers of people to opt out of participating in clinical research for treatments of genetic diseases. Fewer participants in genetic research lead to slower development of treatments, beneficial drugs, and cures. The Committee seeks to provide assurances that participants in genetic clinical trials will not be subject to genetic discrimination in health insurance and employment. Therefore, the Committee intends for this legislation to prohibit discrimination on the basis of participation in clinical research that involves subjects with an elevated genetic risk for disease.

Similar concerns exist in the growing field of genetic counseling and advice. It has been reported that many individuals avoid even the most general genetic services for fear of the consequences. The Committee bill seeks to protect all genetic counseling or advice to consider or pursue medical interventions to reduce risk of future onset of hereditary diseases.

## DISCRIMINATION IN PREMIUMS AGAINST THE GROUP AS A WHOLE

While current law protects individuals in a group from being charged premiums or contributions that are higher than the premiums or contributions for similarly situated individuals, there is no such protection in current law for the group as a whole. Thus, this section prohibits a health insurance issuer offering health coverage in connection with a group health plan from adjusting premium or contribution amounts for a group on the basis of genetic information concerning an individual in the group or a family member of the individual.

## LIMITATION ON GENETIC TESTING

Section 101(b) places limits on a group health plan's ability to request or require an individual, or the family member of the individual, to take a genetic test. As the decision to take a genetic test is a personal one influenced by many factors, including whether any treatment exists for a particular disease, the Committee included this prohibition to ensure that individuals would not feel compelled to take a genetic test. However, the Committee also wishes to ensure that this provision does not interfere with health care practices that could be beneficial to the individual. Accordingly, several clarifications of this provision are included in the legislation. For instance this provision does not limit in any manner the authority of the treating health care professional to request that an individual or family member undergo a genetic test. However, the treating health care professional may not require the individual or family member to undergo a genetic test.

The Committee believes that, given different motivations by and perceptions of health plans versus treating health care professionals, this distinction is warranted. However, the Committee is also aware that some health plans go beyond the insurance function and engage in wellness and disease management programs; and the Committee does not wish to discourage such efforts. Thus, Section 101(b) makes clear that this legislation does not limit the authority of a health care professional who is employed by or affiliated with the group health plan or health insurance issuer who is providing health care services to the enrolled individual as part of a bona fide wellness program from notifying such individual about the availability of a genetic test or providing information about the genetic test.

The provision prohibiting a health plan from requesting or requiring an individual to undergo a genetic test was included to protect health plan participants from actions that would allow a health plan to obtain genetic information to be used for the purposes of insurance discrimination. It only addresses the act of requesting or requiring an individual to undergo a test. The Committee recognizes that this provision does not address the use, disclosure, or collection of existing test results and intends for the flow of genetic information to be governed by the HHS medical privacy rules and Section 104 of Title I of this legislation.

## ENFORCEMENT AND REMEDIES

The Committee modified the provisions of the bill with respect to remedies. HR 493 as introduced relied on ERISA's existing enforce-

ment scheme plus the addition of specific injunctive relief requirements and administrative penalties to protect victims of genetic information discrimination and related violations. While the Committee supports clarifying and strengthening the legal protections afforded to individuals under ERISA, the Committee was concerned that providing relief solely for genetic information violations would create an uneven legal structure and could be interpreted to undermine existing ERISA enforcement.

The Committee is painfully aware of the narrow interpretation that the courts have given to the remedies available for violations of ERISA. The Committee reiterates its view that ERISA itself and its legislative history demonstrate that Congress used the terms “appropriate relief” or “appropriate equitable relief” intending for those terms to be interpreted broadly so as to provide meaningful redress to aggrieved individuals.

The Committee does not find it practicable to use genetic information legislation to address broader weaknesses resulting from judicial interpretations of ERISA’s enforcement scheme. For this reason, the bill reported by the Committee relies on the existing enforcement scheme to redress violations of the Act. Enforcement of this section relies on section 502 of ERISA, which provides ERISA plan participants with a private right of action, as well as Secretarial enforcement mechanisms.

The bill encourages the Secretary of Labor to assist individuals aggrieved under the Act and provides the Secretary specific monetary penalty authority to redress and discourage violations of the law.

#### PRIVACY AND CONFIDENTIALITY

In general, the Committee believes that treating all health information in a consistent or similar matter will encourage third-party payers to cover genetics tests, technologies, and services. Consistent treatment of all medical information is important in enabling genetics to become part of main stream medicine. Thus, the Committee has concluded, especially with respect to the “use and disclosure” of information, that it is inherently difficult to separate genetic information from other medical information in the delivery of health care and medical research, and therefore inconsistent rules for the “use and disclosure” of different categories of health information would likely be burdensome and potentially harmful to patient care.

The legislation generally recognizes that the HHS medical privacy regulations apply to the “use and disclosure” of genetic information, provided that such regulations are not in conflict with this Title. However, a provision in the medical privacy regulations pertaining to underwriting and insurance rating is inherently discriminatory, and thus inconsistent with the purpose of this legislation. Specifically, there is a provision in the privacy regulations, under the heading of “health care operations,” that allows, without prior consent, a covered entity to “use or disclose” genetic information for purposes of premium rating, underwriting, or establishing or renewing a contract for coverage or insurance. Since one of the purposes of this legislation is to prevent discrimination in premium rates, this provision prohibits a plan or issuer from using or disclosing genetic information for purposes of underwriting, deter-

mining eligibility to enroll, premium rating, or the creation, renewal or replacement of a plan, contract or coverage for health insurance or benefits.

In addition, the legislation states that a covered entity shall not request, require, or purchase genetic information concerning a participant, beneficiary, or enrollee prior to the enrollment and in connection with such enrollment under the plan, coverage, or policy. This language was included because the HHS medical privacy regulations presume that covered health care entities possess health care information and thus the regulations focus on the “use and disclosure” of protected health information. Since health insurance issuers typically treat underwriting as a separate business function and process from coverage decisions and medical management, the Committee believes that this important layer of protection will not adversely impact the delivery of patient care and health care improvement activities.

The Committee believes that if a covered entity is barred from using or disclosing genetic information for purposes of underwriting, it should not be able to collect such information in the first place as part of the underwriting, application, or some other pre-enrollment process or interaction. Underwriting includes modification or imposition of preexisting condition exclusion periods or other coverage limitations.

However, the Committee also recognizes that there may be situations in which a health plan or insurance issuer obtains genetic information prior to enrollment, but not in connection with that particular enrollment. For instance, an individual seeking coverage under a plan currently may have been enrolled in the plan previously, and therefore the plan has likely, in making coverage determinations or conducting disease management activities, collected genetic information prior to the individual’s current enrollment. Or, if a family member of an individual enrolling for coverage under a plan is already a member of the plan, such plan would likely have collected genetic information “prior to enrollment.” The Committee does not intend to prohibit this type of collection and thus includes in the legislation the phrase “and in connection with such enrollment” to clarify. However, the Committee emphasizes that, regardless of the means by which genetic information is collected, whether in connection with enrollment or not, Sections 101–103 of the legislation prohibits health plans and health insurance issuers from using genetic information to adjust premiums or determine eligibility.

The Committee understands that genetic information permeates health information and that covered entities may inadvertently or unintentionally acquire genetic information. For instance, a health insurance issuer may purchase another health plan and all of its medical records, or request medical records or previously taken lab tests for purposes of underwriting. Or, in filling out an application for insurance that includes a medical questionnaire, an individual may voluntarily offer additional health information, such as family medical information which is considered genetic information under this bill. Thus, a provision addressing “incidental collection” is included in the legislation to make clear that if a plan, or an issuer obtains genetic information incidental to the requesting, requiring, or purchasing of other information concerning an individual, such

request, requirement, or purchase shall not be considered a violation if it is not obtained for purposes of underwriting and any genetic information obtained incidentally is not used or disclosed in violation of the HHS medical privacy regulations.

The legislation applies to all group health plans and issuers that are otherwise covered by the HHS medical privacy rules. Therefore, there are a very limited number of plans and issuers that are covered by the nondiscrimination provisions of this bill, but not under this section (such as a group health plan with less than 50 participants that self-administers). The Committee believes that since the privacy provisions contained in this legislation are inextricably linked to and coordinated with the HHS privacy regulations, it would be difficult for an entity to comply with the requirements of this section without also complying with all of the medical privacy regulations. The Committee did not wish to introduce for the first time such a substantial burden on very small plans. Covered entities under the genetic privacy and confidentiality standards of this legislation are subject to the same penalties and enforcement structure that exist for the HHS privacy regulations under sections 1176 and 1177 of the Social Security Act.

The Committee believes that long term care insurance is not intended to be subject to Section 104. Since benefits for long term care are “excepted benefits” under Section 733(c)(2)(B) of ERISA, Section 2791(c)(2)(B) of the PHSA, and Section 9832(c)(2)(B) of the Internal Revenue Code, it has never been the intent of the bill to subject long term care insurance to any of the bill’s prohibitions with respect to health insurance discrimination on the basis of genetic information or genetic services.

## Title II—Employment

### DEFINITIONS

As a guiding principle, the Genetic Information Nondiscrimination Act of 2007 is designed to extend to individuals in the area of genetic discrimination the same procedures and remedies as are provided under Title VII of the Civil Rights Act of 1964, as amended. These individuals include employees and applicants working in the private sector, in federal and state governments (including presidential and gubernatorial appointees), as well as congressional employees. The corresponding employers of these individuals, as well as employment agencies, labor organizations, and joint labor-management committees are covered by the legislation in the same manner as current law.

As in Title I of the legislation, “genetic information” is defined as information about an individual’s or family member’s genetic tests, or information about the occurrence of a disease or disorder in family members of the individual. Likewise, “genetic test” is defined in the same way under Titles I and II, except that the Employment title does not include an exception for an analysis that is directly related to a manifested disease, disorder, or pathological condition. In making this distinction, the Committee recognizes there are important and necessary uses for non-genetic health information in the health insurance setting that are not applicable in the employment context.

Section 210 specifically provides that the parties “shall not be considered to be in violation of this title based on the use, acquisition, or disclosure of medical information that is not genetic information about a manifested disease, disorder, or pathological condition of an employee or member, including a manifested disease, disorder, or pathological condition that has or may have a genetic basis.”

As stated in the discussion of Title I, the Committee realizes that a family medical history could be used as a surrogate for genetic traits by a health plan or health insurance issuer. A consistent history of a heritable disease in a patient’s family may be viewed to indicate that the patient himself or herself is at increased risk for that disease. For this reason, the Committee deems it important to include family medical history in the definition of “genetic information.” In so doing, the Committee followed the recommendations of numerous leading experts in genetic science. Further, the bill applies to spouses and adopted children of an individual because of the potential discrimination an employee or member could face because of an employer’s or other entities’ concern over potential medical or other costs and their effect on insurance rates.

#### PROHIBITED PRACTICES

Generally, employers, labor organizations, employment agencies, and joint labor-management committees are prohibited from using, acquiring or disclosing the genetic information of an individual or his/her family members.

##### *Use of genetic information*

“Use” of genetic information, as drafted in the legislation, utilizes the language of Section 703 of the Civil Rights Act of 1964, as amended, and the same forms of discriminatory acts are outlawed. These acts include refusing to hire or discharging a person based on the genetic information including family history of disease. For example, it would be unlawful for an employer to refuse to hire an otherwise healthy applicant because of a fear that he may develop Parkinson’s disease because of a family history of such disease. The prohibition also extends to limiting, segregating, or classifying an individual in a way that would deprive him or her of employment opportunities.

##### *Acquisition of genetic information*

Banning the use of genetic information alone would not reach the full range of serious concerns that the Genetic Information Non-discrimination Act is seeking to address. The Committee recognizes that the fear of misuse of genetic information and privacy concerns deter individuals from being tested for genetic disorders, seeking genetic services, or participating in important genetic research. Scientific advances in the field of genetics hold great promise for medical prevention and new treatments and therapies. As a matter of sound public policy, the Committee is concerned that this promise will go unfulfilled if individuals decline to get genetic tests or seek genetic counseling out of fear that they will face discrimination in their employment.

To this end, the legislation makes it unlawful for an employer, labor organization, employment agency, or joint labor-management

committee to request, require, or purchase genetic information, except under limited circumstances. Most notably, this prohibition addresses the concerns raised in the case against Burlington Northern Santa Fe Railroad (BNSF). The company, allegedly without employees' consent or knowledge, conducted genetic tests on blood samples it had previously received from some workers. The U.S. Equal Employment Opportunity Commission filed suit against the company under the Americans with Disabilities Act, relying on the third prong of the definition of "disability" as "being regarded as having such an impairment." The case was ultimately settled so the courts have not had the opportunity to interpret the full application of the "regarded as" prone to genetics discrimination.

The unlawful employment practices specified under section 202 (a)(1) and (2) prohibit employer conduct directed at prospective employees in the hiring process, current employees of the employer and former employees. The prohibited practices are intended to be very broad, making it an unlawful practice to refuse to hire or to discharge an employee on the basis of genetic information or to discriminate against an employee with respect to compensation, terms, conditions and privileges of employment on the basis of that information. Also unlawful are any employment practices that would limit, segregate or classify an employee in any way that would deprive the employee of employment opportunities or otherwise adversely affect the status of the employee on the basis of genetic information.

The Committee intends this bill to prohibit the practice of utilizing genetic information in the evaluation and determination of eligibility of a claim for workers compensation for a work-related injury or illness, as was done in the Burlington-Northern and Santa Fe Railway Company (BNSF) case; a case which prompted passage of this bill. In *BNSF*, the employer sought to require employees to undergo genetic tests in the evaluation of carpal tunnel syndrome related to employment. Although the company denied that it had engaged in any unlawful practice with respect to the collection of genetic information, the U.S. Equal Employment Opportunity Commission mediated a \$2.2 million dollar settlement on behalf of 36 affected workers. The EEOC considered the mere gathering of employees' genetic information to constitute a violation of the Americans with Disabilities Act. The Committee believes that section 202 clearly prohibits such a practice. The prohibition on the use of genetic information for the evaluation of a work-related injury or illness or determination of eligibility for workers compensation is intended to apply to employers and any entity or person acting on the employer's behalf.

The first exception addresses the so-called "water cooler problem," in which an employer unwittingly receives otherwise protected genetic information in the form of family medical history through casual conversations with a worker. The Committee recognizes that conversations among co-workers about the health of a family member are common and intends to prevent such normal interaction from becoming the basis of litigation under this Act. Without the exception, the Committee is concerned that discussion in the workplace of a family member's health condition that is genetically based could be interpreted as an employer requesting or requiring genetic information from an individual. Under the legis-

lation, an employer, labor organization, employment agency, or joint labor-management committee will not violate the ban on acquiring genetic information where it “inadvertently requests or requires family medical history” of the individual or family member of the individual.

The second exception—which preserves employer-sponsored wellness programs—is necessary to achieve the bill’s stated goal of encouraging employees to take advantage of genetic technologies and opportunities to improve human health without fear of discrimination by their employer. To qualify for the exception, this program must be a bona fide wellness program as defined under Section 702 of ERISA. Participation in the program must be voluntary and confidential, and safeguards must be in place to ensure that the sponsoring employer, labor organization, employment agency, or joint labor-management committee does not have access to individually identifiable health information, as defined under the HHS medical privacy regulations.

The Committee did not want restrictions on information about the health condition of a family member to conflict with the certification procedures under federal and state family and medical leave laws. For example, an employee seeking time off to care for a sick family member may be required to certify the request with a note from the treating physician. The doctor’s note may contain genetic information, which is defined for the purposes of this legislation to include family medical history. The third exception eliminates the potential for conflict with existing laws by exempting requests or requirements for family medical history when sought “to comply with the certification provisions of section 103 of the Family and Medical Leave Act of 1993 (29 U.S.C. 2613) or such requirements under State family and medical leave laws.”

The Committee recognizes that family medical history can easily and inadvertently be obtained. The fourth exception, like the first, relates to the inadvertent acquisition of family medical history. The Committee is concerned that the proscriptions of the legislation would be violated, for example, through the purchase of a local newspaper containing the obituary of an employee’s parent who died of breast cancer. This exception was included to satisfy the principle underlying the bill that the rules be clear and that the bill not provide a basis for frivolous claims. Specifically, the fourth exception provides an exemption where an employer, labor organization, employment agency, or joint labor-management committee “purchases documents that are commercially and publicly available (including newspapers, magazines, periodicals, and books, but not including medical databases or court records) that include family medical history.” In referring to “documents,” the Committee is mindful of Rule 34 of the Federal Rules of Civil Procedure that includes the same materials that are electronically available.

The final exception to the rule against requesting, requiring, or purchasing genetic information protects genetic monitoring of biological effects of toxic substances in the workplace, but only in limited circumstances. The employer, labor organization, employment agency, or joint labor-management committee must give written notice. Unless the monitoring is required by federal or state law, the individual must provide prior, knowing, voluntary and written authorization. The individual must be provided the results of the

monitoring. The monitoring must be conducted in compliance with any genetic monitoring regulations, whether promulgated under the Occupational Safety and Health Act (or its state equivalent), the Federal Mine Safety and Health Act, or the Atomic Energy Act. Finally, the monitoring results may only be disclosed to the employer, labor organization, employment agency, or joint labor-management committee in the aggregate and where no individually identifiable information is included. Regardless of whether an exception applies, the bill makes clear that genetic information, once acquired, may not be used or disclosed in violation of the legislation.

*Confidentiality of genetic information*

Faced with concerns about the disclosure of confidential genetic information, individuals may not take advantage of genetic tests, services or counseling, or participate in genetic research. The Committee believes that there are very few instances when an employer, labor organization, employment agency, or joint labor-management committee would have a legitimate need to divulge the genetic information that may be in its possession. The legislation adopts the general rule that such information shall be maintained on separate forms and in separate medical files and be treated as a confidential medical record. This system is intended to be consistent with the ADA's requirements regarding the maintenance and treatment of medical information.

Also as a general rule, an employer, labor organization, employment agency, or joint labor-management committee is prohibited under this legislation from disclosing genetic information. Both for practical reasons and in order not to subject these entities to conflicting legal obligations, five exceptions have been included in the legislation. The genetic information may be provided directly to an individual who receives genetic services. The information may also be disclosed to an occupational or health researcher for research in compliance with 45 CFR Part 46, in response to a court order (with certain limitations), to government officials investigating compliance with this title, and in connection with federal or state family and medical leave certification provisions.

REMEDIES AND ENFORCEMENT

The Committee recognizes that an effective remedial scheme and proper enforcement are a necessary element in ensuring that the protections in this legislation are realized in the workplace.

To this end, the Committee has taken advantage of the expertise and process of the EEOC. The legislation protects applicants or employees of employers defined under the Civil Rights Act of 1964, 42 U.S.C. 2000e(f), state employees, federal employees, Congressional employees, and employees as defined in 3 U.S.C. 411(c). Claimants are required to file a charge with the appropriate enforcement agency, within a certain time period, prior to filing a suit in court. The bill provides for the same compensatory and punitive damages available to prevailing plaintiffs under 42 U.S.C. 1981a.

Because the legislation expressly covers state employees, the Committee notes the record of state discrimination in genetics. Based on early genetic science, states enacted laws that provided for the sterilization of "undesirable" persons having presumed ge-

netic “defects” such as mental retardation, mental disease, epilepsy, blindness, and hearing loss, among other conditions. The first sterilization law was enacted in the State of Indiana in 1907. In the years following, many States enacted legislation that either incorporated provisions or drew inspiration from the first sterilization law. A majority of States adopted sterilization laws to “correct” apparent genetic traits or tendencies. Many of these State laws have since been repealed, and many have been modified to include essential constitutional requirements of due process and equal protection. The Supreme Court’s earliest decision on the constitutionality of state sterilization statutes certainly does not reflect contemporary norms, but the case has never been officially overruled by the Court. *Skinner v. Oklahoma*, 316 U.S. 535 (1942). The current explosion in the science of genetics, and the history of sterilization laws by the States based on early genetic science, compels Congressional action in this area.

#### CONSTRUCTION

The Committee clarified the rules of construction of this bill with other existing laws and added a provision making clear that nothing in Title II should be construed to require any specific benefit for an employee or member or a family member of an employee or member under any group health plan or health insurance issuer offering group health insurance coverage in connection with a group health plan. This same exception was included in Executive Order 13145.

#### V. SECTION-BY-SECTION ANALYSIS

##### Title I—Genetic Non-Discrimination in Health Insurance

Sec. 101.—Amendments to Employee Retirement Income Security Act of 1974 Subsection (a). Prohibition of Health Discrimination on the Basis of Genetic Information or Genetic Services.

Sec. 101(a)(1)—No Enrollment Restriction for Genetic Services. This provision amends ERISA 702(a)(1)(F) to include “information about a request for or receipt of genetics services by an individual or family member of such individual.”

Sec. 101(a)(2)—No Discrimination in Group Premiums Based on Genetic Information. This provision amends ERISA 702(b) to prohibit a health insurance issuer offering group health coverage in connection with a group health plan from adjusting premium or contribution amounts for a group on the basis of genetic information concerning an individual in the group or a family member of the individual.

Sec. 101(b)—Limitations on Genetic Testing. This section amends Section 702 of ERISA to include a prohibition on genetic testing. Specifically, this provision prohibits a group health plan or a health insurance issuer offering group health insurance coverage in connection with a group health plan from requesting or requiring an individual or a family member of such individual to undergo a genetic test. This section does not limit the authority of the treating health care professional to request that such individual or family member undergo a genetic test. Nor does it limit the authority of a health care professional who is employed by or affiliated with the group health plan or health insurance issuer and who is providing

health care services to the enrolled individual as part of a bona fide wellness program from notifying such individual about the availability of a genetic test or providing information about the genetic test. Finally, this section does not authorize or permit a health care professional to require that an individual undergo a genetic test.

**Application to All Plans.**—This provision applies the requirements of the amendments made by section 101 of the Genetic Information Nondiscrimination Act to small group health plans (and group health insurance coverage offered in connection with a group health plan) that are otherwise exempt, under Section 732(a) of ERISA, from the other non-discrimination prohibitions under Section 702 of ERISA. Therefore, the requirements of such amendments apply to a group health plan (and group health insurance coverage offered in connection with a group health plan) that, on the first day of the plan year, has less than two participants who are current employees for any plan year. Such amendments also apply to retiree only group health plans (and group health insurance coverage offered in connection with a group health plan).

**Sec. 101(c)—Definitions.** This section adds new definitions to Section 733(d) of ERISA with respect to genetic non-discrimination.

**Family Member.**—Means the spouse of the individual, a dependent child, including adopted children; and all other individuals related to the individual by up to four degrees.

**Genetic Information.**—Means information about an individual's genetic tests, the genetic tests of family members of the individual, or the occurrence of a disease or disorder in family members of the individual. It does not include information about the sex or age of an individual.

**Genetic Test.**—Means an analysis of human DNA, RNA, chromosomes, proteins, or metabolites, that detects genotypes, mutations, or chromosomal changes. It does not mean an analysis of proteins or metabolites that does not detect genotypes, mutations, or chromosomal changes or an analysis of proteins or metabolites that is directly related to a manifested disease, disorder, or pathological condition that could reasonably be detected by a health care professional with appropriate training and expertise in the field of medicine involved.

**Genetic Services.**—Means a genetic test; genetic counseling (including obtaining, interpreting, or assessing genetic information or providing genetic advice); or genetic education.

**Section 101(d)—Remedies and Enforcement.** This section amends Section 502 of ERISA to clarify and strengthen remedies available to group health plan participants for violations of the genetic non-discrimination provisions added by Title I.

**Secretarial Enforcement Authority.**—The Secretary is provided specific authority to issue administrative penalties for violation of the sections 101 and 104(b).

**Amount of Penalty.**—Specifically, the Secretary of Labor may impose a civil penalty against a group health plan sponsor or issuer for any violation of this Section in the amount of \$100 for each day in the noncompliance with respect to each individual to whom such failure relates. A higher penalty of \$2,500 for each day of non-compliance shall be applied where there is one or more failure with respect to an individual involved and where the plan did not correct the failure within the specified time. A penalty of \$15,000 shall be

applied if the violation under this Title in any year is more than de minimis.

Sec. 101(e)—Regulations and Effective Date. The Secretary of Labor shall issue final regulations not later than one year after enactment. The amendments made by this act shall apply to group health plans for plan years beginning 18 months after enactment.

Sec. 104(b)—Privacy and Confidentiality.

Applicability.—The provisions in this section apply to health insurance issuers (including issuers offering coverage in connection with group health plans).

Prohibition on Underwriting and Premium Rating.—A group health plan or health insurance issuer of a group health plan shall not use or disclose genetic information (including information about a request for or a receipt of genetic services by an individual or family member of such individual) for purposes of underwriting, determining eligibility to enroll, premium rating, or the creation, renewal or replacement of a plan, contract or coverage for health insurance or benefits.

Prohibition on Collection of Genetic Information.

(A) In General.—A group health plan or health insurance issuer shall not request, require, or purchase genetic information for purposes of underwriting, determining eligibility to enroll, premium rating, or the creation, renewal or replacement of a plan, contract or coverage under the plan or for health insurance or benefits.

(B) Limitation Relating to the Collection of Genetic Information Prior to Enrollment.—A group health plan or health insurance issuer shall not request, require, or purchase genetic information concerning a participant, beneficiary, or enrollee prior to the enrollment, and in connection with such enrollment, of such individual under the plan, coverage, or policy.

(C) Incidental Collection.—Where a group health plan or health insurance issuer obtains genetic information incidental to the requesting, requiring, or purchasing of other information concerning an individual, such request, requirement, or purchase shall not be considered a violation if it is not obtained for purposes of underwriting as defined under paragraph (1) and any genetic information obtained incidentally is not used or disclosed in violation of the HHS medical privacy regulations.

Application of Confidentiality Standards.—The requirements of this Section apply only to group health plans and health insurance issuers that are otherwise covered under the HHS medical privacy regulations. Therefore, the health plan exceptions contained in the medical privacy regulations also apply with respect to the requirements under this Section. The requirements of this section do not apply to genetic information that is not considered to be individually-identifiable under HHS medical privacy regulations.

Definitions.—The definitions of “family member,” “genetic information,” “genetic services,” and “genetic test” are identical to the definitions in Section 101 of this bill. However, a new definition of group health plan is included.

Enforcement.—Covered entities under this section are subject to the same penalties that exist for medical privacy regulations under sections 1176 and 1177 of the Social Security Act for privacy and confidentiality violations of genetic information under Section 104.

Preemption.—The preemption provision for this section is the same standard that exists for the medical privacy regulations. Specifically, a requirement under this section shall supersede any contrary provision of State law unless such provision of State law imposes requirements, standards, or implementation specifications that are more stringent than those imposed under this section.

Sec. 105. Assuring Coordination.—The Secretaries of Health and Human Services, Labor and Treasury shall ensure, through the execution of an interagency memorandum of understanding, that regulations, rulings, and interpretations are administered to have the same effect when there are two or more agencies of jurisdiction. Such Secretaries shall pursue coordinated enforcement strategies and assign priorities in enforcement.

Sec. 106. Regulations and Effective Date.—No later than one year after the date of enactment, the Secretaries of HHS, Labor and Treasury shall issue final regulations. The requirements of this Act shall take effect 18 months after enactment.

## Title II—Prohibiting Employment Discrimination on the Basis of Genetic Information

Sec. 201. Definitions.—The section defines the parties covered by the act—employer, employment agency, labor organization—and ensures that state, federal and congressional employees receive the same protections. Family members are defined as the spouse or dependent child of an individual, including adopted children, and all other individuals related by blood to the individual or his/her spouse. Genetic information is defined as information about genetic tests of an individual or his/her family member. Genetic information also means information about the occurrence of disease or disorder in family members of the individual. It does not, however, include information about the sex or age of an individual. The section defines genetic monitoring, services and tests consistent with Title I.

Sec. 202. Employer Practices.—An employer is prohibited from using genetic information to discriminate against an individual in employment. The section also makes it unlawful for an employer to request, require or purchase genetic information. Several specific exceptions are included: where an employer inadvertently requests or requires family medical history information; pursuant to an employer-sponsored wellness program; where the information relating to a family member is requested or required to comply with the certification provisions of federal or state family and medical leave laws; where an employer purchases family medical history information that is publicly available through such items as newspapers, periodicals and books; or where the information is used for genetic monitoring of the biological effects of toxic substances in the workplace. Despite lawful acquisition of the information through these exceptions, the section makes clear that the employer still may not use or disclose the information in violation of the Title.

Sec. 203. Employment Agency Practices.—This section extends parallel obligations and exceptions to employment agencies as apply to employers under Sec. 202.

Sec. 204. Labor Organization Practices.—This section extends parallel obligations and exceptions to labor organizations as apply to employers under Sec. 202.

Sec. 205. Training Programs.—This section extends parallel obligations and exceptions to joint labor-management committees as apply to employers under Sec. 202.

Sec. 206. Confidentiality of Genetic Information.—The section provides that an individual's genetic information shall be treated and maintained as part of the individual's confidential medical records. The recordkeeping requirements shall be consistent with the recordkeeping requirements of the ADA.

Disclosure is prohibited, except to: the individual; an occupational or health researcher; in response to an order of a court; to government officials investigating compliance with this Title; or to the extent that disclosure is made in connection with the employee's compliance with the certification provisions of Section 103 of the Family and Medical Leave Act, or such requirements under state family and medical leave laws.

Sec. 207. Remedies and Enforcement.—The bill incorporates by reference the powers, remedies, and procedures set forth in Title VII of the Civil Rights Act of 1964, as amended. Similar powers, remedies and procedures are specified for state, federal and congressional employees.

Sec. 208. Disparate Impact.—The bill prohibits claims based on disparate impact, and establishes a commission to review the science of genetics and make recommendations to Congress regarding whether to provide a disparate impact cause of action under this Act.

Sec. 209. Construction.—This section provides several rules of construction to clarify the intent of the Committee and to assist courts in interpreting the Title. The section makes clear that this Title shall not be construed to limit the rights or protections of individuals under the Americans with Disabilities Act or the Rehabilitation Act of 1973. Similarly, the section clarifies that Title II does not create violations for employers, employment agencies, labor organizations, or joint labor-management committees of provisions under Title I. The section clarifies that the Act sets the floor for individual rights and protections and does not limit the rights and protections under other federal or state laws. Workers compensation laws are neither expanded nor restricted by the bill. Finally, the section provides rules of construction to ensure the proper operation of federal programs and laws, including the Armed Services Repository of Specimen Samples, occupational health and safety research, and workplace safety and health laws and regulations.

Sec. 210. Medical Information.—That Is Not Genetic Information.—The section makes clear that the Act does not extend to manifested diseases and illnesses.

Sec. 211. Regulations.—Not later than one year after the date of enactment of this title, the Commission shall issue final regulations to carry out this title.

Sec. 212. Appropriations.—There are authorized to be appropriated such sums as may be necessary to carry out this title.

Sec. 213. Effective date.—This title takes effect on the date that is 18 months after the date of enactment.

## Title III—Miscellaneous

Sec. 301. Severability.—If any provision of this Act is held to be unconstitutional, the remainder of the Act shall not be affected thereby.

## VI. EXPLANATION OF AMENDMENTS

An amendment by Mr. Kline was accepted to ensure record keeping of confidential genetic information was consistent with ADA's requirements for medical files containing confidential information to be maintained separate from employee files.

Reps. Walberg/Hoekstra offered an amendment to modify the definition of family member. This amendment would have changed the definition of family member (b) from "a dependent child of the individual" to "a dependent child of the individual, including a child to be born to or to be adopted". The amendment failed by a vote of 20 to 27.

## VII. APPLICATION OF LAW TO THE LEGISLATIVE BRANCH

Section 102(b)(3) of Public Law 104–1, the Congressional Accountability Act, requires a description of the application of this bill to the legislative branch. H.R. 493 prohibits discrimination on the basis of genetic information with respect to health insurance and employment for Congressional and Executive Branch employees. With respect to health insurance, the provisions of H.R. 493 would indirectly apply to the Federal Employees Health Benefits Program (FEHBP) which contracts with insurance issuers and provides coverage to Members and employees of the legislative branch. The impact of this legislation on the FEHBP likely will not be relevant, however, given that the FEHBP already has broad non-discrimination rules in place, and given the fact that, pursuant to existing laws and regulations, eligibility for enrollment in the FEHBP is based solely on employment with the Federal Government, not medical conditions. With respect to employment, Executive Order 13145, issued February 10, 2000, prohibits discrimination in Federal employment based on genetic information, and current laws and regulations ensure that disqualification for Federal employment can only be based on job-related criteria.

## VIII. REGULATORY IMPACT STATEMENT

The Committee has determined that there will be minimal increases in the regulatory burden imposed by this bill.

Title I of the bill generally builds on existing regulatory structures and industry practices. It is composed of several sections and applies to group health plans, group health insurance, insurers in the individual market, and issuers of Medicare supplemental policies. All non-governmental and many non-Federal State and local governmental group health plans are subject to existing protections under ERISA, PHSA, and IRC that pertain to discrimination based on health-status. These plans are also currently subject to the HHS medical privacy rules. While the legislation adds to the substance of these existing requirements, it does not add any major new concepts or requirements, such as a notice requirement. Based on

these factors, the Committee has determined that there will be negligible regulatory impact with respect to group health plans.

Although insurance issuers of Medicare supplemental policies and individual policies are not subject to Federal law banning genetic discrimination, many States have already passed laws in this area. In addition, the majority of these issuers are currently subject to the HHS medical privacy rules. Thus, the Committee has determined that there will be minimal regulatory burden imposed with respect to insurance issuers Medicare supplemental policies and individual policies.

#### IX. UNFUNDED MANDATE STATEMENT

Section 423 of the Congressional Budget and Impoundment Control Act (as amended by Section 101(a)(2) of the Unfunded Mandates Reform Act, P.L. 104-4) requires a statement of whether the provisions of the reported bill include unfunded mandates.

See CBO estimate.

#### X. EARMARK STATEMENT

H.R. 493 does not contain any congressional earmarks, limited tax benefits, or limited tariff benefits as defined in clause 9(d), 9(e) or 9(f) of rule XXI.

**COMMITTEE ON EDUCATION AND LABOR**  
**U.S. HOUSE OF REPRESENTATIVES – 110<sup>th</sup> CONGRESS**

ROLL CALL: 1                      BILL: H.R. 493                      DATE: 2/17/2007  
 AMENDMENT NUMBER: 3    DEFEATED 20 to 27  
 SPONSOR/AMENDMENT: WALBERG/HOEKSTRA

MEMBER	AYE	NO	PRESENT	NOT VOTING
Mr. MILLER, Chairman		X		
Mr. KILDEE, Vice Chairman	X			
Mr. PAYNE		X		
Mr. ANDREWS		X		
Mr. SCOTT		X		
Ms. WOOLSEY		X		
Mr. HINOJOSA		X		
Mrs. McCARTHY		X		
Mr. TIERNEY		X		
Mr. KUCINICH		X		
Mr. WU		X		
Mr. HOLT		X		
Mrs. SUSAN DAVIS		X		
Mr. DANNY DAVIS		X		
Mr. GRIJALVA		X		
Mr. TIMOTHY BISHOP		X		
Ms. SANCHEZ		X		
Mr. SARBANES		X		
Mr. SESTAK		X		
Mr. LOEBSACK		X		
Ms. HIRONO		X		
Mr. ALTMIRE	X			
Mr. YARMUTH		X		
Mr. HARE		X		
Ms. CLARKE		X		
Mr. COURTNEY		X		
Ms. SHEA-PORTER		X		
Mr. McKEON	X			
Mr. PETRI	X			
Mr. HOEKSTRA	X			
Mr. CASTLE		X		
Mr. SOUDER	X			
Mr. EHLERS	X			
Mrs. BIGGERT		X		
Mr. PLATTS				X
Mr. KELLER	X			
Mr. WILSON	X			
Mr. KLINE	X			
Mr. INGLIS				X
Mrs. McMORRIS RODGERS	X			
Mr. MARCHANT	X			
Mr. PRICE	X			
Mr. FORTUNE	X			
Mr. BOUSTANY	X			
Mrs. FOXX	X			
Mr. KUHL	X			
Mr. ROB BISHOP	X			
Mr. DAVID DAVIS	X			
Mr. WALBERG	X			
<b>TOTALS</b>	<b>20</b>	<b>27</b>		<b>2</b>

## XI. COMMITTEE CORRESPONDENCE

None.

## XII. STATEMENT OF OVERSIGHT FINDINGS AND RECOMMENDATIONS OF THE COMMITTEE

In compliance with clause 3(c)(1) of rule XIII and clause 2(b)(1) of rule X of the Rules of the House of Representatives, the Committee's oversight findings and recommendations are reflected in the body of this report.

## XIII. NEW BUDGET AUTHORITY AND CBO COST ESTIMATE

With respect to the requirements of clause 3(c)(2) of rule XIII of the House of Representatives and section 308(a) of the Congressional Budget Act of 1974 and with respect to requirements of 3(c)(3) of rule XIII of the House of Representatives and section 402 of the Congressional Budget Act of 1974, the Committee has received the following estimate for H.R. 493 from the Director of the Congressional Budget Office:

*H.R. 493—Genetic Information Nondiscrimination Act of 2007*

H.R. 493 would amend the Employee Retirement Income Security Act of 1974 (ERISA), the Public Health Service Act, and Title XVIII of the Social Security Act to prohibit the use of genetic information (including results of genetic tests and family history of disease) by employers in employment decisions and by health insurers and health plans in making enrollment determinations and setting insurance premiums.

CBO estimates that enacting the bill would increase the number of individuals who obtain health insurance by about 600 people per year, nearly all of whom would obtain insurance in the individual market. The bill would affect federal revenues because the premiums paid by some of those newly insured individuals would be tax-deductible.

CBO estimates that enacting H.R. 493 would reduce revenues by less than \$500,000 in each year from 2008 through 2017, by \$1 million over the 2008–2012 period, and by \$2 million over the 2008–2017 period. (These estimates include reductions in off-budget receipts from Social Security payroll taxes of less than \$500,000 over the 2008–2012 period, and slightly less than \$1 million over the 2008–2017 period.) The bill's requirements would apply to Medicare Supplemental Insurance, which could affect direct spending for Medicare. However, we estimate that the bill would have no significant effect on direct spending.

The bill would require the Secretaries of Health and Human Services (HHS), Labor, and the Treasury to issue regulations to carry out the provisions of this bill, and would require the Secretaries of HHS and Labor to enforce those provisions. In addition, six years after enactment, the bill would establish a commission to review the science of genetics and to make recommendations to the Congress on the need to establish a disparate impact standard for genetic discrimination. The bill would authorize the appropriation of such sums as necessary to establish the commission and to carry out the other provisions of the bill. Assuming the appropriation of the necessary amounts, CBO estimates that implementing H.R.

493 would increase discretionary spending by less than \$500,000 in 2008 and by \$2 million over the 2008–2017 period.

H.R. 493 would preempt some state laws that establish confidentiality standards for genetic information, and would restrict how state and local governments use such information in employment practices and in the provision of health care to employees. The preemption and the limitations on state and local actions would be intergovernmental mandates as defined in the Unfunded Mandates Reform Act (UMRA), but there is little indication that state, local, or tribal governments currently engage in or are likely to engage in the activities that would be prohibited by the bill. Consequently, CBO estimates that the costs of the mandates would not be significant and would not exceed the threshold established in UMRA (\$66 million in 2007, adjusted annually for inflation).

The bill contains private-sector mandates on health insurers, health plans, employers, labor unions, and other organizations. CBO estimates that the direct cost of those requirements would not exceed the annual threshold specified in UMRA (\$131 million in 2007, adjusted annually for inflation) in any of the first five years the mandates would be effective.

The CBO staff contacts for this estimate are Shinobu Suzuki (for federal costs), Leo Lex (for the state and local impact), and David Auerbach (for the private-sector impact). This estimate was approved by Peter H. Fontaine, Deputy Assistant Director for Budget Analysis.

#### XIV. STATEMENT OF GENERAL PERFORMANCE GOALS AND OBJECTIVES

In accordance with clause 3(c) of House Rule XIII, the goal of H.R. 493 is to protect individuals from discrimination in health insurance and employment on the basis of genetic information.

#### XV. CONSTITUTIONAL AUTHORITY STATEMENT

Under clause 3(d)(1) of rule XIII of the Rules of the House of Representatives, the Committee must include a statement citing the specific powers granted to Congress in the Constitution to enact the law proposed by H.R. 493. The Committee believes that the amendments made by this bill, which amends ERISA and provides protections against employment discrimination are within Congress' authority under Article I, section 8, clause 1 and clause 3.

#### XVI. COMMITTEE ESTIMATE

Clause 3(d)(2) of rule XIII of the Rules of the House of Representatives requires an estimate and a comparison of the costs that would be incurred in carrying out H.R. 493. However, clause 3(d)(3)(B) of that rule provides that this requirement does not apply when the Committee has included in its report a timely submitted cost estimate of the bill prepared by the Director of the Congressional Budget Office under section 402 of the Congressional Budget Act.

XVII. CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

In compliance with clause 3(e) of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as reported, are shown as follows (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italic, existing law in which no change is proposed is shown in roman):

**EMPLOYEE RETIREMENT INCOME SECURITY ACT OF 1974**

AN ACT To provide for pension reform.

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

SHORT TITLE AND TABLE OF CONTENTS

SECTION 1. This Act may be cited as the “Employee Retirement Income Security Act of 1974”.

TABLE OF CONTENTS

Sec. 1. Short title and table of contents.

TITLE I—PROTECTION OF EMPLOYEE BENEFIT RIGHTS

\* \* \* \* \*

Subtitle B—Regulatory Provisions

\* \* \* \* \*

PART 7—GROUP HEALTH PLAN REQUIREMENTS

\* \* \* \* \*

SUBPART B—OTHER REQUIREMENTS

\* \* \* \* \*

Sec. 714. *Privacy and confidentiality of genetic information.*

\* \* \* \* \*

TITLE I—PROTECTION OF EMPLOYEE BENEFIT RIGHTS

\* \* \* \* \*

SUBTITLE B—REGULATORY PROVISIONS

\* \* \* \* \*

PART 5—ADMINISTRATION AND ENFORCEMENT

CIVIL ENFORCEMENT

SEC. 502. (a) A civil action may be brought—

(1) \* \* \*

\* \* \* \* \*

(6) by the Secretary to collect any civil penalty under paragraph (2), (4), (5), (6), ~~[(7), or (8)]~~ (7), (8), or (9) of subsection (c) or under subsection (i) or (l);

\* \* \* \* \*

(c)(1) \* \* \*

\* \* \* \* \*

(9) SECRETARIAL ENFORCEMENT AUTHORITY RELATING TO USE OF GENETIC INFORMATION.—

(A) GENERAL RULE.—*The Secretary may impose a penalty against any plan sponsor of a group health plan, or any health insurance issuer offering health insurance coverage in connection with the plan, for any failure by such sponsor or issuer to meet the requirements of subsection (a)(1)(F), (b)(3), or (c) of section 702 or of section 714 in connection with the plan.*

(B) AMOUNT.—

(i) IN GENERAL.—*The amount of the penalty imposed by subparagraph (A) shall be \$100 for each day in the noncompliance period with respect to each participant or beneficiary to whom such failure relates.*

(ii) NONCOMPLIANCE PERIOD.—*For purposes of this paragraph, the term “noncompliance period” means, with respect to any failure, the period—*

(I) *beginning on the date such failure first occurs; and*

(II) *ending on the date such failure is corrected.*

(C) MINIMUM PENALTIES WHERE FAILURE DISCOVERED.—*Notwithstanding clauses (i) and (ii) of subparagraph (D):*

(i) IN GENERAL.—*In the case of 1 or more failures with respect to a participant or beneficiary—*

(I) *which are not corrected before the date on which the plan receives a notice from the Secretary of such violation; and*

(II) *which occurred or continued during the period involved;*

*the amount of penalty imposed by subparagraph (A) by reason of such failures with respect to such participant or beneficiary shall not be less than \$2,500.*

(ii) HIGHER MINIMUM PENALTY WHERE VIOLATIONS ARE MORE THAN DE MINIMIS.—*To the extent violations for which any person is liable under this paragraph for any year are more than de minimis, clause (i) shall be applied by substituting “\$15,000” for “\$2,500” with respect to such person.*

(D) LIMITATIONS.—

(i) PENALTY NOT TO APPLY WHERE FAILURE NOT DISCOVERED EXERCISING REASONABLE DILIGENCE.—*No penalty shall be imposed by subparagraph (A) on any failure during any period for which it is established to the satisfaction of the Secretary that the person otherwise liable for such penalty did not know, and exercising reasonable diligence would not have known, that such failure existed.*

(ii) PENALTY NOT TO APPLY TO FAILURES CORRECTED WITHIN CERTAIN PERIODS.—*No penalty shall be imposed by subparagraph (A) on any failure if—*

(I) *such failure was due to reasonable cause and not to willful neglect; and*

(II) *such failure is corrected during the 30-day period beginning on the first date the person otherwise liable for such penalty knew, or exercising*

*reasonable diligence would have known, that such failure existed.*

(iii) **OVERALL LIMITATION FOR UNINTENTIONAL FAILURES.**—*In the case of failures which are due to reasonable cause and not to willful neglect, the penalty imposed by subparagraph (A) for failures shall not exceed the amount equal to the lesser of—*

(I) *10 percent of the aggregate amount paid or incurred by the plan sponsor (or predecessor plan sponsor) during the preceding taxable year for group health plans; or*

(II) *\$500,000.*

(E) **WAIVER BY SECRETARY.**—*In the case of a failure which is due to reasonable cause and not to willful neglect, the Secretary may waive part or all of the penalty imposed by subparagraph (A) to the extent that the payment of such penalty would be excessive relative to the failure involved.*

(F) **DEFINITIONS.**—*Terms used in this paragraph which are defined in section 733 shall have the meanings provided such terms in such section.*

**[(9)] (10)** The Secretary and the Secretary of Health and Human Services shall maintain such ongoing consultation as may be necessary and appropriate to coordinate enforcement under this subsection with enforcement under section 1144(c)(8) of the Social Security Act.

\* \* \* \* \*

**PART 7—GROUP HEALTH PLAN REQUIREMENTS**

**SUBPART A—REQUIREMENTS RELATING TO PORTABILITY, ACCESS, AND RENEWABILITY**

\* \* \* \* \*

**SEC. 702. PROHIBITING DISCRIMINATION AGAINST INDIVIDUAL PARTICIPANTS AND BENEFICIARIES BASED ON HEALTH STATUS.**

(a) **IN ELIGIBILITY TO ENROLL.**—

(1) **IN GENERAL.**—Subject to paragraph (2), a group health plan, and a health insurance issuer offering group health insurance coverage in connection with a group health plan, may not establish rules for eligibility (including continued eligibility) of any individual to enroll under the terms of the plan based on any of the following health status-related factors in relation to the individual or a dependent of the individual:

(A) \* \* \*

\* \* \* \* \*

(F) Genetic information (*including information about a request for or receipt of genetic services by an individual or family member of such individual*).

\* \* \* \* \*

(b) **IN PREMIUM CONTRIBUTIONS.**—

(1) \* \* \*

(2) **CONSTRUCTION.**—Nothing in paragraph (1) shall be construed—

(A) to restrict the amount that an employer may be charged for coverage under a group health plan *except as provided in paragraph (3)*; or

\* \* \* \* \*

(3) *NO DISCRIMINATION IN GROUP PREMIUMS BASED ON GENETIC INFORMATION.*—For purposes of this section, a group health plan, or a health insurance issuer offering group health insurance coverage in connection with a group health plan, shall not adjust premium or contribution amounts for a group on the basis of genetic information concerning an individual in the group or a family member of the individual (including information about a request for or receipt of genetic services by an individual or family member of such individual).

(c) *GENETIC TESTING.*—

(1) *LIMITATION ON REQUESTING OR REQUIRING GENETIC TESTING.*—A group health plan, or a health insurance issuer offering health insurance coverage in connection with a group health plan, shall not request or require an individual or a family member of such individual to undergo a genetic test.

(2) *RULE OF CONSTRUCTION.*—Nothing in this part shall be construed to—

(A) limit the authority of a health care professional who is providing health care services with respect to an individual to request that such individual or a family member of such individual undergo a genetic test;

(B) limit the authority of a health care professional who is employed by or affiliated with a group health plan or a health insurance issuer and who is providing health care services to an individual as part of a bona fide wellness program to notify such individual of the availability of a genetic test or to provide information to such individual regarding such genetic test; or

(C) authorize or permit a health care professional to require that an individual undergo a genetic test.

(d) *APPLICATION TO ALL PLANS.*—The provisions of subsections (a)(1)(F), (b)(3), and (c) shall apply to group health plans and health insurance issuers without regard to section 732(a).

(e) *GENETIC INFORMATION OF A FETUS.*—Any reference in this section to genetic information concerning an individual or family member of an individual shall, with respect to such an individual or family member of an individual who is a pregnant woman, include genetic information of any fetus carried by such pregnant woman.

\* \* \* \* \*

SUBPART B—OTHER REQUIREMENTS

\* \* \* \* \*

**SEC. 714. PRIVACY AND CONFIDENTIALITY OF GENETIC INFORMATION.**

(a) *APPLICABILITY.*—Except as provided in subsection (d), the provisions of this section shall apply to group health plans, and health insurance issuers offering health insurance coverage in connection with such plans, without regard to section 732(a).

(b) *PROHIBITION ON UNDERWRITING, ELIGIBILITY TERMINATION, PREMIUM RATING, AND PLAN FORMULATION.*—Notwithstanding sec-

tion 104(a)(2)(A) of the Genetic Information Nondiscrimination Act of 2007, a group health plan, or a health insurance issuer offering health insurance coverage in connection with such a plan, shall not use or disclose genetic information (including information about a request for or a receipt of genetic services by an individual or family member of such individual) for purposes of underwriting, determinations of eligibility to enroll, premium rating, or the creation, renewal, or replacement of a group health plan or health insurance coverage offered in connection with such a plan.

(c) PROHIBITION ON COLLECTION OF GENETIC INFORMATION.—

(1) IN GENERAL.—A group health plan, or a health insurance issuer offering health insurance coverage in connection with such a plan, shall not request, require, or purchase genetic information (including information about a request for or a receipt of genetic services by an individual or family member of such individual) for purposes of underwriting, determinations of eligibility to enroll, premium rating, or the creation, renewal or replacement of a plan, contract or coverage for health insurance or health benefits.

(2) LIMITATION RELATING TO THE COLLECTION OF GENETIC INFORMATION PRIOR TO ENROLLMENT.—A group health plan, or a health insurance issuer offering health insurance coverage in connection with such a plan, shall not request, require, or purchase genetic information (including information about a request for or a receipt of genetic services by an individual or family member of such individual) concerning a participant or beneficiary prior to the enrollment, and in connection with such enrollment, of such participant or beneficiary under the plan or coverage.

(3) INCIDENTAL COLLECTION.—Where a group health plan, or a health insurance issuer offering health insurance coverage in connection with such a plan, obtains genetic information incidental to the requesting, requiring, or purchasing of other information concerning a participant or beneficiary, such request, requirement, or purchase shall not be considered a violation of this subsection if—

(A) such request, requirement, or purchase is not in violation of paragraph (1); and

(B) any genetic information (including information about a request for or receipt of genetic services) requested, required, or purchased is not used or disclosed in violation of subsection (b).

(d) APPLICATION OF CONFIDENTIALITY STANDARDS.—The provisions of subsections (b) and (c) shall not apply—

(1) to group health plans, or health insurance issuers offering health insurance coverage in connection with such plans, that are not otherwise covered under the regulations promulgated by the Secretary of Health and Human Services under part C of title XI of the Social Security Act (42 U.S.C. 1320d et seq.) and section 264 of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d–2 note); and

(2) to genetic information that is not considered to be individually-identifiable health information under the regulations promulgated by the Secretary of Health and Human Services under part C of title XI of the Social Security Act (42 U.S.C.

1320d et seq.) and section 264 of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d-2 note).

(e) DEFINITIONS.—In this section:

(1) GENETIC INFORMATION; GENETIC SERVICES.—The terms “family member”, “genetic information”, “genetic services”, and “genetic test” have the meanings given such terms in section 733(d).

(2) GROUP HEALTH PLAN; HEALTH INSURANCE ISSUER.—The terms “group health plan” and “health insurance issuer” include only those plans and issuers that are covered under the regulations described in subsection (d)(1).

SUBPART C—GENERAL PROVISIONS

SEC. 731. PREEMPTION; STATE FLEXIBILITY; CONSTRUCTION.

(a) CONTINUED APPLICABILITY OF STATE LAW WITH RESPECT TO HEALTH INSURANCE ISSUERS.—

(1) IN GENERAL.—Subject to paragraph (2) and except as provided in [subsection (b)] subsections (b) and (c), this part shall not be construed to supersede any provision of State law which establishes, implements, or continues in effect any standard or requirement solely relating to health insurance issuers in connection with group health insurance coverage except to the extent that such standard or requirement prevents the application of a requirement of this part.

\* \* \* \* \*

(c) SPECIAL RULES RELATING TO PRIVACY AND CONFIDENTIALITY OF GENETIC INFORMATION.—

(1) IN GENERAL.—A provision or requirement under section 714 or a regulation promulgated under such section shall supersede any contrary provision of State law unless such provision of State law imposes requirements, standards, or implementation specifications that are more stringent than the requirements, standards, or implementation specifications imposed under such section or such regulations. No penalty, remedy, or cause of action to enforce such a State law that is more stringent shall be preempted by such section.

(2) RULE OF CONSTRUCTION.—Nothing in paragraph (1) shall be construed to establish a penalty, remedy, or cause of action under State law if such penalty, remedy, or cause of action is not otherwise available under such State law.

[(c)] (d) RULES OF CONSTRUCTION.—Except as provided in section 711, nothing in this part shall be construed as requiring a group health plan or health insurance coverage to provide specific benefits under the terms of such plan or coverage.

[(d)] (e) DEFINITIONS.—For purposes of this section—

(1) STATE LAW.—The term “State law” includes all laws, decisions, rules, regulations, or other State action having the effect of law, of any State. A law of the United States applicable only to the District of Columbia shall be treated as a State law rather than a law of the United States.

\* \* \* \* \*

**SEC. 733. DEFINITIONS.**

(a) \* \* \*

\* \* \* \* \*

(d) OTHER DEFINITIONS.—For purposes of this part—

(1) \* \* \*

\* \* \* \* \*

(5) FAMILY MEMBER.—The term “family member” means with respect to an individual—

- (A) the spouse of the individual;
- (B) a dependent child of the individual; and
- (C) any other individual who is a first-degree, second-degree, third-degree, or fourth-degree relative of an individual described in subparagraph (A) or (B).

(6) GENETIC INFORMATION.—

(A) IN GENERAL.—Except as provided in subparagraph (B), the term “genetic information” means information about—

- (i) an individual’s genetic tests;
- (ii) the genetic tests of family members of the individual; or
- (iii) the occurrence of a disease or disorder in family members of the individual.

(B) EXCLUSIONS.—The term “genetic information” shall not include information about the sex or age of an individual.

(7) GENETIC TEST.—

(A) IN GENERAL.—The term “genetic test” means an analysis of human DNA, RNA, chromosomes, proteins, or metabolites, that detects genotypes, mutations, or chromosomal changes.

(B) EXCEPTIONS.—The term “genetic test” does not mean—

- (i) an analysis of proteins or metabolites that does not detect genotypes, mutations, or chromosomal changes; or
- (ii) an analysis of proteins or metabolites that is directly related to a manifested disease, disorder, or pathological condition that could reasonably be detected by a health care professional with appropriate training and expertise in the field of medicine involved.

(8) GENETIC SERVICES.—The term “genetic services” means—

- (A) a genetic test;
- (B) genetic counseling (including obtaining, interpreting, or assessing genetic information); or
- (C) genetic education.

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**PUBLIC HEALTH SERVICE ACT**

\* \* \* \* \*

TITLE XXVII—REQUIREMENTS RELATING TO HEALTH INSURANCE COVERAGE

PART A—GROUP MARKET REFORMS

Subpart 1—Portability, Access, and Renewability Requirements

\* \* \* \* \*

**SEC. 2702. PROHIBITING DISCRIMINATION AGAINST INDIVIDUAL PARTICIPANTS AND BENEFICIARIES BASED ON HEALTH STATUS.**

(a) IN ELIGIBILITY TO ENROLL.—

(1) IN GENERAL.—Subject to paragraph (2), a group health plan, and a health insurance issuer offering group health insurance coverage in connection with a group health plan, may not establish rules for eligibility (including continued eligibility) of any individual to enroll under the terms of the plan based on any of the following health status-related factors in relation to the individual or a dependent of the individual:

(A) \* \* \*

\* \* \* \* \*

(F) Genetic information (*including information about a request for or receipt of genetic services by an individual or family member of such individual*).

\* \* \* \* \*

(b) IN PREMIUM CONTRIBUTIONS.—

(1) \* \* \*

(2) CONSTRUCTION.—Nothing in paragraph (1) shall be construed—

(A) to restrict the amount that an employer may be charged for coverage under a group health plan, *except as provided in paragraph (3)*; or

\* \* \* \* \*

(3) NO DISCRIMINATION IN GROUP PREMIUMS BASED ON GENETIC INFORMATION.—*For purposes of this section, a group health plan, or a health insurance issuer offering group health insurance coverage in connection with a group health plan, shall not adjust premium or contribution amounts for a group on the basis of genetic information concerning an individual in the group or a family member of the individual (including information about a request for or receipt of genetic services by an individual or family member of such individual).*

(c) GENETIC TESTING.—

(1) LIMITATION ON REQUESTING OR REQUIRING GENETIC TESTING.—*A group health plan, or a health insurance issuer offering health insurance coverage in connection with a group health plan, shall not request or require an individual or a family member of such individual to undergo a genetic test.*

(2) RULE OF CONSTRUCTION.—*Nothing in this part shall be construed to—*

(A) *limit the authority of a health care professional who is providing health care services with respect to an individual to request that such individual or a family member of such individual undergo a genetic test;*

(B) limit the authority of a health care professional who is employed by or affiliated with a group health plan or a health insurance issuer and who is providing health care services to an individual as part of a bona fide wellness program to notify such individual of the availability of a genetic test or to provide information to such individual regarding such genetic test; or

(C) authorize or permit a health care professional to require that an individual undergo a genetic test.

(d) APPLICATION TO ALL PLANS.—The provisions of subsections (a)(1)(F), (b)(3), and (c) shall apply to group health plans and health insurance issuers without regard to section 2721(a).

\* \* \* \* \*

Subpart 4—Exclusion of Plans; Enforcement; Preemption

SEC. 2721. EXCLUSION OF CERTAIN PLANS.

(a) \* \* \*

(b) LIMITATION ON APPLICATION OF PROVISIONS RELATING TO GROUP HEALTH PLANS.—

(1) \* \* \*

(2) TREATMENT OF NONFEDERAL GOVERNMENTAL PLANS.—

(A) ELECTION TO BE EXCLUDED.—[If the plan sponsor] Except as provided in subparagraph (D), if the plan sponsor of a nonfederal governmental plan which is a group health plan to which the provisions of subparts 1 through 3 otherwise apply makes an election under this subparagraph (in such form and manner as the Secretary may by regulations prescribe), then the requirements of such subparts insofar as they apply directly to group health plans (and not merely to group health insurance coverage) shall not apply to such governmental plans for such period except as provided in this paragraph.

\* \* \* \* \*

(D) ELECTION NOT APPLICABLE TO REQUIREMENTS CONCERNING GENETIC INFORMATION.—The election described in subparagraph (A) shall not be available with respect to the provisions of subsections (a)(1)(F) and (c) of section 2702 and the provisions of section 2702(b) to the extent that such provisions apply to genetic information (or information about a request for or the receipt of genetic services by an individual or a family member of such individual).

\* \* \* \* \*

SEC. 2722. ENFORCEMENT.

(a) \* \* \*

(b) SECRETARIAL ENFORCEMENT AUTHORITY.—

(1) \* \* \*

\* \* \* \* \*

(3) ENFORCEMENT AUTHORITY RELATING TO GENETIC DISCRIMINATION.—

(A) GENERAL RULE.—In the cases described in paragraph (1), notwithstanding the provisions of paragraph (2)(C), the following provisions shall apply with respect to an action

under this subsection by the Secretary with respect to any failure of a health insurance issuer in connection with a group health plan, to meet the requirements of subsection (a)(1)(F), (b)(3), or (c) of section 2702.

**(B) AMOUNT.—**

(i) **IN GENERAL.**—The amount of the penalty imposed under this paragraph shall be \$100 for each day in the noncompliance period with respect to each individual to whom such failure relates.

(ii) **NONCOMPLIANCE PERIOD.**—For purposes of this paragraph, the term “noncompliance period” means, with respect to any failure, the period—

(I) beginning on the date such failure first occurs; and

(II) ending on the date such failure is corrected.

**(C) MINIMUM PENALTIES WHERE FAILURE DISCOVERED.—**Notwithstanding clauses (i) and (ii) of subparagraph (D):

(i) **IN GENERAL.**—In the case of 1 or more failures with respect to an individual—

(I) which are not corrected before the date on which the plan receives a notice from the Secretary of such violation; and

(II) which occurred or continued during the period involved;

the amount of penalty imposed by subparagraph (A) by reason of such failures with respect to such individual shall not be less than \$2,500.

(ii) **HIGHER MINIMUM PENALTY WHERE VIOLATIONS ARE MORE THAN DE MINIMIS.**—To the extent violations for which any person is liable under this paragraph for any year are more than *de minimis*, clause (i) shall be applied by substituting “\$15,000” for “\$2,500” with respect to such person.

**(D) LIMITATIONS.—**

(i) **PENALTY NOT TO APPLY WHERE FAILURE NOT DISCOVERED EXERCISING REASONABLE DILIGENCE.**—No penalty shall be imposed by subparagraph (A) on any failure during any period for which it is established to the satisfaction of the Secretary that the person otherwise liable for such penalty did not know, and exercising reasonable diligence would not have known, that such failure existed.

(ii) **PENALTY NOT TO APPLY TO FAILURES CORRECTED WITHIN CERTAIN PERIODS.**—No penalty shall be imposed by subparagraph (A) on any failure if—

(I) such failure was due to reasonable cause and not to willful neglect; and

(II) such failure is corrected during the 30-day period beginning on the first date the person otherwise liable for such penalty knew, or exercising reasonable diligence would have known, that such failure existed.

(iii) **OVERALL LIMITATION FOR UNINTENTIONAL FAILURES.**—In the case of failures which are due to reasonable cause and not to willful neglect, the penalty im-

posed by subparagraph (A) for failures shall not exceed the amount equal to the lesser of—

- (I) 10 percent of the aggregate amount paid or incurred by the employer (or predecessor employer) during the preceding taxable year for group health plans; or
- (II) \$500,000.

(E) *WAIVER BY SECRETARY.*—In the case of a failure which is due to reasonable cause and not to willful neglect, the Secretary may waive part or all of the penalty imposed by subparagraph (A) to the extent that the payment of such penalty would be excessive relative to the failure involved.

\* \* \* \* \*

Subpart [3] 2—Other Requirements

\* \* \* \* \*

**SEC. 2753. PROHIBITION OF HEALTH DISCRIMINATION ON THE BASIS OF GENETIC INFORMATION.**

(a) *PROHIBITION ON GENETIC INFORMATION AS A CONDITION OF ELIGIBILITY.*—A health insurance issuer offering health insurance coverage in the individual market may not establish rules for the eligibility (including continued eligibility) of any individual to enroll in individual health insurance coverage based on genetic information (including information about a request for or receipt of genetic services by an individual or family member of such individual).

(b) *PROHIBITION ON GENETIC INFORMATION IN SETTING PREMIUM RATES.*—A health insurance issuer offering health insurance coverage in the individual market shall not adjust premium or contribution amounts for an individual on the basis of genetic information concerning the individual or a family member of the individual (including information about a request for or receipt of genetic services by an individual or family member of such individual).

(c) *GENETIC TESTING.*—

(1) *LIMITATION ON REQUESTING OR REQUIRING GENETIC TESTING.*—A health insurance issuer offering health insurance coverage in the individual market shall not request or require an individual or a family member of such individual to undergo a genetic test.

(2) *RULE OF CONSTRUCTION.*—Nothing in this part shall be construed to—

(A) limit the authority of a health care professional who is providing health care services with respect to an individual to request that such individual or a family member of such individual undergo a genetic test;

(B) limit the authority of a health care professional who is employed by or affiliated with a health insurance issuer and who is providing health care services to an individual as part of a bona fide wellness program to notify such individual of the availability of a genetic test or to provide information to such individual regarding such genetic test; or

(C) authorize or permit a health care professional to require that an individual undergo a genetic test.

## Subpart 3—General Provisions

**SEC. 2761. ENFORCEMENT.**

(a) \* \* \*

[(b) **SECRETARIAL ENFORCEMENT AUTHORITY.**—The Secretary shall have the same authority in relation to enforcement of the provisions of this part with respect to issuers of health insurance coverage in the individual market in a State as the Secretary has under section 2722(b)(2) in relation to the enforcement of the provisions of part A with respect to issuers of health insurance coverage in the small group market in the State.]

(b) *SECRETARIAL ENFORCEMENT AUTHORITY.*—*The Secretary shall have the same authority in relation to enforcement of the provisions of this part with respect to issuers of health insurance coverage in the individual market in a State as the Secretary has under section 2722(b)(2), and section 2722(b)(3) with respect to violations of genetic nondiscrimination provisions, in relation to the enforcement of the provisions of part A with respect to issuers of health insurance coverage in the small group market in the State.*

\* \* \* \* \*

## PART C—DEFINITIONS; MISCELLANEOUS PROVISIONS

**SEC. 2791. DEFINITIONS.**

(a) \* \* \*

\* \* \* \* \*

(d) **OTHER DEFINITIONS.**—

(1) \* \* \*

\* \* \* \* \*

(15) **FAMILY MEMBER.**—*The term “family member” means with respect to an individual—*

(A) *the spouse of the individual;*

(B) *a dependent child of the individual, including a child who is born to or placed for adoption with the individual; and*

(C) *all other individuals related by blood to the individual or the spouse or child described in subparagraph (A) or (B).*

(16) **GENETIC INFORMATION.**—

(A) **IN GENERAL.**—*Except as provided in subparagraph (B), the term “genetic information” means information about—*

(i) *an individual’s genetic tests;*

(ii) *the genetic tests of family members of the individual; or*

(iii) *the occurrence of a disease or disorder in family members of the individual.*

(B) **EXCLUSIONS.**—*The term “genetic information” shall not include information about the sex or age of an individual.*

(17) **GENETIC TEST.**—

(A) **IN GENERAL.**—*The term “genetic test” means an analysis of human DNA, RNA, chromosomes, proteins, or me-*

tabolites, that detects genotypes, mutations, or chromosomal changes.

(B) EXCEPTIONS.—The term “genetic test” does not mean—

(i) an analysis of proteins or metabolites that does not detect genotypes, mutations, or chromosomal changes; or

(ii) an analysis of proteins or metabolites that is directly related to a manifested disease, disorder, or pathological condition that could reasonably be detected by a health care professional with appropriate training and expertise in the field of medicine involved.

(18) GENETIC SERVICES.—The term “genetic services” means—

(A) a genetic test;

(B) genetic counseling (such as obtaining, interpreting, or assessing genetic information); or

(C) genetic education.

\* \* \* \* \*

**SECTION 1882 OF THE SOCIAL SECURITY ACT**

CERTIFICATION OF MEDICARE SUPPLEMENTAL HEALTH INSURANCE POLICIES

SEC. 1882. (a) \* \* \*

\* \* \* \* \*

(o) The requirements of this subsection are as follows:

(1) \* \* \*

\* \* \* \* \*

(4) The issuer of the medicare supplemental policy complies with subsection (s)(2)(E) and subsection (x).

\* \* \* \* \*

(s)(1) \* \* \*

(2)(A) \* \* \*

\* \* \* \* \*

(E)(i) An issuer of a medicare supplemental policy shall not deny or condition the issuance or effectiveness of the policy, and shall not discriminate in the pricing of the policy (including the adjustment of premium rates) of an eligible individual on the basis of genetic information concerning the individual (or information about a request for, or the receipt of, genetic services by such individual or family member of such individual).

(ii) For purposes of clause (i), the terms “family member”, “genetic services”, and “genetic information” shall have the meanings given such terms in subsection (x).

\* \* \* \* \*

(x) LIMITATIONS ON GENETIC TESTING.—

(1) GENETIC TESTING.—

(A) LIMITATION ON REQUESTING OR REQUIRING GENETIC TESTING.—An issuer of a medicare supplemental policy

shall not request or require an individual or a family member of such individual to undergo a genetic test.

(B) *RULE OF CONSTRUCTION.*—Nothing in this title shall be construed to—

(i) limit the authority of a health care professional who is providing health care services with respect to an individual to request that such individual or a family member of such individual undergo a genetic test;

(ii) limit the authority of a health care professional who is employed by or affiliated with an issuer of a medicare supplemental policy and who is providing health care services to an individual as part of a bona fide wellness program to notify such individual of the availability of a genetic test or to provide information to such individual regarding such genetic test; or

(iii) authorize or permit a health care professional to require that an individual undergo a genetic test.

(2) *DEFINITIONS.*—In this subsection:

(A) *FAMILY MEMBER.*—The term “family member” means with respect to an individual—

(i) the spouse of the individual;

(ii) a dependent child of the individual, including a child who is born to or placed for adoption with the individual; or

(iii) any other individuals related by blood to the individual or to the spouse or child described in clause (i) or (ii).

(B) *GENETIC INFORMATION.*—

(i) *IN GENERAL.*—Except as provided in clause (ii), the term “genetic information” means information about—

(I) an individual’s genetic tests;

(II) the genetic tests of family members of the individual; or

(III) the occurrence of a disease or disorder in family members of the individual.

(ii) *EXCLUSIONS.*—The term “genetic information” shall not include information about the sex or age of an individual.

(C) *GENETIC TEST.*—

(i) *IN GENERAL.*—The term “genetic test” means an analysis of human DNA, RNA, chromosomes, proteins, or metabolites, that detects genotypes, mutations, or chromosomal changes.

(ii) *EXCEPTIONS.*—The term “genetic test” does not mean—

(I) an analysis of proteins or metabolites that does not detect genotypes, mutations, or chromosomal changes; or

(II) an analysis of proteins or metabolites that is directly related to a manifested disease, disorder, or pathological condition that could reasonably be detected by a health care professional with appropriate training and expertise in the field of medicine involved.

(D) *GENETIC SERVICES.*—The term “genetic services” means—

(i) a genetic test;

(ii) genetic counseling (such as obtaining, interpreting, or assessing genetic information); or

(iii) genetic education.

(E) *ISSUER OF A MEDICARE SUPPLEMENTAL POLICY.*—The term “issuer of a medicare supplemental policy” includes a third-party administrator or other person acting for or on behalf of such issuer.

## MINORITY VIEWS

### INTRODUCTION

H.R. 493, the “Genetic Information Nondiscrimination Act”—embodies a proposition that all members of the Committee and, indeed, Congress would likely endorse. Simply put, no employee should face discrimination on the basis of his or her genetic make-up or on any characteristic other than his or her ability to do the job. Similarly, no employee should risk his or her health insurance status simply because of the possibility that they might someday develop an illness. The bill was drafted with those fundamental principles in mind, and as it has worked its way through the legislative process, it includes a number of provisions to ensure that those principles are fulfilled, while minimizing the potential for unintended consequences.

In many ways, H.R. 493 provides a model for how a Committee process is meant to work. Members were presented with well-intentioned legislation; heard meaningful testimony on it and its potential impact on employers and employees alike; raised and debated legitimate concerns; and worked together to bridge the gap between where possible. That said, there remain issues within the bill on which persons of good conscience can and will disagree. Not all concerns raised with the bill have been addressed, including several significant ones. It is the hope of Committee Republicans that as this bill continues its way through the legislative process, these discussions will continue. We set forth our concerns, and highlight other areas in which the bill has been significantly approved, in these Minority Views below.

### SUMMARY OF H.R. 493, THE GENETIC INFORMATION NONDISCRIMINATION ACT

H.R. 493 is divided into two titles. Title I, relating to discrimination in health insurance, includes amendments to the Employee Retirement Income Security Act (ERISA) which fall within the jurisdiction of the Committee on Education and Labor. Other provisions relating to the Public Health Service Act and the Social Security Act fall within the jurisdiction of the Committees on Energy and Commerce and Ways and Means, respectively.

Title II, relating to discrimination in employment, falls solely within the jurisdiction of the Committee on Education and Labor.

### TITLE I: HEALTH INSURANCE

Title I applies to employer-sponsored group health plans, health insurance issuers in the group market, and state and local non-federal governmental plans. It generally prohibits group health plans and health insurance issuers from adjusting premiums or contribution amounts or establishing enrollment restrictions on the basis of

genetic information, and from seeking or requesting certain genetic information from covered individuals.

#### TITLE II: EMPLOYMENT PROVISIONS

In general, Title II prohibits the use of genetic information in employment decisions, such as hiring, firing, job assignments, promotions, and the like. This prohibition extends to employers, unions, employment agencies, and labor management training programs. In addition, under the bill, an employer is prohibited from requesting, requiring, or purchasing genetic information about an employee or family member, except with employee consent, and only for specific reasons such as genetic monitoring of biological effects of toxic substances in the workplace, use in wellness programs, or compliance with the Family and Medical Leave Act or its state equivalent. Finally, section 206 of the bill adopts broad restrictions and confidentiality requirements with respect to the collection and dissemination of genetic information.

#### CONCERNS WITH H.R. 493

Advocates of federal genetic nondiscrimination legislation argue that such legislation is necessary to ensure that individuals avail themselves of genetic testing without fear of reprisal in their employment or health insurance coverage. Others argue that the case has not yet been made that federal legislation is prudent or necessary—there has been no evidence of large-scale employer genetic testing or discrimination—and in any case, if federal legislation is to be adopted, it should be carefully drawn to address real concerns and not lead to frivolous litigation, inconsistent or contradictory standards, or undue burden on employers. Finally, many question whether existing federal laws and regulations provide adequate protection from the potential of genetic nondiscrimination. In addition, more than half of the states have enacted laws that restrict the use of genetic information in health insurance and employment decisions.

It was made clear at the Subcommittee on Health, Employment, Labor and Pensions hearing held on February 14, 2007 that both Republicans and Democrats share the same view—that discrimination on the basis of genetic information or makeup should be unlawful. That said, with respect to H.R. 493 in particular, a number of provisions within the bill has raised concerns among stakeholders and many Members, in both Title I (covering health insurance) and Title II (covering discrimination in employment by various actors).

With respect to Title I, many have expressed concern that the bill may discourage rather than encourage medically-indicated testing, and may limit consumer access to appropriate coverage and treatment. Genetic tests often need to be done to confirm a suspected diagnosis or to predict an appropriate response and therapy. Some types of treatment, as well as coverage decisions by health insurance plans, require identification of an individual's genotype in order to evaluate a course of treatment and eligibility for coverage under a health benefits plan. For example, National Institutes of Health (NIH) guidelines state that hepatitis C virus should

be treated for a longer duration if the viral genotype guide has been identified (i.e., 24 weeks vs. 48 weeks of therapy). While a health care provider will need this genetic information to determine the appropriate treatment, most individuals will be unable to access the therapy unless their health insurance plan pays for it under the benefits plan or contract. By forbidding the health plan or health insurer to “request or require” genetic information necessary to make a decision about benefits coverage, the bill can have the unintended consequence of limiting consumer access to life-saving treatment.

Similarly, others have expressed concern that the bill prevents health insurance plans from using “genetic tests” to promote preventive screening and disease management, contrary to the Health Insurance Portability and Access Act (HIPAA). The bill may serve to undermine the very valid concerns expressed in HIPAA that health insurance plans need certain kinds of medical information to assure appropriate treatment and coverage. While claiming that it does not restrict legitimate uses and disclosures of information as allowed by HIPAA by and between “covered entities” (which includes health care providers and health insurance plans), the bill’s language unfortunately prohibits health insurance plans from recommending to either an individual and/or his or her treating provider that a genetic test be performed—a test, as noted above, that may be necessary to confirm a suspected diagnosis or predict response to therapy.

For example, if an individual is enrolled in a disease management program (e.g., for breast cancer), or needs coverage for an illness or disease (discussed above), the health insurance plan is restricted from “requesting or requiring” an individual to undergo a genetic test. The result is that health insurance plans may not be allowed access to relevant information about an individual’s genetic tests. This restriction sets up a conflict with HIPAA and regulations which do not set restrictions about the categories of information that can be permissibly shared between HIPAA covered entities when needed for treatment, payment, or health care operations.

Despite improvements in the text made during Committee consideration, discussed *infra*, significant concerns remain among some Members and stakeholders with Title II of the bill, as well. Again, we hope good faith efforts can be made to resolve at least some of these issues before the bill comes to the Floor of the House.

First and foremost, the legislation would create a new cause of action against employers based on claims of genetic discrimination, including punitive and compensatory damages (for potentially even minor infractions, such as recordkeeping or paperwork violations). The prospect of these penalties could well invite additional litigation. As was noted at the Subcommittee on Health, Employment, Labor and Pensions hearing on January 30, 2007, by one witness:

All parties share the goal of eliminating discrimination any [sic] in the workplace, from the hiring process to providing benefits. When a company intentionally discriminates, remedies should be available. However, the [Genetic Information Nondiscrimination in Employment] Coalition opposes legislation that that would expose employers to

baseless litigation and would provide punitive and compensatory damages absent actual discrimination. The receipt of genetic information as part of an ADA accommodation dialogue should not create even the possibility of conduct violating any law. Assisting an employee receive health insurance coverage should never give rise to a cause of action. Given the availability of significant protections under other laws, administrative enforcement and equitably based remedies (including loss of wages and benefits) should be sufficient to allay fear of possible discrimination while mitigating the risk of a dramatic increase in baseless and inherently expensive litigation. Unfortunately, [H.R. 493] resorts to jury trials with punitive and compensatory damages for any violation, without distinction, which will necessarily invite additional litigation.

Testimony of Burton J. Fishman, on behalf of the Genetic Information Nondiscrimination in Employment Coalition, Subcommittee Hearing, "Protecting Workers from Genetic Discrimination," January 30, 2007 (emphasis added).

Under the legislation, separate state laws that set higher standards on genetic information would not be preempted. Thus, employers and health plans that operate in multiple states would potentially be subject to multiple and conflicting state and federal requirements governing the same subject matter and activities. Again, as Mr. Fishman testified:

H.R. 493 would not create a single federal standard, but unfortunately would allow a patchwork of state standards to impose inconsistent requirements. Any Federal legislation should recognize the problems faced by employers as they try to comply with the numerous genetic discrimination laws already in existence. More than 30 states have enacted laws prohibiting discrimination based on genetic information. However, these laws vary widely. If Congress enacts legislation barring employment discrimination based on genetic information then it should include a safe harbor providing that employers in compliance with the federal standards cannot be liable under state or local laws banning such discrimination. There should be only one standard, *your* standard.

Id.

Finally, the bill provides for an employer to collect certain specified genetic information in connection with a request for leave certification under the federal Family and Medical Leave Act (FMLA) or state law analogues. The employer community has expressed concern that this definition is unduly restrictive and may not permit the collection of information in other leave situations not expressly covered by the FMLA or state law. Many have also expressed concerns that the bill's provisions in section 206 governing the confidential treatment of information may, in fact, be unduly limiting, and limit an employer's ability to share genetic information within the ambit of legitimate, professional duty.

## COMMITTEE CONSIDERATION OF H.R. 493

H.R. 493 was considered by the full Committee on Wednesday, February 14, 2007. Two amendments to the text of the bill as introduced were adopted by the Committee, apart from those fundamental concerns set forth above. These amendments address several of the concerns that have been raised with the bill. A third amendment was not adopted, leaving at least one critical issue unresolved. We are hopeful that these issues will be resolved as this legislation continues to work its way through the various committees of jurisdiction in the House, and prior to its consideration on the House Floor.

## CHAIRMAN'S MARK

The Committee adopted without objection an Amendment in the Nature of a Substitute offered by Chairman George Miller as his Chairman's mark. Chairman Miller's mark incorporates several important changes to the text of H.R. 493 as introduced.

Foremost, the Chairman's mark provides a critical protection to ensure that H.R. 493 is not construed to require an employer to provide health care coverage for any specific genetic condition. In doing so, the mark adopts the existing standard of Executive Order 13145, which provides protection from genetic discrimination to federal employees, but expressly states that: "Nothing in this order shall be construed to \* \* \* require specific benefits for an employee or dependent under the Federal Employees Health Benefits Program or similar program." See Executive Order No. 13145, "To Prohibit Discrimination in Federal Employment Based on Genetic Information," (February 8, 2000), sec. 1-402. The Chairman's mark mirrors this important protection by adding a new clause (7) to section 209 of the bill (relating to Rules of Construction), which clause expressly provides that nothing in the bill shall be construed to "require any specific benefit for an employee or member or a family member of an employee or member under any group health plan or health insurance issuer offering group health insurance coverage in connection with a group health plan." In this manner, the mark makes clear that under H.R. 493, no employer can be compelled (by lawsuit or otherwise) to provide a specific health benefit to any employee or beneficiary based on his or her genetic status.

The Chairman's mark also cabins H.R. 493's nearly limitless definition of "family member" to provide that the family member of an individual includes only the individual's spouse or dependent child, and those relatives related within the first-, second-, third-, or fourth-degree. By doing so, the mark insures that claims of genetic discrimination on the basis of genetic information regarding family members who are so far removed and attenuated so as to be without meaning are excluded from the bill's coverage.

Finally, the Chairman's mark ensures that long-term care insurance is not inadvertently subject to the privacy and confidentiality requirements contained in section 104 of H.R. 439. As long-term care insurance is an "excepted benefit" under Section 733(c)(2)(B) of ERISA, the placement of section 104's restrictions within Subpart B of part 7 of subtitle B of title I of ERISA will ensure that those exclusions are imported into H.R. 493.

Committee Republicans welcome and support each of these changes, which address some, if not all, of the concerns that have been raised with the legislation.

THE KLINE RECORDKEEPING AMENDMENT

During consideration of the bill, the Committee adopted by voice vote an amendment offered by Representative Kline of Minnesota. During the January 30, 2007 Subcommittee hearing on H.R. 493, concern was expressed that the bill's recordkeeping requirements could be construed to require employers to adopt a new set of recordkeeping requirements for employee records containing genetic information, while maintaining existing rules for employee records that contain health information, but do not contain genetic health information (as is currently required under federal law, by, e.g., the Americans with Disabilities Act). As one witness testified:

H.R. 493 would require employers to follow one set of rules for handling genetic information and a different set for handling health care information. As a result, employers would have to distinguish between genetic information and other health care information they collect in the course of providing benefits, accommodations for the disabled, and a safe workplace, in general. *Indeed, in many cases, employers might be required to keep two or more sets of confidential health care files for employees—one for records with genetic information, one for records with other health care information, one for insurance matters.*

Testimony of Burton J. Fishman, on behalf of the Genetic Information Nondiscrimination in Employment Coalition, Subcommittee Hearing, "Protecting Workers from Genetic Discrimination," January 30, 2007 (emphasis added).

The Kline Amendment addresses this issue, and ensures that H.R. 493 does not create a duplicative, costly, and complicated set of additional recordkeeping requirements for employers. The Kline Amendment simply provides that with respect to the employer recordkeeping requirements of the bill, an employer will meet its obligations under H.R. 493 if it maintains employee health records containing genetic information in the same manner that it maintains and treats confidential medical records under section 102(d)(3)(B) of the Americans With Disabilities Act. The Kline Amendment ensures that employee health records containing genetic information are protected and safeguarded from disclosure, while eliminating the possibility that H.R. 493 would be construed to require a new recordkeeping system to be adopted.

ENSURING THAT THE BILL PROTECTS ALL INDIVIDUALS FROM GENETIC DISCRIMINATION, INCLUDING THOSE IN UTERO, EX UTERO, AND THROUGHOUT THE ADOPTION PROCESS: THE WALBERG/HOEKSTRA AMENDMENT

In general, the protections of H.R. 493 from discrimination on the basis of information are extended not only to covered individuals, but, as defined in various sections of the statute, to those individuals' "family members." As introduced, H.R. 493 defined "family member" to include, inter alia, "a dependent child of the indi-

vidual, including a child who is born to or placed for adoption with the individual” (emphasis added). The inclusion of the phrase “born to” raised significant concern among many Republicans, including supporters of the bill, insofar as it could readily be read to exclude children not yet born, whether in utero or otherwise. Similarly, the phrase “placed for adoption with” raised concern that a child who was in the process of an adoption placement—but who had not yet completed the process and thus was not as a matter of law “placed” for adoption—would be excluded from the bill’s protections.

During the Subcommittee hearing on genetic discrimination on January 30, 2007, a number of Members of the Committee raised concern with this particular phrasing, and that it would exclude, e.g., protection from genetic discrimination based on the results of a child’s in utero genetic testing, or that an embryo being prepared for transfer to the uterus after in vitro fertilization might be excluded from the bill’s coverage. For their part, supporters of the bill, including Members of both parties, appeared confident that the bill’s language, as drafted, protected against those scenarios, but that they were, in any case, amenable to examining the issue more closely.

The Chairman’s mark made two substantive changes to the definitions contained within the bill that bear some relevance to this point. First, the mark modified the definition of “family member” in relevant sections of the bill<sup>1</sup> in an attempt to address the issue. Under the Chairman’s mark, a “family member” is defined to include only “a dependent child of the individual”—the phrase “born to or placed for adoption with”—is wholly deleted from the definition. Second, the bill added a new section relating to the “Genetic Information of a Fetus” which provides that: “Any reference in this section to genetic information concerning an individual or family member of an individual shall, with respect to such an individual or family member of an individual who is a pregnant woman, include genetic information of any fetus carried by such pregnant woman.”

While the Chairman’s mark appears to be an effort to address the concerns with the definition of “family member” this language falls short of addressing a number of Members’ concerns. Namely, it remains unclear under the Chairman’s mark whether the protections of the bill apply to children still in utero, embryos outside of the body of the mother (for example, being prepared for transfer to the uterus after in vitro fertilization), and, in the absence of language on the point, to adopted children or least those in the adoption process.

At best, the new provision is ambiguous. It is not clear from the definition of “genetic information of a fetus” whether genetic information of an unborn fetus would cover the unborn at the earliest stages of pregnancy. Medically, the term “fetus” is often used to encompass the unborn from nine weeks of pregnancy on, while the term “embryo” is used to describe the unborn from conception to eight weeks of age. The term “fetus” in human subject protection

<sup>1</sup>Note that changes were made to the language in the bill only insofar as that language arose within sections of the bill within the Committee’s jurisdiction. The Chairman’s mark did not, for example, address the “born to” issue in definitional sections of the bill within the jurisdiction of other committees of the House.

regulations explicitly includes an embryo or fetus at any stage of pregnancy. See, e.g., Human Subject Protection Regulations, 45 C.F.R. Part 46 section 46.202(c) (defining “fetus” as “the product of conception from implantation until delivery”). In the absence of a similar and specific inclusion, the Chairman’s mark thus could be interpreted to exclude protection of the genetic information about the unborn in a pregnant woman from conception to eight weeks of age, and thus allow discrimination against the embryo as well as family members.

Second, it is plain from the text that the provision excludes an embryo outside of a woman’s uterus. Parents undergoing in vitro fertilization may have pre-implantation genetic diagnosis performed on the embryo ex utero to determine potential genetic disorders in the embryo. Since such genetic information about the embryo is obtained from an embryo outside of a pregnant woman, it would be excluded from protection under the Chairman’s mark. As such, health insurance companies or employers could potentially discriminate against individuals based on genetic information obtained from an embryo ex utero.

Finally, while the original definition of dependent child would have included children “who are placed for adoption with” the individual, the Chairman’s mark removes that clause, leaving it unclear whether adopted children (including those in the adoptive process) are covered under the non-discrimination provisions.

For these reasons, Representative Walberg, joined by Representative Hoekstra, offered an amendment that would simply have provided that the definition of a “family member” includes a dependent child of the individual, “including a child who is to be born to or to be placed for adoption with the individual.” The Walberg/Hoekstra Amendment was rejected on a recorded vote of 20–27.

The bill was reported favorably from the Committee on February 14, 2007 by a voice vote. That fact notwithstanding, the issue of whether the bill’s protections apply to individuals based on genetic information from children in utero irrespective of age (thus protecting not only those children but conceivably their family members from discrimination on the basis of genetic information); whether genetic information about embryos outside of a pregnant woman are protected under the legislation; and whether adopted children shall be covered under the bill at all stages of the adoptive process, raise grave substantive concerns for numerous Republican Members. In that light, the bill’s approval by voice vote on a motion to report should not be construed as satisfaction with the language contained in the mark, and if the issue is not more clearly addressed and resolved prior to the bill coming to the Floor, we expect the question to raise serious questions as to whether Republican Members can, in good faith, support this bill on the House Floor.

#### OTHER ISSUES: CLINICAL TRIALS

Insofar as one of the factors motivating this legislation is the fear expressed that individuals may be dissuaded from participating in clinical trials of new genetic therapies for fear of discrimination in the workplace or in the provision of their health benefits, Committee Republicans support construction of the bill’s broad protec-

tions against the use of genetic information by health insurers and employers to explicitly protect those who participate in clinical trials. It is our position—and we understand, a view shared by the Majority—that the legislation’s provisions include these individuals without the need for specific reference. Nevertheless, we would take this opportunity to make clear our view that the bill’s protections expressly include these individuals.

#### CONCLUSION

As we noted at the outset, Committee Republicans are united in their belief that no individual should be discriminated on the basis of his or her genetic makeup, nor should they be dissuaded from seeking the best and most thorough medical screening, testing, and treatment for fear that the results may be used to discriminate against them in their workplace, or in the provision of their health insurance and benefits. In that light, we fully support the intent of H.R. 493, but recognize that areas of the bill remain open to improvement. As this bill continues to work its way through the legislative process, we stand ready to work with our Committee Majority colleagues, with other committees of jurisdiction, and with all interested stakeholders to ensure that any legislation that comes to the House Floor represents the best product it can be.

HOWARD P. MCKEON.  
 TOM PETRI.  
 PETE HOEKSTRA.  
 MARK SOUDER.  
 RIC KELLER.  
 JOE WILSON.  
 JOHN KLINE.  
 K. MARCHANT.  
 TOM PRICE.  
 LUIS FORTÚNO.  
 CHARLES W. BOUSTANY, Jr.  
 ROB BISHOP.  
 DAVID DAVIS.  
 TIM WALBERG.

