The Truth: The Genetic Information Nondiscrimination Act (GINA)

The Definition of Genetic Information is Accurate, Reasonable, and Useful

The definition has been crafted with extreme care to ensure it does not cover any tests used for diagnostic or treatment purposes for diseases already clinically present. The definition of "genetic test" explicitly excludes any test that is "directly related to a manifested disease, disorder, or pathological condition." The bill authors were keenly aware of the need to ensure that diagnostic tests must be allowed to proceed and be treated differently.

- A genetic test to classify cancer types is not included in this definition of genetic information, because this would be a diagnostic test on cancer, which is a manifested disease. The same holds true for genotyping of viruses.
- Blood type status is not predictive of disease, hence is not protected under this legislation. If a mother develops Rh incompatability requiring genotyping of her blood type, this would be a manifest disease and also is not protected by this bill.
- Cytochrome P450 testing does not predict disease nor is it associated with disease. Rather, it is useful in guiding treatments for manifest diseases, which is allowed in this legislation.
- Viral genotyping of Hepatitis C would not be regulated under GINA since it addresses a manifested disorder.
- "Personalized medicine" to determine the most effective treatment for a disease that has already manifested would not be covered by GINA.

At the same time, all genetic information that indicates a predisposition to disease deserves protection, regardless of the motivations of those who collected it. Limiting protection to only that information that is collected for the express purpose of measuring genetic risk would create a major loophole that fails to protect Americans from genetic discrimination.

GINA Protects Patients Without Restricting Access to Care

Health professionals may request a genetic test to aid the diagnosis of a manifest condition or guide treatment for the clinical symptoms of a manifest condition. These genetic tests are not protected by GINA since the condition is manifest. Moreover, the FDA has changed the labeling of many medications to include recommendations for genetic tests. Since these medications are used to treat manifest disease, the drug's companion genetic test is allowed under GINA.

GINA Section 101 focuses on enrollment and premium issues because it is embedded within 29 USC 1182, ERISA's regulatory provisions related to "Portability, Access, and Renewability" passed in HIPAA in 1997. The question of "authorizing coverage for a line of treatment or coverage requires certain genetic diagnostic tests" is a non-issue because no part of the bill applies to any issues related to diagnosis or treatment of a manifested disorder.

A specific Rule of Construction (Sec. 101 (b)(c)(2)(A) and (B)) states that health care professionals are free to request and recommend genetic tests to their patients. The bill does not prohibit insurers from suggesting that a person might consider a particular genetic test that is available. However, the plan may not explicitly request or require (i.e. as a condition of coverage or renewal) a genetic test.

GINA Enables Preventive Screening and Will Not Interfere with Disease Management

Predictive genetic tests can provide people with opportunities to intervene and make health decisions that will dramatically reduce their risk of developing disease. For example, someone at risk for hereditary breast cancer can choose preventative surgeries and lifestyle changes to reduce their risk for developing cancer. Many people avoid predictive genetic tests out of fear of losing their health insurance or their jobs. GINA will eliminate these fears and enable people to pursue genetic testing and take steps to prevent disease and improve their health.

GINA allows insurers and healthcare professionals to notify an individual about the availability of the test. However, they cannot require that the individual take the test. All decisions about whether to actually take a test should rest with the patient, without any explicit or implicit threat to their coverage. Additionally, a specific Rule of Construction (Sec. 101 (b)(c)(2)(A) and (B)) states that health care professionals are free to request genetic tests of and recommend them to their patients.

GINA Protects Genetic Information Obtained through Prenatal Diagnosis Procedures

The discrimination that GINA is aimed at -- employment and insurance-- does not happen to fetuses. Fetuses have neither employers nor insurers. They receive their health insurance through the pregnant woman's policy. There is no mechanism for the insurer to discriminate directly against the fetus.

The pregnant woman is protected by current law during the pregnancy from acts of discrimination by insurers or employers. Under HIPAA (which covers federally-regulated self-insured employers as well as the state-insured group market) and laws in 50 states (individual market), the insurer is not permitted to cancel the pregnant woman's insurance once she becomes pregnant. The pregnant woman is also protected from employment discrimination through other federal and state laws such as the Pregnancy Discrimination Act and the Family and Medical Leave Act.

Under 50 state laws, individual insurers must permit a newborn child to be added to the insurance policy within 30 days of birth. No preexisting condition exclusions are permitted.

Once the child is born, GINA applies to him/her just as it applies to any other individual: his or her genetic information is protected regardless of when the test was performed unless the disease is manifest. And any information that might be revealed about the parents through a prenatal test IS the genetic information of the parents and is protected as such under GINA.

The Definition of Family Member is Clear, Succinct, and Appropriate

The Surgeon General launched a family medical history initiative because the Department of Health and Human Services recognized the important role this type of genetic information plays in predicting risk for disease. A pedigree is a very useful tool for health professionals and may include multiple generations and degrees of relationship. All of the genetic information contained in a pedigree should be protected, not just information on first, second, and third degree relatives.

Many adoption services collect family medical history information for adopted children so that they will have the opportunity to learn about their future health risks and, hopefully, prevent the onset of disease. Adopted children deserve access to their biological family's health information and the same protections from genetic discrimination as everyone else.

If a parent is discriminated against and the family's coverage is dropped, the entire family – including the adopted child -- has been discriminated against, regardless of the lack of a blood tie. The same is true if an adopted child is discriminated against and other, non-blood relative family members lose their coverage in the process. In fact, this would be an especially pernicious form of discrimination because it has absolutely no scientific basis in fact due to the lack of the blood relation.

GINA Does Not Mandate Coverage for Medical Treatments

GINA does not address insurance coverage of medical treatment anywhere in the bill language and hence, does not require employers to offer health insurance plans that provide treatment for genetic diseases. GINA only affects enrollment determinations and premium settings, and does not create any mandates on coverage for treatments.

GINA Will Not Affect the Adoption of Electronic Health Records

The language requires employers to keep genetic information separate from all other personnel information, such as job performance evaluations. The legislation does not require health professionals to maintain separate files, and therefore, will not delay the adoption and transition to electronic medical records.

Title I Allows Underwriting in the Individual Market

The bill allows medical underwriting in the individual market. The authors went to great lengths and consulted with the insurance industry to ensure that the bill would not impact medical underwriting on the basis of *current health status*, which is the primary basis used by insurers upon which to base their rating decisions. Individual insurance plans may not discriminate on the basis of genetic information as defined in the bill – which explicitly excludes any active or pre-existing health conditions.

GINA Allows For the Construction of Effective Risk Pools in the Group Market

Under HIPAA, insurance companies are prohibited from charging one person in a group a different premium from all others in that group based on genetic information. However, HIPAA allowed insurers to raise premiums for the entire group based on one member's genetic information. GINA closes this loophole by stating that a potential predisposition to a disorder which may or may not ever manifest itself should not be permissible grounds for raising insurance rates for a group plan. Insurers may continue to construct effective risk pools using information such as claims history and geographic location, as is currently the practice.

GINA Does Not Impact the Ordinary Review of Claims Data or Health Plan Administration

Some have raised questions that insurers' review of claims data would be impacted by GINA because claims could include diagnostic test results. These concerns are entirely unfounded for three reasons:

- Claims data should consist of information regarding charges submitted and paid. Unlike the medical record, it should not include test result information. As has been noted by some, a request for a test does not reveal the result. This information should not be a valid basis for discrimination.
- Even if genetic test results were included, they would not be covered by GINA if they were conducted in association with diagnosing or treating a manifested disorder.
- The definition of family member is not problematic because an individual would only be submitting claims for him or herself and any family members covered under the policy. The insurance claims of any more distant family member would not be involved in a claims review process.

Similarly, GINA does not impact other administrative activities under the bill. Presumably, some of these operations would be separate from underwriting, enrollment and renewal processes and would not present opportunities for discrimination. Any decision related to claims, such as the review of whether a given treatment is medically appropriate, would take place in relation to a manifested health condition and would not be covered by GINA.

The Remedies Outlined in Title I are Necessary and Reasonable

GINA does not allow a general private right of action for genetic discrimination in health insurance. Individuals must exhaust administrative remedies, including review of decisions by the insurer. The bill includes a narrow exception in which an individual may go to court when a court determines that exhausting the administrative remedies could place them at risk of "irreparable harm." This must be demonstrated to the court by a preponderance of the evidence. Individuals are free to use administrative and other remedies if they choose, including review of decisions by the insurer. This is all consistent with current ERISA law.

Many provisions of ERISA place liability upon plan administrators personally. Other parts of ERISA may place liability on plans as a whole, other administrators, the individual(s) deemed liable by the court, etc. There are a number of different standards used in the statute. Placing liability on a plan administrator is an established and accepted precedent.

Title II Allows Monitoring for Employee Safety

GINA allows employers to collect information for genetic monitoring of the biological effects of toxic substances in the workplace, as long as the collection is performed in a transparent manner. Employees should be informed of this testing in writing, have the right to consent to testing, and should be informed of the results. Genetic information is the most personal, fundamental information one can possess about an individual. Moreover, genetic information has serious implications not only for the individual, but for his or her family members. For that reason, federal law should embrace the concept that decisions about genetic information – including a decision about whether to acquire that information – should rest solely with the individual.

GINA Preserves States' Ability to Provide Stronger Protections

Civil rights laws establish a mandatory minimum standard for all states. They do not establish maximum protections that a state can provide. A federal cap of this type would be unprecedented for a civil rights law. Genetic discrimination should not be treated differently than discrimination based on disability, gender, race or any other factor. The passage of GINA would guarantee that all Americans have the same baseline protections. Individual states would have the flexibility to enact laws with stronger protections, but they would be required at least to match that which is provided by GINA. Employers have managed these variations among state and federal civil rights laws for decades without detriment.

Title II Protects Employers from the Unintentional Collection of Genetic Information

GINA protects employers who inadvertently request or require family medical history of an employee or family member of the employee by specifically exempting such acts. It creates a specific safe harbor for the inadvertent collection of information under Sec. 202 (1) and (3), as well as other exceptions under (2), (4), and (5).

Title II Protects Employers from Frivolous Lawsuits

The remedies provisions of GINA are the same as all civil rights laws. Claims are subject to the investigative, administrative enforcement and mediation procedures of the U.S. Equal Opportunity Commission prior to the filing of a lawsuit. Congress has established these mandatory procedures as a method of investigating and resolving disputes. Damage claims are also subject to monetary limits based on the size of the employer.